UNITED STATES DISTRICT COURT

DISTRICT OF KANSAS

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In re EPIPEN (EPINEPHRINE INJECTION, USP) MARKETING, SALES PRACTICES AND ANTITRUST LITIGATION

This Document Relates To: CONSUMER CLASS CASES

(1) Local 282 Welfare Trust Fund, (2) Rosetta) Serrano, (3) Lesley Huston, (4) Kenneth Evans,) (5) Cassandra Bredek, (6) Christopher Rippy,) (7) Nikitia Marshall, (8) Elizabeth Huelsman,) (9) Kimberly Corcoran, (10) Stacee Svites, (11) Lauren Coale, (12) Rachel Fernandez,) (13) Raymond Buchta III, (14) Lee Seltzer,) (15) Kimberly Dollander, (16) Linda Wagner, (17) Denya Anderson, (18) Vishal Aggarwal,) (19) Erin Korte-Lamparter, (20) Alene McDaniel, (21) Joy Shepard, (22) Eileen Montet, (23) Lorraine Wight, (24) Teia Amell,) (25) Todd Beaulieu, (26) Anastasia Johnston, (27) Annette Sutorik, (28) Heather DeStefano,) (29) Elizabeth Williamson, (30) Shannon Clements, (31) Mark Kovarik, (32) Miriam) Clarke, (33) Laura Chapin, (34) Maria) Giurland, (35) Michael Gill, (36) Suzanne) Harwood, (37) Donna Wemple, (38) Cassandra) Cobb, (39) Sonya North, (40) Christina James,) (41) David H. Smith, (42) Lori Collins, (43) Jae Jones, (44) Jennifer Walton, (45) April) Sumner, (46) Meredith Krimmel, (47) Landon) Ipson, (48) Kenneth Steinhauser, (49) John Dodge, (50) Amie Vialet De Montbel,

No. 2:17-md-02785-DDC-TJJ (MDL No: 2785)

CONSOLIDATED CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

[Caption continued on following page]

(51) Donna Anne Dvorak, (52) Connie)
Stafford, (53) Francis Myers, (54) Heather)
Ruland, (55) Curt Palmer, (56) Angie)
Nordstrum, and (57) Carly Bowersock,)
Individually and on Behalf of All Others)
Similarly Situated,)
)
Plaintiffs,)
)
VS.)
(1) Mylan N.V., (2) Mylan Specialty L.P.,)
(3) Mylan Pharmaceuticals, Inc., (4) Heather	
Bresch, (5) Pfizer, Inc., (6) King)
Pharmaceuticals, Inc., and (7) Meridian	(
Medical Technologies, Inc.,)
)
Defendants.)
)

CONSOLIDATED CLASS ACTION COMPLAINT

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DEMAND FOR JURY TRIAL
PRAYER FOR RELIEF

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Plaintiffs, individually and on behalf of all others similarly situated, bring this Consolidated Class Action Complaint against Defendants Mylan N.V.; Mylan Specialty L.P.; Mylan Pharmaceuticals, Inc.; Heather Bresch; Pfizer, Inc.; King Pharmaceuticals, Inc.; and Meridian Medical Technologies, Inc. (collectively, "Defendants") and allege the following based upon personal knowledge, information and belief, and investigation of counsel:

INTRODUCTION

1. This case presents one of the most egregious examples of corporate greed and malfeasance in our nation's history. For nearly a decade, Defendants have preyed on American children and adults, bilking them for hundreds of millions of dollars. Plaintiffs bring this suit to obtain justice, enjoin Defendants' unlawful activities, and recover damages.

2. Every day, millions of Americans live with the risk that severe allergic reactions will cut short their lives. These children and adults require immediate access to a common drug known as epinephrine, which is delivered by injection. One dose of epinephrine can mean the difference between life and death. Of necessity, because there is no meaningful competition in the market, the vast majority of American children and adults with severe allergies turn to a simple, decades-old device to administer an epinephrine dose: the EpiPen autoinjector.¹

3. The EpiPen is manufactured by two subsidiaries of Defendant Pfizer (Defendants King Pharmaceuticals and Meridian Medical Technologies) and sold in the United States by Defendant Mylan, which states on its website that its mission is: "Do what's right, not what's easy" and that "Integrity" is one of its "Values." It also states: "Doing what's right is sacred to us. We

¹ For simplicity, this Complaint uses the term "EpiPen" to refer to the EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, EpiPen Jr. 2-Pak®, My EpiPen®, LIFE HAPPENS®, EpiPen4Schools®, Never-See-Needle®, and Be Prepared® (collectively or individually, the "EpiPen"). (hereafter without [®] for readability)

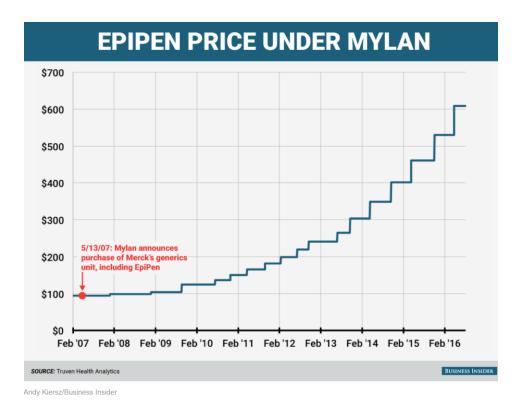
behave responsibly, even when nobody's looking."²

4. Since at least 2009, however, Defendants have done the opposite of "what's right." Instead, Defendants devised an illegal scheme to monopolize the market for epinephrine autoinjector devices. As a result, millions of Americans relying on this life-saving device have paid exorbitant prices for EpiPens that are in no way tethered to or constrained by a competitive market.

5. Unlawfully exercising its monopoly power, Mylan hiked the list price for two EpiPens to \$608 in 2016, up from \$100 in 2007—an increase of over 600%.³ Were the price increases attributable to market conditions, increases in manufacturing costs, or shortages in the supply of epinephrine? Absolutely not. They were driven solely by unaccountable executives and companies who sought to profit off of human misery and fear.

² About Us, MYLAN N.V., <u>http://www.mylan.com/en/company/about-us</u>, (last visited Aug. 31, 2016).

³ Mark Zaleski, *Mylan Overcharged Medicaid for EpiPen for Years, Despite Warnings*, STAT (Oct. 5, 2009), <u>https://www.statnews.com/pharmalot/2016/10/05/mylan-overcharged-medicaid-epipen/</u>, (last visited Jan. 31, 2017)



6. The EpiPen price hikes were the fruits of a multi-faceted, fraudulent scheme to obtain and maintain a monopoly in the market for epinephrine autoinjectors at the expense of American consumers and third party payors. To effectuate this scheme, Defendants combined and conspired to:

- Misclassify the EpiPen under Medicaid's Medical Drug Rebate Program to save hundreds of millions of dollars in rebates;
- Utilize their Medicaid savings to offer aggressive rebates and incentives to Pharmacy Benefit Managers, conditioned on excluding competitors from the market;
- Use Mylan's Access to Schools program to hook consumers on its product, meanwhile conditioning the provision of free EpiPens to schools on the exclusion of competitor products;
- Engage in deceptive marketing programs to restrain and prevent competition;
- Assert and prosecute invalid patents to dissuade competitors from entering the market

for epinephrine autoinjectors;

- Intervene in regulatory proceedings to delay competitors' entry in the market;
- Enter into unlawful pay-for-delay settlement agreements with competitors to maintain Mylan's monopoly;
- Convince regulators and the public that a medical need justified Mylan's decision to sell EpiPens solely in 2-paks, thereby exercising monopoly power to double consumer and third-party payor expenses; and
- Falsely testify to Congress in an effort to avoid scrutiny and government action.

These unlawful acts have resulted not only in this private suit, but on January 30,
 2017, the Federal Trade Commission announced that it is investigating numerous possible federal law violations by Mylan in connection with the EpiPen.⁴

8. It is time to put a stop to Defendants' galling actions that have endangered the lives of millions of Americans, all while funneling hundreds of millions of dollars in illegal profits to Defendants' coffers. It is also time to send a message that the law will not tolerate the fraudulent and anticompetitive actions of America's pharmaceutical giants. This case is of immense importance to Plaintiffs, members of the Classes they seek to represent, and the American public.

9. For all Defendants' unlawful actions alleged herein, Plaintiffs seek to recover damages and overpayments from at least 2009 through the present, as well as injunctive relief under the federal antitrust laws and various state consumer protection and antitrust laws. Plaintiffs also seek treble damages, attorneys' fees, costs, and punitive damages.

⁴ David McLaughlin, et al., Bloomberg, *Mylan Faces U.S. Antitrust Investigation on EpiPen Practices*, January 30, 2017, <u>https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices</u>, last visited Jan. 31, 2017)

PARTIES

10. Plaintiff Local 282 Welfare Trust Fund ("Local 282") is an employee health and welfare benefit plan with its principal place of business at 2500 Marcus Ave., Lake Success, NY 11042. Local 282 purchased, paid and/or provided reimbursement for EpiPen products, other than for resale, at supracompetitive prices in the states of Connecticut, Florida, Georgia, Nevada, New Jersey, New York, North Carolina, Ohio, Pennsylvania, and South Carolina during the Class Period and was thereby injured. All payments made by Local 282 were for EpiPen prescriptions obtained for personal, family, or household use.

11. Plaintiff Rosetta Serrano is a resident and citizen of Oklahoma. She has purchased numerous EpiPen 2-Paks in Kansas, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. The cost to Ms. Serrano has been significant over the years; EpiPen 2-Paks have cost her up to \$135.69 out of pocket, after insurance. All purchases made were for personal, family, or household use.

12. Plaintiff Lesley Huston is a resident and citizen of Douglas County, Kansas. She purchases EpiPen 2-Paks as a result of potential anaphylaxis during exercise as an avid runner. Ms. Huston purchased EpiPen 2-Paks on or about the following dates: July 24, 2012 (when she paid \$216.70); March 28, 2014 (when she paid \$313.18); June 3, 2015 (when she paid \$489.32); and March 16, 2016 (when she paid \$50 copay and her insurance paid \$489.80). Prior to the EpiPen 2-Pak, Ms. Huston purchased single injectors for her personal needs. All purchases made were for personal, family, or household use.

13. Plaintiff Kenneth Evans is a resident and citizen of Alabama. He purchased EpiPen 2-Paks, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$600 out of pocket, after insurance. All purchases were made for personal, family, or household use.

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14. Plaintiff Cassandra Bredek is a resident and citizen of Arizona. She purchased approximately four EpiPen 2-Paks per year for her minor son who is allergic to tree nuts and peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. The cost to Ms. Bredek has been significant over the years; EpiPen 2-Paks have cost her up to \$2,475 out of pocket, after insurance. All purchases made were for personal, family, or household use.

15. Plaintiff Christopher Rippy is a resident and citizen of Arkansas. He purchased approximately three to four EpiPen 2-Paks per year for his minor daughter who has a food allergy, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. The cost to Mr. Rippy has been significant over the years; EpiPen 2-Paks have cost him up to \$374.24 out of pocket, after insurance. All purchases were made for personal, family, or household use.

16. Plaintiff Nikitia Marshall is a resident and citizen of California whose seven-yearold son has an allergy to nuts and grass. She purchased an EpiPen 2-Pak at a Kaiser Permanente pharmacy in Walnut Creek, California on or about August 28, 2015, and again in 2017. Her purchase was made for personal, family, or household use.

17. Plaintiff Elizabeth Huelsman is a resident and citizen of California. Plaintiff Huelsman has purchased multiple EpiPen products for personal, family, or household purposes. Plaintiff Elizabeth Huelsman has been purchasing EpiPens for more than 28 years and actually began purchasing EpiPen products prior to Mylan's acquisition of the product line. Ms. Huelsman requires the use of an epinephrine auto-injector due to her severe allergy to bee stings and has purchased one to two EpiPen products every year until 2015 when the product became costprohibitive to her. She now carries only expired EpiPen products. Because her insurance does not cover EpiPen products, Ms. Huelsman has paid between \$150 and \$300 out of pocket for EpiPen products, after the use of Mylan-issued coupons. Ms. Huelsman purchased EpiPen 2-Paks from

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CVS Pharmacy, located at 14735 Ventura Blvd., Sherman Oaks, CA 91403 on at least the following dates: April 11, 2011 (when she paid \$79.22); August 13, 2010 (when she paid \$71.52); April 22, 2009 (when she paid \$55.63); and July 18, 2007 (when she paid \$50.89). She also purchased EpiPen 2-Paks from Walgreens Store #11735, located at 16100 Ventura Blvd., Encino CA 91436 on at least the following dates: March 28, 2015 (when she paid \$80.00); April 17, 2014 (when she paid \$80.00); and June 16, 2012 (when she paid \$176.46).

18. Plaintiff Kimberly Corcoran is a resident and citizen of California and has needed to purchase EpiPen products for her minor son since 2011, following a diagnosis of a peanut allergy shortly before his second birthday; an allergy which he will likely not outgrow and will likely require a prescription emergency treatment option for the duration of his life. Plaintiff Corcoran is required to purchase and maintain six pens at all times: two at school, two at home, and two at daycare. Ms. Corcoran purchased EpiPen Jr. 2-Paks from Kaiser Permanente's Northern California location on at least the following dates: October 20, 2011, October 21, 2011, November 20, 2012, August 21, 2014, and October 28, 2016. Ms. Corcoran has paid co-pays ranging from \$5.00 to \$40.00 towards the cost of the EpiPen Jr. 2-Paks. The remainder of the cost has been paid by her Kaiser Permanente health insurance plan. Ms. Corcoran is concerned about the effect her need for an EpiPen has had on her insurance premiums and what future insurance changes would mean to her ability to purchase EpiPens, and she is worried about the cost-prohibitive price of the pens for many American families. As a result of Defendants' conduct, alleged below, Plaintiff Corcoran has suffered a concrete and particularized injury. Due to Defendants' unconscionable increase in the price of the EpiPen, Plaintiff Corcoran has been rendered unable to leave her employer-provided health plan which covers the EpiPen. Specifically, as a result of Defendants' conduct, and, in order to ensure that she can afford and continue to receive the life-saving

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treatment, she was prevented from changing her insurance in order to gain favorable terms and prevented from making a change in her employment for more favorable terms. Plaintiff's interest in her employment, the terms of her employment, the terms of her insurance, as well as the economic consequences of those terms are, among others, legally protected interests that have been infringed upon by Defendants' illegal sales practices and she maintains a personal and legally protected interest in the outcome of this matter.

19. Plaintiff Stacee Svites is a resident and citizen of Colorado. She purchased approximately two EpiPen 2-Paks per year for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. The cost to Ms. Svites has been significant over the years; EpiPen 2-Paks have cost her up to \$260 out of pocket, after insurance.

20. Plaintiff Lauren Coale is a resident and citizen of Connecticut. She purchased approximately three to four EpiPen 2-Paks per year for her minor daughter who is allergic to shellfish and peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

21. Plaintiff Rachel Fernandez is a resident and citizen of Connecticut. She purchases EpiPens for her minor daughter, who is allergic to bee stings, and for herself, as she is allergic to tree nuts. She last purchased an EpiPen for her daughter in September 2015. She pays approximately \$700 for EpiPens for herself and her daughter. She has purchased EpiPens for personal, family, or household purposes, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

22. Plaintiff Raymond Buchta III is a resident and citizen of Delaware. He has purchased EpiPen 2-Paks for his minor son who is allergic to milk, eggs, and peanuts, since 2010. The cost to Mr. Buchta has been significant over the years; EpiPen 2-Paks have cost him up to

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\$1,137.58 out of pocket, after insurance. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

23. Plaintiff Lee Seltzer is a resident and citizen of Florida. He purchased approximately two EpiPen 2-Paks per year for his minor son who is allergic to peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$75 out of pocket, after insurance. All purchases were made for personal, family, or household use.

24. Plaintiff Kimberly Dollander is a resident and citizen of Georgia. She purchased approximately one EpiPen 2-Pak per year for her minor daughter who is allergic to tree nuts and peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$289 out of pocket, after insurance. All purchases were made for personal, family, or household use.

25. Plaintiff Linda Wagner is a resident and citizen of Hawaii. She purchased approximately one EpiPen 2-Pak per year for her food, plant, and mold allergies, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$200 out of pocket, after insurance. All purchases were made for personal, family, or household use.

26. Plaintiff Denya Anderson is a resident and citizen of Idaho. She purchased approximately two EpiPen 2-Paks per year for her minor child who is allergic to peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$724.32 out of pocket, after insurance. All purchases were made for personal, family, or household use.

27. Plaintiff Vishal Aggarwal is a resident and citizen of the State of Illinois. Plaintiff Aggarwal purchased an EpiPen 2-Pak from a CVS pharmacy in Plainfield, Illinois for \$628.93 on

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June 13, 2016, and an EpiPen Jr. 2-Pak for \$479.75 on November 6, 2015. All purchases were made for personal, family, or household use.

28. Plaintiff Erin Korte-Lamparter is a resident and citizen of Illinois. She purchased approximately two EpiPen 2-Paks per year for her minor child, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$80 out of pocket, after insurance. All purchases were made for personal, family, or household use.

29. Plaintiff Alene McDaniel is a resident and citizen of Indiana. She purchased approximately two EpiPen 2-Paks per year for her minor child who is allergic to nuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$250 out of pocket, after insurance. All purchases were made for personal, family, or household use.

30. Plaintiff Joy Shepard is a resident and citizen of Kentucky. She purchased approximately one EpiPen 2-Pak per year for her two minor sons who are allergic to tree nuts, and for herself, as she suffers from a bee sting allergy. EpiPen 2-Paks have cost her up to \$120 out of pocket, after insurance. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

31. Plaintiff Eileen Montet is a resident and citizen of Louisiana. She is allergic to, among other things, mold, dust, dog hair, and certain pollens. She last purchased EpiPens in June or July of 2016 from Thrifty Way Pharmacy in Abbeville, Louisiana. She paid a \$100 co-pay for the EpiPens. She has purchased EpiPens for personal, family, or household purposes, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

32. Plaintiff Lorraine Wight is a resident and citizen of Maine. She purchased approximately two EpiPen 2-Paks per year for her minor daughter who is allergic to peanuts,

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including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

33. Plaintiff Teia Amell is a resident and citizen of Maryland. She purchased approximately four EpiPen 2-Paks per year for her minor daughter who is allergic to peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$529.39 out of pocket, after insurance. All purchases were made for personal, family, or household use.

34. Plaintiff Todd Beaulieu is a resident and citizen of Massachusetts. He has been purchasing EpiPens for more than ten years. Mr. Beaulieu requires the use of an epinephrine autoinjector due to his severe allergy to insect venom. As a result, he stores six to eight pens at all times—including two at his workplace, two at home, and two in his car. Mr. Beaulieu also stores expired pens in order to ensure pens are always close-at-hand. The cost to Mr. Beaulieu has varied significantly over the years, but has ranged from \$15.00 to close to \$300.00 out-of-pocket, after insurance. Mr. Beaulieu purchased EpiPen 2-Paks from CVS Pharmacy #0634, located 189 Summer Street Kingston, MA 02364 on at least the following dates: April 5, 2016 (when he purchased four pens for \$308.82); July 23, 2014 (when he purchased four pens for \$211.73); July 13, 2013 (when he purchased two pens for \$72.27); and June 30, 2013 (when he purchased two pens for \$72.27).

35. Plaintiff Anastasia Johnston (individually and on behalf of Claire Johnston, a minor) is a resident and citizen of Michigan. Anastasia purchases EpiPens for her daughter, Claire Johnston, who is allergic to wasp stings, yellow jacket stings, and possibly honeybee stings. Anastasia last purchased an EpiPen for Claire in July or August 2016 from a CVS Pharmacy in Troy, Michigan. In the Spring of 2016, Anastasia could not purchase an EpiPen for Claire because

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the price was approximately \$800. Anastasia has purchased EpiPens for personal, family, or household purposes, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

36. Plaintiff Annette Sutorik is a resident and citizen of Michigan. She purchased approximately six to eight EpiPen 2-Paks per year for her minor child and for herself, as they each suffer from allergies. The cost to Ms. Sutorik has been significant over the years, with frequent copays of \$35, after insurance. EpiPen 2-Paks have cost her up to \$361.15 out of pocket, after insurance. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

37. Plaintiff Heather DeStefano is a resident and citizen of Minnesota. She purchased approximately two EpiPen 2-Paks per year for her minor child and for herself, as they both suffer from allergies. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$1986.75 out of pocket, after insurance.

38. Plaintiff Elizabeth Williamson is a resident and citizen of Mississippi. Elizabeth is allergic to, among other things, dust and mold. Elizabeth was prescribed an EpiPen in conjunction with allergy shots she was receiving. Elizabeth last purchased EpiPens during the summer of 2016, with a co-pay of \$150, from Fred's Pharmacy in Monticello, Mississippi. Elizabeth has purchased EpiPens for personal, family, or household purposes, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

39. Plaintiff Shannon Clements is a resident and citizen of Missouri. She has purchased EpiPen 2-Paks, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

40. Plaintiff Mark Kovarik is a resident and citizen of Nebraska. He purchased

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approximately two EpiPen 2-Paks yearly for his wife, Michelle, who is allergic to several antibiotics, and his minor daughter, who is allergic to eggs. EpiPen 2-Paks have cost him up to \$180 out of pocket, after insurance. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

41. Plaintiff Miriam Clarke is a resident and citizen of Nevada. She purchased EpiPen 2-Paks for her daughter who suffers from allergies, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

42. Plaintiff Laura Chapin (individually and on behalf of her minor son Fionn Chapin) is a resident and citizen of New Hampshire. Fionn Chapin is a three-year-old who is allergic to tree nuts and peanuts. She last purchased EpiPens in December 2015 or January 2016 for approximately \$594. She purchases EpiPens for personal, family, or household purposes.

43. Plaintiff Maria Giurland is a resident and citizen of New Jersey. Maria is allergic to latex and hornet stings. She last purchased EpiPens in July 2016 from a Rite Aid Pharmacy in Long Branch, New Jersey. She paid approximately \$668 for the EpiPens. She has purchased EpiPens for personal, family, or household purposes.

44. Plaintiff Michael Gill is a resident and citizen of New York. Plaintiff Gill has needed to purchase the EpiPen since he was diagnosed with a severe tree nut allergy and has purchased an EpiPen 2-Pak from a New York Wegmans Dewitt pharmacy on at least the following dates: April 28, 2017 (when he paid \$77.82); and May 16, 2016 (when he paid \$32.12). All purchases were made for personal, family, or household use.

45. Plaintiff Suzanne Harwood is a resident and citizen of New York. She purchased EpiPen 2-Paks, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

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46. Plaintiff Donna Wemple is a resident and citizen of New York. She purchased approximately four to six EpiPen 2-Paks per year for her minor daughter who is allergic to peanuts, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

47. Plaintiff Cassandra Cobb is a resident and citizen of North Carolina. She has a peanut allergy. She purchases EpiPens approximately every 3-4 months and as of October 2016, she last purchased EpiPens in August 2016 from Walgreens. She pays approximately \$500-\$600 for the EpiPens. She uses EpiPens for personal, family, or household purposes.

48. Plaintiff Sonya North is a resident and citizen of Ohio. She purchased frequent EpiPen 2-Paks for her minor children who have allergies, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$300 out of pocket, after insurance. All purchases were made for personal, family, or household use.

49. Plaintiff Christina James is a resident and citizen of Oklahoma. She purchased approximately one to two EpiPen 2-Paks per year, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$225 out of pocket, after insurance. All purchases were made for personal, family, or household use.

50. Plaintiff David H. Smith is a resident and citizen of Oregon. He purchased approximately four EpiPen 2-Paks per year for his minor son who has several allergies, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

51. Plaintiff Lori Collins is a resident and citizen of Pennsylvania. She has purchased EpiPens for personal, family or household purposes, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

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52. Plaintiff Jae Jones is a resident and citizen of Pennsylvania. She purchased EpiPen 2-Paks yearly, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$183.47 out of pocket, after insurance. All purchases were made for personal, family, or household use.

53. Plaintiff Jennifer Walton (individually and on behalf of Jonathan Clements, a minor) is a resident and citizen of South Carolina. She purchases EpiPens for her 15-year-old son, Jonathan Clements, who is allergic to peanuts. She has continually purchased EpiPens since she became aware of Jonathan's allergy when he was three years old, approximately twelve years. She last purchased EpiPens in 2013. She has not been able to purchase EpiPens since 2013 because of the price increase. She has purchased EpiPens for personal, family, or household purposes.

54. Plaintiff April Sumner is a resident and citizen of Tennessee. Plaintiff Sumner purchases EpiPens for her ten-year-old son, Eric Sumner, who is allergic to eggs and peanuts and her husband, Micah Sumner, who has certain food allergies. She has continually purchased EpiPens since she became aware of Micah's allergies in 2004. Plaintiff Sumner purchased EpiPen 2-Paks from a CVS pharmacy on at least the following dates: September 29, 2011 (when she paid \$71.56); July 13, 2010 (when she paid \$20.97); and September 29, 2008 (when she paid \$41.14). Plaintiff Sumner also purchased the EpiPen Jr. from a CVS pharmacy on at least the following dates: September 30, 2012 (when she paid \$86.39); July 30, 2012 (when she paid \$86.39); October 31, 2011 (when she paid \$71.56); November 18, 2010 (when she paid \$57.63); September 22, 2009 (when she paid \$106.34); and September 26, 2008 (when she paid \$41.14). Finally, Plaintiff Sumner purchased a single EpiPen from a CVS pharmacy on at least the following dates: August 1, 2016 (when she paid \$139.75); November 20, 2015 (when she paid \$421.71); October 13, 2014 (when she paid \$244.100); December 16, 2014 (when she

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paid \$88.66); October 27, 2013 (when she paid \$4.31); July 27, 2013 (when she paid \$160.77); and July 25, 2013 (when she paid \$160.77). All purchases were made for personal, family, or household use.

55. Plaintiff Meredith Krimmel is a resident and citizen of Texas. She purchased approximately four to eight EpiPen 2-Paks per year for her minor child who is allergic to cashews and pistachios, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$300 out of pocket, after insurance. All purchases were made for personal, family, or household use.

56. Plaintiff Landon Ipson is a resident and citizen of Utah. He purchased approximately three EpiPen 2-Paks for his minor daughter, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$700 out of pocket, after insurance. All purchases were made for personal, family, or household use.

57. Plaintiff Kenneth Steinhauser is a resident and citizen of Utah. He purchased EpiPen 2-Paks yearly, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. All purchases were made for personal, family, or household use.

58. Plaintiff John Dodge is a resident and citizen of Vermont. He purchased approximately eight EpiPen 2-Paks per year for his minor son who suffers from several allergies, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$300 out of pocket, after insurance. All purchases were made for personal, family, or household use.

59. Plaintiff Amie Vialet De Montbel is a resident and citizen of Virginia. She purchased approximately four EpiPen 2-Paks per year for her minor child who is allergic to milk protein, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks

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have cost her up to \$697.99 out of pocket, after insurance. All purchases were made for personal, family, or household use.

60. Plaintiff Donna Anne Dvorak is a resident and citizen of Virginia. Plaintiff Dvorak purchases EpiPens for her 13-year-old daughter, Summer Dvorak, who has been diagnosed with food allergies. Plaintiff Dvorak has continually purchased EpiPens since she became aware of Summer's allergies in May of 2013. Plaintiff Dvorak purchased an EpiPen 2-Pak from a Giant Pharmacy in Fairfax, Virginia, on at least the following dates: October 8, 2016 (when she paid \$636.01); August 26, 2013 (when she paid \$40.00); and May 6, 2013 (when she paid \$40.00). All purchases were made for personal, family, or household use. Plaintiff joined the "No Nuts Mom Group" as a member in 2014. The group is dedicated to learning, educating, supporting, and connecting with others about food allergies.

61. Plaintiff Connie Stafford is a resident and citizen of Washington. She received her first prescription for EpiPens in 2000 and has been consistently purchasing one to two EpiPen products every year for the past 16 years. Ms. Stafford requires an epinephrine auto-injector due to her severe allergy to insect venom. The cost to Ms. Stafford has varied significantly over the years but, in 2014, Ms. Stafford paid between \$200 and \$300 for an EpiPen 2-Pak, after insurance. Specifically, Ms. Stafford purchased an EpiPen 2-Pak from a Walmart Supercenter Pharmacy, located at 1221 South Hayford Road, Airway Heights, WA 99001, on November 8, 2013 for a total out-of-pocket cost of \$271.24. All purchases were made for personal, family, or household use, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400.

62. Plaintiff Francis Myers is a resident and citizen of West Virginia. He purchased approximately one to two EpiPen 2-Paks per year as he is allergic to bee stings and CT-Scan contrast dye. All purchases were made for personal, family, or household use, including since 2014

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when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$260 out of pocket, after insurance.

63. Plaintiff Heather Ruland is a resident and citizen of Wisconsin. She purchased approximately four EpiPen 2-Paks per year for her minor son who is allergic to bee stings, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost her up to \$40 out of pocket, after insurance. All purchases were made for personal, family, or household use.

64. Plaintiff Curt Palmer is a resident and citizen of Wyoming. He purchased approximately ten EpiPen 2-Paks per year as he is allergic to wasp stings, including since 2014 when the price for an EpiPen 2-Pak exceeded \$400. EpiPen 2-Paks have cost him up to \$500 out of pocket, after insurance. All purchases were made for personal, family, or household use.

65. Plaintiff Angie Nordstrum is a resident and citizen of Colorado. Ms. Nordstrum's dependent has food allergies for which she has purchased several EpiPens annually. As a result of Defendant's conduct alleged herein, Ms. Nordstrum has been forced to pay increasingly higher prices for these EpiPens. Although a portion of Ms. Nordstrum's purchases have been covered by insurance, her share of the cost has increased steadily. For example, on September 10, 2012, Ms. Nordstrum paid \$227.24 for an EpiPen two-pack, but on November 25, 2012, she paid \$249.61 for a two-pack. Then on August 23, 2013, she paid \$271.99 for one more EpiPen two-pack.

66. Plaintiff Carly Bowersock is a resident and citizen of Ohio. Ms. Bowersock's dependent has food allergies for which she has purchased several EpiPens annually. As a result of Defendant's conduct alleged herein, Ms. Bowersock has been forced to pay increasingly higher prices for these EpiPens. Although a portion of Ms. Bowersock's purchases has been covered by insurance, her share of the cost has increased steadily. For example, on October 12, 2010, when

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the price for an EpiPen two pack was \$135.02, Ms. Bowersock paid \$54.01 for two two-packs. By November 28, 2012, the price of an EpiPen two-pack had escalated to \$237.69 and her out-ofpocket cost for her two two-packs rose to \$95.07. On November 15, 2013 Ms. Bowersock paid the full price for two EpiPen two-packs, which had now risen to \$299.92. Thus, she paid a total of \$599.84 for both packs. By December 26, 2015, the price for an EpiPen two-pack had ballooned to \$522.09 per pack and Ms. Bowersock paid \$208.84 for two two-packs.

67. **Defendant Mylan N.V.** is a Netherlands entity. Mylan N.V. was originally incorporated as a private limited liability company, New Moon B.V., in the Netherlands in 2014. Mylan became a public limited liability company in the Netherlands through a corporate tax inversion (what it calls an "acquisition of the EPD Business") on February 27, 2015. Mylan's corporate seat is located in Amsterdam, the Netherlands, and its principal executive offices are located in Hatfield, Hertfordshire, England and its group's global headquarters are located in Canonsburg, Pennsylvania. Mylan N.V. is not registered to do business in the State of Kansas, but does business in the State of Kansas.

68. Given the corporate inversion that occurred in 2015, further discovery is needed to unravel the corporate maze of entities deliberately structured by Mylan's corporate counsel to avoid U.S. taxes while allowing Mylan's world headquarters to remain in Pennsylvania. Because of the purposeful obfuscation of the Mylan enterprise, it is unclear what capitalization or role Mylan N.V. has in the operations of Mylan Specialty L.P.

69. **Defendant Mylan Specialty L.P.** is a limited partnership with its principal office address at 781 Chestnut Ridge Road, 3rd Floor, Morgantown, WV 26505. Its general partner is Dey, Inc., which is located at 110 Allen Road, Basking Ridge, NJ, 07920. Mylan Specialty, L.P.

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is a wholly owned subsidiary of Mylan N.V. and as a result is authorized to accept service on behalf of Mylan N.V.

70. Mylan Specialty L.P. was known as Dey Pharma until 2012, when it changed its name to align its operations under the Mylan brand.

71. Mylan Specialty L.P. is not registered to do business in the State of Kansas, but does business in the State of Kansas, so it can be served through the Kansas Secretary of State. Mylan Specialty L.P. purposefully directs its activities into the State of Kansas (including the prescription, sale, and use of EpiPens) and the harms alleged in this Complaint arise out of and relate to those activities because Mylan Specialty L.P. (either on its own, or working in concert or in a joint venture with its other affiliates and/or distributors with whom it has a close relationship) ships hundreds or thousands of EpiPens to the State of Kansas through the EpiPens4Schools program.

72. As alleged herein, the EpiPen4Schools program is fundamental to Mylan's scheme to monopolize the market and raise prices, as well as to ensure it maintains a dominant market share so that it can exclude competition and keep prices elevated. But for the EpiPen4Schools program, Mylan would not have the same market penetration or brand recognition that it has now, and it was reasonably foreseeable that Mylan Specialty L.P. would be hauled into court in Kansas to answer for the EpiPen4Schools program. In administering this program, Mylan Specialty L.P. (either on its own or working in concert with others with whom it enjoys a close relationship) directly advertises and targets numerous Kansas schools. Mylan and BioRidge Pharma jointly are listed on the website, http:///www.epipen4schools.com, last accessed October 25, 2016, and on that site Mylan advertises to schools in Kansas.

73. As Wells Fargo analyst David Maris has pointed out, the EpiPen4Schools Program

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is "a complicated maze of specialty distribution companies," and Mylan appears to go out of its way to make the maze convoluted.⁵ In any event, Mylan displays the logo for Mylan N.V. on the website for EpiPen4Schools, which confirms that Mylan N.V. (not just its subsidiaries, including Mylan Specialty L.P.) is inextricably intertwined with and actively involved in promoting, running, and advertising the program to schools and residents in Kansas.

74. Mylan Specialty L.P. purposefully directs its activities into the State of Kansas (including the prescription, sale, and use of EpiPens) and the harms alleged in this Complaint arise out of and relate to those activities because Mylan Specialty L.P. (either on its own, or working in concert or in a joint venture with distributors with whom it has a close relationship) sells or coordinates the shipment of thousands of EpiPens to hospitals, schools, pharmacies, and other entities in Kansas. Mylan Specialty L.P. purposefully directs its activities into the State of Kansas and the harms alleged in this Complaint arise out of and relate to those activities because Mylan Specialty L.P. employs professional sales representatives and regional field trainers who visit and solicit hospitals and doctors in Kansas, and those sales representatives promote and generate the sale of EpiPens to Kansas residents.

75. Mylan Specialty L.P. operates in a close relationship with Mylan N.V., BioRidge Pharma, Mylan Pharmaceutical, Inc., Mylan Inc., and other Mylan subsidiaries. Without all of the Mylan entities conspiring to work together, the EpiPen price increases complained about herein would not have been sustainable, and each of the Mylan entities would not have profited from the negligent misrepresentations and would not have been unjustly enriched from Kansas schools,

⁵ Mylan's (MYL) Epipen4Schools Program is a Complicated Maze of Speciality Distribution Cos – Wells Fargo's Maris, STREETINSIDER (Aug. 29, 2016), http://www.streetinsider.com/Analyst+Comments/Mylans+%28MYL%29+Epipen4Schools+Pro gram+is+a+Complicated+Maze+of+Specialty+Distribution+Cos+-+Wells+Fargos+Maris/11979781.html, (last visited Feb. 1, 2017)

consumers, and entities.

76. **Defendant Mylan Pharmaceuticals Inc.** is headquartered in Canonsburg, Pennsylvania, and conducts extensive business nationwide, including in Kansas. It purposefully directs its conduct and sales into Kansas, and works in tandem with other Mylan entities to promote and generate the sale of EpiPens to Kansas residents.

77. Together, Mylan N.V., Mylan Specialty L.P. and Mylan Pharmaceuticals, Inc. are collectively referred to herein as "Mylan" and the "Mylan Defendants."

78. **Defendant Heather Bresch** is the CEO of Mylan N.V. and a resident of Sewickley Heights, Pennsylvania.

79. **Defendant Pfizer, Inc.** is a global pharmaceutical company with its global headquarters at 235 East 42nd Street, New York, New York 10017. Through its subsidiaries King Pharmaceuticals, Inc. and Meridian Medical Technologies, Inc., Pfizer supplies Mylan with 100% of its EpiPens.

80. **Defendant King Pharmaceuticals, Inc.** is headquartered at 501 5th Street, Bristol, Tennessee. King is a wholly-owned subsidiary of Pfizer, Inc. King performs basic research and develops, manufactures, markets and sells branded prescription pharmaceutical products and animal health products.

81. **Defendant Meridian Medical Technologies, Inc.** is headquartered at 6350 Stevens Forest Road, Suite 301, Columbia, Maryland. In 2011, Pfizer acquired King Pharmaceuticals. As part of that acquisition, Pfizer also acquired Meridian, which "develops and manufactures the EpiPen" sold by Mylan.⁶ Both Pfizer entities operated and managed the EpiPen

⁶ 2011 Financial Report, PFIZER INC. (2011),

https://www.pfizer.com/files/annualreport/2011/financial/financial2011.pdf, (last visited Jan. 31, 2017).

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Pricing Enterprise in order to artificially increase EpiPen sales and revenue to benefit Pfizer, which reported over \$339 million alone in 2015 off EpiPen sales.

82. Together, Pfizer, Inc., King Pharmaceuticals, Inc., and Meridian Medical Technologies, Inc., are collectively referred to herein as "Pfizer" or the "Pfizer Defendants."

JURISDICTION AND VENUE

83. This Court has jurisdiction over this action pursuant to <u>28 U.S.C. §1332(d)</u> because this is a class action in which the aggregate amount in controversy exceeds \$5,000,000 (exclusive of interest and costs), the number of the members of the Class exceeds 100, and at least one member of the putative Class is a citizen of a state different from that of one of the defendants. This Court also has jurisdiction over this matter pursuant to <u>28 U.S.C. §§1331</u> and <u>1337</u>. The Court has supplemental jurisdiction over plaintiffs' pendent state law claims pursuant to <u>28 U.S.C.</u> <u>§1367</u>.

84. This Court has personal jurisdiction over Defendants because Defendants are amenable to service of process, are co-conspirators, and each has minimum contacts with this District and has purposefully availed itself of the privilege of conducting business in this state.

85. Venue is proper in this forum pursuant to <u>28 U.S.C. § 1391</u> because a substantial part of the events giving rise to these claims occurred in this District, including EpiPen sales made by Defendants; each Defendant is subject to personal jurisdiction in this District; and Defendants transact business in this District.

BACKGROUND AND FACTUAL ALLEGATIONS

A. Allergies, Anaphylaxis, and Epinephrine

86. The EpiPen is a disposable, prefilled automatic injection device for delivery of epinephrine (also known as adrenaline) used in the treatment of severe allergic reactions known as

anaphylaxis.

87. Anaphylaxis is a severe life-threatening allergic reaction that can occur rapidly after exposure to an allergen. Anaphylaxis manifests in a variety of symptoms, including swelling of the tongue and throat, vomiting, reduced blood pressure, difficulty breathing, and if untreated, death.

88. Food allergens are the most common triggers of anaphylaxis, but medications, latex, and insect bites can also cause anaphylaxis. A food allergy occurs when the body's immune system mistakenly identifies a food protein as a threat and attacks it. The most common food allergens include everyday items like peanuts, milk, soy, wheat, and shellfish. Epinephrine is also used to treat anaphylaxis caused by exercise or unknown substances. It is available only by prescription.

89. According to Food Allergy Research & Education—an allergy advocacy and research group—approximately 15 million people have food allergies in the United States. One out of every thirteen children in the United States has serious food allergies. Each year, allergic reactions account for about 200,000 emergency room visits.⁷

90. Anaphylaxis is always considered a life-threatening medical emergency.

91. Epinephrine is very effective at treating anaphylaxis, but it must be administered immediately. A delay in receiving epinephrine of as little as 30 minutes can result in death.

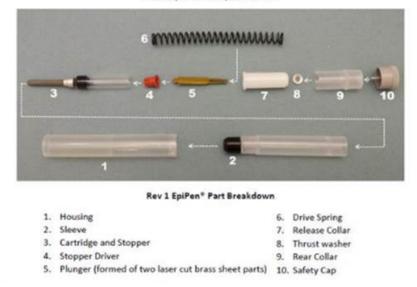
92. In the vast majority of cases, an epinephrine auto-injector is the most effective device for quickly administering epinephrine. As shown in the below diagram, an auto-injector device injects epinephrine into a muscle through the device's spring-loaded needle.⁸

⁷ Selena Larson, *Outrageous EpiPen prices lead some people to make their own*, CNNMoney, Sept. 24, 2016.

⁸ Ben Popken, *Mylan's Upgraded EpiPen Torn Apart By Experts*, NBC NEWS (Sept. 20, 2016), <u>http://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-inside-n652651</u>, (last visited Jan. 31, 2017).



Rev 1 EpiPen® Complete Device



93. Patients prone to anaphylaxis are advised to carry an epinephrine auto-injector at all times to be used in an emergency where they are at risk of having a severe allergic reaction. In short, epinephrine auto-injectors save lives.

B. The EpiPen

94. The auto-injector device was first developed by Survival Technology, Inc. in the 1970s to administer a nerve agent antidote for the United States military. This original auto-injector was called the ComboPen. It was subsequently modified to deliver epinephrine, thus creating the EpiPen.⁹ The United States Food and Drug Administration approved the EpiPen on December 22, 1987, under New Drug Application 019430.

⁹ Matt Reimann, *The Story of the EpiPen: From Military Technology to Drug-Industry Cash Cow*, TIMELINE (Aug. 20, 2016), <u>https://timeline.com/epipen-technology-drug-industry-b28d19036dee#.seg6n7dls</u>, (last visited Jan. 31, 2017).

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95. The EpiPen is used to treat signs and symptoms of an allergic emergency, some of which include hives, redness of the skin, tightness in the throat, breathing problems, and/or a decrease in blood pressure. The EpiPen has two important automatic components: needle injection and medication dispensing. It works by delivering epinephrine to reverse the effects of allergens by relaxing the muscles around airways and tightening blood vessels to maintain respiratory and cardiovascular function. "According to national food allergy guidelines, epinephrine is the *only* recommended first-line treatment for anaphylaxis."¹⁰

96. In 1996, Survival Technology, Inc. merged with Meridian Medical Technologies,¹¹ which one year later sold the exclusive right to market and distribute the EpiPen to Dey LP. Dey LP is a subsidiary of Merck KGaA, a German multinational pharmaceutical company.¹²

97. Mylan acquired Dey LP and the right to market and distribute the EpiPen line of epinephrine auto-injector devices from Merck KGaA as part of broader 2007 acquisition deal.¹³

98. According to Mylan, the EpiPen "is used in the treatment of severe allergic reactions" and "is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s."¹⁴

99. The EpiPen provides a 0.3 mg dose of epinephrine, while the EpiPen Jr. contains a0.15 mg dose. EpiPens have a one-year expiration period and patients are advised to replace them

¹³ Tara Parker-Pope & Rachel Rabkin Peachman, *EpiPen Price Rise Sparks Concern for Allergy Sufferers*, N.Y. TIMES (Aug. 22, 2016), <u>http://well.blogs.nytimes.com/2016/08/22/epipen-price-rise-sparks-concern-for-allergy-sufferers/</u>, (last visited Jan. 31, 2017).

¹⁴ MYLAN N.V. 10-K (2015),

¹⁰ See What is Epinephrine?, Epipen.com, https://www.epipen.com/about-epipen/what-is-epinephrine (emphasis in original) (last visited Mar. 7, 2017).

¹¹ Meridian Medical Technologies 10-K Filing (Jul. 31, 1997).

¹² Marilyn Case, *EpiPen Recall Points to Broader Concerns*, WALL ST. J. (May, 10, 1998), <u>http://www.wsj.com/articles/SB895440623631960000</u>, (last visited Jan. 31, 2017).

https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231xdo c.htm, (last visited Jan. 31, 2017).

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after their expiration date. The EpiPen Jr., for kids, has a retail price that is the same as the EpiPen, despite containing half the medicine (0.15 mg instead of 0.3mg) of the EpiPen. Mylan itself states that food allergies among U.S. children are "on the rise, now affecting one in 13" kids.¹⁵

100. Mylan has worldwide rights to the EpiPen auto-injector, which is supplied to Mylan by the Pfizer Defendants.

101. In 2003, the first alternative to EpiPen was introduced under the name Twinject, which was eventually renamed Adrenaclick. For the past 13 years, various companies have produced Adrenaclick, with Impax acquiring the rights in March 2015. Impax currently produces both Adrenaclick and a generic version.¹⁶ Adrenaclick's market share has ranged from only 2% in 2013 to 8% in 2016.¹⁷

102. The EpiPen is the most prevalent epinephrine injection device with nearly 4 million prescriptions written last year alone.

103. The number of patients filling a prescription for an EpiPen has grown 67 percent over the past seven years. "[F]or doctors, who write prescriptions for the name they know best, the EpiPen brand 'is like Kleenex,' says Robert Wood, a pediatric allergist at Johns Hopkins University School of Medicine."¹⁸

¹⁵ Mylan Applauds New Federal Legislation to Increase Anaphylaxis Preparedness in Schools, MYLAN INC. (Nov. 14, 2013), <u>http://newsroom.mylan.com/press-releases?item=123181</u>, (last visited Jan. 31, 2017).

¹⁶ In May 2010, a generic epinephrine auto-injector was released for distribution. This epinephrine auto-injector has no trade name currently and is distributed by Greenstone, a generic division of Pfizer. It has been authorized by Shionogi, the maker of Adrenaclick, as a generic of Adrenaclick.

¹⁷ Sam Wood, A cheaper way to get epinephrine pen, if you know how, Philly.com, Aug. 31, 2016; see also Carrier & Minniti, "The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals" 102 CORNELL L. REV. ONLINE 53, 57–58 (Jan. 2017)

¹⁸ Cynthia Koons and Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG (Sep. 23, 2015), <u>http://www.bloomberg.com/news/articles/2015-09-</u>23/how-marketing-turned-the-epipen-into-a-billion-dollar-business, (last visited Jan. 31, 2017).

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104. Mylan, however, has exploited this demand for its product by engaging in unconscionable and anti-competitive conduct that has left thousands of children and adults exposed to a risk of death from a food allergy or bee sting simply because they or their families cannot afford to pay the hundreds of dollars Mylan now charges for EpiPens. Those families who can pay have each been overcharged by thousands. Those who cannot pay face a terrible lose-lose decision: (1) take their chances with an expired EpiPen; or (2) go without and pray that an ambulance arrives before they or their child die from anaphylactic shock.

105. Millions of other children in families who cannot afford insurance must be covered by Medicaid. Others who have insurance with high deductibles and co-insurance find themselves forced to pay hundreds or thousands of dollars for just a few packs of the EpiPen.

106. By 2015, Mylan gained at least an 85% market share (and likely higher) of the epinephrine injector market.

107. According to Kevin Deane, head of medical technologies for PA Consulting Group (a global technology and design firm that sold a drug delivery technology company to Pfizer in 2004) "the base components for each EpiPen, including the plastic cap, tube, and needle, might cost between \$2 to \$4 to purchase."¹⁹ And the EpiPen contains "essentially [the] same core technology that [has been] there for many years."²⁰

108. In fact, two engineering industry experts peg the total cost of making an EpiPen
2-Pak at between \$8.02 and \$10.03, and that "even include[s] the bright-yellow box."²¹

¹⁹ Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than \$30*, NBC NEWS (Sep. 6, 2016), <u>http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091</u>, (last visited Jan. 31, 2017).

 $^{^{20}}$ *Id*.

²¹ Tracy Seipel, *EpiPen Outrage: Silicon Valley Engineers Figure Real Cost to Make Lifesaving Auto-Injector Two-Pack* — *about* \$8, Mercury News (Oct. 1, 2016),

C. Pharmaceutical Industry Market Overview

109. It is widely known among pharmaceutical companies—and the Wall Street analysts and traders who determine their stock prices— that "generic drugs quickly take sales from brand drugs. Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months."²²

110. Thus, "it is in brand firms' interests to delay generic entry. Every day a brand firm can control the market and forestall entry is a day it could gain monopoly profits. In the Hatch-Waxman setting, this is particularly tempting since brands could face generic entry before the end of the patent term."²³

111. The Federal Food, Drug, and Cosmetic Act, <u>21 U.S.C. § 301</u> *et seq.* ("FDCA"), governs the manufacturing, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a company that wants to sell a new drug must submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") and provide scientific data demonstrating that the drug is safe and effective for a specific indication. *See id.* § 355(b)(1). The process to obtain FDA approval for an NDA is lengthy and very expensive.

112. As compensation for enduring this regulatory burden, drug manufacturers are allowed to protect their new products by listing applicable patents in the FDA's "Orange Book." *Id.* at § 355(b)(1), (c)(2). The Orange Book includes all FDA-approved prescription drugs, their approved generic equivalents, and any patents that purportedly protect each drug.

113. Drug patents typically last twenty years. The exclusivity period of a patent creates

http://www.mercurynews.com/2016/10/01/epipen-outrage-silicon-valley-engineers-figure-truecost-to-make-lifesaving-auto-injector-about-10/, (last visited Jan. 31, 2017).

²² Michael A. Carrier & Carl Minniti, "*Citizen Petitions: Long, Late-Filed, and At-Last Denied*," 66 AM. U. L. REV. 305, 312 (Dec. 2016).

²³ *Id.* at 313.

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incentives for drug innovation by allowing drug innovators to recoup their initial research and development costs and make a substantial profit on top.

114. The FDA has authority to grant manufacturers additional exclusivity periods to incentivize the development of particularly beneficial or necessary drugs. For instance, a manufacturer is eligible to receive five years of additional FDA exclusivity if it develops a "new chemical entity" ("NCE"); three years if it develops a new, but non-NCE product; and seven years if it develops a drug that treats a rare condition. These periods of FDA exclusivity, beyond the ordinary patent term of twenty years, often compensate for unfairness in the ordinary patent process and incentivize the development of drugs in traditionally unprofitable markets.

115. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known commonly as the Hatch-Waxman Act ("Hatch-Waxman"), to facilitate competition from low-price generic drugs while maintaining the incentive for companies to research and develop new products. Hatch-Waxman permits generics to come to market as soon as brand drugs lose patent protection, and it encourages generic manufacturers to challenge the scope and validity of existing brand patents.

116. Once the FDA has approved a brand drug, Hatch-Waxman allows a generic manufacturer to obtain similar approval by filing an Abbreviated New Drug Application ("ANDA") specifying that the generic has the same active ingredient and is "biologically equivalent" ("bioequivalent") to the reference brand drug. The ANDA application process allows generic manufacturers to rely on a reference drug's original clinical studies, thereby reducing the cost and time necessary to bring a generic drug to market.

117. Generic drugs, on average, cost 80-85% less than their brand-name counterparts.

118. When a company seeks to market a generic counterpart to a brand drug, the

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company must certify it will not infringe any patents listed in the Orange Book for the reference drug. An ANDA-filer must certify it will not infringe any patents claiming to cover the reference product because: (1) no patents are listed in the Orange Book; (2) all applicable patents have expired; (3) the applicant will not introduce a generic drug until all applicable patents have expired; or (4) all applicable patents are invalid or will not be infringed by the proposed generic product. *Id.*

119. The fourth option is called a "Paragraph IV Certification" and usually triggers litigation between the generic applicant and the NDA holder.²⁴

120. If the patent owner (branded pharmaceutical company) initiates a patent infringement action against the ANDA filer within 45 days, the FDA may not grant final approval of an ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(G)(5)(B)(iii). It is well recognized that branded pharmaceutical companies routinely commence patent infringement litigation against generic companies in order to invoke the automatic 30-month stay and improperly perpetuate their monopoly.

121. Besides Hatch-Waxman, generic substitution laws in all fifty states also strongly encourage the use of generic drugs. These laws allow, and sometimes require, pharmacists to fill brand prescriptions with cheaper AB-rated generic equivalents, unless the prescribing physician directs otherwise. An "AB-rated" generic drug is a generic equivalent drug determined by the FDA to meet strict bioequivalence testing standards basically showing that it has the same efficacy and safety profile as the referenced brand drug.

²⁴ The filing of a 'Paragraph IV' ANDA gives rise to a cause of action for patent infringement. *See* <u>35 U.S.C. § 271(e)(2)(A)</u>.

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122. As a result of the public policy encouraging lower-priced generics, as codified in the Hatch-Waxman Act and state substitution laws, brand manufacturers typically lose 80-90% market share within one year of generic competition.

123. Price is the only material difference between generic drugs and their corresponding brand versions. Because generic versions of a corresponding brand drug product are commodities that are not differentiated through advertising or other means, the primary basis for generic competition is price.

124. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by a brand manufacturer in order to extend its monopoly over a particular product. In most industries, the person who selects a product for purchase must also pay for that product. Therefore, normally, the price of the product plays a critical role in the consumer's choice of products and, consequently, sellers have a strong incentive to lower the price of their products to remain competitive.

125. The pharmaceutical marketplace, however, suffers from a "disconnect" between purchase price and product selection. The patient (and in many cases his or her insurer or health plan) has the obligation to pay for the pharmaceutical product, but the patient's physician chooses the product the patient will buy.

126. Studies repeatedly show physicians are usually unaware of the costs of pharmaceutical products and even when physicians are aware of the relative cost, they are insensitive to price differences, because they do not bear the costs of the drugs being purchased. This creates a marketplace in which price plays a comparatively unimportant role in product selection and there is very little cross-elasticity of demand among differentiated products within a therapeutic class of drugs. As a result, this gives brand manufacturers the ability to raise or maintain

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price substantially above competitive levels without losing sales (unless, of course, there is an ABrated generic of the brand drug available).

127. Many pharmaceutical manufacturers, including Mylan, exploit this feature of the pharmaceutical marketplace. Brand manufacturers employ large numbers of sales representatives and marketing teams, who parade throughout hospitals and physicians' offices to persuade doctors to prescribe branded products. These sales or marketing representatives do not advise doctors of the cost of the brand products.

128. State substitution laws were specifically designed to fix the disconnect between the doctors who prescribe (but do not pay for) the drugs and the individuals and institutions who pay for (but do not select) the drugs.

D. Mylan's History of Anti-Competitive Conduct

129. Mylan has already been caught and successfully pursued for predatory monopolization and charging unconscionable prices to consumers. This makes the violations in this case willful and part of long-standing pattern and practice by Mylan.

Lorazepam and Clorazepate: FTC Investigation and Settlement

130. In 1998, the Federal Trade Commission ("FTC") and 32 states filed suit against Mylan and four other companies alleging Mylan leveraged its dominant market position to extract exclusive dealing agreements from three of the defendants that supplied the Active Pharmaceutical Ingredient ("API") used to manufacture two generic drugs – lorazepam and clorazepate.

131. In exchange for these exclusive dealing agreements, Mylan offered to share a percentage of its gross profits with the other defendants. In so doing, the FTC and state attorneys general alleged that Mylan effectively denied its competitors access to the most important ingredient for producing these drugs.

132. The states also alleged Mylan tried to enter into an exclusive licensing agreement

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with the fourth defendant to control the distribution of lorazepam made with an alternative API, a formulation Mylan did not even have FDA approval yet to sell. The states alleged that Mylan's attempt to control the supply of that alternate formulation, when it was not yet approved to sell it, further demonstrated the anticompetitive nature of Mylan's actions.

133. The complaints averred that after securing the exclusive dealing agreements, Mylan raised the price of clorazepate tablets in amounts ranging from 1,900% to over 3,200%, and raised the price of lorazepam tablets by amounts ranging from 1,900% to 2,600%. In 2000, In 2000, the *New York Times* reported that Mylan agreed to pay \$147 million to the Federal Trade Commission—at the time, the "largest ever" settlement "reached by the [FTC] in an anti-competitive case"—after Mylan "improperly cornered the market on raw materials for two widely prescribed drugs and then raised the price of those drugs, in some instances more than 3,000 percent."²⁵ It was reported that "[t]his illegal conduct has cost consumers millions of dollars over the past two years,' said Betty D. Montgomery, the attorney general of Ohio. 'What makes this behavior even more unconscionable is that these drugs, especially lorazepam, are antianxiety mediations frequently prescribed for nursing home and hospice patients, including those suffering from long-term debilitating conditions such as Alzheimer's disease.' She added, 'The bulk of the restitution will go back into the pockets of the affected seniors, where it belongs.'"²⁶

EpiPen Formulary Manipulation: DOJ Investigation and Settlement

134. Mylan also has a history of manipulating Medicaid's Medical Drug Rebate Program ("MDRP") to extract higher payments for what are actually "generic" drugs. Sanofi, a Mylan

 ²⁵ Stephen Labaton, *Generic-Drug Maker Agrees to Settlement in Price-Fixing Case*, N.Y. TIMES, (July 13, 2000) <u>http://www.nytimes.com/2000/07/13/business/generic-drug-maker-agrees-to-settlement-in-price-fixing-case.html</u>, (last visited Jan. 31, 2017).
 ²⁶ Id.

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competitor, has alleged that Mylan used this tactic to create a war chest from which it could pay exceedingly large discounts to Pharmacy Benefit Managers ("PBMs") and third-party payors in exchange for excluding competitors from their drug formularies.

135. On September 28, 2016, Senators Richard Blumenthal, Chuck Grassley, and Amy Klobuchar sent a letter to U.S. Attorney General Loretta Lynch inquiring whether the U.S. Department of Justice ("DOJ") had considered an investigation into whether Mylan violated the law when it apparently misclassified its EpiPen for purposes of the MDRP.²⁷

136. As explained in the letter, Congress created the MDRP to help protect states from high pharmaceutical prices by requiring drug companies to pay a percentage of their revenues to states in the form of rebates. Companies pay a rebate of only 13% for non-innovator (generic) drugs, but must pay at least 23.1% for innovator (brand name) drugs.

137. To limit the rebates it would have to pay, Mylan reported the EpiPen as a noninnovator or generic drug, notwithstanding the fact that Mylan used aggressive enforcement of its own patent-protected monopoly over the EpiPen as a tool to limit competition and to keep its prices exorbitantly high. As a result, Mylan avoided hundreds of millions in Medicaid rebates.

138. This misclassification rebate scheme was illegal. On October 7, 2016, Mylan announced it had reached a \$465 million settlement with the DOJ resolving an investigation by the DOJ into whether Mylan manipulated the classification of EpiPens covered by Medicaid.

139. Then, on August 17, 2017, the DOJ confirmed the settlement and its terms requiring Mylan to "pay \$465 million to resolve claims that they violated the False Claims Act by knowingly

²⁷ Letter from Senators Richard Blumenthal, Chuck Grassley & Amy Klobuchar to Attorney General Loretta E. Lynch, Sept. 28, 2016, *available at*

http://www.grassley.senate.gov/news/news-releases/senators-ask-justice-department-consider-investigating-mylans-medicaid-rebates.

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misclassifying EpiPen as a generic drug to avoid paying rebates owed primarily to Medicaid.". According to Acting United States Attorney William D. Weinreb, "Mylan misclassified its brand name drug, EpiPen, to profit at the expense of the Medicaid program." According to the DOJ's release:

The settlement resolves the government's allegations that *Mylan, by erroneously reporting EpiPen as a generic drug to Medicaid despite the absence of any therapeutically equivalent drugs, was able to demand massive price increases in the private market while avoiding its corresponding rebate obligations to Medicaid.* Between 2010 and 2016, Mylan increased the price of EpiPen by approximately 400 percent yet paid only a fixed 13 percent rebate to Medicaid during the same period. The government further alleged that although Mylan was well-aware that its drug was not a generic, it nevertheless claimed generic status for EpiPen in the Medicaid program to avoid paying a higher rebate.²⁸

140. As a condition of the settlement, Mylan was required to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General (HHS-OIG) that requires, among other things, an independent review organization to annually review multiple aspects of Mylan's practices relating to the Medicaid drug rebate program.²⁹ Mylan will be monitored for a period five years and has been required to establish and maintain a Compliance Program that includes, among other requirements:

> a. the immediate appointment of a Compliance Officer for the entire term of the CIA who shall be responsible for, among other things, developing and implementing policies, procedures, and practices designed to ensure

²⁸ Department of Justice – Office of Public Affairs, *Mylan Agrees to Pay* \$465 *Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates*, Aug. 17, 2017, available at https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liabilityunderpaying-epipen-rebates.

²⁹ Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Mylan Inc. and Mylan Specialty L.P, August 16, 2017, available at

https://oig.hhs.gov/fraud/cia/agreements/Mylan_Inc_and_Mylan_Specialty_LP_08162017.pdf

compliance with the CIA and with Federal health care program requirements, making periodic (at least quarterly) reports regarding compliance matters, written documentation of such reports to be made available to OIG;

- b. the immediate creation of a Compliance Committee to be chaired by the Compliance Officer and which shall support the Compliance Officer in fulfilling his/her responsibilities. Minutes of the Compliance Committee meetings shall also be made available to OIG; and
- c. the delegation to the Board of Directors of individual responsibility for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of the CIA, and demanding, among other things, that the Board disclose to the OIG a description of documents and other materials reviewed in complying with this requirement and for each reporting period, adopt a resolution, signed by each member of the Board, summarizing its review and oversight of Mylan's compliance with Federal health care program requirements and the CIA.³⁰

141. As explained by Gregory E. Demske, Chief Counsel to the Inspector General for the U.S. Department of Health and Human Services, "Our five-year corporate integrity agreement requires intensive outside scrutiny to assess whether Mylan is complying with the rules of the Medicaid drug rebate program. . . . In addition, the CIA requires individual accountability by Mylan board members and executives."³¹

142. According to the DOJ, "The government's intervention in this matter illustrates the

³⁰ CIA

³¹ DOJ Release, Aug. 17, 2017.

government's emphasis on combating healthcare fraud."³²

Generic Drug Formulary Manipulation: DOJ Investigation and Settlement

143. This misconduct regarding rebates repeats a pattern of such abuses that harkens back to a 2009 settlement Mylan reached with the DOJ over similar manipulations of Medicaid payments for covered generic drugs.

144. In 2009, the DOJ announced that Mylan and several other companies had "agreed

to pay a settlement to resolve allegations that [they] had sold innovator drugs that were

manufactured by other companies and had classified those drugs as non-innovator drugs for

Medicaid rebate purposes. As a result of the improper classification of these drugs, the companies

underpaid their rebate obligations under the Medicaid Rebate Program."33

145. The DOJ Press release went on to explain:

Mylan and UDL agreed to pay \$118 million to resolve allegations that they underpaid their rebate obligations with respect to several Mylan drugs (nifedipine extended release tablets, flecainide acetate, selegiline HCL, Orphenadrine Citrate Aspirin and Caffeine tablets, Triamterene/Hydrochlorothiazide, Propoxyphene HCL/Aspirin/Caffeine, HCL. Propoxyphene Prophyxphene Napsylate/Acetaminophen, Ibuprofen tablets, Bumetanide, Cephalexin and Cefactor) and several UDL drugs (nifedipine extended release tablets, selegiline HCL, Triamterene & HCTZ, Propox Naps & APAP, Flecainide Acetate, Trihexyphenidyl, Ranitidine HCL syrup, Sucralfate Suspension, Selegiline HCL and Bumetanide). Because the Medicaid program is funded by both the federal and state governments, the federal government received \$60,896,476.00, the states \$49,824,389.00 of the settlement amount and \$7,279,135.00 will be paid to entities that participated in the Public Health Service's Drug Pricing Program.

146. These past and present actions further demonstrate that Mylan's overly aggressive

tactics of dominating the market for EpiPens and then milking consumers and third-party payors

³² DOJ Release, Aug. 17, 2017.

³³ U.S. Department of Justice Press Release, *Four Pharmaceutical Companies Pay \$124 Million for Submission of False Claims to Medicaid*, Oct. 19, 2009, *available at* https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-

false-claims-medicaid.

for every cent of profit it can extract, legally or otherwise, is simply consistent with its past practices.

E. The EpiPen Scheme: Mylan's Predatory Monopolization, Racketeering, Unconscionable Sales, and Deceptive and Unfair Trade Practices

147. As a result of the economic forces driving the pharmaceutical industry, Mylan devised several ways to ensure that competitors did not enter the epinephrine auto-injector market, did not launch competing devices, and did not offer a generic alternative to the brand name EpiPen.

148. The EpiPen Scheme committed by Mylan and the other Defendants can be divided into roughly four parts:

(1) illegally maintaining its monopoly powers by (a) paying powerful Pharmacy Benefit Managers to exclude Mylan's competition; (b) signing up schools to anticompetitive exclusive dealing contracts; (c) using misleading advertising to damage competing products; and (d) restraining competitors, like Teva, via patent infringement suits, illegal pay-for-delay settlements, manipulating the FDA's citizen petition process;

(2) fraudulently paying doctors and committees to endorse the 2-Pak launch of the EpiPen as medically necessary and launching the EpiPen 2-Pak (while simultaneously withdrawing the individual EpiPen in the United States; and

(3) making materially misleading and false statements to conceal the ongoing EpiPen Scheme.

1. Defendants' Illegal Acquisition and Maintenance of Mylan's Monopoly

149. Firms that have monopoly power can exclude rivals and harm the competitive process.³⁴ Where a firm has monopoly power, buyers are not able to switch away from its products because the loss of supply is too great. This gives the firm with monopoly power the ability to

³⁴ See Robert Pindyck & Daniel Rubinfeld, *Microeconomics* 366-68 (7th ed. 2009).

impose exclusionary conditions on its buyers that can adversely affect rivals.

150. Mylan, with the assistance and support of its co-conspirator co-defendants, possesses and exercises the power to exclude rivals and has illegally acquired and maintained its monopoly power. Defendants have done this in several ways, including by (a) paying PBMs to shut out competition, (b) coercing schools to enter into exclusive dealing contracts, and (c) manipulating patent infringement litigation to forestall entry of generic and novel competitors, among other anticompetitive means.

a. Mylan Abuses the EpiPen Monopoly by Paying PBMs to Exclude Competition

151. A monopolist is defined by its ability to raise prices without sacrificing sales volume. That is the very essence of market power.

152. As explained in more detail below, Defendants used this power to raise prices which then afforded them larger margins on the sale of each EpiPen. Mylan used these larger margins to offer aggressive rebates and incentives to certain Pharmacy Benefit Managers to exclude competitors from their Preferred Drug Lists—rebates other manufacturers could not afford to match because they lacked the market power to increase prices without sacrificing sales volume. In this way, Defendants abused their monopoly power to harm competition.

153. PBMs played an active role in Mylan's anti-competitive and fraudulent scheme. They serve as gatekeepers between drug and medical supply manufacturers on the one hand, and health insurers and patients on the other. Specifically, PBM's administer a health coverage provider's prescription benefit program by developing the coverage provider's formulary (the list of prescription benefits included in coverage at various pricing "tiers"), processing claims, creating a network of retail pharmacies that provide discounts in exchange for access to a provider's plan participants, and negotiating with manufacturers.

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154. While PBMs could use their leveraged position in the market to drive down the prices for medical products by forcing manufacturers to lower their list prices, instead, as detailed in the below chart, they and Mylan figured out a way to game the system for their mutual benefit: To gain exclusive preferred formulary access, Mylan inflated its list prices and then "rebated" or kicked back a significant portion of that list price to the PBMs.

155. PBMs are third-party administrators of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans.

156. According to the American Pharmacists Association ("APhA"):

PBMs are primarily responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. For the most part, they work with self-insured companies and government programs striving to maintain or reduce the pharmacy expenditures of the plan while concurrently trying to improve health care outcomes.³⁵

157. The significant majority of patients with prescription drug insurance coverage receive their benefits through a "third party payor" whose drug formulary is determined by a PBM. During the 2013 to 2015 period, commercial third-party payors made up approximately 71% of the epinephrine auto-injector market in the United States.

158. Access to the third-party payor's drug formulary (as set by the PBM) is therefore critical to the success of an epinephrine auto-injector. The devices are almost exclusively distributed to individual patients and caregivers rather than through hospitals or other health care providers. Further, because they are necessary, life-saving devices, patients generally will not tolerate a lengthy appeals process to get coverage if their prescribed epinephrine auto-injector is

³⁵ *Pharmacy Benefit Management*,

https://www.pharmacist.com/sites/default/files/files/Profile_24_PBM_SDS_FINAL_090707.pdf.

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not readily available—they will simply choose the device that is covered with no hassle. Thus, market access is based almost entirely on contracts with third-party payors that are negotiated by PBMs.

159. Another major gateway to the epinephrine auto-injector market in the United States is through state Medicaid providers. State-based Medicaid plans, which also use drug formularies, made up an additional 16% of the Epinephrine auto-injector market during the 2013 to 2015 period. Together, commercial payors and Medicaid made up nearly 90% of the Epinephrine auto-injector market in the U.S. over these three years. Having access to the drug formularies of these thirdparty payors is crucial to entering and competing vigorously in the epinephrine auto-injector market.

160. Patients with prescription drug insurance coverage through a third-party payor typically are not freely able to choose a new payor or pick-and-choose among payors for a particular brand of drug. Many patients receive third-party payor coverage through employer-sponsored plans, which may offer coverage through a specific payor. And most plans require patients to choose coverage during a limited time period each year, and patients are unable to choose a new coverage plan until the following year.

161. In short, prescription drug insurance plans only cover costs for drugs that appear on their PBMs' formulary, or list of covered drugs. They do not cover any of the costs for drugs that do not appear on their formularies.

162. Express Scripts and CVS Caremark are the two largest PBMs in the United States.In 2014, they combine to cover well over 50% of the PBM market in the United States.

163. In 2013, CVS Caremark became the first PBM to issue a list of *excluded* drugs that would not be covered by insurance plans for which it provided services. In 2014, Express Scripts

followed suit and issued its own Preferred Drug List *Exclusions*.

164. The PBMs did this, in part, as a negotiation tool to leverage greater discounts and rebates for drugs that are *not* excluded from its formulary. Defendants, however, saw this as an opportunity to exclude rivals.

165. Defendants took advantage of Mylan's monopoly power and in response to this perceived opportunity, Mylan hiked prices by 15% in July 2013. It then tacked on four more successive 15% increases in February 2014, September 2014, April 2015 and November 2015, taking the price from \$304 all the way up to \$530 in the course of less than 30 months.

166. By doing this, Mylan created additional profit margin from which it could pay a portion of these monopoly profits to PBMs in the form of significantly higher rebates and percentage discounts. For example, in her congressional testimony, Mylan's CEO offered a chart that showed while the Wholesale Acquisition Cost for EpiPen two-packs rose from \$401 in September 2014 to \$530 in November 2015, Mylan's profit per two-pack actually *dropped* from \$235 to \$219 respectively. On information and belief, this temporary drop in profit margin was due to larger rebates paid to PBMs.

167. As they knew at the time, defendants' largest competitors, Auvi-Q[®] (hereafter without [®] for readability) and Adrenaclick, could not raise prices to inflate their margins, and thus could not offer PBMs similarly inflated rebates or discounts on their products.

168. On information and belief, in exchange for defendants' increased rebates and discounts, Express Scripts added Auvi-Q to its 2014 Preferred Drug List *Exclusions*, and CVS Caremark added Adrenaclick to its 2014 list of Formulary Drug *Removals* – thus effectively removing these EpiPen alternatives from consumer and other end-payor choice.

169. Defendants' exclusion of the Auvi-Q is one of the more prominent examples of

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how its rebate scheme, coupled with its intentional underpayment of Medicaid rebates, excluded a would-be competitor and harmed competition. Auvi-Q is a small epinephrine auto-injector with automated voice instructions. Notably, the battery that powers the voice instructions of Auvi-Q was designed to last for several years, well beyond the one-year shelf life of the epinephrine in the device (the same epinephrine shelf life as in similar epinephrine auto-injectors). The device was also designed so that Auvi-Q's injection mechanism works independently of the battery and other electronic features of Auvi-Q. That way, Auvi-Q would not need battery power to deliver its life-saving medicine.

170. As part of the approval process for Auvi-Q, the FDA determined that the epinephrine used in Auvi-Q was bioequivalent to the epinephrine in the EpiPen. This meant that the active ingredient in both the EpiPen and Auvi-Q were equivalent. However, because the devices were not identical, and were designed to use different procedures, Auvi-Q could not be substituted automatically for the EpiPen by a pharmacist because Epinephrine auto-injectors require the patient or caregiver to be trained on a particular device.

171. On January 28, 2013, Sanofi launched Auvi-Q. Sanofi was already well-known in the allergy space at the time for the drug Allegra®, and it brought its resources and reputation to Auvi-Q. Sanofi spent tens of millions of dollars promoting Auvi-Q and educating physicians and key allergy awareness groups on the benefits of Auvi-Q. Sanofi also hired a large sales force to compete with Mylan.

172. Sanofi matched many of Mylan's promotional programs, to maximize patients' access to Auvi-Q. Sanofi offered a discount program for schools to have access to Auvi-Q. Sanofi also offered coupons to cover patients' co-pays to help offset the higher out-of-pocket cost of Auvi-Q, due to its lower status on third party payor drug formularies. Sanofi launched Auvi-Q at

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price parity with EpiPen, in part to ensure that Auvi-Q would be treated equally with the EpiPen in terms of patients' access.

173. Importantly, when Auvi-Q was launched, it was generally covered on drug formularies – albeit at a less preferred level – with key third-party payors.

174. Mylan responded to Auvi-Q's initial success by taking steps to ensure that Auvi-Q would be blocked from drug formularies going forward. Beginning around May 2013, upon information and belief, Mylan began to proactively pitch large rebates to the PBMs that controlled the formularies for third-party payors—30% or higher—expressly conditioned on the EpiPen gaining exclusive position on the formulary, and causing Auvi-Q to now be identified as *excluded or severely restricted* on drug formularies.

175. Before the launch of the Auvi-Q, epinephrine auto-injectors were considered a "managed" product category; that is, PBM's historically did not place competing injectors into different status tiers or otherwise "prefer" one product over another.

176. Before the launch of the Auvi-Q, Mylan did not typically offer rebates for the EpiPen and, where it did so, Mylan's rebates were generally low, often below 10%. After Auvi-Q launched, Mylan began to offer much larger rebates—30% or higher. These extremely large rebates were conditioned on exclusivity. In other words, Mylan offered these large rebates only if it could ensure that Auvi-Q would not have access to the market. Combined with the EpiPen's extremely high market share, these rebates created an offer that PBMs (who would in turn each share a portion of those rebates) could not turn down, and that Sanofi could not match.

177. Mylan was leveraging its durable greater-than-90% market share in getting PBMs to exclude Auvi-Q from their recommended formularies. And, Mylan's rebates were approximately 100-200% larger (at least) than what they paid before Sanofi launched Auvi-Q—if

Mylan had previously offered rebates at all.

178. Further, because of Mylan's price increases, Mylan's net prices on the EpiPen were soon higher after it began its exclusionary rebates than they were before the rebates began. For example, if Mylan offered no rebate or very low rebates on the EpiPen when it was priced at \$200 (as it was around February 2012, when Mylan announced the settlement of patent infringement lawsuit that would allow Auvi-Q to launch as soon as November 2012), but offered a 30% rebate on the EpiPen when it was priced at \$300 (as it was by January 2014, when Mylan's large, exclusionary rebates went into effect), Mylan's net price after the rebate, \$210, exceeded the \$200 price before Mylan's large exclusionary rebates began. Mylan conditioned those rebates on Auvi-Q being blocked and put in a highly restricted formulary position. These rebates caused PBMs to begin to restrict the epinephrine auto-injector category for the first time. There was no legitimate business reason for Mylan's deep conditional rebates other than to block Auvi-Q from the market.

179. Mylan offered similar rebates to other third-party payors, such as state-based Medicaid formularies. Mylan was successful in having Auvi-Q excluded from coverage in many states due to these rebates.

180. In Georgia, for example. Mylan conditioned its rebates on the requirement that the EpiPen be the only auto injector with preferred status, and that the state exclude all branded and generic auto injectors.

181. Delaware, too, received a "positioned offer" (which is simply industry-jargon for an offer based on exclusivity) of higher rebates in return for excluding Mylan's competitors.

182. Sanofi tried to match Mylan's rebates, but EpiPen's already-dominant market share created from anticompetitive conduct, combined with Mylan's and the PBM's scheming behind the scenes to enrich themselves, prevented fair competition. If Sanofi matched Mylan's offer and

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provided a 30% rebate to convince a PBM to list Auvi-Q at parity with the EpiPen for preferred brand name drugs, but Mylan did not provide a rebate (or provided a much smaller rebate) because the PBM had not granted the EpiPen exclusive coverage, then the PBM and the third-party payors they represent would have foregone the Mylan rebate on the high percentage of the epinephrine auto-injector market that was held by the EpiPen, while only gaining the Sanofi rebate on a smaller percentage of the market. This meant that a new entrant, like Sanofi, would need to offer rebates far in excess of the 30% rebates offered by Mylan.

183. When PBMs saw the offer of a 30% rebate from Mylan, which again at the time had a 90%+ market share, they saw (and told Sanofi) that there was no way for Sanofi to match, as Mylan's proposed rebate far exceeded Auvi-Q's projected sales. PBMs confirmed to Sanofi that Mylan's dominant EpiPen market share made it impossible for Sanofi to match Mylan's rebate. Put simply, Mylan made PBMs a never-before-made financial offer "they could not refuse." This is a textbook example of the illegal use of monopoly power to exclude competition resulting in harm to consumers and third-party payors.

184. To paint Mylan's illegal monopolistic conduct in stark terms, analysts working for the State of Nebraska calculated that over 50% of auto injector users would need to switch away from the EpiPen for the state just to break even when considering the rebate Mylan offered in exchange for exclusivity.

185. While these large rebates had the intended effect of foreclosing Auvi-Q from the market, they also diverted a large portion of the EpiPen's price increases away from Mylan. To offset the loss of those revenues and as detailed in part above, Mylan intentionally *underpaid* hundreds of millions in other rebates to the Medicaid Drug Rebate Program that is was required to pay.

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186. For years, Mylan had been misclassifying the EpiPen as a "non-innovator" drug in the Medicare and State-based Medicaid space.

187. The EpiPen did not meet the criterial for generic or "non-innovator" drugs, yet Mylan maintained the self-identified classification on the Medicaid Drug Rebate Program as a non-innovator drug, even though the Center for Medicaid and CHIP Services "expressly told Mylan that the product is incorrectly classified."³⁶ This scheme enabled Mylan to amass millions of dollars each year in unpaid rebates to cash-strapped state Medicaid agencies. In fact, as alleged above, Mylan recently settled claims regarding these underpaid rebates for \$465 million, although it is estimated that it underpaid substantially more claims than that. By contrast, Mylan's competitor Sanofi properly classified Auvi-Q as an innovator drug and paid disproportionately larger rebates to Medicaid, which curtailed its ability to offer significant rebates to PBM's to keep pace with those Mylan offered for the EpiPen.

188. Perversely, the outstanding underpaid rebates led benefit managers to continue favoring the EpiPen over competitors in the expectation of receiving a large make-up payment if and when Mylan was forced to classify the EpiPen as a brand. As one analyst noted, "If CMS requires Mylan to recalculate their rebates to reflect a branded status as we are expecting, the federal rebate has the potential to increase drastically."

189. This exclusionary conduct had an immediate impact on EpiPen's market share. For example, while Auvi-Q had steadily been gaining market share up to 13% in 2013, its exclusion from drug formularies immediately cut its share to 8% in January 2014, further dropping to around

³⁶ *See* Letter from Andrew M. Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, to Senator Ron Wyden (Oct. 5, 2016), *available at*

https://www.finance.senate.gov/imo/media/doc/Wyden%20EpiPen%20Medicaid%20Letter%20f rom%20CMS%2010.5.16.pdf.

7% by May 2014. Others observing the market recognized what Defendants had done. As reported in an *NBC News* article dated September 6, 2016, citing pharmaceutical industry analyst and advisor Adam Fein:

Pharmaceutical companies will sometimes pay PBMs steeper discounts in order to shut out their competition, said Fein. And, in the past, two of the biggest PBM companies have excluded EpiPen competitors from coverage: In 2014, Express Scripts excluded Auvi-Q, and in 2015 Caremark didn't cover Adrenaclick. This meant that if your insurance company was their customer, you would not be able to get the EpiPen alternative without paying full retail price.³⁷

190. That article went on to quote Express Scripts spokesman Brian Henry, who

acknowledged that "[i]n 2014 and 2015, we [Express Scripts] leveraged the competition between

EpiPen and Auvi-Q to earn additional discounts for our clients.""38

191. Mylan has also acknowledged that it leverages its rebate deals and formulary

position to protect and enhance its market share. In a Q3 2013 analyst call, Mylan CEO Bresch

stated:

As far as EPIPEN goes, we had a phenomenal quarter. I couldn't be happier with the results that EPIPEN continues to produce, and the return on our investment of education and awareness and direct-to-consumer advertising has very much paid off. And as I said, we see a lot of runway room left.

There's still a fairly small number of at risk patients for anaphylaxis carrying an EPIPEN, and we believe that our message is being heard. And as far as the competition landscape goes, as we've said all along, that shared voice in a market like this that shows this much reaction to education and awareness is beneficial, obviously, for the patient, and we believe we'll continue to get our very much disproportionate share around this marketplace for years to come.

I think as far as pricing, our formulary position, we are in a number one formulary position with all the major formularies and don't see any of that changing next year.³⁹

³⁷ Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than \$30*, NBC News, Sept. 6, 2016, *available at* http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091.

 $^{^{38}}$ *Id.*

³⁹ Mylan Q3 2013 Earnings Conference Call, Oct. 31, 2013.

192. Likewise, in a Q2 2014 analyst conference call, the following exchange occurred:

Elliot Wilbur – Needham & Company, LLC, Research Division

First question is for Heather with regard to the EpiPen franchise. Obviously seeing a lot of noise in the market and a lot of shifting regarding formulary positioning and I guess despite the fact that EpiPen is a dominant product in the category and sort of the price leader, it's still maintained very strong formulary positioning.

And I'm just curious sort of what the trend has been in rebating on the product? Whether that strong formulary position has come increasingly at the cost of higher rebates?

And maybe you could just sort of talk about kind of ability to grow the product sort of in excess of the Rx volume growth trends that we're currently seeing in the marketplace. And then just as a second question here and just to confirm, Heather, delays in expected product approval activities are purely a function of FDA timelines and don't have anything to do with recent inspection observations at any of your facilities.

Mylan CEO Heather Bresch

Okay. Sure. So what I'd say, Elliot, around EpiPen obviously when you've got a multiple epinephrine product marketplace, it leads to a more competitive positioning, both with the pharmacies, as well as payers. *I think that given the breadth and scope of our business, that we've been able to manage and to obviously remain very competitive in that structure*.

But with that being said, we're going to do whatever we need to do to really maintain that market leadership, and like I said, and continue to look at ways that we can enhance and add to this franchise. So I think the strong script trends are just indicative of how much runway room is still out there.

Because I think as we continue to educate, like I said, not only customers, but truly everything from schools to establishments on how important to have access to EpiPen is, we've just continued to see those campaigns very much take hold and very much continue to drive these script trends throughout the United States. So I think, like I said, it's just indicative of how much runway is left and the return on our capital being very high based on the demand that it's creating in the marketplace.⁴⁰

193. And again in a Q4 2015 analyst call, Bresch stated:

[T]hroughout 2015, especially at the beginning of the year . . . Mylan had been very proactive, in maintaining our market share in a very competitive multi-epinephrine

⁴⁰ Mylan Q2 2014 Earnings Conference Call, Aug. 7, 2014.

marketplace. And that involved entering contracts with our payers, long-term multi-year contracts.

* * *

I think what we did say, is that we were very proactive. And I had very – I think very straightforward conversations with all of the investors and shareholders, that *we were maintaining market share. And to do so, that required aggressive rebating*, and that's why that we absorbed much of that during 2015.

* * *

As far as the contracts that I mentioned, look we were – as I mentioned in 2015, the aggressiveness came from the current multi-epinephrine market and the players that were in there, including Auvi-Q and Sanofi.⁴¹

194. In fact, when Mylan CEO Heather Bresch was called to testify to a Congressional committee investigating the high price of the EpiPen, she expressly admitted that Mylan's payment of rebates and other "allowances"—whatever those are—to PBMs has directly contributed to the sky-rocking price of the EpiPen: "Bresch said that for every \$608 EpiPen two-pack, Mylan receives \$274. The remaining \$334 go to other players in the supply chain – middle men, including pharmacy benefit managers, or PBMs."⁴² What Bresch neglected to emphasize, however, is that it is Mylan that sets the price for EpiPens.

195. Going further, Bresch herself points fingers at the PBM Defendant "middlemen" (even though they are not "middlemen", but formulary consultants) to explain the exorbitant price of EpiPens: "Bresch asserted [that] Mylan had little choice but to jack up the EpiPen list price to accommodate the middlemen's demands for rebates and fees."⁴³ And she alleged that blaming

⁴¹ Mylan Q4 2015 Earning Conference Call, Feb. 10, 2016.

⁴² CBS News, *Mylan CEO on EpiPen drug price controversy: "I get the outrage"* (Jan. 27, 2017), http://www.cbsnews.com/newsepipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out.pdf.

⁴³ Michael Hiltzik, *How 'price-cutting' middlemen are making crucial drugs vastly more expensive*, L.A. Times (June 9, 2017), http://www.latimes.combusiness/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.

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manufacturers like Mylan for high drugs costs is unfair: "the only face that you see on that medicine is the pharmaceutical manufacturer," Bresch said. "Where in reality there's at least five entities touching that product,"⁴⁴ which she includes PBMs in the below chart prepared by Mylan.⁴⁵ That chart misleadingly suggests the PBMs are actually in the supply chain, when in fact they are not and do not actually "touch" the product, though PBMs do have an impact on product usage and thus pricing of EpiPens:



196. And in the below-excerpted portion of an interview with CNBC, Ms. Bresch

reiterated Mylan's position:

<u>Bresch</u>: So look, no one's more frustrated than me. I've been in this business for 25 years.

Brian Sullivan (CNBC): But you're the one raising the price, though. How can you be frustrated?

<u>Bresch</u>: My frustration is there's a list price of \$608. There is a system. There are -I laid out that there are four or five hands that the product touches and companies that it goes through before it ever gets to that patient at the counter. No one-everyone should be frustrated. I am hoping that this is an inflection point for this county. Our health care is in a crisis. It's no different than the mort-gage crisis back in 2007. This bubble is going to burst.

⁴⁴ *Id*.

⁴⁵ Mylan, *The Entire Economic Story of the U.S. Pharmaceutical Supply Chain* (2017), http://www.mylan.com/-/media/mylancom/images/featured_stories/supply-chain.jpg.

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197. Despite Bresch's claims regarding the role that PBMs plan in drug pricing, manufacturers like Mylan are no less at fault. Their conduct deprives patients of a fair price for epinephrine auto-injectors—a price that would result from the operation of normal market forces. Mylan maintains the ability to sell EpiPen products to the millions of Americans who depend on them, without having to lower the "real," net prices to gain market share via formulary inclusion. Instead, they bargain for that market share by providing ever-larger rebates and other kickbacks to PBMs and entering into exclusive relationships with those PBMs, inflating the prices paid by consumers for EpiPens in order to preserve their net realized price and sales volumes.⁴⁶

198. Although Bresch routinely peppers her public statements with reference to a "very competitive" marketplace, as described above the marketplace is in fact dominated by EpiPen and Mylan continues to do everything in its power to exclude competition unlawfully. Mylan's "aggressive" positioning of EpiPen within the dominant formularies is facilitated only by the company's monopoly power which allows it to charge consumers *higher* prices for its product which it then shares with PBMs (which create the formularies) through substantially enhanced rebates in exchange for *excluding* insurance coverage for rival products. The net effect of this is to harm the competitive process, and not to compete legally in a way that would promote competition or the benefits to consumers from robust and fair competition.

b. Defendants' Manipulate Access to Schools through Lobbying and Illegal Exclusive Dealing Arrangements to Enhance and Protect the EpiPen Monopoly

199. Through a carefully orchestrated nationwide lobbying effort on state and federal levels, Defendants have created an important sub-market for epinephrine auto-injectors in the

⁴⁶ Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, Wall St. J., (Oct. 7, 2016, 5:46 PM), https://www.wsj.com/articles/insulin-pricessoar-while-drugmakers-share-stays-flat-1475876764.

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nation's public schools, and then excluded competitors from this market through exclusive dealing contracts with those schools. The importance of access to this submarket for nascent competitors is heightened by the unique medical need for this product, and the educational marketing opportunities the submarket affords, as explained in greater detail below.

200. Mylan used its school programs to hook consumers on its product and to set the table for the predatory conduct that followed. A prominent health care law professor, Nicholson Price, has compared Mylan's tactics to those of a drug dealer: "'It's kind of like the first hit's for free,' says Nicholson Price, an assistant professor at the University of Michigan Law School. 'You want to start people off with your product, and getting these products in at schools is a great way.'"⁴⁷

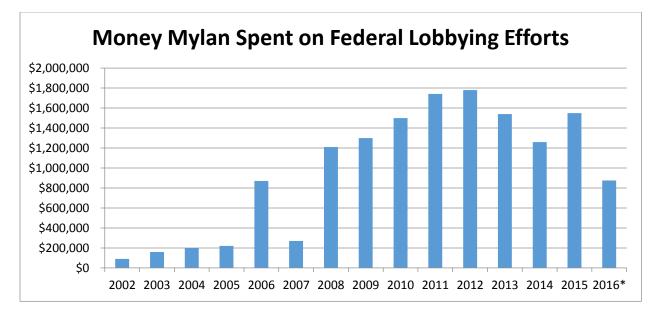
201. The pharmaceutical industry has some of the most active lobbyists on Capitol Hill and in state houses around the country. In fact, the industry regularly spends nearly \$250 million a year lobbying Congress.

⁴⁷ Pauline Bartolone, *EpiPen's Dominance Driven by Competitors' Stumbles and Tragic Deaths*, NATIONAL PUBLIC RADIO (Sep. 7, 2016), <u>http://www.npr.org/sections/health-shots/2016/09/07/492964464/epipen-s-dominance-driven-by-competitors-stumbles-and-tragic-deaths</u>, (last visited Jan. 31, 2017).



202. Until recently, however, Mylan had not been among the top spending pharmaceutical lobbying groups. That changed shortly after Mylan purchased the rights to EpiPen.

203. Beginning in 2008, a company that had spent less than \$2 million on lobbying in the prior six years combined, upped its federal lobbying budget to \$1.2 million annually. Since then, at a time when industry-wide spending on lobbying has declined, Mylan has spent nearly \$12 million lobbying Capitol Hill alone, and that figure does not account for the considerable funds Mylan has spent lobbying state houses across the country.



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204. Mylan's lobbying efforts had a primary objective – to gain access to parents, educators, and medical professionals by creating a submarket for EpiPens in public schools.

205. That effort has been enormously successful. Today, 37 states *permit* their public schools to stockpile epinephrine auto-injectors, and another 11 states actually *require* such stockpiling.

206. As the dominant supplier of epinephrine auto-injectors, Mylan's lobbying efforts did not just result in *access* to schools, it actually made its product *mandatory* for schools in many states.

207. Mylan also spent a reported \$4 million specifically lobbying Congress to pass the School Access to Emergency Epinephrine Act, a law that would give federal funding priority to schools that stockpiled epinephrine auto-injectors. President Barrack Obama signed that bill into law in 2013.

208. Adding school districts to the market for auto-injectors created a substantial additional need for EpiPens. There are now more than 67,000 school districts that purchase EpiPens, and they are typically "bulk" purchasers. For example, the public schools in Fairfax County, Virginia, annually order about 1,100 EpiPen 2-Paks each year to have on hand for their 180,000 students.⁴⁸

209. But opening up new markets for the EpiPen was not even the primary advantage of these new laws. Gaining access to school nurses and creating familiarity with the EpiPen among parents has made the product as ubiquitous as Kleenex. As the *Washington Post* recently noted: "Although these legislative efforts were not supposed to benefit a particular company, the

⁴⁸ Ike Swetlitz & Ed Silverman, *Mylan may have violated antitrust in its EpiPen sales to schools, legal experts say*, STAT, Aug. 25, 2016, *available at* https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/.

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brand has such a lock on the market that when President Obama signed the School Access to Emergency Epinephrine Act in 2013, a news announcement simply called it the 'EpiPen Law.'"⁴⁹

210. As the *Washington Post* recognized, while that law gave financial incentives to schools to stock EpiPens, it also allowed "trained school personnel to administer the treatment to students."⁵⁰ "'That was a Trojan horse,' said David Morris, a Wells Fargo analyst. 'That was, "Let's get it in schools to help people," but it helps market EpiPen and promote it as the trusted product in schools."⁵¹

211. R. Adams Dudley, a pulmonologist at the University of California at San Francisco, observed:

[Mylan's] most brilliant maneuver, clearly, was giving them [EpiPens] away to schools and making it the thing that they could say, 'Well, the nurse knows how to use it'... What are parents afraid of? Their child will be away from them, and they won't be there to use it. If they can say the school nurse knows how to use an EpiPen; she's never seen an Adrenaclick ... It's just a fear thing.⁵²

212. Thus, Mylan's lobbying efforts expanded its monopoly by creating a critical new submarket for epinephrine auto-injectors in schools. It also created a sales and marketing channel that was invaluable in entrenching its already dominant market position. Access to this market was critical to any nascent competitor that sought, or might seek, to introduce its own epinephrine auto-injectors.

213. Having succeeded in essentially mandating stockpiling of epinephrine autoinjectors in schools, Mylan then acted swiftly to ensure that no other competitor could operate in this new and important space. To ensure this new avenue remained completely out of reach from

⁴⁹ Carolyn Johnson & Catherine Ho, *How Mylan, the maker of EpiPen, became a virtual monopoly*, Washington Post, Aug. 26, 2016.

 $^{^{50}}$ *Id*.

⁵¹ *Id*.

⁵² *Id.*

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competition, Mylan gave free and discounted EpiPens to school districts that now had to (or were strongly encouraged to) comply with these new regulations, *but also made those offers contingent on the schools entering into illegal exclusive dealing agreements with Mylan*.

214. In August 2012, Mylan launched the "EpiPen4Schools" program, which provided EpiPens to schools at a discounted rate. The program, which has grown to include more than 67,000 schools, provided EpiPens to schools at a discounted price of \$112.10 in 2015, \$350 less than the list price at the time.

215. In order to qualify for this discount, however, schools had to sign a contract agreeing not to purchase any products from Mylan's competitors for a period of 12 months.⁵³ For example, schools taking part in Mylan's discounted EpiPen program had to certify in writing that the school *"will not purchase any products that are competitive products to EpiPen*® *Auto-Injectors."*

216. In addition to providing discounted injectors, the program also provided for free EpiPen sets to be sent to certain schools. As described in one report, "[w]hile this sounds like a generous thing for Mylan to do, we predict that Mylan is simply seeding the schools for automatic replenishment when the product expires."⁵⁴

217. As noted antitrust expert Professor Herbert Hovenkamp has stated, use of exclusive dealing contracts while possessing market power can violate the antitrust laws. As reported by *STAT News*:

⁵³ Sen. Blumenthal & Sen. Klobuchar Press Release, *Blumenthal & Klobuchar Call for Immediate Federal Investigation into Possible Antitrust Violations by EpiPen Manufacturer*, Sept. 6, 2016.

⁵⁴ BMO Capital Markets, "Mylan: A Generic Generic Company; Initiating With Underperform," May 9, 2013, at 10.

"It is illegal to issue a discount on the condition the customer not acquire a competitor's goods – if the effect may be to substantially lessen competition," said Herbert Hovenkamp, a University of Iowa law professor and antitrust expert.

At issue is the notion of an exclusionary contract, which requires a customer to promise not to deal with a competitor. Exclusionary contracts are a common tactic for keeping a lock on a market, Hovenkamp said.

But using such a contract while also having a dominant market share may hinder competition, which he explained can be an antitrust violation. Last year, EpiPen made up 89 percent of the epinephrine auto-injector market, according to IMS Health, a market research firm.⁵⁵

218. Public schools notoriously operate under very strict budgets. In states that now require schools to stockpile epinephrine auto-injectors, that duty comes with a significant cost. Schools in states that permit the stockpiling of auto-injectors also face intense pressure to do so from concerned parents and, in part, out of the potential legal liability that attends a decision *not* to stock such potentially life-saving devices in the face of a foreseeable risk posed by the potentially life-threatening allergies of some of their students.

219. Leveraging its dominant market position, Mylan has foreclosed competition in this submarket by offering to supply a portion of each school's need for auto-injectors with free or discounted stock *in exchange for entering into exclusive dealing contracts with those schools*.

220. By foreclosing this important submarket from its rivals, Defendants have harmed competition that affects both the price of auto-injectors and the ability of nascent competitors to introduce competing products in this important environment.

221. In an admission of guilt, Mylan later eliminated the requirement that schools participating in the EpiPen® School Discount Program commit to exclusively use EpiPens against any other epinephrine auto-injector.

⁵⁵ Ike Swetlitz & Ed Silverman, *Mylan may have violated antitrust law in its EpiPen sales to schools, legal experts say*, STAT, Aug. 25, 2016, *available at* https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/.

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222. The effective exclusion of EpiPen's would-be competitors such as Auvi-Q and Adrenaclick from the educational market did not go unnoticed. On September 6, 2016, New York Attorney General Eric T. Schneiderman announced the commencement of his office's investigation into Mylan: "A preliminary review by the Office of the Attorney General revealed that Mylan Pharmaceuticals may have inserted potentially anticompetitive terms into its EpiPen sales contracts with numerous local school systems."⁵⁶

223. In September 2016, two United States Senators—Senator Richard Blumenthal and Senator Amy Klobuchar—asked the Federal Trade Commission to investigate whether Mylan violated federal antitrust laws to protect EpiPens from competition.⁵⁷

224. According to Senator Richard Blumenthal's office: "Schools [who used the EpiPen4Schools Program] were required to sign a contract agreeing not to purchase any products from Mylan's competitors for a period of 12 months—conduct that can violate the antitrust laws when taken by a monopolist."⁵⁸

225. In response, Mylan has made a number of false statements concerning the EpiPen4Schools program.

226. Under oath, when testifying to Congress on September 21, 2016, Ms. Bresch testified, "And we've made great strides in providing access to EpiPen Auto-Injectors in public

 ⁵⁶ Press Release, A.G. Schneiderman Launches Antitrust Investigation Into Mylan Pharmaceuticals Inc., Maker of Epipen, Sept. 6, 2016, available at http://www.ag.ny.gov/pressrelease/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker.
 ⁵⁷ Dan Mangan, New York Attorney General Launches Antitrust probe of Mylan's EpiPen

Contracts, CNBC (Sept. 6, 2016), <u>http://www.cnbc.com/2016/09/06/new-york-attorney-general-launches-antitrust-probe-of-mylans-epipen-contracts.html</u>, (last visited Jan. 31, 2017).

⁵⁸ Richard Blumenthal, Blumenthal & Klobuchar, *Call for Immediate Federal Investigations into Possible Antitrust Violations by EpiPen Manufacturer* (Sept. 6, 2016), <u>https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-and-klobuchar-call-for-immediate-federal-investigation-into-possible-antitrust-violations-by-epipen-manufactrurer</u>, (last visited Jan. 31, 2017).

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places, starting with schools. In the last four years alone, Mylan provided seven hundred thousand free EpiPen Auto-Injectors to more than 66,000 schools across America, with no strings attached."⁵⁹

227. That statement was false and misleading because Mylan did attach strings to the schools who received EpiPens. In fact, Mylan required receiving schools to sign a contract agreeing not to purchase any products from Mylan's competitors for a period of 12 months.⁶⁰

228. By making this false and misleading statement, Ms. Bresch intended to confuse and conceal Mylan's ongoing fraudulent and anti-competitive EpiPen Scheme from regulators and consumers.

c. Mylan's Use of Misleading Advertising to Exclude Competition

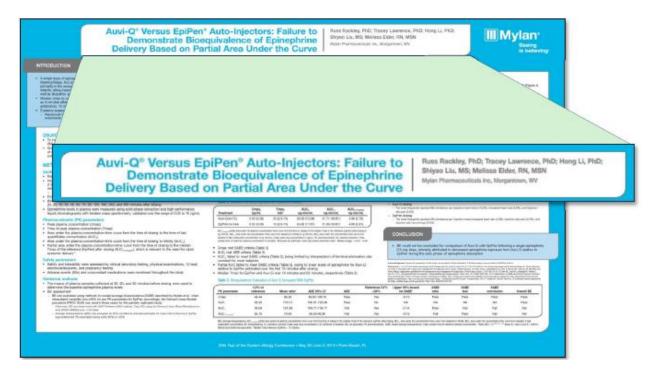
229. Mylan also created and spread misinformation about Auvi-Q and its bioequivalence to EpiPen. In approving Auvi-Q, the FDA determined that the epinephrine in Auvi-Q is bioequivalent to the epinephrine in the EpiPen. But Mylan funded and promoted a study entitled "Auvi-Q versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve." That was a misleading title not intended for legitimate scientific debate. It was not intended to question the FDA's procedure in determining bioequivalence among epinephrine auto-injectors generally. The Mylan study was intended to undermine the FDA's conclusion that Auvi-Q demonstrated bioequivalence to the epinephrine in

⁵⁹ *Testimony of Mylan CEO Heather Bresch*, UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM (Sep. 21, 2016), <u>https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf</u>, (last visited Jan. 31, 2017).

⁶⁰ Richard Blumenthal, *Call for Immediate Federal Investigations into Possible Antitrust Violations by EpiPen Manufacturer* (Sept. 6, 2016),

https://www.blumenthal.senate.gov/newsroom/press/release/blumenthal-and-klobucharcall-for-immediate-federal-investigation-into-possible-antitrust-violations-by-epipenmanufactrurer, (last visited Jan. 31, 2017).**Error! Hyperlink reference not valid.**

the EpiPen—and directly contradicted the FDA's conclusion. An image of Mylan's materials presenting the study is below:



230. Mylan's presentation of this data was intended to influence the opinions of key thought leaders in the allergy field against Auvi-Q, and to influence key allergy advocacy groups to turn against Auvi-Q.

231. Mylan also used other strategies to combat competition from Auvi-Q. When Auvi-Q was released in 2013, Mylan's CEO, Heather Bresch, was quoted stating that "EpiPen has been tried and true for 25 years.... It's not easily confused with a Blackberry or your phone in your purse or your backpack."⁶¹ Mylan's fear mongering to doctors, patients, parents, and caregivers was that Auvi-Q would be mistaken for some other technology device and not carried when needed to treat an anaphylactic episode.

⁶¹ Katie Thomas, *Brothers Develop New Device to Halt Allergy Attacks*. N.Y. TIMES, Feb. 3, 2013, *available at* http://www.nytimes.com/2013/02/02/business/auvi-q-challenges-epipen-with-a-new-shape-and-size.html

232. Mylan also made misleading statements to physicians, through the mail and wires, regarding Auvi-Q's exclusion from the marketplace. Mylan distributed materials to physicians touting that the EpiPen is the "preferred brand" for major health plans covering 95 million patients. An image of these materials is below:

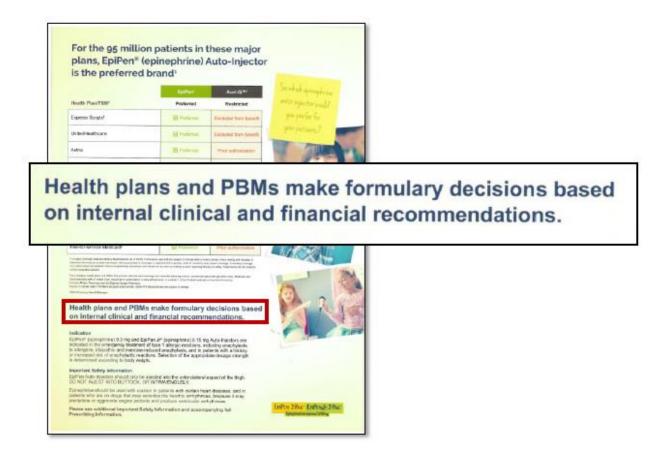


233. Through its anticompetitive conduct, Mylan itself created Auvi-Q's status of being "Excluded from Benefit," "Not Covered," "Non-Formulary," Stepedit,"⁶² or "Prior Authorization" with these plans. Mylan paid formularies to exclude Auvi-Q from coverage, but then marketed, through the use of mail and wires, to physicians that Auvi-Q was not covered by formularies and

⁶² "Step-edit" means that another drug must be tried first prior to the listed drug being covered.

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suggested that the decision to exclude Auvi-Q from formulary was based on clinical recommendations, rather than on Mylan's huge, conditional rebate offers. Images of the flyer are below:



234. Mylan disseminated other misleading materials showcasing the effects of its exclusionary conditional rebates. In January 2014, just after all of Mylan's anticompetitive rebates went into effect blocking Auvi-Q from some of the largest third-party payors, Mylan sent physicians marketing materials stating that Mylan was the "Preferred" EAI device for 99% of patients, while Auvi-Q was "Preferred" for only 2%:

Subject: Requisted formulary of From: Mylan Formulary Team < Date: 1/31/2014 10:48 AM To:	overage information noreply@mylanformula	ry.com>
	ENPIN 2PAR ENPINE 2	Pac
Helio Dr.		
Thank you for taking the time to use Auto-Injectors.	tok with me about fipiPen® (epi	nephrine) and EpiPen Jr. [®] (epine
To follow up our conversation, I wan		
EpiPen [®] and EpiPer Preferred brand lives o	1. 2	mercial: Medicare Pi
Auvi-Q [®] Preferred brand lives covered 2		° 1°
Comm	ercial: Formulary Status	by Plan
Top Plans in Your Area	EpiPen® Formulary Status	Auvi-Q"
BCBS of North Carolina	Tier 2/Preferred	Formulary Status Tier 3/Non Preferred
CIGNA Pharmacy Management	Tier 2/Preferred (QL)	Tier 3/Non Preferred (QL
CIGNA HealthCare of North Carolina	Tier 2/Preformed (QL)	Tier 3/Non Preferred (QL
Aetna Pharmacy Management	Tier 2/Preferred	Tier 3/Non Preferred (QL
	Tier 2/Preformed	Tier 3/Non Preferred

235. These marketing materials compounded the "spillover" effects from Mylan's blocking of Auvi-Q from the market. Mylan did not only block Auvi-Q from the market with its anti-competitive conditional discounts. Mylan then proactively touted the fact that Auvi-Q was blocked from the market, ensuring that physicians would think that the EpiPen was the only realistic choice for their patients.

d. Defendants' Illegal Pay-for-Delay Settlements

236. Mylan also engaged in illegal pay-for-delay settlements in an effort to maintain its monopoly. Mylan faced actual and potential generic competition from several companies from at least 2009. These companies recognized that the EpiPen was becoming increasingly overpriced, and as generic companies so often do, they sought to compete with Mylan on price because the drug delivered in the EpiPen (epinephrine) is not patented and costs about \$1.

237. To restrain this competition, Mylan and its co-conspirators added numerous patents to the already-patented EpiPen to stop generics from being able to launch. Mylan or its co-conspirators have four patents on the EpiPen. These patents are not designed to enhance the product but rather to simply stop generic competitors.

238. During the question and answer period of its Q-1 2009 Earnings Call with Wall Street analysts, Mylan's Heather Bresch was asked about generic competition to the EpiPen and whether that posed a challenge to Mylan's earnings. In response, Ms. Bresch stressed that Mylan was adding yet another patent to the already-patented EpiPen device that "will also put in another barrier to entry because that now that market preferential would be the needle protected device and drug of which we have IP and stuff around. So I just think it is a very, very difficult hurdle to get through, and so feel confident that EpiPen is in good shape."⁶³

239. In that same earnings call, Ms. Bresch further assured the Wall Street analysts that Mylan was confident that no generics could compete because Mylan was adding to its patents on the EpiPen, and that any generic has "to match identically" the underlying drug or device, which is "really the hurdle when you talk about a drug and device product such as EpiPen."⁶⁴

 ⁶³ Mylan Inc. Q1 2009 Earnings Call Transcript, SEEKING ALPHA (May 1, 2009), <u>http://seekingalpha.com/article/134619-mylan-inc-q1-2009-earnings-call-transcript?part=single</u>, (last visited Jan. 31, 2017).
 ⁶⁴ Id.

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240. Two of the co-conspirators working with Mylan are subsidiaries of Pfizer, Inc. In 2011, Pfizer acquired King Pharmaceuticals, Inc. As part of that acquisition, Pfizer acquired a subsidiary, Meridian, which "develops and manufactures the EpiPen" sold by Mylan.⁶⁵

241. The Mylan and Pfizer defendants have a unified interest in protecting the EpiPen monopoly. That is because while Pfizer and its subsidiaries owned the patents protecting the EpiPen and is the contract supplier of the product, Mylan owns the trademarked brand names and controls the worldwide marketing and sale of the products. Their divided intellectual property ownership of the EpiPen and their licensing agreements for it have caused the two companies to work collaboratively to enhance the products sales volume and profitability. Defendants' EpiPenrelated revenues rise (or fall) together. If the EpiPen patents are invalidated, or if other competitors gain market share, both stand to lose, and so they have stood together to fend off competitors and protect the EpiPen patents.

242. Since Mylan acquired the rights to market and sell the EpiPen from Merck in 2007, it has purchased its EpiPens exclusively from King (that supplies the generic epinephrine), and King's subsidiary Meridian (that holds the relevant patents and manufactures the pens).

243. In October 2010, Pfizer purchased King (which owned Meridian) and has acted as Mylan's sole provider of EpiPens ever since.

244. At the time of the Pfizer acquisition, Mylan was rightly concerned that Pfizer might try to compete with Mylan by marketing the same device to consumers under a different trade name.⁶⁶ But rather than compete with Mylan, Pfizer agreed to continue supplying the device to

⁶⁵ 2011 Financial Report, PFIZER INC. (2011),

https://www.pfizer.com/files/annualreport/2011/financial/financial2011.pdf, (last visited Jan. 31, 2017).

⁶⁶ See Jim Edwards, In \$3.6B King Deal, Pfizer Gets a Small but Important EpiPen Monopoly, MoneyWatch, Oct. 12, 2010.

Mylan under terms that are not publicly available.

245. On information and belief, that agreement provides for the sale of EpiPens to Mylan at a contract price which has recently escalated along with EpiPen's market dominance, recently rising from roughly \$80 per unit to \$86 per unit.

246. Pfizer's revenue on sales of the EpiPen has also increased along with Mylan's as EpiPen's market dominance has grown.

Year	Unit Sales Volume of EpiPen	Pfizer's EpiPen Revenue ⁶⁷	Unit Price
2012	3,310	\$263M	\$79.50
2013	3,416	\$273M	\$80.00
2014	3,656	\$294M	\$80.00
2015	3,930	\$339M	\$86.00

247. In 2014, Mylan Specialty LP took over as the sponsor of the EpiPen patents in the Orange Book. Meridian had been the prior sponsor of those patents. It is unclear exactly why Mylan took over sponsorship of the patents, or what consideration may have been exchanged between Mylan and Pfizer related to that change. The change in sponsorship does, however, continue to show concerted action by Mylan and Pfizer to share the burdens and rewards of their EpiPen monopoly.

248. Mylan and the Pfizer worked together to stop generic competition to the EpiPen by filing patent infringement lawsuits against at least three generic EpiPen rivals: Sandoz, Teva, and Intelliject. As Pfizer reported to investors in 2011:

King brought patent-infringement actions against Sandoz in the U.S District Court for the District of New Jersey in July 2010 and against Teva

⁶⁷ From Pfizer's Financial Statements, Appendix A, 2012-2015.

Pharmaceutical Industries and Intelliject, Inc. (Intelliject) in the U.S. District Court for the District of Delaware in August 2009 and January 2011, respectively, as the result of their abbreviated new drug applications with the FDA seeking approval to market epinephrine injectable products. The two actions in Delaware subsequently were consolidated. Sandoz and Teva Pharmaceutical Industries are challenging and Intelliject challenged two patents, which expire in 2025, covering the next generation auto-injector for use with epinephrine that is sold under the EpiPen brand name. In February 2012, the action against Intelliject was settled. Under the settlement agreement, Intelliject may launch its epinephrine injectable product no earlier than November 15, 2012, subject to final approval by the FDA.⁶⁸

249. Thus, Mylan layered its EpiPen with numerous extraneous patents in order to hinder and delay generic competition. These patents were not intended to improve the safety of the product; they were added to restrain generic competition and further monopolize the market.

250. But the patent infringement lawsuits jeopardized the EpiPen franchise, and Mylan took further steps to make sure its patents remained valid, to include entering into anti-competitive settlements with impending generic manufacturers.

i. The Teva Settlement

251. Defendants implemented a "pay-for-delay" to stop Teva's imminent generic competition, which threatened to undo the patents on the EpiPen and further threatened a generic competitor (even if the patents were not invalidated).

252. Teva filed an Abbreviated New Drug Application (ANDA) seeking approval to market a generic EpiPen in December 2008.

253. In response, King and Meridian commenced litigation against Teva, *King Pharm.*, *Inc., et al, v. Teva Parenteral Med., Inc., et al.*, No. 1:09-cv-00652 (D. Del. Aug. 8, 2009) alleging infringement of U.S. Patent No. 7,449,012. King filed a First Amended Complaint on November 11, 2010 to include a claim of infringement on U.S. Patent No. 7,794,432.

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254. King and Meridian subsequently dropped all claims related to the alleged infringement of the '012 patent, leaving on the claims related to the '432 patent. *See Id.* at Docket No. 124. Following discovery, the case against Teva proceeded to a four-day bench trial in March, 2012.

255. According to Pfizer's counsel, the most important claim terms at issue in the bench trial, all present in claims 19 or 20 of the '432 Patent, were "a first locked retracted position," the claim that "energy released from the stored energy source to drive the needle during the medicament dispensing operation is not transferred to the needle cover," and "attenuating kickback."

256. Teva argued that its generic version of the next-generation epinephrine autoinjector, as submitted in its ANDA, did not infringe the '432 Patent for a number of reasons. *First*, Teva's generic equivalent relied on manual insertion of the needle into the patient, not requiring "a stored energy source capable of driving the plunger within the cartridge to dispense the medicament through the needle assembly." *Second*, Teva's generic equivalent did not have a needle cover that locks in place, as opposed to the '432 Patent which requires "the needle cover having a first locked retracted position." *Third*, Teva's generic equivalent did not have energy released from the stored energy source, in direct contradiction to the claims of the '432 Patent.

257. In addition to the obvious differences in Teva's auto-injector, as well as favorable claim constructions by the court, the bench trial included evidence of three pieces of "prior art references" which Teva contended invalidated the '432 Patent.

258. The parties settled on April 27, 2012. The actual settlement agreement is confidential and has not been made public, which prevents Plaintiffs (as well as the United States Senate) from probing the terms or illegality of the settlement. And because the settlement terms

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have been kept confidential, the public has been unable to determine the amount of the reverse payment.

259. But on its face, the settlement raises alarming concerns that Mylan restrained generic competition from Teva.

260. Under the terms of the settlement, Teva agreed to delay the launch of its generic auto-injector for three years, until June 22, 2015.⁶⁹

261. The Teva settlement was also intended to foreclose all other auto-injector generic competition for the same time period as well. Defendants knew that an agreed-to delay with Teva would be subject to the Hatch-Waxman Act's 180-day exclusivity award, which grants a six-month exclusivity period to the first generic to challenge a brand firm's patent, claiming it is invalid or not infringed. The exclusivity period does not begin until the first-filing generic enters the market. In the case of Teva – as the first filer – that would be a minimum of three years in the future. Thus, as a result of Teva's delayed market entry, Defendants delayed all generics seeking ANDA applications based on the EpiPen.

262. Delaying the entry of Teva's generic EpiPen allowed King, Meridian, and Mylan to continue sharing millions of dollars in unlawful monopoly profits, and actually allowed Defendants to further exclude other potential generic competitors an additional 180 days under the Hatch-Waxman Act because Teva was the first-filer on the patents-in-suit.

263. Upon information and belief, in settling the Teva litigation, Defendants and Teva entered into an unlawful agreement whereby Defendants provided significant consideration, incentives, and benefits to Teva to delay bringing their competing product to market.

⁶⁹ Mylan and Pfizer Announce Epinephrine Auto-Injector Settlement Agreement with Teva, MYLAN INC. (Apr. 26, 2012), <u>http://newsroom.mylan.com/press-releases?item=123144</u>, (last visited Jan. 31, 2017).

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264. Defendants have kept the terms of the Teva settlement confidential; it is not publicly available on the court docket for the case, and all defendants failed to include the terms of the settlement in filings with the Securities & Exchange Commission.

265. From the facts surrounding the settlement, it can be reasonably inferred that King and Meridian made a substantial "reverse payment" to Teva to convince it to delay bringing its competing generic auto-injector to market:

- a. The Teva Court's *Markman* rulings on the interpretation of the '432 patent were favorable to Teva;
- b. At the time of a settlement, a full bench trial had been conducted and further anticipated litigation expenses would have been marginal compared to expenses already incurred at the time of the settlement;
- c. No rational economic actor with a viable product (and who had spent millions of dollars developing it) would refrain from entering a lucrative "blockbuster" market for 36 months unless it received monetary compensation in exchange for non-entry.
- 266. <u>Other publicly available information from the Federal Trade Commission further</u>

supports the reasonable inference that the Teva settlement was an illegal pay-for-delay scheme.

267. As noted in a 2012 Federal Trade Commission report, fiscal year 2012—when the

Teva settlement was submitted to the FTC for review-saw "a record number of settlements

involved potential pay-for-delay agreements."70

268. In the same report, the FTC found that in patent settlements involving a "first-filer,"

as Teva was here, a majority of the settlements did involve explicit compensation in return for

delayed entry. Specifically, the report found that in fiscal year 2012:

a. There were 43 settlements involving generic drugs considered "first-filers" (which includes the King/Meridian-Teva settlement);

⁷⁰ See FTC, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreement Filed in FY2012, *available at* https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement (last accessed May 16, 2017).

- b. Of those 43 settlements, 39 contained restrictions on the date of generic entry (which also includes the King/Meridian-Teva settlement); and
- c. Of those 39 settlements restricting generic entry, 23 settlements (59%) provided for explicit compensation to the generic manufacturer.⁷¹
- 269. These statistics alone give rise to a plausible inference that Teva was one of the 23

first-filers that received compensation in exchange for its three-year delay.

270. In conjunction with Pfizer, whose subsidiaries (King and Meridian) worked with

Mylan to suppress competition, Mylan issued a press release (via interstate wire) on April 26,

2012, about the Teva pay-for-delay settlement:

Mylan Inc. (Nasdaq: MYL) and Pfizer Inc. (NYSE: PFE) today announced that Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Teva that will resolve pending patent litigation related to its abbreviated new drug application (ANDA) for a generic epinephrine auto-injector.

According to the terms of the settlement, Teva may launch a generic epinephrine auto-injector covered by its ANDA on June 22, 2015 or earlier under certain circumstances, subject to receipt of approval from the U.S. Food and Drug Administration. Teva currently does not have tentative approval from the FDA for its epinephrine auto-injector product.

Meridian manufactures EpiPen Auto-Injector and Mylan Specialty markets and distributes the product in the United States.⁷²

271. Further supporting the conclusion that the Teva settlement was unlawful, part of

the valuable consideration Teva received in exchange for dropping its meritorious challenge to the

EpiPen patents included the compromise of another patent litigation between Teva and Mylan--

this one relating to the blockbuster drug Nuvigil.

272. In December 2009, Teva's predecessor, Cephalon, filed a patent infringement

⁷¹ See id. It is worth noting that the FTC found only that the remaining 16 settlements did not contain "explicit compensation" to the generic manufacturer.

⁷² *Id.*

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action against Mylan after Mylan filed an ANDA to market a generic version of Nuvigil. Nuvigil was a critical drug for Cephalon, at the time accounting for nearly \$1 billion in sales annually, or roughly half the company's total sales.

273. Like the EpiPen litigation, this case was filed in the District of Delaware and proceeded at a similar pace to the EpiPen litigation. By the time Teva acquired Cephalon in October 2011, the Nuvigil litigation was in full swing.

274. Then, with Teva at the helm and a trial set for July 2012, the parties abruptly announced a settlement of the action—four days after they announced the settlement of the EpiPen litigation. The settlements, when viewed together, show both Teva and Mylan exchanging highly valuable delayed entries (in addition to other settlement consideration that is not publicly available) to settle their respective cases and protect their valuable monopolies.

275. Recall that in the EpiPen litigation, the settlement delayed Teva's market entry until June 2015. In the Novigil litigation, the settlement delayed Mylan's market entry until June 2016. Procuring delays to entry for both of these blockbuster drugs (with annual sales both hovering around \$1billion) of even a few months would have been quite valuable. Here, procuring delays of several years was worth hundreds of millions of dollars for all parties involved.

276. The Nuvigil settlement caught by surprise some of Teva's financial analysts that had been monitoring the situation. As one analyst noted during a Teva earnings call on May 9, 2012: "I was a little surprised to see you settle for generic entry on Nuvigil in 2016, especially with what you just said about the first positive bipolar study." However, the settlement of that action looks more rational (and more anticompetitive) when viewed in the context of the *quid pro quo* of the EpiPen settlement.

277. As for Mylan, the settlement benefits were also substantial. As Mylan's CEO

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Heather Bresch made clear in an earnings call with company analysts on July 26, 2012, "So we certainly have seen a benefit [to growing the EpiPen market] and obviously, now with the runway absolutely clear for us through 2015, through our settlement with Teva, I can assure you, we are going to continue as we see those response continue to invest in EpiPen as a franchise."

278. Additionally, because a bench trial had already been completed at the time of the Teva settlement, it is unlikely that any reverse payment to Teva could be justified as preventing any significant litigation costs.

279. The most common indicator of whether a payment is large is by comparison to "the payor's anticipated future litigation costs."⁷³ Here, the parties settled *after* concluding a bench trial, and therefore *after* the bulk of their litigation costs (in both dollars and time) were incurred.

280. The settlement has also come under congressional scrutiny as an illegal "pay for delay" agreement.⁷⁴

281. By settling with Teva, Mylan was able to remove all competition from Teva from at least 2012 until 2015. During this 36-month period (a total of 1,095 days), Mylan dramatically raised the price of the EpiPen and forced American consumers to pay exorbitant prices for the EpiPen 2-Pak. Indeed, EpiPen prices more than doubled during the period in which Teva did not enter the market. Mylan did so with full comfort that Teva could not present a generic competition threat to its prices or market share.

282. It is reasonable to conclude that the settlement caused Teva to delay its attempts to ultimately enter the epinephrine auto-injector market. Knowing that entry was no longer possible

⁷³ FTC v. Actavis, <u>133 S. Ct. at 2237</u>.

⁷⁴ See Ben Seal, U.S. Senator Prods Mylan on EpiPen 'Pay for Delay' Concerns, Nat'l L.J., Sept. 28, 2016, available at http://www.nationallawjournal.com/id=1202768792860/US-Senator-Prods-Mylan-on-EpiPen-Pay-for-Delay-Concerns?slreturn=20170114165452.

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in the immediate future, it is reasonable to infer that Teva reduced the resources it would have allocated to its competing product but-for the settlement, or otherwise adjusted its timeline before the FDA.

283. It is also reasonable to conclude that Mylan's successful efforts to exclude competitors from formularies, as discussed above, has further influenced Teva's decisions as to whether and when to enter the market.

284. Finally, given the trial court's previous rulings, it requires no great leap to infer that, had the parties waited for a decision, the '432 patent would have been found invalid. That, in turn, would have removed the most significant barrier to entry for Teva—or any other putative generic manufacturer, making it more likely that at least one would have entered or attempted to enter the market.

ii. The Intelliject Settlement

285. Yet another example of defendants' abuse of patent litigation to protect their EpiPen monopoly are their actions against Intelliject, the inventor of the Auvi-Q, when that company sought approval for an EpiPen competitor device.

286. Intelliject is a company that was essentially founded on a single venture, creation of epinephrine auto-injector that would compete with the EpiPen. Rather than pursue a generic version, Intelliject sought to create its own unique delivery device.

287. On November 30, 2009, pharmaceutical giant Sanofi-Aventis ("Sanofi") announced it had obtained the rights to Intelliject's epinephrine auto-injector and that under the license, Sanofi would be responsible for the manufacturing and commercialization of the product while Intelliject would be responsible for the ongoing development and for obtaining regulatory approval.

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288. With Sanofi now providing financial and marketing support, Intelliject's prospects for developing a competing epinephrine auto-injector became very real for defendants.

289. When the Intelliject device, dubbed the e-cue (and later renamed Auvi-Q), was ready to embark on the approval process, Intelliject submitted an NDA (not an ANDA) with the FDA on September 29, 2010.

290. They did not pursue approval through the more streamlined ANDA process because the EpiPen and the e-cue were very different devices, both in appearance and operation.

291. The EpiPen is a device shaped like a writing pen, with a safety cap on one end and a spring-loaded needle on the other end. In order to activate the EpiPen, the safety cap must be removed and the end with the spring-loaded needle pressed against the thigh.

292. E-cue, on the other hand, was shaped flat and rectangular, like a credit card, and incorporated a safety tab mechanism on the needle end of the device. The e-cue also used a voice prompt system that provided step-by-step instructions on how to use the device in order to prevent accidental needle sticks. The device also does not require a safety cap because its needle retracts, requires less piercing time (less than 1 second compared to 5 seconds for EpiPen), and is less painful because its needle is designed to pierce the skin at exactly 90 degrees.

293. Not content to simply compete with a new auto-injector rival, however, Defendants, through King, filed a patent infringement lawsuit against Intelliject on January 19, 2011 to block FDA approval of its NDA. *King Pharm., Inc. v. Intelliject, Inc.*, No. 09-652-GMS (D. Del. Jan 19, 2011).

294. King alleged the e-cue device infringed the '432 Patent, entitled "Automatic Injector with Kickback Attenuation." As noted above, that patent was not obtained by Meridian until September 14, 2010, *well over a year after Intelliject began development of the e-cue and*

only two weeks before Intelliject filed its NDA.

295. Meridian filed the '432 Patent in the Orange Book on September 15, 2010, *the very day after it was issued* by the Patent Trademark Office. The alacrity with which Meridian filed the '432 Patent in the Orange Book was inconsistent with its prior history. For example, the '012 Patent was not filed in the Orange Book for more than eight months after the patent was granted. On information and belief, Meridian rushed to submit the '432 Patent in the Orange Book before Intelliject filed its NDA.

296. On August 1, 2011, Intelliject announced the FDA had given the e-cue tentative final approval. According to Intelliject's press release:

Obtaining a tentative approval means that the product review is complete and the submission met the FDA's requirements to be approved. The FDA reserves final approval of the product, however, until all exclusivity or patent challenges have been resolved, specifically the current patent litigation brought against Intelliject by King Pharmaceuticals, Inc. (King) and Meridian Medical Technologies, Inc. (Meridian). Final FDA approval is required before a product can be marketed in the United States.

297. Meanwhile, defendants' patent litigation dragged on for another six months.

298. On February 16, 2012, Mylan and Pfizer (again jointly) announced they had reached a settlement with Intelliject over their patent litigation. Although the terms of that deal are confidential, the parties did reveal that the agreement prevented Intelliject and Sanofi from launching their e-cue device for another nine months, until November 15, 2012. The relatively short duration of delay before entry of the e-cue likely indicates the strength of Intelliject's defenses to the patent litigation.

299. Nevertheless, on information and belief, Intelliject and Sanofi agreed not to enter the market until November 15, 2012 in exchange for valuable consideration.

300. On August 10, 2012, the FDA granted final approval of Intelliject's NDA, but

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pursuant to the settlement consumers would not have access to the e-cue until November 2012. Thus, defendants blocked this potential competitor for almost two years.

301. That settlement, too, was announced by Mylan, despite Mylan not being a party to the underlying suit.

iii. The Sandoz "Stay-and-Delay" Agreement

302. In 2010, Sandoz, Inc. ("Sandoz") made a similar attempt to enter the market through a generic alternative to EpiPen. As with Teva, defendants conspired to have King file a patent infringement suit against Sandoz in response to its ANDA filing. According to a 2016 U.S. Securities and Exchange Commission ("SEC") Form 10-Q filed by Pfizer, Sandoz's ANDA is ongoing⁷⁵ and the litigation is stalled with the court entering an order staying the FDA process and administratively terminating the action, to be reopened upon letter request by any of the parties.⁷⁶ No party has reopened the case.

303. Staying the litigation also stays any definitive ruling on a challenge to the EpiPen patents. On information and belief, Defendants entered into an agreement with Sandoz to stay the case indefinitely in exchange for valuable consideration to Sandoz.

iv. Mylan's Manipulation of the FDA's Citizen Petition Process

304. As Teva's market entry loomed, defendants needed another member of their team to create more delay. Delay has been an immensely valuable core of defendants' scheme. Indeed, "[f]or a billion-dollar drug product like the EpiPen, each day of delay mean[s] an extra \$3 million."⁷⁷ Thus, in January 2015, Mylan made another play to forestall Teva's entry by filing a

⁷⁵ Pfizer SEC Form 10-Q for the quarterly period ended July 3, 2016, filed August 11, 2016, at 33.

⁷⁶ *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 10-cv-3568 (D.N.J. May 10, 2011), Dkt. No. 66.

⁷⁷ Carrier & Minniti, *supra* note 17, 102 CORNELL L. REV. ONLINE at 66.

"citizen petition" with the FDA.

305. A citizen petition is intended for members of the public to raise safety concerns with the FDA but, in this case, was being used by defendants as an anticompetitive means of continuing to block Teva from competing with them for auto-injector sales. Such petitions by brand drug manufacturers "are almost always (92%) denied" but typically have the effect, absent some intervening event, of impeding market entry efforts of a generic for about 150 days, while the FDA considers the petition.⁷⁸

306. As leading antitrust scholar Michael Carrier of Rutgers Law School recently explained: "Brand firms' filing of citizen petitions with the U.S. Food and Drug Administration ("FDA") has almost entirely slipped beneath the radar. In theory, citizen petitions could raise concerns that a drug is unsafe. But in practice they bear a dangerous potential to extend brand monopolies by delaying approval of generics, at a potential cost of millions of dollars per day."⁷⁹

307. Citizen petitions cost little for the companies that file them. Consisting of boilerplate arguments, generally involving scientific data regarding a drug's manufacturing process, they are easy to file. Nor are there any consequences to filing frivolous petitions.⁸⁰

308. Of course, "[n] ot all citizen petitions raise anti-competitive concern. But one type is potentially troublesome: the so-called '505(q)' petition. These are petitions that ask the FDA to take a particular action against a pending generic application. In fact, Congress specifically

⁷⁸ *Id.* at 64.

⁷⁹ Michael A. Carrier, et al., "*Citizen Petitions: Long, Late-Filed, and At-Last Denied*," 66 AM. U. L. REV. 305 (Dec. 2016).

⁸⁰ Carrier & Wander, "Citizens Petitions: An Empirical Study", 34 CARDOZA L. REV. 249, 279 (Oct. 2012) (citing The Generic Drug Maze: Speeding Access to Affordable, LifeSaving Drugs: Hearing Before the S. Spec. Comm. on Aging, 109th Cong. 6 (2006) (available at http://aging.senate.gov/publications/7202006.pdf) (statement of defendant Heather Bresch, then Senior Vice President of Corporate Strategic Development, Mylan Laboratories, Inc.)).

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addressed these petitions when it passed a law requiring the FDA to resolve them in an expedient manner to avoid generic delay.⁸¹

309. As detailed in a recent study by Professor Carrier, "brand firms file 92% of 505(q) petitions—each attacking a proposed generic."⁸²

310. Professor Carrier recently focused on the filing of citizens' petitions by Mylan against Teva's generic competitor to the EpiPen. As he explains, "Mylan received significant unwanted attention in 2016 for its price hike for EpiPen, but its citizen petition escaped notice. The lifecycle of EpiPen reveals how Mylan used citizen petitions along with settlements to delay generic entry."⁸³

311. As 2015 unfolded and its pay for delay agreement with Teva was about to expire,

Mylan had to take a further anti-competitive step to stifle generic competition from Teva:

But as Teva's entry loomed, Mylan reached into its toolkit to pull out a citizen petition, which it filed on January 16, 2015, a mere six months before Teva was scheduled (pursuant to the settlement) to enter the market. In its petition, Mylan contended that Teva should be required to demonstrate that its product was the "same as" Mylan's EpiPen. In other words, even though the parties had already agreed through settlement to delay Teva's generic entry for more than three years, Mylan sought to *further* delay the entry of Teva's generic through its citizen petition.

In addition to its January 2015 petition, the company waited almost *five months* after filing and only weeks before the FDA was required to respond, until May 2015, to supplement its petition with a 48-page independent study purportedly showing that patients would not use Teva's generic product correctly.

Given that Teva's generic product had been in development for at least *six years* before the petition's filing, this late-filing of a supplemental study implicates

⁸¹ *Id.*

⁸² Id.

⁸³ *Id.* ("Firms have employed a combination of settlements and product hopping to ensure that they can switch to a new version before generics enter the market on the old version... Brands' use of citizen petitions could be a valuable addition to this strategy. By requesting that the FDA make a decision on safety and efficacy—often by reviewing a wealth of material and studies—brands could buy additional time in which to delay generic entry.").

significant timing questions. Why would such a study be submitted only weeks before the FDA was required to respond under the FDA's 150-day clock? ⁸⁴

312. The citizen's petition filed by Mylan had other indicia that is was a sham and filed

as an anti-competitive tactic motivated not by concern for public, but for the purpose of protecting

Mylan's EpiPen monopoly.

313. First, as noted, Mylan waited until just before the FDA's response was due to

submit a supplemental "study" from a consulting firm. Although the study purportedly found that

Teva's device would not be effective, the study had numerous flaws that demonstrate Mylan was

not acting in good faith in relying on it. For example,

- a. The study lacked a control group;
- b. The study did not use the actual generic device, but instead used a prototype;
- c. The study used a small number of participants;
- d. The researchers failed to provide the study participants with the proper instructions for using the prototype; and
- e. The researchers merely told the participants to watch a video rather than actually use the prototype.⁸⁵
- 314. Second, as further explained by Professor Carrier:

Shedding even more light on the questionable petition and supplemental study is its timing. In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008. And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010. This material included "detailed product descriptions, drawings, and instructions for use" for Teva's proposed generic.

At the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.

⁸⁴ *Id.* (emphasis in original).

⁸⁵ Ed Silverman, *How Mylan Tried to Keep Teva from Selling a Generic* EpiPen, STAT (Aug. 31, 2016), <u>http://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/</u>, (last visited Jan. 31, 2017).

* * *

We think it reasonable to conclude that Mylan's (1) filing of a petition years after invariably knowing about Teva's generic, (2) filing of a petition calculated to delay entry after settlement, and (3) late-filing of a supplemental study together comprised a strategy to delay Teva's ANDA approval *beyond* the *already-delayed* agreed entry date of July 22, 2015.⁸⁶

315. A key part of Mylan's petition was the argument that anything other than an identical product may make it difficult for patients in an emergency situation to use a generic safely and effectively in keeping with instructions for EpiPen.⁸⁷ Thus, in addition to evergreening the EpiPen patents and taking repeated steps to thwart any challenges to the validity of those patents, Mylan argued that anything other than an exact replica of its product should not be approved. In other words, because EpiPen's market dominance had made the device as ubiquitous as "Kleenex," largely through Mylan's lock-down of the school sub-market for auto-injectors (as described above), *no other competing device design should ever be approved*.

316. Mylan's submission of a significantly flawed study in support of its citizen petition was deceptive and misleading, and was merely a sham intentionally designed to delay the entry of a generic competitor into the epinephrine auto-injector market.

317. Even more, Mylan's petition against Teva relied on a medical statement from a Dr. Eli Meltzer that sought to downplay the generic device from Teva. Meltzer, however, was paid roughly \$95,000 in fees in 2014 and 2015 by Mylan, according to the Open Payments federal database.⁸⁸

318. Thus—just as with its payments to Dr. Lieberman of the NIAID panel—Mylan's

⁸⁶ *Id.* at 64-66 (footnotes omitted; emphasis in original).

 ⁸⁷ Ex Silverman, *How Mylan tried to keep Teva from selling a generic EpiPen*, STAT, Aug. 31, 2016, *available at* https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/.
 ⁸⁸ Id.

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reliance and promotion of Dr. Meltzer's paid-for opinions, without disclosing his status as a company shill, were fraudulent and deceptive.

319. The FDA ultimately rejected Teva's generic product when it was under review. But according to Professor Carrier, it is likely that "Teva may have been able to fix those problems if the patent lawsuit had not delayed its ability to enter the market."⁸⁹ Further, while Teva's application was ultimately denied by the FDA in February 2016, defendants could not have known that at the time they executed their plan to block Teva. Moreover, their plan did not just block Teva, but all competition from anyone entering the generic epinephrine auto-injector market.

320. Thus, Mylan's 1-2 punch of a pay-for-delay settlement in tandem with filing a citizen's petition against Teva demonstrates Mylan's anti-competitive intent to delay and then further hinder generic competition.

321. In sum, Mylan implemented numerous different anti-competitive and deceptive tactics to restrain and delay generic competition from Teva and other generic companies.

322. But for Mylan's anti-competitive assault campaign, Teva would have entered the market much sooner and fixed the deficiencies that led to the FDA's rejection of Teva's generic. By sidelining Teva from 2012 to 2015, Mylan, King, and Meridian disrupted Teva's trajectory toward FDA approval and also gained a three-year guaranteed monopoly period in which Mylan could raise prices on consumers without any fear of generic competition from Teva. This occurred only because Mylan and its co-conspirators artificially restrained Teva.

323. The greatest increase in the EpiPen price occurred between 2013–2016, which generic competition from Teva—had it launched a competing product in 2013—would have demolished.

⁸⁹ Id.

324. Likewise, Mylan's anti-competitive tactics also deterred and prevented numerous other potential generics companies from developing and launching competing products from 2009 to present.

e. Mylan Unlawfully Exercised Its Monopoly Power to Force American Consumers—and Only American Consumers—to Purchase EpiPens in Pairs.

325. In further exercise of Mylan's monopoly power and recognizing an opportunity to exploit consumers and third-party payors, Ms. Bresch and Mylan pounced in 2011 by requiring the purchase of EpiPens in pairs, or 2-Paks. Mylan announced the change on August 24, 2011. Until then, from 1987 until 2011, the EpiPen was sold individually in the United States.

326. When it launched the EpiPen 2-Pak, Mylan announced simultaneously that it would stop selling individual EpiPens in the United States. As displayed in the below photo,⁹⁰ the EpiPen 2-Pak is just two individual EpiPens literally tied together with a grey piece of plastic. There is no medical reason to force customers to purchase a "2-Pak" instead of individual EpiPens.

⁹⁰ Pauline Bartolone, *EpiPen's Dominance Driven by Competitors' Stumbles and Tragic Deaths*, NATIONAL PUBLIC RADIO (Sep. 7, 2016), <u>http://www.npr.org/sections/health-shots/2016/09/07/492964464/epipen-s-dominance-driven-by-competitors-stumbles-and-tragic-deaths</u>, (last visited Jan. 31, 2017).



Mylan lobbied state legislatures for laws that require schools to stock EpiPens.

327. A United States customer can no longer purchase a single or individual EpiPen, and a doctor prescribing the EpiPen in the United States can no longer successfully write a prescription for an individual EpiPen. Mylan has stopped this from happening by forcing American customers to purchase only the EpiPen 2-Pak—or nothing at all.

328. In contrast, consumers in every other country can continue to purchase an individual EpiPen. For example, in France, two EpiPens cost about \$85. In Canada, an EpiPen sells for just over \$100 per device, distributed by Pfizer Canada via a license from Mylan.

329. Nothing changed in 2011 that justified Mylan's decision to force customers in the United States to purchase the EpiPen 2-Pak or nothing at all. Mylan's decision was driven solely by its desire to exercise unlawfully its monopoly power to pump up its sales and revenue numbers, so that its executives would gain more bonuses and the stock price would climb.

330. Mylan's own packaging materials reveal that there is no medical reason for requiring the purchase of two EpiPens, remarkably providing no instructions to users on how and when to employ a second dose of epinephrine. Mylan's written materials for patients in the EpiPen packaging only provide marketing information about how the EpiPen 2-Pak is bundled and sold

as a 2-Pak. Mylan does not provide patients with medical instructions or guidelines regarding the use of the EpiPen 2-Pak. In its written materials enclosed within the EpiPen 2-Pak, Mylan states only the following regarding the 2-Pak or use of the second EpiPen:

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) are available as EpiPen 2-Pak, NDC 49502-500-02, a pack that contains two EpiPen Auto-Injectors (epinephrine injections, USP, 1:1000, 0.3 mL) and one EpiPen Auto-Injector trainer device.

EpiPen Jr Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) are available as EpiPen Jr 2-Pak, NDC 49502-501-02, a pack that contains two EpiPen Jr Auto-Injectors (epinephrine injections, USP, 1:2000, 0.3 mL) and one EpiPen Auto-Injector trainer device.

EpiPen 2-Pak and EpiPen Jr 2-Pak also include an S-clip to clip two carrier tubes together. 91

331. Mylan does purport to include some information on its website (but not in its

product packaging) about when to use the second EpiPen,⁹² but its guidance is too shallow and

vague, especially for patients who don't access the website in an emergency.

332. In the packaging and instructions for the EpiPen, Mylan does not actually provide

a guideline or medical instructions for when to actually use the second EpiPen.

333. Taken together, a reasonable inference is that Mylan sells the EpiPen in a 2-Pak to maximize the return on its monopoly power. If there were a legitimate medical reason for the 2-Pak, Mylan would provide patients with clear medical guidelines and instructions for using the second EpiPen within the packaging of the 2-Pak. The lack of those guidelines and instructions

⁹¹ *Prescribing Information*, MYLAN SPECIALTY L.P., <u>https://www.epipen.com/en/prescribing-information</u>, (last visited Jan. 5, 2017).

⁹² Dosage and Administration, MYLAN SPECIALTY L.P., <u>https://www.epipen.com/en/hcp/about-epipen/dosage-and-administration</u>, (last visited Jan. 5, 2017).

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reveal Mylan's statements about the 2-Pak are a fraudulent pretext, are deceptive, and are not anchored to a genuine medical concern for patient safety.

334. Revealing the true motivation behind the 2-Pak purchasing requirement, Ms. Bresch referred to the move to EpiPen 2-Paks—and other similar opportunities that Mylan's marketing efforts forced upon consumers—as "big events that we've started to capitalize on."⁹³

335. Mylan attempted to justify the 2-Pak purchasing requirement by pointing to food and allergy guidelines for which it bought and paid. Mylan's purported reason for the switch was fraudulent, misleading, and deceptive, and Mylan and its executives (including Heather Bresch, who was quoted repeatedly and interjected herself into the EpiPen statements) repeatedly committed wire fraud and mail fraud when executing the hard switch to the EpiPen 2-Pak.

336. On August 24, 2011, Mylan issued via interstate wire from Basking Ridge, NJ, a news release entitled, "Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively" with the sub headline: "Decision aligns with recent clinical guidelines for patients at risk for or who have experienced anaphylaxis to have immediate access to two doses of epinephrine." In that release, Mylan stated that it would "exclusively offer the EpiPen 2-Pak and EpiPen Jr 2-Pak (epinephrine) Auto-Injector 0.3/0.15 mg, to encourage physicians and patients to follow recommendations by the National Institute of Allergy and Infectious Diseases (NIAID). While there is no safety issue with the EpiPen and EpiPen Jr single package, Dey will transition away from distributing and marketing these configurations in the U.S."⁹⁴

⁹³ Cynthia Koons and Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG (Sep. 23, 2015), <u>http://www.bloomberg.com/news/articles/2015-09-</u>23/how-marketing-turned-the-epipen-into-a-billion-dollar-business, (last visited Jan. 31, 2017).

⁹⁴ Dey Pharma, L.P., *Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively*, PR NEWSWIRE (Aug. 24, 2011), <u>http://www.prnewswire.com/news-releases/dey-pharma-to-offer-epipen-2-pak-and-epipen-jr-2-pak-exclusively-128306923.html</u>, (last visited Jan. 31, 2017).

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337. In that August 24, 2011 press release (via an interstate wire), Ms. Bresch (who was President of Mylan at the time) stated: "Many people may not be aware that recent food allergy guidelines state that patients at risk for or who have experienced anaphylaxis should have immediate access to two doses of epinephrine. The decision to exclusively offer the EpiPen 2-Pak, which contains two single EpiPen Auto-Injectors, aligns with these guidelines, as well as with the 2011 World Allergy Organization (WAO) anaphylaxis guidelines which recommend that physicians consider prescribing more than one epinephrine auto-injector."⁹⁵

338. In its August 24, 2011, press release, Mylan deceptively suggested that requiring all U.S. consumers to buy the 2-Pak or nothing at all was in line with the NIAID December 2010 report.⁹⁶ Reading the whole report, however, exposes that Mylan misrepresented the NIAID findings to manufacture a pretext for the "hard switch." Read closely, the NIAID's guidelines apply to patients who have already suffered food allergy-induced anaphylaxis requiring hospital treatment.⁹⁷ That is a tiny fraction. The guidelines do not support Mylan's imposition of a "hard

⁹⁵ *Id*.

⁹⁶ Dey Pharma, L.P., Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively, PR NEWSWIRE (Aug. 24, 2011), http://www.prnewswire.com/news-releases/dey-pharma-to-offerepipen-2-pak-and-epipen-jr-2-pak-exclusively-128306923.html, (last visited Jan. 31, 2017). ⁹⁷ Boyce, et al., Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel, 126 J. Allergy Clin. Imunol. 6, S19 (Dec. 2010) (emphasis added) ("6.4.2. Discharge plan following treatment for food induced anaphylaxis. All patients who have experienced anaphylaxis should be sent home with the following: Anaphylaxis emergency action plan; Epinephrine auto-injector (2 doses); Plan for monitoring auto-injector expiration dates; Plan for arranging further evaluation; Printed information about anaphylaxis and its treatment; The treating health care professional should consider referral of the patient to a specialist such as an allergist/immunologist. 6.4.2.1. Anaphylaxis emergency action plan. Patients should be given a written anaphylaxis emergency action plan that contains information about self-injection of epinephrine prior to discharge 261,303 (see sample action plan in Appendix E). Patients should be instructed on the value of medical identification jewelry to easily identify themselves as patients with anaphylaxis potential and their food allergen triggers. 6.4.2.2. Epinephrine auto-injector (or 2-dose prescription). All patients experiencing anaphylaxis should be provided directly with an epinephrine auto-injector

switch" to the 2-Pak upon the *entire* U.S. population.

339. The statements in the August 24, 2011 interstate wire press release were fraudulent,

deceptive, half-truths, and/or misleading because:

- a. The NIAID study Mylan cited did not apply the general population. It applied only to a narrow subset: allergy sufferers who had already (1) been hospitalized for (2) a food allergy.
- b. Despite purporting to rely on the WAO <u>global</u> standard, Mylan did not impose a forced sale of the EpiPen 2-Pak <u>globally</u>. In the same August 24, 2011 press release, in fact, Mylan stated: "The single EpiPen Auto-Injector package configuration will continue to be available outside of the U.S."⁹⁸ Thus, the suggestion that the EpiPen 2-Pak was medically required was a fraudulent pretext.
- c. Patients and their doctors already had "access to two doses of epinephrine."⁹⁹ Doctors could and often did write a prescription for two EpiPens. There was no need to mandate something patients could already purchase.
- d. The medical guideline recited by Mylan did not state that only two doses of epinephrine should be sold. Instead, as a fraudulent pretext, Mylan used the vague statement by the allergy association (which it had already tainted by paying the members to endorse the 2-Pak) to provide a false pretext for selling only the 2-Pak.
- e. Nothing mandated that Mylan sell the EpiPen exclusively as a 2-Pak or not at all.
- f. No medical studies support the decision to sell the EpiPen exclusively as a 2-Pak.
- g. From 1987 until 2011, the EpiPen was sold individually without incident, and nothing suddenly changed in 2011 that required Mylan to only sell the 2-Pak.
- h. When Mylan switched to the 2-Pak in 2011, it did not order a recall or insist that all U.S. EpiPen patients immediately go buy a second EpiPen. If, in fact, the second EpiPen was so critical for medical reasons, it would have done so.
- i. Mylan's global sales and marketing for the EpiPen prove the medical need was a false pretext. Even though Mylan's 2011 interstate wire relied on the World Health Organization, and there are over 190 countries in the world, in only one—the United States—did Mylan force customers to purchase a 2-Pak of the EpiPen.

or, if this is not possible, with a prescription (recommended prescription is for 2 doses of epinephrine), and advised to fill it immediately.").

 $^{^{9\}bar{8}}$ Id.

⁹⁹ Id.

- j. According to a study conducted by the American Academy of Allergy, Asthma & Immunology, only a "small number of patients . . . require a second dose" and "the device is mainly sold in packs of two due to imperfect product design" causing "14 percent of parents [to] . . . accidentally stick the needle in their own thumb instead of in their child's leg, as compared to zero percent of parents using" a competitor's product.¹⁰⁰
- k. Mylan offers no medical guidelines or instructions to EpiPen 2-Pak consumers within the EpiPen packaging or on the device regarding how or when to use or even how to store the second EpiPen in the 2-Pak.
- 1. Mylan's evidence that between 1-20% of patients might need a second device makes no scientific sense. The margin of 1-20% is so wide as to be meaningless, and further evidences that Mylan stretched the facts to provide a false justification for the hard switch to the 2-Pak.
- 340. Moreover, in addition to only applying to subset of the general population, the

NIAID panel relied on by Mylan to justify the change to the 2-Pak was influenced and tainted by

Mylan's financial contributions (known and unknown, which further discovery will uncover) to

its members. Again, in the August 24, 2011 press release, Mylan quoted one of the doctors (Dr.

Phillip Lieberman) on the NIAID panel:

Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at University of Tennessee College of Medicine, and member of the NIAID-sponsored expert panel added: "The guidelines recognize that **up to 20%** of those who receive epinephrine will require more than one dose before symptoms are relieved. In addition, the need for additional epinephrine cannot be reliably predicted at the onset of a reaction. Therefore, consistent with the guidelines, patients prescribed an epinephrine auto-injector should be given a prescription which allows two doses."¹⁰¹

341. On its face, Dr. Lieberman's recommendation to mandate that the EpiPen be sold

¹⁰⁰ Lucy Bayly & Emma Margolin, *How Mylan's Multimillion-Dollar Marketing Convinced Us We Need the EpiPen*, NBC NEWS (Aug. 25, 2016), <u>http://www.nbcnews.com/business/business-news/how-mylan-s-multimillion-dollar-marketing-convinced-us-we-need-n637781</u>, (last visited Jan. 31, 2017).

¹⁰¹ Dey Pharma, L.P., *Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively*, PR NEWSWIRE (Aug. 24, 2011), <u>http://www.prnewswire.com/news-releases/dey-pharma-to-offer-epipen-2-pak-and-epipen-jr-2-pak-exclusively-128306923.html</u>, (last visited Jan. 31, 2017).

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exclusively in a 2-Pak to American customers is nonsensical. Stripping doctors of the option of prescribing one or two EpiPens (and allowing patients the financial choice of whether to purchase one or two EpiPens to treat an allergic reaction they are not very likely to have, given that they are aware of the allergy and take steps to avoid it), Dr. Lieberman points to "up to 20%"¹⁰² of patients to mandate that all 100% of patients be forced to purchase a 2-Pak of EpiPens at the inflated prices charged by Mylan. Giving Dr. Lieberman the full benefit of the 20% number, Mylan is forcing 80% of patients to purchase an extra, unneeded device that expires annually and costs an extra \$300 per EpiPen 2-Pak purchased.

342. Nor does Dr. Lieberman explain why all patients are forced to buy a 2-Pak rather than just "a prescription which allows two doses." ¹⁰³ There is a world of difference between these two options, and the hard switch to the 2-Pak was a false pretext.

343. Nor does Dr. Lieberman explain why, if his statement is medically sound, the EpiPen is required to be sold in a 2-Pak only in the United States. Mylan's attempts to require the 2-Pak in other countries (which can only be uncovered through discovery) will shed light on this.

344. Dr. Lieberman's willingness to shill for Mylan is easy to explain: Mylan paid him money in exchange for his pro-Mylan statements. Because of subsequently enacted medical disclosure laws, Dr. Lieberman now is forced to disclose that he has "[s]erved as an advisor or consultant" and also "[s]erved as a speaker or a member of a speakers' bureau" for Mylan Laboratories Inc.¹⁰⁴ Indeed, in 2015, he was paid to speak by Mylan Specialty on the topic of

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ Phillip L. Lieberman, *Bridging the Gaps in Anaphylaxis Care: A Clinical Case Review*, MEDSCAPE (July 30, 2015), <u>http://www.medscape.org/viewarticle/847839_sidebar1</u>, (last visited Jan. 31, 2017).

"Bridging the Gaps in Anaphylaxis Care: A Clinical Case Review."¹⁰⁵

345. The medical disclosure laws for payments to doctors were not mandatory at the time of Dr. Lieberman's 2011 endorsement, so discovery is needed to confirm the full scope of his financial relationship with Mylan.

346. At the time he made his statements on August 24, 2011, Dr. Lieberman did not disclose that he was being paid by Mylan as a consultant. Mylan's reliance on statements by Dr. Lieberman and the NIAID panel is misleading and deceptive because Mylan failed to disclose the "bought-and-paid-for" nature of the statements.

347. By simultaneously removing the individual EpiPen from the United States market while forcing consumers to switch to the EpiPen 2-Pak, and then making consumers pay an inflated price for the EpiPen 2-Pak, Mylan intentionally violated the antitrust laws, RICO, and state consumer protections statutes.

2. Mylan's Relentless EpiPen Price Increases

348. Once Mylan's anti-competitive and fraudulent scheme was deployed, Mylan was able to raise the price of the EpiPen to supra-competitive levels without any concern of competitors undercutting its inflated price.

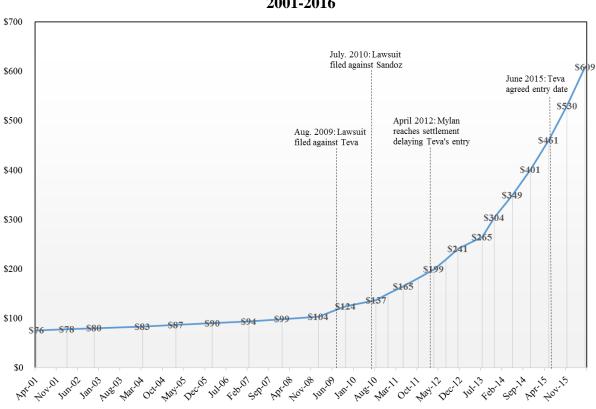


Figure 1: Wholesale EpiPen Prices 2001-2016

349. When Mylan first acquired the EpiPen in 2007, it was priced at approximately \$57 per EpiPen or a little over \$100 for two.

350. Since late 2009, Mylan has raised the price of the EpiPen 15 times.

351. Mylan's price increases have occurred in tandem with, and often following shortly after, its most significant anti-competitive actions.

352. On October 12, 2009, Mylan raised the price of two EpiPens to \$124.

353. In 2011, Mylan stopped selling single EpiPens in the United States. Instead, Mylan began requiring the EpiPen be purchased in two-packs (the "EpiPen 2-Pak"), which doubled the price consumers must pay, even if they need only one EpiPen. Although Mylan cited its concern for patient safety in moving to two-pack only sales, it continues to sell single EpiPens

Source: Wells Fargo Equity Research, "Mylan N.V.: MYL: Despite Recent Drop, We Remain on the Sidelines," Feb. 19, 2016, at 18.

internationally.

354. The timing of the 2-Pak launch in 2011 coincided with Mylan's overall scheme to defraud consumers once it had sidelined, bad-mouthed, restrained, and/or paid off all of its competitors. Without any concern of being undercut, Mylan was free to force consumers to purchase the 2-Pak—or nothing at all.

355. In October 2011, two years and four price increases later, Mylan increased the price of an EpiPen 2-Pak to \$181.

356. After four more price increases, by July 17, 2013, an EpiPen 2-Pak cost \$265.

357. Three more price increases raised the price of an EpiPen 2-Pak to \$401 in November 2014.

358. After the EpiPen price had more than doubled by 2014, a group of Mylan executives repeatedly raised concerns internally over Mylan's profiteering at the expense of children. When confronted with those concerns, Mylan Chairman Robert Coury reportedly "raised both his middle fingers and explained, using colorful language, that anyone criticizing Mylan, including its employees, ought to go copulate with themselves."¹⁰⁶

359. Mylan then continued to hike the price of the EpiPen 2-Pak throughout 2015 and into 2016. One of those increases came in November 2015, one month after the Auvi-Q, a competing device, was removed from the market.

360. As of May 2016, an EpiPen 2-Pak cost around \$608.

361. According to one report, the benefits of EpiPen price increases have accrued largely to defendants, rather than to other members of the supply chain (*i.e.*, pharmacies, PBMs and

¹⁰⁶ Charles Duhigg, *Outcry Over EpiPen Prices Hasn't Made Them Lower*, N.Y. TIMES (June 4, 2017), https://mobile.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html, (last visited October 10, 2017).

distributors): "We believe that Mylan has been raising list price consistently for years, and we believe that Mylan has realized most of that benefit – not the PBMs [(pharmacies)] and not the distributors."¹⁰⁷ Using data published by IMS Health (shown in Table 1 below), the same report estimates that the weighted average cost ("WAC") of EpiPen "has increased by ~30% per year from 2011 through 2015" and has been realizing growth in net prices of 23%.¹⁰⁸

	IMS Sales	IMS Units	IMS WAC	IMS Sales	IMS Units	IMS WAC
Year	(\$ Millions)	(000's)		% Change	% Change	% Change
2011	\$393	3,173	\$132			
2012	\$650	3,310	\$201	65%	4%	52%
2013	\$837	3,416	\$254	29%	3%	26%
2014	\$1,201	3,656	\$337	43%	7%	33%
2015	\$1,691	3,930	\$445	41%	7%	32%

 Table 1: IMS EpiPen Sales

362. The high price is exacerbated by the fact EpiPens generally have to be replaced annually, due to expiration.

363. Since Mylan acquired the right to sell the EpiPen, the price of EpiPens in the United States has become completely unterhered to their production cost and is unethical and unfair to consumers given the relatively miniscule cost of making the EpiPen device. The dose of epinephrine in an EpiPen costs about \$1.00, and a two-pack of EpiPens costs less than \$10 to make.¹⁰⁹

364. Thus, Mylan has tripled the price of the EpiPen since 2012, even though its costs increased only about 15%.

 ¹⁰⁷ Leerink Partners Equity Research, "Pharmacy Benefit Managers: PBMs Use Competing Products to Reduce Costs – EpiPen's Price is Mylan's Issue," Aug. 26, 2016, at 2.
 ¹⁰⁸ *Id.* at 3.

¹⁰⁹ Tom Cahill, *Silicon Valley Engineers: EpiPen Only Costs* \$8 *to Make Despite Selling for* \$700, U.S. UNCUT, <u>http://usuncut.com/class-war/epipen-sells-for-700-only-costs-8-to-make/</u>, (last visited Feb. 1, 2017).

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365. The hike in prices has forced some people living with allergies, as well as EMTs and other first responders, to resort to riskier manual syringes—a development that doctors warn present public health dangers, including an increased risk of the wrong dosage.

366. Non-experts are forced to either go without life-saving medication or inject the epinephrine themselves using a syringe that "carries the risk of injection into a vein, instead of muscle, which can be fatal."¹¹⁰

367. Consumers' outcry over the price of EpiPens has been emphatic, and the Federal Trade Commission has been flooded with complaints by consumers who can no longer afford their medication.

368. Mylan's price gouging is forcing consumers to (a) keep on hand old or expired EpiPens, (b) not buy new ones when they expire, or (c) never purchase them at all.

369. The conduct of Mylan is so reprehensible that Wall Street is speaking out: "It's a real challenge to understand how a management team sits around a board table and makes a decision to raise the price of a lifesaving medication over and over and over, and when the P.R. storm hits, decides to blame someone else for that price increase," said David Maris, an analyst for Wells Fargo.¹¹¹

370. Wall Street, in fact, has responded to Mylan's foul play by hammering its stock price, anticipating a wave of civil and criminal actions that will be launched against Mylan and its executives.

 ¹¹⁰ Emily Willingham, Why Did Mylan Hike EpiPen Prices 400%? Because They Could,
 FORBES (Aug. 22, 2016), <u>http://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/#32036983477a</u>, (last visited Jan. 31, 2017).
 ¹¹¹ Katie Thomas, Painted as EpiPen Villain, Mylan's Chief Says She's No Such Thing, N.Y.
 TIMES (Aug. 26, 2016), <u>http://www.nytimes.com/2016/08/27/business/painted-as-a-villain-mylans-chief-says-shes-no-such-thing.html</u>, (last visited Jan. 31, 2017), attached hereto as
 "Exhibit A."

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371. Mylan's CEO, Heather Bresch, was quoted in the *New York Times* on August 27,
2016, as saying that the decisions surrounding the price of the EpiPen are "unconscionable."¹¹²

372. In doing so, she pointed the finger at virtually everyone but Mylan, insisting, "I am running a business. I am a for-profit business. I am not hiding from that."¹¹³

373. Plaintiffs agree with Ms. Bresch that the pricing of the EpiPen is "unconscionable." But they blame Mylan, because Mylan directly controls the list price paid by retail consumers and has increased the list price intentionally in order to reap excessive profits, artificially inflate the compensation of Mylan executives, and artificially boost Mylan's stock price (until Wall Street caught on and the stock crashed in late 2016).

374. Because Mylan sets the list price for the EpiPen, Mylan dictates the price paid by the end purchaser, *i.e.*, the consumer. Even though some consumers pay a different amount at different pharmacies, Mylan ultimately sets the list price for all retail consumers in the United States and directly causes the damages to end purchasers.

375. During a Forbes Summit interview on December 1, 2016, Bresch falsely asserted that Mylan has invested \$1 billion in developing the EpiPen in creating "access and awareness and improving the product."¹¹⁴

376. When confronted by the national media over her price gouging in connection with the EpiPen, Ms. Bresch stated, "No one's more frustrated than me."¹¹⁵

377. As a columnist in Forbes magazine responded:

¹¹² *Id*.

¹¹³ *Id.*

¹¹⁴ Arlene Weintraub, *Mylan CEO Bresch Admits 'Full Responsibility' for EpiPen Price Hikes*, FORBES (Dec. 1, 2016), <u>http://www.forbes.com/sites/arleneweintraub/2016/12/01/mylan-ceobresch-admits-full-responsibility-for-epipen-price-hikes/#1b820306125b</u>, (last visited Jan. 31, 2017).

¹¹⁵ *Id.*

That seems unlikely[.]...I can't speak to how one measures frustration, but for Bresch to have averred that 'no one' exceeds her in it can mean only one of two things: She is either willfully insoluciant about the real anger people feel when what should be an affordable lifesaving purchase is wrested from their control, or she is that detached from what it means to purchase high-deductible insurance because it's all you can afford, to have a child who will die if they encounter a molecule from a peanut or a bee sting, to be forced to pinch and save to obtain the one thing that will prevent your child's death, and even be forced to compromise the life-saving intervention by using expired or jury-rigged versions. That's a level of anxiety, anger, fear and frustration that is immeasurable, but it surely exceeds whatever frustration Bresch feels.¹¹⁶

378. Ms. Bresch has publicly referred to the EpiPen as her "baby," she has personally made several materially false statements regarding the pricing, cost, and profit off the EpiPen. She personally appeared before the House Oversight Committee in September 2016 to testify under oath regarding the EpiPen, she personally appeared at the Forbes Summit on December 1, 2016, to discuss the EpiPen pricing, and her compensation has ballooned almost in lockstep with the swelling price of the EpiPen.

379. Ms. Bresch rose through the ranks at Mylan based on the EpiPen (she was hired as a low-level employee and became CEO by positioning herself on the back of the EpiPen franchise); as its sales skyrocketed, so did her position in the company.

380. Ms. Bresch has orchestrated and spearheaded the EpiPen scheme; she was the mastermind behind the scheme and the point person who tried to conceal Mylan's fraud in 2016 by appearing in numerous media publications and at the Forbes Health Summit in December 2016 and before Congress in September 2016.

381. Ms. Bresch was summoned to testify before Congress at the end of November 2016, but she "refused to testify" before the Senate hearing, where Senator Chuck Grassley (R-Iowa)

¹¹⁶ Arlene Weintraub, *Mylan CEO Bresch Admits 'Full Responsibility' for EpiPen Price Hikes*, FORBES (Dec. 1, 2016), <u>http://www.forbes.com/sites/arleneweintraub/2016/12/01/mylan-ceo-bresch-admits-full-responsibility-for-epipen-price-hikes/#1b820306125b</u>, (last visited Jan. 31, 2017).

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had planned to review with her, under oath, the \$465 million settlement Mylan agreed to pay the Department of Justice ("DOJ") after it was caught overcharging Medicaid by falsely classifying the EpiPen as a generic drug or device.¹¹⁷

382. Despite dodging Congress's request that she provide testimony under oath, Ms. Bresch attended the Forbes Health Summit the next day, on December 1, 2016, and made further statements connecting her personally to the EpiPen price hikes and the strategy and direction of the EpiPen.

383. In a video of a December 1, 2016, interview of Ms. Bresch from the Forbes Summit, Ms. Bresch nods in agreement with the statement that the decision to increase the price of the EpiPen is "wholly [her] decision and responsibility." As Forbes reported, Ms. Bresch stated in response to this statement: "We absolutely raised the price and take full responsibility for that."¹¹⁸

384. During the Forbes Summit interview on December 1, she falsely asserted that Mylan has invested over \$1 billion over the last eight years in developing the EpiPen in creating "access and awareness and improving the product."¹¹⁹

385. This statement is misleading or false because \$1 billion was not directed to actual product improvements and because Mylan suggests it has invested money in improving the product when, in fact, Mylan has invested in lobbying and paying its executives rather than improving the product.

386. The \$1 billion misleading or false statement by Mylan is an attempt to conceal its behavior, so it operates to extend any applicable statute of limitations that might apply to the claim alleged herein.

¹¹⁹ *Id*.

¹¹⁷ *Id*.

¹¹⁸ *Id*.

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387. As she has orchestrated the price gouging of American consumers through price hikes on the EpiPen, Ms. Bresch and Mylan have ensured that her own salary has surged by 671%—from \$2.5 million in 2007 to nearly \$19 million in 2015—in tandem with the soaring percentage increase in the price of EpiPens.

388. Mylan has also systematically engaged in a massive lobbying and marketing effort that abused governmental power to aid the inflated purchase price of the EpiPen, artificially taking sales of the EpiPen franchise from \$200 million to over \$1 billion.

389. According to Mylan in its 2015 10-K, "A significant portion of Mylan Specialty's revenues are derived through the sale of the EpiPen Auto-Injector. The EpiPen Auto-Injector is the number one dispensed epinephrine auto-injector and as a global franchise reached \$1 billion in annual net sales for the second year in a row."¹²⁰

390. In 2015, sales of the EpiPen reached \$1 billion in annual net sales for the second straight year.

391. The EpiPen, in fact, accounts for 40% of Mylan's profits but only 10% of its revenue. This makes sense because Mylan is primarily a generics company that makes low margins.

392. Bresch, as the mastermind, used the EpiPen 2-Pak scheme to enrich herself and other Mylan executives in extra bonuses. In late 2016, this fraudulent scheme was exposed:

Drug maker Mylan (MYL), under fire for sharply raising prices of a life-saving allergy treatment, two years ago urged executives to hit ambitious five-year sales and profit targets with a special incentive plan.

¹²⁰ MYLAN N.V. 10-K (2015),

https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231xdo c.htm, (last visited Jan. 31, 2017).

If achieved, the special one-time award, offered to more than 100 "key employees," would mean tens of millions of dollars in bonuses for the executives of the Netherlands-based company.

The plan's goal is to double Mylan's 2013 adjusted earnings per share of \$2.89 to \$6 by the end of 2018, an "ambitious" 16% compound annual growth rate, according to the company's 2014 proxy statement.

Since the incentive plan was enacted, the cost of EpiPen two-packs negotiated by insurers and employers has risen from less than \$400 to more than \$600....

The Wall Street Journal reported Thursday on the incentive plan, which was also detailed last week by Business Insider. With a potential increase of \$82 million to the top five executives, Mylan management might see EpiPen price hikes as a way to make the aggressive targets.

"When they thought they would have a revenue or profit shortfall somewhere else they decided to get more aggressive on EpiPen, because that is where they thought they would be able to raise some prices, make some more profit and make their targets," Ronny Gal, an analyst at Sanford C. Bernstein, told USA TODAY.¹²¹

3. Comparison to Prices and Markets for Epinephrine Auto-Injectors in Europe

393. Compared to the United States, the cost for a set of two EpiPens in Europe ranges

from only about \$100 in France and the United Kingdom to just over \$200 in Germany.

394. While Europe's significantly lower prices are, in part, the result of legislation

restricting price increases on branded drugs, a portion of the lower prices can be attributed to

pricing discipline imposed by competition from two alternative products that are not offered for

sale in the United States.

395. In the United Kingdom, non-contractual price agreements between the Department

of Health and the Association of the British Pharmaceutical Industry ("ABPI") are established

under the Pharmaceutical Price Regulation Scheme ("PPRS") for all branded medicines available

¹²¹ Mike Snider, *EpiPen Maker Ties Bonuses to Profit Targets*, USA TODAY, (Sept. 1, 2016), <u>http://www.usatoday.com/story/money/business/2016/09/01/epipen-maker-ties-bonuses-profit-targets/89710582/</u>, (last visited Jan. 31, 2017).

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from the National Health Service ("NHS"). "The purpose of the scheme is to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry."¹²² In February 2009, the PPRS reduced prices by an estimated 3.9%.

396. There are also, however, two alternative products currently available in the United Kingdom that have prevented Mylan from achieving the same dominant market share it has in the United States.

397. Jext, sold by Alk-Abello and approved for sale in Europe in 2011, has gained an estimated 11% of the European market for epinephrine auto-injectors. A set of two Jext pens costs the NHS about 48 pounds, *down about 17% since 2013*.

398. According to a 2012 report, the cost per dose for Jext was initially higher than the cost of EpiPen, in part due to Jext's longer shelf life.

Costs per dose (£)	EpiPen	Jext
0.15 mg	26.45	28.77
0.3 mg	26.45	28.77

399. The other alternative to EpiPen, Emerade, was introduced in 2014 and has an estimated 20% of the market in the United Kingdom and Sweden and 6% of the market in Germany.¹²³

400. As a result of this competition in Europe, EpiPens and other epinephrine autoinjectors are considerably more affordable there.

¹²² Anaphylaxis Campaign, *Statement – EpiPen pricing situation in the US – 26th August 2016*, Anaphylaxis.org.uk, Aug. 26, 2016, *available at* http://www.anaphylaxis.org.uk/2016/08/26/ statement-epipen-pricing-situation-us-26th-august-2016/.

¹²³ A third alternative, Anapen, was introduced in 2011. That product was sold in the United Kingdom, but is no longer available.

4. False Statements Regarding Coupons, Rebates, and the Generic EpiPen

401. Mylan and Ms. Bresch also have made repeated and false statements regarding Mylan's coupon program, rebate program, and the launch of its generic EpiPen. These false statements have misled consumers and caused consumers to continually pay an inflated price for the EpiPen.

402. Mylan's false statements have also been used to conceal Mylan's earlier fraud, its earlier deception, and its earlier antitrust violations.

403. Mylan has stated publicly on its website and to the media throughout at least 2016 that 80% of consumers with insurance pay nothing for the EpiPen, but this statement is at best a half-truth:

Mylan also claims that nearly 80% of people with commercial insurance have been paying nothing whatsoever for their EpiPens, thanks to the special savings card mentioned above. This is hard to believe. The card had been limiting one's saving to \$100 per EpiPen two-pack. Considering that the retail price of the EpiPen is over \$600, and that the average American worker nowadays has a high-deductible health plan that requires him to pay out of pocket before insurance kicks in, it's hard to see how the majority of EpiPen users have been getting them for free. What's more, if most people have been receiving their EpiPens for free, there would be no real reason for Mylan to suddenly feel compelled to expand the discounting program.¹²⁴

404. Even giving Mylan the full weight of this statement, Mylan knows that charges these consumers' insurance companies several hundred dollars for each EpiPen 2-Pak, which results in increased insurance premiums. Every time Mylan charges insurance companies for the EpiPen, consumers everywhere are harmed by increased premiums and higher co-pays. As the Los <u>Angeles Times</u> has explained, Mylan's refusal to price the EpiPen at a reasonable amount simply "means the insurers and employers that pay the bulk of the EpiPen cost for many patients will

¹²⁴ Brad Tuttle, *Mylan Cuts EpiPen Prices, Blames Obamacare Rather Than Greed for High Costs*, <u>Time</u>, Aug 25, 2016, available at: <u>http://time.com/money/4466052/epipen-prices-cut-mylan-gouging/</u>

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continue to do so, contributing to higher health insurance costs. 'That's just going to come out in the premiums,' said Sabrina Corlette, a research professor at Georgetown University's Health Policy Institute."¹²⁵

405. Third-party payors, therefore, are directly harmed by Mylan's statement that 80% of consumers with insurance pay nothing. Mylan seeks to have consumers fill prescriptions that it knows will be paid by third-party payors at inflated prices.

406. Mylan has an EpiPen discount program, but it is riddled with exceptions and is under-utilized. The coupons and rebates offered by Mylan "are wolves in sheep's clothing," according to Leemore Dafny, a professor at Harvard Business School.¹²⁶ A coupon or drug rebate "can reduce the portion of the drug that you pay yourself, but it doesn't do anything to lower the share paid by your insurance company, which can be hundreds or thousands of dollars more."¹²⁷

407. The over \$600 wholesale price for a package of EpiPens stops many needy consumers from ever pursuing the medicine because they are unsophisticated and unaware of the complex and all-too-often confusing rebate and coupon programs, which require access to doctors, a computer, printer, and a familiarity with the labyrinth-like maze of the U.S. health care system.

408. The recent announcement by Mylan that it will sell a \$300 generic version of the EpiPen (in competition with itself) "is likewise a calculated maneuver. If Mylan is prepared to offer a \$300 generic injector, made in the same factories with the same components, why doesn't it just sell the EpiPen for the lower price? The answer is all business and no medicine: Mylan can

¹²⁵ Associated Press, *EpiPen Maker Boosts Discount Programs but Holds Price Steady, Despite Outrage*, L.A. TIMES (Aug. 25, 2016), <u>http://www.latimes.com/business/la-fi-mylan-epipen-cost-20160825-snap-story.html</u>, (last visited Jan. 31, 2017).

¹²⁶ Margot Sanger-Katz, *Drug Coupons: Helping a Few at the Expense of Everyone*, N.Y. TIMES (Oct. 12, 2016), <u>http://www.nytimes.com/2016/10/13/upshot/drug-coupons-helping-a-few-at-the-expense-of-everyone.html</u>, (last visited Jan. 31, 2017). ¹²⁷ *Id*

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hang onto the market for doctors and patients who demand the trusted brand name, while cornering an incipient generic market."¹²⁸

409. In reality, Mylan's \$300 generic version of own its product (an unprecedented move in Big Pharma) proves that its own \$608 list price for the exact same product—manufactured by the exact same company in the exact same facilities for the exact same cost—is unconscionable and that Mylan is willfully price gouging consumers.

410. Mylan confesses actual knowledge on its own website that consumers with high deductible insurance plans are punished by its price increases: "With the current changes in the healthcare insurance landscape, an increasing number of people and families have enrolled in high deductible health plans, and deductible amounts continue to rise. This current and ongoing shift has presented new challenges for consumers, and now they are bearing more of the cost."¹²⁹

411. In late August 2016, recognizing that it had been caught by the national media gouging people who depend on the product to stay alive, Mylan announced plans to introduce a generic version of the EpiPen with a list price of \$300. Thus, Mylan will sell the same product under two names, at two price points, in competition with each other.

412. This absurd move surprised the industry and merely highlighted that Mylan was charging double the price of what even Mylan considers reasonable; Mylan's decision to launch the generic is proof that even Mylan knows it gouges customers with a \$608 list price.

413. Even at \$300, the generic will still be triple the price of the EpiPen in 2007, when Mylan acquired the product and began steadily raising its price.

¹²⁸ Elisabeth Rosenthal, *The Lesson of EpiPens: Why Drug Prices Spike, Again and Again*, N.Y. TIMES (Sept. 2, 2016), <u>http://www.nytimes.com/2016/09/04/opinion/sunday/the-lesson-of-epipens-why-drug-prices-spike-again-and-again.html.</u>, (last visited Jan. 31, 2017).

¹²⁹ Mylan's Commitment to EpiPen (epinephrine injection, USP) Auto-Injector Access, MYLAN N.V., <u>http://newsroom.mylan.com/access</u>, (last visited Sep. 8, 2016).

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414. Robert Weissman, the president of the corporate watchdog organization Public Citizen, was not impressed by Mylan's launch of a generic EpiPen. "The weirdness of a generic drug company offering a generic version of its own branded but off-patent product is a signal that something is wrong," he said in a statement. ¹³⁰

415. "Coupons, discount cards and patient assistance programs are a false solution for consumers hit with gigantic out-of-pocket costs," Weissman continued. ¹³¹ "First, many consumers will not use the coupons or the programs. Second, many consumers with high deductibles or no insurance will still need to pay far too much for EpiPens—\$300 for a set of two—a problem made worse by the facts that many families purchase multiple sets of EpiPens and that EpiPens must be replaced every year." ¹³²

416. Mylan also falsely attributes the rise in the EpiPen to its "outreach" programs, but

this is a false way of trying to write-off "marketing" as charity:

Mylan has tried to make a case that there are reasons for the EpiPen's price hikes. The company says it has spent millions on anaphylaxis and allergy awareness campaigns, and that it has given away 700,000 EpiPens in 65,000 schools since 2012. Mylan might refer to these efforts as "outreach." However, you might think of them by another term: "marketing." The point of these campaigns, like the millions Mylan has spent annually on advertising and lobbying, is to create an atmosphere in which it can maximize EpiPen sales. Mylan is trying to say that its product's price is so high because the company spends so much money trying to sell it to people.¹³³

5. False Statements to Congress Under Oath on September 21, 2016

417. From the time Mylan acquired the EpiPen in 2007 until at least October 2016,

¹³⁰ Robert Weissman, *Mylan's Announcement on EpiPen Prices: Too Little Too Late*, PUBLIC CITIZEN (Aug. 25, 2016), <u>http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=7987</u>, (last visited Jan. 31, 2017).

¹³¹ *Id.*

¹³² *Id.*

¹³³ Brad Tuttle, *Mylan Cuts EpiPen Prices, Blames Obamacare Rather Than Greed for High Costs*, <u>Time</u>, Aug 25, 2016, available at: <u>http://time.com/money/4466052/epipen-prices-cut-mylan-gouging/</u>

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Mylan repeatedly and falsely certified to federal officials that the EpiPen was "generic" and a "non-innovator product." For this reason, in 2016, Mylan was forced to pay over \$465 million to avoid fraud charges by the federal government related to Mylan's abuse of Medicaid.

418. Congress was so outraged by the pricing of the EpiPen that it called for hearings. Ms. Bresch testified before Congress in late September 2016 in an attempt to defend her inflated pricing of the EpiPen. That testimony went poorly for her and prompted Congress to raise further questions regarding her candor and truthfulness for the statements she made under oath.

419. Before Ms. Bresch testified under oath to Congress on September 21, 2016, she was required to fill out and sign a Committee on Oversight and Government Reform Witness Disclosure Requirement – "Truth in Testimony" – form.¹³⁴ In that form, she stated:

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

I am testifying for Mylan, N.V., for which I am the Chief Executive Officer, and testifying for Mylan, N.V.'s subsidiary, Mylan Specialty, L.P., which markets and sells the EpiPen® Auto-Injector.

.... [portion of form regarding federal grants received omitted]

I certify that the above information is true and correct. Date: 19 SEPIL Signature

420. In this disclosure, Ms. Bresch states that she is speaking for both Mylan Specialty and Mylan N.V.

421. Ms. Bresch's statements made to Congress on September 21, 2016, were designed

to conceal Mylan's ongoing fraud and to distract and confuse the public from uncovering Mylan's

¹³⁴ *Testimony of Mylan CEO Heather Bresch*, UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM (Sep. 21, 2016), <u>https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf</u>, (last visited Jan. 31, 2017).

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ongoing antitrust, racketeering, and consumer protection violations. Ms. Bresch sought to cover her tracks and the tracks of Mylan and conceal the misleading and fraudulent scheme she had devised and orchestrated.

422. On September 21, 2016, Ms. Bresch testified under oath to Congress, "After rebates and various fees, Mylan actually receives \$274 [for the sale of each EpiPen 2-Pak]. Then you must subtract our cost of goods which is \$69. This leaves a balance of \$205. After subtracting all EpiPen Auto-Injector related costs our profit is \$100, or approximately \$50 per pen."¹³⁵

423. This statement was false and misleading. In fact, the <u>Wall Street Journal</u> has reported that Mylan's profit from the EpiPen was 60% higher than Ms. Bresch stated in her sworn testimony.¹³⁶

424. As the <u>Wall Street Journal</u> further reported:

Ms. Bresch came to the hearing with a poster that showed how various costs along the way resulted in a \$100 profit per two-pack. A major factor, the poster said, were 'direct EpiPen related' costs that Mylan pegged at \$105 per two-pack.

The poster didn't say anything about tax costs, which it turns out made up the majority of the \$105. Mylan's chief executive similarly didn't mention the tax calculation in her testimony, even when Rep. Jason Chaffetz (R., Utah), the committee chairman, zeroed in on the \$105 direct-cost figure and asked 'what is in that number?'

Ms. Bresch cited sales, marketing and disease-awareness costs.

The \$100 profit figure, or \$50 per pen, was greeted with incredulity by committee members. Rep. Stephen Lynch (D., Mass.) said 'the numbers don't work, based on the documents you've given us.'

Rep. Buddy Carter (R., Ga.), a pharmacist, called Ms. Bresch's explanation of EpiPen's pricing a 'shell game.' He reminded Ms. Bresch she was under oath and asked: 'Is that the truth, \$50 per pen?

¹³⁵ *Id.*

¹³⁶ Mark Maremont, *Mylan's EpiPen Pretax Profits* 60% *Higher Than Number Told to Congress*, WALL ST. J. (Sep. 2, 2016), <u>http://www.wsj.com/articles/mylan-clarifies-epipen-</u> <u>profit-figures-it-provided-to-congress-last-week-1474902801</u>, (last visited Jan. 31, 2017).

425. The Financial Times also covered Ms. Bresch's testimony before Congress¹³⁷:

The auto-injector contains roughly \$1 worth of adrenalin, which can ward off anaphylactic shock if injected quickly enough following a severe allergic reaction.

"When the juice is a dollar and you're selling it for \$600, there's some room for profit," said Jason Chaffetz, a Republican congressman from Utah, and chair of the House Committee on Oversight and Government Reform.

In a heated exchange with Ms Bresch, Mr Chaffetz said he found it hard to believe her claim that Mylan only generated \$50 of profit on each EpiPen, and drew attention to the outsized pay packet received by the company's executives in recent years.

"You have five executives in five years that earned nearly \$300m," Mr Chaffetz said.

426. Below is a photo of the poster ("EpiPen Auto-Injector Estimated Profitability")

displayed by Ms. Bresch to the House Oversight Committee on September 21, 2016.¹³⁸

	EpiPen® Auto-Injector Estimated Profitability		
	Wholesale Acquisition Cost Price - Rebates & Allowances	\$608 \$334 \$274	
	Mylan Revenue - Cost of Goods Sold	- \$ 69 \$205	
3	- Direct EpiPen® Auto-Injector Costs	- \$105	
	Mylan Approx. Profit per Two-Pack	\$100	
	Mylan Approx. Profit per Pen	\$ 50	Heather Breach, the chief enerative of
MS. BRESCH			Mylan, toxifying on Capitol Hill last month at a congruenional bearing on EppPen prior increases. Airs framine/Associated Press

427. This poster contained several materially false or misleading statements regarding

¹³⁷ David Crow, *Mylan Chief Comes Under Fire Over Costs of EpiPen*, FINANCIAL TIMES (Sept. 21, 2016), <u>https://www.ft.com/content/64f0cb22-8040-11e6-bc52-0c7211ef3198</u>, (last visited Feb. 1, 2017)

¹³⁸ Margot Sanger-Katz, *Drug Coupons: Helping a Few at the Expense of Everyone*, N.Y. TIMES (Oct. 12, 2016), <u>http://www.nytimes.com/2016/10/13/upshot/drug-coupons-helping-a-few-at-the-expense-of-everyone.html</u>, (last visited Jan. 31, 2017).

the cost, profit, and launch of the generic EpiPen.

428. On September 21, 2016, Ms. Bresch also stated under oath to Congress at least the

following false or misleading statements:

- a. "Over the last decade, Mylan's medicines reduced U.S. healthcare costs by approximately \$180 billion."¹³⁹
- b. "In the more than 8 years we have owned the EpiPen product, we have worked diligently and invested to enhance the product and make it more available. In fact, we have invested more than one billion dollars in the efforts. On many fronts we have succeeded. We put a much improved EpiPen device on the market in 2009. We've also invested so that we can soon offer a longer shelf life, which means patients will go longer before needing a refill."¹⁴⁰
- c. "And today, approximately 85 percent of EpiPen patients pay less than \$100 for a 2-unit package and a majority pay less than \$50."¹⁴¹
- 429. Fortune reported on Bresch's statements to Congress regarding Mylan's profits and

taxes related to the EpiPen, Bresch's compensation, and Bresch's assertion that Mylan has saved

America over \$180 billion over a decade. As Fortune exposed, each of these factual assertions was

either false or "might be considered misleading at best."¹⁴²

430. Ms. Bresch's statements were also false and misleading because the increased price

for the EpiPen has to be paid by someone, and that someone is the end-users through cash

payments, co-pays, deductibles, or higher insurance premiums.

REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM (Sep. 21, 2016), https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf, (last visited Jan. 31, 2017).

^{431.} Ms. Bresch's statements were also false and misleading because (a) the meteoric

¹³⁹ Testimony of Mylan CEO Heather Bresch, UNITED STATES HOUSE OF

¹⁴⁰ *Id.*

 $^{^{141}}$ *Id*.

¹⁴² Sy Mukherjee, *3 Highly Dubious Claims Mylan's CEO Made to Congress*, FORTUNE (Sep. 26, 2016), <u>http://fortune.com/2016/09/26/mylan-epipen-profit-higher-congress/</u>, (last visited Jan. 31, 2017).

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rise in the EpiPen price did not coincide with the alleged expenditures made by Mylan; (b) the alleged expenditures made by Mylan were not to make the product more available to the public, but to find some excuse to extend its patents on the EpiPen so the price could be jacked up further and for a longer period of time; (c) it cannot be rationalized that raising the price of a product makes it more affordable and accessible to the masses; as Mylan knows, the opposite is true; and, (d) Mylan's mandate that everyone buy two EpiPens, via the forced hard switch, obviously also reduces the public's access and ability to buy the EpiPen.

432. As a result, Ms. Bresch and Mylan acted to conceal the misleading and fraudulent scheme perpetrated by Mylan since at least 2009, and further confuse American consumers.

433. In the poster displayed by Ms. Bresch to Congress, she represents under oath that the EpiPen list price is \$608. This proves that Mylan sets and controls the list price down to the exact dollar: \$608. Thus, although Mylan tries to publicly blame the PBMs for inflating the price of the EpiPen and adding a bloated "middle man" charge, her ability to state under oath the exact list price—with the share taken by the PBMs included and not added on later—proves that Mylan is involved directly, fully, and conclusively in all pricing decisions regarding the EpiPen.

434. Ms. Bresch testified to Congress that Mylan had to raise the price of EpiPens from \$100 to \$600 in order to recoup the more than one billion dollars Mylan has invested "to enhance the product and make it more available." ¹⁴³

435. That testimony was, at best, misleading. To begin, Mylan does not manufacture the EpiPen. It is manufactured by Meridian, a Pfizer subsidiary.

436. Also, raising prices does not make a product more available. Others have

¹⁴³ *Testimony of Mylan CEO Heather Bresch*, UNITED STATES HOUSE OF REPRESENTATIVES COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM (Sep. 21, 2016), *see supra*.

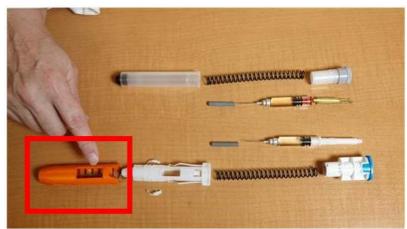
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recognized that Bresch's testimony was deceptive. For example, according to PA Consulting Group, a UK-based technology consulting firm that designs auto-injectors for pharmaceutical companies, Mylan's improvements to the EpiPen since 2009 likely required redesign and capital costs running into the "double-digit millions." That is a far cry from the \$1 billion figure Ms. Bresch cited during her testimony.

437. In reality, most of the money Mylan has spent on the EpiPen has not gone to creating a superior product, but towards marketing and lobbying costs, which Mylan deceptively labels "access and awareness programs."

438. According to Dr. Julie C. Brown, a University of Washington School of Medicine pediatric emergency physician, Mylan's "redesign" uses the same core device that's been in use for some time.¹⁴⁴

439. As the below image indicates, the most notable difference between the original and redesigned EpiPen is a plastic sheathing —hardly a justification for a 500% price increase.



http://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-insiden652651

440. Further, according to Mylan, the re-design includes many cosmetic changes, such

¹⁴⁴ Ben Popken, *Mylan's Upgraded EpiPen Torn Apart By Experts*, NBC NEWS (Sept. 20, 2016), <u>http://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-inside-n652651</u>, (last visited Jan. 31, 2017).

as changing the color of the plastic used.

441. When asked by investigative reporters about the company's 400-500% increase in

prices, Mylan provided the following list of 'improvements', none of which come close to

justifying Mylan's extreme price increases:

Next-Generation Auto-Injector Product Features

- Built-in needle protection with a Never-See-Needle® -- there is no exposed needle before or after use
- An ergonomically-designed, easy-to-grasp oval barrel with illustrated instructions that allow for rapid understanding and proper use of EpiPen® Auto-Injector. The oval shape also prevents the device from rolling out of reach during an emergency
- One-step flip-top carry case that allows for rapid, single-handed removal
- Bright orange colors and arrows to help quickly identify the needle end of the device and reduce the risk of accidental thumb puncture and accidental injection of the product into the patient's or caregiver's finger
- Color changes made so the two strengths looked different from one another – yellow for 0.3mg and green for 0.15mg – to help patients, caregivers and healthcare providers quickly distinguish between the two strengths.
- Trainer changed to a grey body so there would be no confusion between Trainer and EpiPen® Auto-Injector to decrease the likelihood a patient or caregiver would accidentally use the trainer (which has no drug) instead of the actual device to treat an anaphylactic reaction.

Thanks, Lauren

> Lauren Kashtan Head of North America Communications Mylan 1000 Mylan Boulevard Canonsburg, PA 15317

http://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-insiden652651

442. Although Ms. Bresch swore that Mylan's profit on the EpiPen is only \$100 per sale,

that number is likely wrong: "According to the Wall Street Journal, the company tweaked that

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number around by adding in a 37.5% U.S. tax rate to those calculations. Without that assumption, the company's take on a pair of pens leaps from the \$100 per two-pack that Bresch cited to about \$160 per two-pack."¹⁴⁵

443. The false testimony to Congress about Mylan's tax rate was especially disgraceful because in 2014 Mylan reincorporated in the Netherlands solely to dodge paying U.S. taxes.¹⁴⁶

444. In 2014, Mylan executed a tax inversion to transform itself on paper into a Netherlands corporate shell so that it could avoid paying taxes in the United States—despite having its operations in the United States and its employees benefit from the greatness of America's infrastructure and consumer base, plus tax-payer funded police, fire, and other city-services.

445. "[Tax] filings also show that under a special, one-time stock grant created in 2014, top executives—including Ms. Bresch—stand to reap further riches at least partly on the back of price increases on the EpiPen."¹⁴⁷ Indeed, "the timing of the one-time stock grant to executives is striking—especially when set against the history of EpiPen price rises."¹⁴⁸

446. In fact, "Mylan began significantly stepping up the pace of its EpiPen price increases just a few months after the company announced the special grant in February 2014. While price increases in the previous four years averaged 22 percent annually, in 2014 and 2015 Mylan increased EpiPen prices 32 percent each year."¹⁴⁹

447. The inescapable conclusion is that Mylan's course of conduct was designed with

 ¹⁴⁵ Emily Willingham, Whoops, Mylan Underreported EpiPen Profits to Congress, FORBES (Sep. 26, 2016), <u>http://www.forbes.com/sites/emilywillingham/2016/09/26/whoops-mylan-underreported-epipen-profits-to-congress/#4b2ef1016e2a</u>, (last visited Jan. 31, 2017).
 ¹⁴⁶ Id.

¹⁴⁷ Gretchen Morgenson, *EpiPen Price Rises Could Mean More Riches for Mylan Executives*, N.Y. TIMES (Sep. 1, 2016), <u>http://www.nytimes.com/2016/09/04/business/at-mylan-lets-pretend-</u> <u>is-more-than-a-game.html</u>, (last visited Jan. 31, 2017).

¹⁴⁸ *Id*.

¹⁴⁹ *Id*.

only one objective in mind—to reap a windfall on a lifesaving drug.

448. By testifying under oath to the House Oversight Committee on September 21, 2016, and providing repeatedly false testimony, as catalogued above, Ms. Bresch corruptly sought to influence and disrupt an "official proceeding" (*i.e.*, a hearing before the United States Congress).

F. Relevant Market and Mylan's Market Power

449. The relevant product market is the market for epinephrine injector devices.

450. There are no adequate substitutes for epinephrine auto-injectors. EpiPen is priced at a premium compared to other epinephrine auto-injectors and, as a result of Defendants' conspiracy, prices of competing products have not been able to discipline EpiPen's prices.

451. Despite the high margins earned on EpiPen sales, few substitutes have emerged in the epinephrine auto-injector market. Those competitors that have managed to enter the market have been met with limited success. According to a Barclays Capital analyst report, "EpiPen has faced competitors previously, although none have gained competitive traction."¹⁵⁰

452. At all relevant times, Mylan had substantial market power and/or monopoly power in the market for the epinephrine auto-injector because Mylan had the power to maintain the price of the EpiPen at supra-competitive levels without losing substantial sales to competitors.

453. A small but significant, non-transitory price increase for the EpiPen by Mylan would not have caused Mylan to lose significant sales to other competitors sufficient to make such a price increase unprofitable.

454. EpiPen did not <u>exhibit</u> significant, positive cross-elasticity of demand with respect to price.

455. Price does not typically drive prescriptions for medications, including those for

¹⁵⁰ Barclays Capital Equity Research, "Mylan Inc.: Overcoming EpiPen's Wall of Worry," Mar. 7, 2012, at 1.

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epinephrine auto-injectors. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing most pharmaceutical products to patients without a prescription written by a doctor. Patients and third-party payors have the obligation to pay for the pharmaceutical product, but it is ultimately the doctors who choose which product the patient will buy. This disconnect was exploited by Mylan to maintain its monopoly and unconscionable price increases.

456. At the same time, numerous studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals. Moreover, even when they are aware of the costs, doctors are insensitive to prices because they do not pay for the products. The net result is an atypical marketplace in which price plays a comparatively smaller role in product selection.

457. Thus, unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the initial purchasing decision for prescription drugs and devices is generally made by doctors, not by consumers of those products.

458. At all relevant times, Mylan had, and exercised, the power to exclude and restrict competition in the market for epinephrine auto-injector devices.

459. During the relevant time, Mylan has been able to profitably maintain the price of the EpiPen well above competitive levels.

460. The relevant geographic market is the United States and its territories. Mylan's 2010 Form 10-K confirms that the "principal market" for the company's specialty segment, which includes EpiPen sales, is "pharmaceutical wholesalers and distributors, pharmacies and healthcare institutions primarily in the U.S."¹⁵¹

461. Mylan has sold the EpiPen in the United States since at least January 1, 2009 at prices well in excess of the competitive price.

462. Mylan's market share in the market for epinephrine injector devices in the United States has constantly remained above 80% since at least January 1, 2009. As shown in Table 2 below, Epipen maintained a 94% share of the epinephrine auto-injector market from 2009 to 2012, decreasing slightly from 2009 to 2010 and increasing to nearly 100% in 2012. According to one report, "[a]s Epipen has been able to maintain its share despite Twinject competition, we would not be surprised to see ongoing price increases for the franchise."¹⁵²

Product/Trademark 2009 2010 2012 2011 EpiPen 95.70% 99.50% 94.70% 94.10% Andrenaclick/Twinject 0.20% 1.00% 3.40% 5.10% Generic Epinephrine 3.20% 1.90% 0.70% 0.20%

 Table 2: Epinephrine Auto-Injector Market Shares, 2009-2012

Source: Leerink Swann Healthcare Equity Research, "Mylan, Inc.: EpiPen Survey Confirms Auvi-Q Threat; We Believe Shares Reflect Competition," Apr. 9, 2013, at 18.

463. EpiPen's market share began to fall slightly in 2013 with the introduction of Auvi-Q, as shown in Figure 2 below. After dropping to 88% in December 2013, EpiPen's market share reversed its downward trend, increasing to 93% in May 2014.

¹⁵¹ Mylan SEC Form 10-K for the fiscal year ended December 31, 2010, filed February 24, 2011, at 80.

¹⁵² J.P. Morgan North American Equity Research, "Mylan Inc.: A Closer Look at Dey," Apr. 1, 2009, at 4.

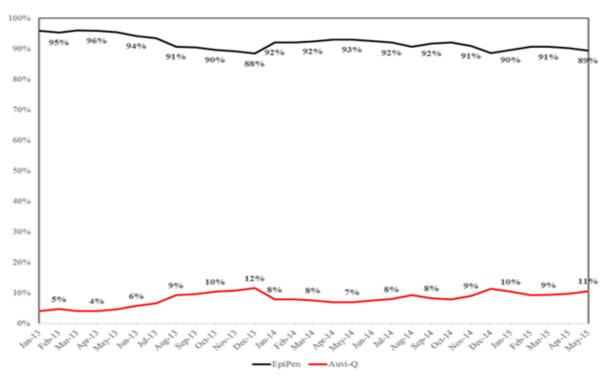


Figure 2

464. In October 2015, Auvi-Q left the market, leading to a "substantial increase in EpiPen volume growth."¹⁵³

465. The epinephrine auto-injector market is now worth an estimated \$1.3 billion annually with Mylan's EpiPen sales accounting for 85%.

G. Barriers to Entry

466. The market for epinephrine auto-injectors in the United States is characterized by difficult entry conditions and durable barriers to entry that have protected and fortified Mylan's monopoly power.

467. For example, because epinephrine auto-injectors must be prescribed by a medical professional, there is a lengthy FDA approval process that any potential new entrants must undergo to enter the market. In addition, to convince consumers to switch to a new epinephrine auto-

¹⁵³ BTIG Equity Research, "Mylan N.V.: Epipen Market Shares Surge Post Auvi-Q Recall; Buy," Nov. 30, 2015, at 1.

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injector, any new entrant must show that the epinephrine used in the device is bioequivalent to the EpiPen.

468. Prescriptions for epinephrine auto-injectors are also infrequently refilled, usually only once per year unless there is a further need due to an anaphylactic event. Additionally, because the EpiPen has been the dominant epinephrine auto-injector in the market for decades, most caregivers and physicians are trained on the EpiPen but not on any potential alternative.

469. The repeated failure of new entrants underscores the significant barriers to entry in this market. Previous entrants to the market, including Twinject® and AdrenaclickTM, have failed to gain significant market share. Both devices shared the EpiPen's basic design. Both were discontinued. Indeed, Mylan's Bresch has "been pretty vocal about the fact that [she] think[s] the bar to get an AB-rated substitutable product is very high."¹⁵⁴

470. According to the 2016 Orange Book, an annual compilation of brand name drugs and their associated patents, Defendants currently own four patents related to epinephrine autoinjectors, all of which are set to expire in November 2025. Defendants' control over these patents means that firms seeking entry with a generic injector product prior to 2025 can only do so by certifying that each patent is invalid or will not be infringed by a generic device.

471. Given their collective scheme, to quote a 2012 analyst report, defendants "ha[ve] been taking steps on multiple fronts to stymie generics, including the introduction of a redesigned auto-injector in 2009 that offers some incremental safety features and carries additional IP

¹⁵⁴ Transcript, Mylan Inc., Analyst / Investor Day, at 7 (Aug. 1, 2013). Without an AB-rating, even if a device is approved by the U.S. Food and Drug Administration and shown to be bioequivalent to the EpiPen®, a pharmacist would not be able to automatically substitute the alternative device when a patient's prescription specifies the EpiPen®. *See* U.S. Food & Drug Admin., Orange Book Preface, *available at*

https://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm (last updated Jan. 24, 2017).

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protection.¹⁵⁵ Specifically, in a 2009 earnings call, Mylan's CEO Heather Bresch "told investors that the company would be introducing a new version of EpiPen's auto-injector device, one with patent protection that would make it more difficult for a generic competitor to enter. The month that the company launched the improved product, Mylan boosted the list price of the drug by 20 percent." According to Jacob Sherkow, an associate professor at New York Law School, by revising its product, Mylan was "essentially wiping the slate clean – if any generic company wants to create a generic version, they're going to have to start a lawsuit."¹⁵⁶

472. The delivery device is an additional barrier to entry.

473. In describing the increases in EpiPen prices, a 2016 article stated that "[c]ompetition could drop the price of EpiPens, but there are hurdles to entering the marketplace. A device can never fail Therefore, they go through exhaustive, continuous testing that constitutes a significant capital investment for a drugmaker."¹⁵⁷

474. As explained by one commentator:

Epinephrine is extremely cheap – just a few cents per dose. The complications come from producing the easy auto-injecting devices. Mylan "owns" their auto-injector device design, so competitors must find work-arounds in their devices to deliver the epinephrine into the patient's body. This task, coupled with the tangled mess of FDA red tape, has proven to be difficult for would-be EpiPen competitors. It's like expecting somebody to come up with a new way to play baseball without bases, balls, gloves, or bats, but still getting the game approved by the MLB as a baseball game substitute.¹⁵⁸

¹⁵⁵ *See* Susquehanna Financial Group, "Mylan, Inc.: A Good Growth Story that Should Have Legs," Mar. 14, 2012, at 12.

¹⁵⁶ Carolyn Y. Johnson & Catherine Ho, *How Mylan, the maker of EpiPen, became a virtual monopoly*, Washington Post, Aug. 26, 2016.

¹⁵⁷ Adam Rubenfire, *Lack of competition leads to EpiPen pricing woes*, Modern Healthcare, Mar. 28, 2016, *available at*

http://www.modernhealthcare.com/article/20160328/NEWS/160329971.

¹⁵⁸ Jonathan Newman, *The Lack of EpiPen Competitors is the FDA's Fault*, Mises Wire, Aug.

^{24, 2016,} *available at* https://mises.org/blog/lack-epipen-competitors-fdas-fault. *See also* Carrier & Minniti, *supra* note 17, 102 CORNELL L. REV. ONLINE at 53 ("The medicine in an EpiPen costs only pennies per dose.").

475. Until the EpiPen delivery device patents expire, or are successfully challenged, the capital investment in developing a new and dependable delivery device is an expensive hurdle to leap.

476. In addition to patents, federal and state regulations governing epinephrine autoinjector sales have created additional barriers to entry. One report noted that it did not "expect a generic version of EpiPen for the next several years" and that even if Teva were to have succeeded in patent litigation, "both regulatory hurdles and patient preference based on the strength of the brand for EpiPen will provide protection to the franchise."¹⁵⁹ Another report stated that FDA approval would likely be the "largest obstacle facing Teva and other generic companies in their attempts to market a generic version of EpiPen."¹⁶⁰

477. In November 2013, after extensive lobbying efforts by defendants, President Obama signed the School Access to Emergency Epinephrine Act, which "gave funding preferences for asthma treatment grants to states that maintained an emergency supply of [epinephrine]."¹⁶¹ As the "near sole supplier of the devices" due to defendants' conspiracy and actions taken to maintain the EpiPen monopoly, passage of this law meant that "Mylan [and the other defendants] stood to make even more money."¹⁶² In 2010, only eight states had epinephrine legislation in schools. By 2016, 48 states had enacted policies or laws allowing or requiring schools to stock

¹⁵⁹ Barclays Capital Equity Research, "Mylan Inc.: Overcoming EpiPen's Wall of Worry," Mar. 7, 2012, at 3.

¹⁶⁰ UBS Investment Research, "Mylan Inc.: Don't Underestimate EpiPen," July 30, 2012, at 5.

 ¹⁶¹ Aaron E. Carroll, *The EpiPen, a Case Study in Health System Dysfunction*, N.Y. Times, Aug. 23, 2016. Although this article states the law required schools to maintain an emergency supply of "EpiPens", the law actually requires only an emergency supply of epinephrine and does not specify any particular epinephrine product.
 ¹⁶² Id

epinephrine auto-injectors.¹⁶³

478. By utilizing Mylan's EpiPen's market power, defendants, through Mylan, further required schools to enter into exclusive dealing agreements with Mylan in exchange for supply of EpiPens, as explained in more detail below. Thus, defendants have manipulated these regulations to erect further barriers to entry.

479. As a potentially lifesaving medical device, familiarity with the product is critical to its sales. Parents of children with food or insect allergies want peace of mind that not only will they know how to use the auto-injector in the event of an emergency, but that any other caretaker or bystander on hand will know how to use it as well.

480. For instance, in describing Teva's expected entry into the epinephrine auto-injector generics market in 2015, one report stated that it did not expect the product's introduction to result in a "typical oral-generic-like generic switch."¹⁶⁴ This is because "EpiPen has unique circumstances: a life-saving device, often for kids, with extremely strong brand-recognition and patient familiarity.... [M]any patients would be very uncomfortable with a 'generic' or different looking/named device."¹⁶⁵

481. Requirements for patient training have also discouraged substitution in some instances. During a 2009 earnings call, Mylan's CEO explained the importance of training:

482. Given the fact that how important training is of the product and the importance and the enhancements that have been made, we certainly believe that if there were ever to be a generic on the market it would have to match the product that we have. But like I said, we see that as

¹⁶³ EpiPen4Schools Infographics, *available at* https://www.mylan.com/-

[/]media/mylancom/files/news/epipen4schools%20infographics.pdf (last visited Mar. 7, 2017). ¹⁶⁴ Jeffries Equity Research, "Antares Pharma, Inc. (ATRS): Initiating at Buy; Self-Injecting Profitable Growth," Dec. 19, 2012, at 23. ¹⁶⁵ Id.

unlikely.166

483. Firms that have monopoly power are able to exclude rivals and harm the competitive process.¹⁶⁷ Where a firm has monopoly power, buyers are not able to switch away from its products because the loss of supply is too great. This gives the firm with monopoly power the ability to impose exclusionary conditions on its buyers that can adversely affect rivals.

484. Mylan, with the assistance and support of its co-conspirator co-defendants, possesses and exercises the power to exclude rivals and has illegally acquired and maintained its monopoly power. Defendants have done this in several ways, including by (a) paying PBMs to shut out competition, (b) coercing schools to enter into exclusive dealing contracts, and (c) manipulating patent infringement litigation to forestall entry of generic and novel competitors, among other anticompetitive means.

H. Tying the EpiPen 2-Pak

485. In selling the EpiPen only as a 2-Pak, Mylan also engaged in illegal tying.

486. At the time, Mylan held a large percentage of the market.

487. As explained above, the FDA did not require the 2-Pak and Mylan does not sell the 2-Pak in any other country except the United States.

488. No medical basis supported the hard switch to the 2-Pak, as explained above. The medical study Mylan cited was a false pretext. The study Mylan cited only applied to a narrow subset of patients, and Mylan latched on to this study to justify a hard switch for the entire U.S. population.

489. There are no directions on when to take two at a time or even when and how long to wait before providing them back-to-back—and certainly the study that Mylan relies on does not

¹⁶⁶ Mylan Q3 2009 Earnings Conference Call, Oct. 29, 2009.

¹⁶⁷ See Robert Pindyck & Daniel Rubinfeld, Microeconomics 366-68 (7th ed. 2009).

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provide scientific or medical evidence of either when to use a double dose or even factors or information for actual doctors to consider when prescribing a double dose.

490. In truth, and as Mylan's advertising above shows, Mylan was trying to capture not just the original prescription market, but with its 2-Pak, capture the "spare" or "extra" auto-injector market at well.

I. Antitrust Injury and Harm to Plaintiffs and Competition

491. Mylan engaged in willful anti-competitive conduct to artificially maintain and exploit its monopoly in the epinephrine auto-injector market in the United States. As a result, Mylan was, and still is, able to preserve its monopoly, charge supra-competitive prices, and restrict consumer choice among epinephrine injector devices in the United States.

492. Defendants' anti-competitive scheme as alleged above had the purpose and effect of unreasonably restraining competition and injuring consumers by protecting the EpiPen from competing products. In sum, but for Defendants' unlawful conduct alleged herein, Plaintiffs and Class Members would have paid less for both branded and generic versions of EpiPen by: (a) substituting their purchases of EpiPen with less-expensive generic versions of EpiPen; (b) purchasing generic EpiPen at lower prices sooner; (c) purchasing individual, rather than pairs, of EpiPen injectors; (d) buying spare auto-injectors that were generic or cheaper brands; and (e) purchasing branded EpiPen at a reduced price. As a consequence, Plaintiffs and other members of the Class have sustained substantial losses and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

493. EpiPen prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct. The inflated prices the Class paid are traceable to, and the foreseeable result of, defendants' conduct.

494. The institutional structure of pricing and regulation in the pharmaceutical drug

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industry ensures that overcharges at the higher level of distribution are passed on to third party payors and consumers. Wholesalers and retailers passed on the inflated prices of the EpiPen to Plaintiffs and Class Members.

495. Through the unlawful acts and practices described above, Mylan has harmed competition and innovation by forcing out competitors in the relevant product market, and it has harmed consumers by causing them to buy the EpiPen when they otherwise would have been able to purchase a competitor's product and/or to pay a substantially inflated price for the EpiPen.

496. Defendants have maintained Mylan's monopoly through patent misuse, anticompetitive reverse settlements, sham citizens' petitions, tying, and by saturating the market with misinformation suggesting that its pricing is fair, and that the EpiPen 2-Pak is superior and medically necessary for American consumers.

J. Effect on Interstate and Intrastate Commerce

497. The EpiPen was sold by Mylan across state lines at all relevant times.

498. Contracts, bills, and other forms of business communications pertaining to the EpiPen transmitted in a continuous and uninterrupted flow across state lines in the exchange of intrastate and interstate commerce.

499. In furtherance of their efforts to monopolize and restrain competition in the market for epinephrine auto-injectors, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Defendants were within the flow of and have substantially affected interstate commerce.

500. Mylan's anti-competitive conduct occurred in part in trade and commerce within the states set forth herein. Mylan's conduct had substantial interstate and intrastate effects because retailers within each state have been foreclosed from offering cheaper generic versions of the EpiPen and consumers have been overcharged for each EpiPen purchased and, since 2011, have

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been forced to purchase the EpiPen 2-Pak every time they purchase an EpiPen. This directly impacted and disrupted commerce for consumers and the Class Members within each state who have been forced to continue to pay supra-competitive prices. The Class Members would have paid less for their EpiPens but for Mylan's anti-competitive and deceptive and unfair trade and sales practices.

501. Defendants' anticompetitive conduct has substantial and intended intrastate effects on consumers and third-party payors within each state who have paid unlawful prices for EpiPens that would have and should have been lower but for Defendants' anticompetitive conduct. Defendants' conduct has affected interstate and intrastate commerce in each of the states.

K. Equitable Tolling, Discovery Rule, and Fraudulent Concealment

502. Plaintiffs repeat and re-allege the allegations set forth above. At all times relevant to this Complaint, Defendants took active steps to conceal their unlawful activities, including the combination and conspiracy alleged herein. For example and without limitation, Defendants concealed their efforts to exclude generic competition through the assertion and prosecution of invalid patents, ultimately reaching unlawful settlements that to this date have been kept confidential. Defendants further concealed their efforts to obtain and maintain a monopoly and to engage in a fraudulent scheme, including by without limitation falsely claiming that the switch to a 2-Pak sales format was driven by medical necessity.

503. **Discovery Rule:** Plaintiffs and the members of the Classes had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until on or about (at the earliest) August 22, 2016, the date Congress publicly announced its investigation of EpiPen pricing.

504. Plaintiffs and members of the Classes are consumers and third-party payors who had no direct contact or interaction with Defendants and had no means from which they could have

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discovered the combination and conspiracy described in this Complaint before August 1, 2016.

505. No information in the public domain was available to Plaintiffs and members of the Classes concerning Defendants unlawful activities, including the combination or conspiracy alleged herein, prior to August 1, 2016, the date the public first learned of a Congressional investigation into Mylan's unlawful pricing practices. Further, the members of the Classes had no means of obtaining any facts or information concerning the Defendants unlawful activities, including the combination and conspiracy alleged herein, all of which were purposefully concealed by Defendants.

506. For these reasons, the statute of limitations as to Plaintiffs' and the Classes' claims did not begin to run, and has been tolled with respect to the claims that Plaintiffs and the members of the Classes have alleged in this Complaint.

507. **Fraudulent Concealment:** In the alternative, application of the doctrine of fraudulent concealment tolled the statute of limitations on the claims asserted herein by Plaintiffs and the Classes. Plaintiffs and the members of the Classes did not discover, and could not discover through the exercise of reasonable diligence, the existence of the conspiracy alleged herein until on or about (at the earliest) August 22, 2016, the date Congress publicly announced its investigation of EpiPen pricing.

508. Before that time, Plaintiffs and the members of the Classes were unaware of Defendants' unlawful conduct, and did not know before then that they were paying supracompetitive prices for EpiPens through during the Class Period. Defendants provided no information, actual or constructive, to Plaintiffs and members of the Classes that even hinted to Plaintiffs that they were being injured by Defendants' unlawful conduct.

509. The affirmative acts of Defendants alleged herein, including acts in furtherance of

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the unlawful combination and conspiracy, were wrongfully concealed and carried out in a manner that precluded detection.

510. By their very nature, Defendants' anticompetitive conspiracy and unlawful combination and fraudulent scheme were inherently self-concealing. EpiPens are not exempt from antitrust, RICO, and state consumer protection regulation and, thus, Plaintiffs and members of the Classes reasonably considered the epinephrine auto-injector industry to be a competitive industry. Accordingly, a reasonable person under the circumstances would not have been alerted to begin to investigate the legitimacy of the Defendants' EpiPens prices before August 22, 2016.

511. Plaintiffs and the members of the Classes could not have discovered the alleged unlawful activity, including the conspiracy or combination alleged herein, at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by the Defendants and their co-conspirators to avoid detection of, and fraudulently conceal, their unlawful conduct.

512. Because the alleged unlawful conduct, including the combination or conspiracy alleged herein was self-concealing and affirmatively concealed by Defendants, Plaintiffs and members of the Classes had no knowledge of the alleged unlawful conduct, or of any facts or information that would have caused a reasonably diligent person to investigate, before August 22, 2016.

513. For these reasons, the statute of limitations applicable to Plaintiffs' and the Classes' claims was tolled and did not begin to run until August 22, 2016.

514. **Continuing Tort:** Defendants are estopped from relying on any statute of limitations defense because their illegal, deceptive, and fraudulent practices as alleged herein, which are continuing, have created continuing and repeated injuries to Plaintiffs and the Class.

CLASS ACTION ALLEGATIONS

- 515. Plaintiffs repeat and re-allege every allegation above as if set forth in full herein.
- 516. Pursuant to Federal Rule 23(b)(3) and (2), Plaintiffs bring this suit on their own

behalf and on behalf of a proposed national class of all other similarly situated persons

("Nationwide Class") consisting of:

All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for EpiPen(s), for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale, during the period January 1, 2009 through and until the anticompetitive effects of defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" EpiPen(s) if they paid or reimbursed some or all of the purchase price.

Excluded from the Nationwide Class are:

- a. The Defendants and their officers, directors, management, employees, subsidiaries or affiliates;
- b. All governmental entities, except for government funded employee benefit plans;
- c. Fully insured health plans (*i.e.*, Plans that purchased insurance from another entity that covered 100% of the Plan's reimbursement obligations to its members);
- d. The judges in this case and any members of their immediate families;
- e. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and
- f. All persons who are currently incarcerated.

517. Pursuant to Federal Rule 23(b)(3) and (2), Plaintiffs bring this suit on their own behalf and on behalf of a proposed class of all other similarly situated persons ("State Antitrust and Consumer Protection Class") consisting of:

All persons or entities in the Indirect Purchaser States¹⁶⁸ who purchased and/or paid for some or all of the purchase price for EpiPen(s), for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale, during the period January 1, 2009 through and until the anticompetitive effects of defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" EpiPen(s) if they paid or reimbursed some or all of the purchase price.

Excluded from the State Antitrust and Consumer Protection Class are:

- a. The Defendants and their officers, directors, management, employees, subsidiaries or affiliates;
- b. All governmental entities, except for government funded employee benefit plans;
- c. Fully insured health plans (*i.e.*, Plans that purchased insurance from another entity that covered 100% of the Plan's reimbursement obligations to its members);
- d. The judges in this case and any members of their immediate families;
- e. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and
- f. All persons who are currently incarcerated.
- 518. The Classes consists of millions of purchasers residing throughout the United

States. Accordingly, it would be impracticable to join all Class Members before the Court.

519. Under Rule 23(b)(3), there are numerous and substantial questions of law or fact

common to all of the members of the Class and which predominate over any individual issues.

Included within the common question of law or fact are:

- a. The definition of the relevant product market;
- b. Mylan's market power within the relevant product market;
- c. Whether Mylan monopolized and continues to monopolize the relevant product market using predatory behavior;

¹⁶⁸ The Indirect Purchaser States are the states included in Counts III through VI, VIII, and IX.

- d. Whether Defendants attempted to monopolize and continues to attempt to monopolize the relevant product market using predatory behavior;
- e. Whether Defendants entered into illegal exclusive dealing contracts;
- f. Whether Defendants' conduct constitutes an unreasonable restraint of trade;
- g. Whether Mylan's sale of the EpiPen 2-Pak is predatory behavior;
- h. Whether the EpiPen Enterprise engaged in a pattern of racketeering;
- i. Whether Defendants unlawfully maintained monopoly power through all or part of their overall anti-competitive scheme;
- j. Whether Defendants' anti-competitive scheme suppressed generic EpiPen products or other competing products;
- k. Whether Mylan stopped selling the individual EpiPen in the United States out of legitimate safety concerns or for predatory or anti-competitive reasons;
- 1. Whether the EpiPen Scheme, in whole or in part, has substantially affected interstate and intrastate commerce;
- m. The quantum of overcharges paid by the Class in the aggregate.
- n. Whether the Defendants' conduct was unconscionable;
- o. Whether the Defendants' conduct was unlawful or unfair;
- p. Whether the list price of the EpiPen set by Mylan is unconscionable;
- q. Whether the marketing or sale of the EpiPen by Mylan is unfair or deceptive trade practice or pattern;
- r. Whether Mylan has engaged in price gouging by selling the EpiPen;
- s. Whether Mylan has engaged in an unlawful act while selling the EpiPen; and
- t. Whether Mylan was unjustly enriched by selling the EpiPen at an inflated price.

520. The claims of the Plaintiffs are typical of the claims of Class Members, in that they share the above-referenced facts and legal claims or questions with Class Members, there is a

sufficient relationship between the damage to Plaintiffs and Defendant's conduct affecting Class Members, and Plaintiffs have no interests adverse to the interests other Class Members.

521. Plaintiffs will fairly and adequately protect the interests of Class Members and have retained counsel experienced and competent in the prosecution of complex class actions including complex questions that arise in consumer protection litigation.

522. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

- a. The liability claims presented in this case predominate over any questions of law or fact, if any exist at all, affecting any individual member of the Class;
- b. Absent certification of the Classes, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;
- c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendants has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and members of the Class can seek redress for the harm caused to them by Defendant.

523. Because Plaintiffs seek relief for the entire Classes, the prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications with respect to individual member of the Classes, which would establish

incompatible standards of conduct for Defendant.

524. Further, bringing individual claims would overburden the Courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Classes would, as a practical matter, be dispositive of the interest of other members of the Classes who are not parties to the adjudication and may impair or impede their ability to protect their interests. As a consequence, class treatment is a superior method for adjudication of the issues in this case.

CLAIMS FOR RELIEF

COUNT I Violation of Sections 1 & 2 of the Sherman Act Against All Defendants (on behalf of Plaintiffs and the Nationwide Class)

525. Plaintiffs repeat and re-allege every allegation above and below as if set forth in full herein.

526. Plaintiffs bring this case under §§ 1 and 2 of the Sherman Act and amended to allow injunctive relief under §16 of the Clayton Act (<u>15 U.S.C. §26</u>) individually and on behalf of the Nationwide Class.

527. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to block and delay entry of competing epinephrine autoinjectors. The intended and accomplished goal of the scheme was to maintain Mylan's monopoly power using restrictive and exclusionary conduct to delay FDA approval of competing products. Such conduct injured plaintiff and the Class.

528. It was Defendants' conscious objective to further Mylan's monopoly in the relevant market through the overarching anticompetitive scheme. Defendants conspired to monopolize, and did wrongfully and intentionally maintain monopoly power, with respect to the EpiPen epinephrine

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auto-injector, in violation of §2 of the Sherman Act (<u>15 U.S.C. §2</u>). As a result of this unlawful maintenance of monopoly power, Plaintiff and members of the Class paid artificially inflated prices.

529. Had manufacturers of competing epinephrine auto-injectors entered the market and lawfully competed with the EpiPen in a timely fashion, plaintiffs and other members of the Nationwide Class would have substituted lower-priced competing products for the higher-priced brand name EpiPen for some or all of their epinephrine auto-injector requirements, and/or would have paid lower net prices on their remaining epinephrine auto-injector purchases.

530. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in a per se violation of \$1 of the Sherman Act (<u>15</u> <u>U.S.C. \$1</u>). As a result of this unreasonable restraint on competition, Plaintiffs and members of the Nationwide Class paid artificially inflated prices for their epinephrine auto-injector requirements.

531. Nationwide Class members shall continue to suffer irreparable injury in the absence of permanent injunctive relief.

532. Plaintiffs and the Nationwide Class further seek equitable and injunctive relief pursuant to \$16 of the Clayton Act (<u>15 U.S.C. §26</u>), and other applicable law.

533. Plaintiffs and members of the Nationwid1e Class purchased substantial amounts of EpiPen epinephrine auto-injectors indirectly from Mylan.

534. Plaintiffs and the Nationwide Class, pursuant to Fed. R. Civ. P. 57 and <u>28 U.S.C.</u> <u>§ 2201(a)</u>, hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates §§ 1 and 2 of the Sherman Act (<u>15 U.S.C. §§1</u> and <u>2</u>).

535. Plaintiffs and the Nationwide Class further seek equitable and injunctive relief pursuant to \$16 of the Clayton Act (<u>15 U.S.C. \$26</u>), and other applicable law, to correct for the

anticompetitive market effects caused by the unlawful conduct of defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT II Violation of Section 3 of the Clayton Act Against All Defendants (on behalf of Plaintiffs and the Nationwide Class)

536. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

537. During the relevant period, defendants entered into, renewed and/or enforced exclusionary agreements conditioned on the counterparty's agreement not to use or deal in a competitor product to the EpiPen, including arrangements with PBMs and agreements with public schools under the EpiPen4Schools program.

538. The purpose and ongoing effect of these agreements has been to substantially lessen competition and/or tend to create and maintain a monopoly in the relevant market, in violation of Section 3 of the Clayton Act (<u>15 U.S.C. §14</u>).

539. As a direct and proximate result of these violations, defendants have injured plaintiffs and each Nationwide Class member in their business and property in that each has paid a higher price for epinephrine auto-injectors than would have been paid absent Defendants' concerted unlawful activity.

540. Plaintiffs and each Nationwide Class member shall continue to suffer irreparable injury in the absence of permanent injunctive relief.

541. Plaintiffs and the Nationwide Class further seek equitable and injunctive relief pursuant to §16 of the Clayton Act (<u>15 U.S.C. §26</u>), and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT III Violation of State Antitrust Statutes: Conspiracy (on behalf of Plaintiffs and the State Antitrust and Consumer Protection Class)

542. Plaintiffs repeat and re-allege every allegation above and below as if set forth in full herein.

543. At all times relevant to this dispute, Defendants have engaged in a contract, combination, and/or conspiracy to restrain trade in violation of numerous state laws. Beginning in 2012 with the settlement of the Teva litigation, Defendants [Mylan, King, Meridian] engaged in a continuing illegal contract, combination, and conspiracy in restraint of trade, the purpose and effect of which was to prevent the sale of a generic version of the EpiPen in the United States, thereby protecting the EpiPen from any generic competition for a minimum of three years.

544. By entering into the unlawful agreement, Defendants have participated in an unlawful conspiracy in restraint of trade in violation of state antitrust laws.

545. Plaintiffs and the members of the State Antitrust and Consumer Protection Class have been injured in their business and property by reason of the unlawful contract, combination, and conspiracy alleged herein. Plaintiffs and the State Antitrust and Consumer Protection Class have paid more on their purchases of the EpiPen than they would have paid absent the illegal conduct, and/or were prevented from substituting a cheaper generic for their purchases of the more expensive EpiPen.

546. But for the illegal agreement, Teva would have begun marketing generic versions of the EpiPen well before the 2015 delayed entry date it agreed to.

547. If Teva had entered the market and competed with the EpiPen in a full and timely fashion, Plaintiffs and other State Antitrust and Consumer Protection Class members would have substituted lower-priced generic epinephrine auto-injectors for the higher-priced brand name

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EpiPen for some or all of their purchases, and/or would have received lower prices on some or all of their remaining EpiPen purchases.

548. During the relevant period, Plaintiffs and the other State Antitrust and Consumer Protection Class members purchased substantial numbers of EpiPens. As a result of the illegal conduct alleged herein, Plaintiffs and the other State Antitrust and Consumer Protection Class members were compelled to pay, and did pay, artificially inflated prices for their epinephrine autoinjector requirements. Plaintiffs and all of the other State Antitrust and Consumer Protection Class members paid prices that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) State Antitrust and Consumer Protection Class members were deprived of the opportunity to purchase lower-priced generic epinephrine auto-injectors instead of expensive brand name EpiPens; and/or (2) the price of branded EpiPens was artificially inflated by the illegal conduct.

549. Beginning in 2012 with the settlement of the Intelliject litigation, defendants engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to prevent the sale of a generic version of the EpiPen in the United States, thereby protecting the EpiPen from any generic competition for a period of over three months.

550. By entering into the unlawful agreement, defendants participated in an unlawful conspiracy in restraint of trade in violation of state antitrust laws.

551. Plaintiffs and the members of the State Antitrust and Consumer Protection Class have been injured in their business and property by reason of the unlawful contract, combination and conspiracy. Plaintiffs and the State Antitrust and Consumer Protection Class have paid more on their purchases of the EpiPen than they would have paid absent the illegal conduct, and/or were

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prevented from substituting a cheaper generic for their purchases of the more expensive EpiPen.

552. But for the illegal agreement, Intelliject would have begun marketing generic versions of the EpiPen before the delayed entry date it agreed to.

553. If Intelliject had entered the market and competed with the EpiPen in a full and timely fashion, Plaintiffs and other State Antitrust and Consumer Protection Class members would have substituted lower-priced generic epinephrine auto-injectors for the higher-priced brand name EpiPen for some or all of their purchases, and/or would have received lower prices on some or all of their remaining EpiPen purchases.

554. During the relevant period, Plaintiffs and the other State Antitrust and Consumer Protection Class members purchased substantial numbers of EpiPens. As a result of the illegal conduct alleged herein, Plaintiffs and the other State Antitrust and Consumer Protection Class members were compelled to pay, and did pay, artificially inflated prices for their epinephrine autoinjector requirements. Plaintiffs and all of the other State Antitrust and Consumer Protection Class members paid prices that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) State Antitrust and Consumer Protection Class members were deprived of the opportunity to purchase lower-priced generic epinephrine auto-injectors instead of expensive brand name EpiPens; and/or (2) the price of branded EpiPens was artificially inflated by the illegal conduct.

- 555. Mylan's conduct violated the following state antitrust laws:
 - a. <u>Ala. Code § 6</u>–5–60 *et seq.*, with respect to purchases in Alabama by members of the Class;
 - b. <u>Alaska Stat. §§ 45.50.562</u>, <u>45.50.576(a)</u>, <u>(b)</u>, with respect to purchases in Alaska by members of the Class;
 - c. <u>Ariz. Rev. Stat. §§ 44-1401</u>, *et seq.*, with respect to purchases in Arizona by members of the Class;

- d. <u>Ark. Code Ann. § 4-75-212(b)</u> *et seq.*, with respect to purchases in Arkansas by members of the Class;
- e. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;
- f. <u>D.C. Code Ann. §§ 28-4501</u>, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;
- g. Fla. Stat. § 501.201 *et seq.*, and *Mack v. Bristol-Myers Squibb*, <u>673 So. 2d</u> <u>100, 104</u> (Fla. App. 1996), with respects to purchases in Florida by members of the Class;
- h. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;
- i. 740 Ill. Comp. Stat. 10/1 *et seq.*, with respect to purchases in Illinois by members of the Class;
- j. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;
- k. <u>Kansas Stat. Ann. § 50-101</u>, *et seq.*, with respect to purchases in Kansas by members of the Class;
- 1. Mass. Gen. Laws Ch. 93, § 1 *et seq.*, with respect to purchases in Massachusetts by members of the Class;
- m. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;
- n. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;
- o. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;
- p. <u>Miss. Code Ann. § 75-21-1</u> *et seq.*, with respect to purchases in Mississippi by members of the Class;
- q. Missouri Stat. § 416.011 *et seq.*, with respects to purchases in Missouri by members of the Class;
- r. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

- s. <u>Nev. Rev. Stat. Ann. §§ 598A</u>, *et seq.*, with respect to purchases in Nevada by members of the Class;
- t. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class;
- u. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;
- v. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;
- w. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;
- x. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;
- y. <u>Or. Rev. Stat. §§ 646.705</u>, *et seq.*, with respect to purchases in Oregon by members of the Class;
- z. P.R. Laws Ann. Tit. 10, § 257 *et seq.*, with respect to purchases in Puerto Rico by members of the Class;
- aa. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases in Rhode Island by the Class;
- bb. S.D. Codified Laws Ann. §§ 37-1-3, *et seq.*, with respect to purchases in South Dakota by members of the Class;
- cc. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of the EpiPen at Tennessee pharmacies;
- dd. Utah Code § 76-10-3101 *et seq.*, with respect to purchases in Utah by members of the Class;
- ee. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;
- ff. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

gg. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of the EpiPen at Wisconsin pharmacies.

COUNT IV

Violation of State Antitrust Statutes: Monopolization (on behalf of Plaintiffs and the State Antitrust and Consumer Protection Class)

556. Plaintiffs repeat and re-allege every allegation above as if set forth in full herein.

557. Mylan has knowingly engaged in an anti-competitive scheme designed to delay, hinder, and block the entry of competing products that would decrease its sales of the EpiPen. The intended and accomplished goal of Mylan's scheme was to use restrictive and exclusionary conduct to stifle competition against the EpiPen.

558. This scheme, orchestrated and deployed by Defendants is described above, includes anti-competitive reverse patent settlements, sham citizen petition filings with the FDA, and failing to disclose the bought-and-paid for nature of physician opinions relied upon by Mylan to promote its monopoly over the market.

559. In total, Mylan engaged in predatory behavior, which as a whole constituted an overall scheme to exploit its monopoly power to harm consumers and competitors in violation of antitrust laws.

560. Plaintiffs and State Antitrust and Consumer Protection Class Members are within the same market as Mylan because they are consumers who purchase the EpiPen.

561. Plaintiffs and State Antitrust and Consumer Protection Class Members have suffered harm as a result of paying higher prices for the EpiPen than they would have absent Mylan's anticompetitive conduct and continuing anti-competitive conduct.

562. Mylan's conduct violated the following state antitrust laws:

- a. <u>Ala. Code § 6</u>–5–60 *et seq.*, with respect to purchases in Alabama by members of the Class;
- b. <u>Alaska Stat. §§ 45.50.564</u>, <u>45.50.576(a)</u>, <u>(b)</u>, with respect to purchases in Alaska by members of the Class;
- c. <u>Ariz. Rev. Stat. §§ 44-1401</u>, *et seq.*, with respect to purchases in Arizona by members of the Class;
- d. <u>Ark. Code Ann. § 4-75-212(b)</u> *et seq.*, with respect to purchases in Arkansas by members of the Class;
- e. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;
- f. <u>D.C. Code Ann. §§ 28-4501</u>, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;
- g. Fla. Stat. § 501.201 et seq., and Mack v. Bristol-Myers Squibb, 673 So. 2d 100, 104 (Fla. App. 1996), with respects to purchases in Florida by members of the Class;
- h. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;
- i. 740 Ill. Comp. Stat. 10/1 *et seq.*, with respect to purchases in Illinois by members of the Class;
- j. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;
- k. <u>Kansas Stat. Ann. § 50-101</u>, *et seq.*, with respect to purchases in Kansas by members of the Class;
- 1. Mass. Gen. Laws Ch. 93, § 1 *et seq.*, with respect to purchases in Massachusetts by members of the Class;
- m. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;
- n. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;
- o. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;

- p. <u>Miss. Code Ann. § 75-21-1</u> *et seq.*, with respect to purchases in Mississippi by members of the Class;
- q. Missouri Stat. § 416.011 *et seq*., with respect to purchases in Missouri by members of the Class;
- r. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;
- s. <u>Nev. Rev. Stat. Ann. §§ 598A</u>, *et seq.*, with respect to purchases in Nevada by members of the Class;
- t. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class;
- u. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;
- v. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;
- w. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;
- x. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;
- y. <u>Or. Rev. Stat. §§ 646.705</u>, *et seq.*, with respect to purchases in Oregon by members of the Class;
- z. P.R. Laws Ann. Tit. 10, § 257 *et seq.*, with respect to purchases in Puerto Rico by members of the Class;
- aa. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases in Rhode Island by the Class;
- bb. S.D. Codified Laws Ann. §§ 37-1-3, *et seq.*, with respect to purchases in South Dakota by members of the Class;
- cc. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of the EpiPen at Tennessee pharmacies;

- dd. Utah Code § 76-10-3101 *et seq.*, with respect to purchases in Utah by members of the Class;
- ee. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;
- ff. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class; and
- gg. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of the EpiPen at Wisconsin pharmacies.

563. Plaintiffs and State Antitrust and Consumer Protection Class Members have been injured in their business or property by Mylan's antitrust violation. Their injuries consist of (1) being forced to purchase the EpiPen 2-Pak in the United States, despite the fact Mylan sells the EpiPen individually in every other country, and as a result paying double for every EpiPen purchase; (2) being denied the opportunity to purchase a competing product instead of the 2-Pak of the EpiPen; (3) being denied the opportunity to purchase a lower-priced generic epinephrine auto-injector; and (4) paying higher prices for the EpiPen than they would have paid in the absence of Mylan's wrongful conduct.

564. These injuries are precisely the type of harm that the above-noted antitrust laws were designed to prevent, and flow directly from Mylan's unlawful and anti-competitive conduct.

565. Plaintiffs and State Antitrust and Consumer Protection Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Mylan's anti-competitive conduct. Attorneys' fees and costs are also proper.

COUNT V Violation of State Antitrust Statutes: Attempted Monopolization (on behalf of Plaintiffs and the State Antitrust and Consumer Protection Class)

566. Plaintiffs repeat and re-allege every allegation above as if set forth in full herein.

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567. Mylan has knowingly engaged in an anti-competitive scheme designed to delay and block entry of generic competition to the EpiPen. The intended and accomplished goal of the scheme was to use restrictive and exclusionary conduct to delay the ability of generic manufacturers to launch competing, generic versions of the EpiPen.

568. Mylan acted with specific intent to monopolize the market for epinephrine autoinjectors, causing Plaintiffs and State Antitrust and Consumer Protection Class Members to pay artificially inflated prices for these products.

569. Mylan intentionally and wrongfully attempted to monopolize the market for epinephrine auto-injectors in violation of the state antitrust laws listed above.

570. Plaintiffs and State Antitrust and Consumer Protection Class Members have been injured in their business or property by Mylan's antitrust violation. Their injuries consist of (1) being denied the opportunity to purchase lower-priced generic versions of the EpiPen, and (2) paying higher prices for these products than they would have paid in the absence of Mylan's wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Mylan's conduct unlawful.

571. Plaintiffs and State Antitrust and Consumer Protection Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Mylan's anti-competitive conduct. Attorneys' fees and costs are also proper.

572. Mylan's conduct violated the following state antitrust laws:

- a. <u>Ala. Code § 6</u>–5–60 *et seq.*, with respect to purchases in Alabama by members of the Class;
- b. <u>Alaska Stat. §§ 45.50.564</u>, <u>45.50.576(a)</u>, <u>(b)</u>, with respect to purchases in Alaska by members of the Class;
- c. <u>Ariz. Rev. Stat. §§ 44-1401</u>, *et seq.*, with respect to purchases in Arizona by members of the Class;

- d. <u>Ark. Code Ann. § 4-75-212(b)</u> *et seq.*, with respect to purchases in Arkansas by members of the Class;
- e. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;
- f. <u>D.C. Code Ann. §§ 28-4501</u>, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;
- g. Fla. Stat. § 501.201 et seq., and Mack v. Bristol-Myers Squibb, 673 So. 2d 100, 104 (Fla. App. 1996), with respects to purchases in Florida by members of the Class;
- h. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;
- i. 740 Ill. Comp. Stat. 10/1 *et seq.*, with respect to purchases in Illinois by members of the Class;
- j. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;
- k. <u>Kansas Stat. Ann. § 50-101</u>, *et seq.*, with respect to purchases in Kansas by members of the Class;
- 1. Mass. Gen. Laws Ch. 93, § 1 *et seq.*, with respect to purchases in Massachusetts by members of the Class;
- m. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;
- n. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;
- o. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;
- p. <u>Miss. Code Ann. § 75-21-1</u> *et seq.*, with respect to purchases in Mississippi by members of the Class;
- q. Missouri Stat. § 416.011 *et seq.*, with respects to purchases in Missouri by members of the Class;
- r. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;

- s. <u>Nev. Rev. Stat. Ann. §§ 598A</u>, *et seq.*, with respect to purchases in Nevada by members of the Class;
- t. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class;
- u. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;
- v. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;
- w. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;
- x. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;
- y. <u>Or. Rev. Stat. §§ 646.705</u>, *et seq.*, with respect to purchases in Oregon by members of the Class;
- z. P.R. Laws Ann. Tit. 10, § 257 *et seq.*, with respect to purchases in Puerto Rico by members of the Class;
- aa. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases in Rhode Island by the Class;
- bb. S.D. Codified Laws Ann. §§ 37-1-3, *et seq.*, with respect to purchases in South Dakota by members of the Class;
- cc. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of the EpiPen at Tennessee pharmacies;
- dd. Utah Code § 76-10-3101 *et seq.*, with respect to purchases in Utah by members of the Class;
- ee. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;
- ff. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class; and

gg. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of The EpiPen at Wisconsin pharmacies.

COUNT VI

Violation of State Antitrust Statutes: Tying (on behalf of Plaintiffs and the State Antitrust and Consumer Protection Class)

573. Plaintiffs repeat and re-allege every allegation above as if set forth in full herein.

574. Mylan's forced sale of the EpiPen 2-Pak beginning in 2011 constitutes an illegal tying.

575. EpiPens were previously sold individually because there was sufficient demand for each EpiPen. Some patients were prescribed a single EpiPen and some patients were prescribed two EpiPens. In all situations, doctors and patients were able to choose the medically proper combination for each consumer.

576. Consumers and doctors could also mix and match epinephrine auto-injectors so that not all devices purchased were name brand EpiPens, which are the most expensive device. Consumers could purchase a primary device (EpiPen) and a back-up device (cheaper generic) if needed at all.

577. There was sufficient independent demand for some patients to either not purchase a second EpiPen at all or to purchase an EpiPen and a cheaper, alternative back-up. This was compounded by the fact that each EpiPen expires annually and the vast majority of EpiPens expire before they can be used.

578. Mylan has always faced competition over the EpiPen. Mylan's patents on the EpiPen are only on a device, not the drug, so competitors and potential competitors have always existed and been either entering the market or attempting to do so.

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579. By forcing the purchase of the EpiPen 2-Pak, Mylan artificially restrained and stifled competition from competitors and stopped consumers from purchasing anything but an EpiPen 2-Pak. Consumers no longer had the choice or ability to purchase a back-up or spare device from another manufacturer, or to decline to purchase a second EpiPen based on whether they needed it, chose to purchase it, or were prescribed it by a doctor.

580. Because Mylan forced consumers to purchase the EpiPen 2-Pak or nothing at all, Mylan illegally and artificially destroyed the market for back-up epinephrine auto-injector devices.

581. This maneuver also allowed Mylan to more quickly consolidate and exploit its monopoly power in the relevant market, as well as deter rival generic device makers from seeking to compete. Knowing that Mylan had the market artificially cornered by forcing consumers to purchase a 2-Pak, other potential generic rivals did not enter the market.

582. Mylan coerced consumers by forcing them to buy the EpiPen 2-Pak even if they only wanted to buy an individual EpiPen, as consumers in every other country in the world (except the United States) are able to do.

583. The fact that Mylan sells individual EpiPens in every other country in the world except the United States proves that Mylan does not need to sell the EpiPen 2-Pak and that its only motive to do so is to double its sales revenue in America.

584. Mylan had market power in the epinephrine auto-injector device market, and its market power for the first device (the primary auto-injector) was strong enough that it restrained free competition for the second device that it forced consumers to purchase (the back-up auto-injector).

585. Mylan's tying arrangement had a substantial effect on commerce in the market for the second device.

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586. Plaintiffs and Class Members are within the same market as Mylan because they are consumers who purchase the EpiPen.

587. Plaintiffs and Class Members have suffered harm as a result of paying higher prices for the EpiPen than they would have absent Mylan's anti-competitive conduct and continuing anti-competitive conduct.

588. Mylan's conduct violated the following state antitrust laws:

- a. <u>Ala. Code § 6</u>–5–60 *et seq.*, with respect to purchases in Alabama by members of the Class;
- b. <u>Alaska Stat. §§ 45.50.562</u>, <u>45.50.576(a)</u>, <u>(b)</u>, with respect to purchases in Alaska by members of the Class;
- c. <u>Ariz. Rev. Stat. §§ 44-1401</u>, *et seq.*, with respect to purchases in Arizona by members of the Class;
- d. <u>Ark. Code Ann. § 4-75-212(b)</u> *et seq.*, with respect to purchases in Arkansas by members of the Class;
- e. Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Class;
- f. <u>D.C. Code Ann. §§ 28-4501</u>, *et seq.*, with respect to purchases in the District of Columbia by members of the Class;
- g. Fla. Stat. § 501.201 *et seq.*, and *Mack v. Bristol-Myers Squibb*, <u>673 So. 2d</u> <u>100, 104</u> (Fla. App. 1996), with respects to purchases in Florida by members of the Class;
- h. Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Class;
- i. 740 Ill. Comp. Stat. 10/1 *et seq.*, with respect to purchases in Illinois by members of the Class;
- j. Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Class;
- k. <u>Kansas Stat. Ann. § 50-101</u>, *et seq.*, with respect to purchases in Kansas by members of the Class;

- 1. Mass. Gen. Laws Ch. 93, § 1 *et seq.*, with respect to purchases in Massachusetts by members of the Class;
- m. Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Class;
- n. Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Class;
- o. Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Class;
- p. <u>Miss. Code Ann. § 75-21-1</u> *et seq.*, with respect to purchases in Mississippi by members of the Class;
- q. Missouri Stat. § 416.011 *et seq.*, with respects to purchases in Missouri by members of the Class;
- r. Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Class;
- s. <u>Nev. Rev. Stat. Ann. §§ 598A</u>, *et seq.*, with respect to purchases in Nevada by members of the Class;
- t. N.H. Rev. Stat. Ann. §§ 356:1, *et seq.*, with respect to purchases in New Hampshire by members of the Class;
- u. N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Class;
- v. N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Class;
- w. N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Class;
- x. N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Class;
- y. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class;
- z. P.R. Laws Ann. Tit. 10, § 257 *et seq.*, with respect to purchases in Puerto Rico by members of the Class;

- aa. R.I. Gen. Laws § 6-36-1 *et seq.*, with respect to purchases in Rhode Island by the Class;
- bb. S.D. Codified Laws Ann. §§ 37-1-3, *et seq.*, with respect to purchases in South Dakota by members of the Class;
- cc. Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Class, with thousands of end-payors in Tennessee paying substantially higher prices for branded and generic versions of the EpiPen at Tennessee pharmacies;
- dd. Utah Code § 76-10-3101 *et seq.*, with respect to purchases in Utah by members of the Class;
- ee. Vt. Stat. Ann. tit. 9, § 2453, *et seq.*, with respect to purchases in Vermont by members of the Class;
- ff. W.Va. Code §§ 47-18-1, *et seq.*, with respect to purchases in West Virginia by members of the Class; and
- gg. Wis. Stat. §§ 133.01, *et seq.*, with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of the EpiPen at Wisconsin pharmacies.

589. Plaintiffs and Class Members have been injured in their property by Mylan's antitrust violation. Their injuries consist of (1) being forced to purchase the EpiPen 2-Pak in the United States, despite the fact Mylan sells the EpiPen individually in every other country, and paying double as a result for every EpiPen purchase; (2) being denied the opportunity to purchase a competing product instead of the 2-Pak of the EpiPen; (3) being denied the opportunity to purchase a lower-priced generic EpiPen, and (4) paying higher prices for the EpiPen than they would have paid in the absence of Mylan's wrongful conduct.

590. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Mylan's conduct unlawful.

591. Plaintiffs and Class Members seek damages and multiple damages as permitted by

law for the injuries they suffered as a result of Mylan's anti-competitive conduct.

COUNT VII Violation of The Racketeer Influenced And Corrupt Organizations Act, <u>18 U.S.C. § 1962</u> (on behalf of Plaintiffs and the Nationwide Class)

592. Plaintiffs incorporate by reference each paragraph above and below as though fully set forth herein.

593. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

594. Plaintiffs bring this Count on behalf of the Nationwide Class against the following

Defendants:

- (1) Mylan N.V.;
- (2) Mylan Specialty, LP;
- (3) Heather Bresch (together, as (1)-(3), the "Mylan Defendants");
- (4) Pfizer, Inc.;
- (5) King Pharmaceuticals, Inc.; and
- (6) Meridian Medical Technologies (together, as (4)-(6), the "Pfizer Defendants")

(inclusively, as (1)-(6), for purpose of this Count, the "RICO Defendants").

595. At all relevant times, the RICO Defendants have been "persons" under <u>18 U.S.C. §</u> <u>1961(3)</u>.

596. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." <u>18 U.S.C. § 1962(c)</u>.

597. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section

1962(c), among other provisions. See <u>18 U.S.C. § 1962(d)</u>.

598. For many years, the RICO Defendants aggressively sought to increase the Mylan's control of auto-injector market in the United States. Finding it impossible to achieve their ambitious goals lawfully, however, the RICO Defendants resorted to cheating through their fraudulent scheme and RICO conspiracy.

599. The illegal scheme was developed by the Mylan Defendants and executed by the RICO Defendants, together with a number of other entities including at least four pharmacy benefit managers ("PBMs"): CVS Health Corporation, Express Scripts Inc., Optum Rx Inc. and Prime Therapeutics LLC (collectively referred to in this count as "the PBM Conspirators").

600. The RICO Defendants, along with other entities and individuals including the PBM Conspirators, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (referred to collectively as the **"EpiPen Pricing Enterprise"**), whose purpose was to fraudulently mislead and deceive American consumers to purchase the EpiPen at an inflated price, to purchase the EpiPen as a 2-Pak only, and to cause consumers to pay an artificially inflated price for EpiPens.

601. From at least January 1, 2009, to the present, the affiliation between Mylan N.V., Mylan Specialty, L.P.; Heather Bresch; King; Meridian; Pfizer and the PBM Conspirators has constituted an association-in-fact enterprise, whose activities have affected interstate commerce.

602. As a direct and proximate result of their fraudulent scheme and common course of conduct, the RICO Defendants and the PBM Conspirators illegally extracted revenues of millions or billions of dollars from Plaintiffs and the Class. As explained in detail below, the RICO Defendants' years-long misconduct violated RICO Sections §§ 1962(c) and (d).

A. The EpiPen Pricing Enterprise

603. Each of the RICO Defendants and PBM Conspirators operated or managed the

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affairs of the EpiPen Pricing Enterprise, through a pattern of racketeering activity in violation of <u>18 U.S.C. § 1962(c)</u>.

604. At all relevant times, the RICO Defendants and the PBM Conspirators operated as an association-in-fact enterprise, which was formed for the purpose of engaging in a scheme to defraud the public regarding the pricing of the EpiPen, the medical necessity, quality, and characteristics of EpiPens and the EpiPen 2-Pak, and Mylan's profits and efforts to control the price of the EpiPen.

605. The association-in-fact EpiPen Pricing Enterprise consists of the following entities and individuals:

1. The Mylan Defendants

606. Each of the Mylan Defendants is a "person" under <u>18 U.S.C. § 1961(3)</u>.

607. Mylan N.V. and Mylan Specialty L.P are each distinct legal entities.

608. Heather Bresch is the CEO of Mylan N.V.

609. The Mylan Defendants operated and managed the EpiPen Pricing Enterprise to artificially increase EpiPen sales and revenue and to enrich Mylan's top executives who paid themselves secret bonuses, among other self-serving compensation schemes.

610. As a generics company, Mylan typically makes low margins on drug sales. The EpiPen, a specialty branded drug, was atypical for Mylan to sell and represented a unique, highly-profitable revenue stream for Mylan. Recognizing this opportunity, Ms. Bresch and other executives decided to exploit the EpiPen to generate billions of dollars in revenue for Mylan.

611. Mylan N.V., through Ms. Bresch, was directly involved in nearly all of the sales, pricing, and marketing decisions regarding EpiPens, as catalogued above.

612. Mylan Specialty, LP, is the primary entity that markets, distributes, and sells the EpiPen, as catalogued above.

613. Heather Bresch is the CEO of Mylan N.V. As set forth above, when she testified on behalf of Mylan N.V. and Mylan Specialty, LP, before Congress and signed a Truth in Disclosure Form on September 19, 2016, she made clear that she was appearing on behalf of two Mylan entities:

2. Please list any entity you are testifying on behalf of and briefly describe your relationship with these entities.

I am testifying for Mylan, N.V., for which I am the Chief Executive Officer, and testifying for Mylan, N.V.'s subsidiary, Mylan Specialty, L.P., which markets and sells the EpiPen® Auto-Injector.

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614. Heather Bresch is not, however, the CEO of Mylan Specialty. Thus, it was unusual for her, as the CEO of Mylan N.V. (the Mylan holding company based in the Netherlands), to interject herself into the daily affairs of the EpiPen business.

615. Ms. Bresch played a central role in the EpiPen Pricing Enterprise. As <u>The</u> <u>Washington Post</u> detailed in depth, Ms. Bresch rose through the ranks at Mylan based solely on the EpiPen (she was hired as a low-level employee, then latched on to the EpiPen to receive multiple promotions and eventually became CEO in 2012); as its sales skyrocketed, so did her position in the company.¹⁶⁹

- 616. Ms. Bresch has publicly referred to the EpiPen as her "baby."
- 617. Bresch has personally (a) made several materially false statements regarding the

¹⁶⁹ Amber Phillips, *How a senator's daughter became the CEO of the company at the center of the EpiPen controversy*, <u>The Washington Post</u>, Aug 24, 2016, available at: <u>https://www.washingtonpost.com/news/the-fix/wp/2016/08/24/how-a-senators-daughter-became-ceo-of-the-company-at-the-center-of-the-epipen-controversy/?utm_term=.c149e4e5848e</u> (attached as <u>Exhibit B</u>).

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pricing, cost, and profit off the EpiPen (all detailed above by date, location, and reason for falsity); (b) appeared before the House Oversight Committee on September 21, 2016 to testify under oath regarding the EpiPen; (c) appeared at the Forbes Summit on December 1, 2016, to discuss the EpiPen pricing; and, (d) appeared on CBS on January 27, 2017, and publicly tried to justify the high price with false statements about recouping investments and simultaneously claiming it was to expand access to EpiPens.

618. Her compensation has ballooned almost in lockstep with the swelling price of the EpiPen, which means she was directly motivated to drive up EpiPen sales.

619. She also was a primary speaker in almost every Mylan news release issued from2011 to present regarding the EpiPen, all catalogued above.

620. Ms. Bresch has helped orchestrate the EpiPen Pricing Enterprise, and she was the point person who tried to conceal Mylan's fraud, and when caught, tried to cover it up and then falsely justify it. At every turn, she has made herself the face of the EpiPen controversy, even though Mylan is primarily a generic drug company.

621. Ms. Bresch was also the point person throughout 2016 who personally misled the public and Congress regarding the inflated pricing and cost of the EpiPen. She voluntarily interjected herself into the EpiPen controversy because she had the most at stake.

622. As the <u>New York Times</u> revealed in 2016, Ms. Bresch was personally told that the EpiPen price increases were unfair by multiple Mylan executives. But she overruled them and insisted that the EpiPen price increases go forward:

To understand Mylan's culture, consider a series of conversations that began inside the company in 2014. A group of midlevel executives was concerned about the soaring price of EpiPens, which had more than doubled in the previous four years; there were rumors that even more aggressive hikes were planned. (Former executives who related this and other anecdotes requested anonymity because they had nondisclosure agreements or feared retaliation. Aspects of their accounts were disputed by Mylan.)

In meetings, the executives began warning Mylan's top leaders that the price increases seemed like unethical profiteering at the expense of sick children and adults, according to people who participated in the conversations. Over the next 16 months, those internal warnings were repeatedly aired. At one gathering, executives shared their concerns with Mylan's chairman, Robert Coury.

Mr. Coury replied that he was untroubled. He raised both his middle fingers and explained, using colorful language, that anyone criticizing Mylan, including its employees, ought to go copulate with themselves. Critics in Congress and on Wall Street, he said, should do the same. And regulators at the Food and Drug Administration? They, too, deserved a round of anatomically challenging self-fulfillment.

When the executives conveyed their anxieties to other leaders, including the chief executive, Heather Bresch, these, too, were brushed off, they told me.¹⁷⁰

623. Further discovery will provide information regarding these numerous Mylan

executive whistleblowers.

624. Likewise, in 2012, Ms. Bresch personally forced Mylan to release a commercial for

the EpiPen that was deemed by regulators to be "false and misleading"—even though internally

Mylan executives tried to stop her decision from going forward:

Before the birthday advertisement aired, the ad went through multiple internal review processes. Mylan executives told Ms. Bresch that the commercial was improper. One employee went so far as to send an internal email saying the advertisement would increase the frequency of allergic reactions, according to a person who saw the correspondence.

Ms. Bresch disagreed. She said it was better to act boldly, according to a former executive who participated in that conversation.

So the advertisement went on television. And a record number of consumer complaints arrived at the Food and Drug Administration. The agency ordered the commercial pulled after just a few days because it was "false and misleading," "overstates the efficacy of the drug product" and "may result in serious

¹⁷⁰ Charles Duhigg, Outcry Over EpiPen Prices Hasn't Made Them Lower, New York Times, June 4, 2017, available at: <u>https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html</u> (attached as <u>Exhibit</u> C).

consequences, including death."171

625. For all these reasons, she is personally liable for the EpiPen scheme and all causes of action that flow from it. Other plaintiffs have recognized this fact by suing her individually in lawsuits filed in 2016 following the securities fraud related to the EpiPen Pricing Enterprise.¹⁷²

2. The Pfizer Defendants

626. The Pfizer Defendants are each a corporate "person" under <u>18 U.S.C. § 1961(3)</u>.

627. Each operated or managed the affairs of an enterprise, the EpiPen Pricing Enterprise, through a pattern of racketeering activity in violation of <u>18 U.S.C. § 1962(c)</u>.

628. Mylan and the Pfizer Defendants are in regular and constant communication regarding the EpiPen, and the two Pfizer subsidiaries have done more than simply manufacture the EpiPen product for Mylan.

629. As discussed above, Mylan and the Pfizer Defendants worked together to stop generic competition to the EpiPen by filing patent infringement lawsuits throughout 2009-12 against at least three generic EpiPen rivals: Sandoz, Teva, and Intelliject.

630. Also, on April 26, 2012, Pfizer (via Meridian) and Mylan jointly settled with Teva to sideline the generic competition from Teva, as discussed above.

631. This settlement agreement secretly restrained competition and ensured that the EpiPen Pricing Enterprise could successfully continue without facing competition from Teva.

632. The Pfizer Defendants and Mylan have worked together, even though Pfizer has tried to keep its connection to Mylan quiet. Commentators have identified Pfizer's strong role in

¹⁷¹ *Id*.

¹⁷² See, e.g., Stef Van Duppen v. Mylan et al, Case No. 1:16-cv-07926-JPO, Dkt. #1 (Oct. 11, 2016), http://securities.stanford.edu/filings-documents/1059/MN00_01/20161011_f01c_16CV07926.pdf; Jana Kasperkevic, Mylan CEO Sold \$5m Worth of Stock While EpiPen Price Drew Scrutiny, THE GUARDIAN (Aug. 27, 2016), <u>https://www.theguardian.com/business/2016/aug/27/mylan-ceo-sold-stock-epipen-price-hike-heather-bresch</u>, (last visited Feb. 1, 2017).

the EpiPen Pricing Enterprise:

What isn't as well known is [Mylan's] connection to Pfizer (PFE).

Although Mylan manufactures and sells the actual EpiPen device, Pfizer manufactures the drug the device administers. And although the financial deal between the two companies isn't completely clear, Pfizer has shown increased revenues related to EpiPens for the last few years.

Pfizer picked up the EpiPen when it bought King Pharmaceuticals in 2010. Mylan, at the time, had marketing rights to the dispenser, rights it still holds.

In 2015, Pfizer reported \$339 million in revenues related to EpiPen.¹⁷³

3. The PBM Conspirators

633. The association-in-fact EpiPen Pricing Enterprise also includes at least the following PBMs: CVS Health Corporation, Express Scripts Inc., Optum Rx Inc. and Prime Therapeutics LLC.

634. At all relevant times, each of the PBM Conspirators have been "persons" within the meaning of <u>18 U.S.C. § 1961(3)</u> because they are capable of holding, and do hold, "a legal or beneficial interest in property."

635. For years, the PBM Conspirators provided administrative services on behalf of health plans that offer prescription drug benefits and negotiating with drug manufacturers on their behalf.

636. In the past decade, however, the PBM Conspirators and other PBMs began to exert influence in their role as insurance-industry middle-men to dictate the success or failure of certain drugs in the marketplace by offering to include or threatening to exclude certain medications from some or all of their formularies and, in the process, extracting hundreds of millions of dollars in

¹⁷³ Mark Terry, *What You Don't Know: Pfizer (PFE)'s Connection to Mylan (MYL) and EpiPen*, BIOSPACE (Aug. 26, 2016), <u>http://www.biospace.com/News/what-you-dont-know-pfizers-connection-to-mylan-and/430408</u>, (last visited Jan. 31, 2017).

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the form of 'discounts' or 'rebate' payments from drug manufacturers in exchange.

637. Negotiations between PBMs and drug manufacturers regarding those discounts, however, take place in complex, closed-door meetings, during which PBMs sell access to their formularies in exchange for large rebates or discounts, a substantial portion of which they pocket as pure profit.

638. To facilitate the payment of 'rebates' to PBMs, and ensure their position on certain formularies without impacting their bottom line, the RICO Defendants participated in a scheme with the PBM Conspirators to increase the list price of the EpiPen.

639. This scheme to increase the profits of PBMs through artificially increasing the list price of EpiPens hurts consumers and third-party payors, who are left paying fraudulently obtained, exorbitant, and ever-increasing prices for the EpiPen.

640. The PBM Conspirators leveraged their dominant position in the prescription drug insurance market to demand that drug manufacturers, like the RICO Defendants, pay substantial kickbacks to have their products included or be given priority on the Defendants' formularies. The PBM Conspirators facilitated the scheme by agreeing to provide ever-larger 'discounts' or 'rebates' to the PBM Conspirators to gain or maintain access to their formularies and funding those discounts by artificially increasing the list price of the EpiPen.

641. In furtherance of the goals of the EpiPens Pricing Enterprise, and as described below, the RICO Defendants and the PBM Conspirators affirmatively misrepresented or concealed the existence of the inflated and fraudulent nature of these list price increases as well as the existence, amount, and purpose of the discounts given to the PBM Conspirators to Plaintiffs, the Classes, consumers, health care payers, and the general public. Specifically, the PBM Conspirators claimed that the rebates paid to the PBM Conspirators were for the purpose of lowering drug costs when, in fact, they were quid pro quo payments for formulary access that had the opposite effect for Plaintiff and the members of the Classes.

B. The EpiPen Pricing Enterprise Sought to Illegally Dominate the Market and to Increase Profits and Revenues By Forcing Consumers to Purchase the EpiPen at an Inflated Price and, Since 2011, in a 2-Pak

642. The EpiPen Pricing Enterprise began as early as 2009. On Mylan's Q1 2009 earnings call on April 30, 2009, Ms. Bresch made several statements about Mylan's intent to add more patents on top of the existing EpiPen patents to artificially act as a "barrier" and "hurdle" to free competition from generics so that Mylan could continue to charge inflated prices to consumers. In order to achieve that end, Mylan entered into affiliations with the Pfizer Defendants and medical experts.

643. At all relevant times, the EpiPen Pricing Enterprise: (a) had an existence separate and distinct from each RICO Defendant and the PBM Conspirators; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants and the PBM Conspirators engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Mylan Defendants, the Pfizer Defendants, and other entities and individuals associated for the common purpose of increasing EpiPen sales, including the PBM Conspirators.

644. Each member of the EpiPen Pricing Enterprise shared in the financial windfall generated by the enterprise, and each RICO Defendant shared in the common purpose of forcing consumers to purchase the EpiPen at an inflated price and only in a 2-Pak. Moreover, the PBM Conspirators received direct rebate payments from the RICO Defendants, a large portion of which they pocketed as pure profit, as well as other fees. In exchange, one or more of the RICO Defendants' products received a favorable position on one, or a number, of the PBM Conspirators' formularies, translating into higher sales and profits for RICO Defendants. And because RICO Defendants financed the payment of rebates by inflating the list prices of the EpiPen, they

maintained and, in some cases, increased their profit margins.

645. The EpiPen Pricing Enterprise engaged in, and its activities affected interstate and foreign commerce, because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement and sale or lease of the EpiPen throughout the country, and the receipt of monies from the sale of the same.

646. Within the EpiPen Pricing Enterprise, there was a common communication network by which co-conspirators shared information on a regular basis.

647. Each participant in the EpiPen Pricing Enterprise had a systematic linkage to each other through corporate ties, contractual relationships, financial ties, and continuing coordination of activities.

648. Through the EpiPen Pricing Enterprise, the RICO Defendants and its members functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues and market share, and minimizing losses.

649. While the RICO Defendants participated in, and are members of, the enterprise, they have a separate existence from the enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

650. The RICO Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiffs cannot fully know at present, because such information lies in the Defendants' exclusive control.

651. The PBM Conspirators also exerted substantial control over the EpiPen Pricing Enterprise, and participated in the affairs of the enterprise by: (a) negotiating and/or offering discounts for the RICO Defendants' EpiPen products; (b) misrepresenting and/or concealing the

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existence, amount, or purpose of the discounts negotiated for EpiPen products; (c) misrepresenting and/or concealing the effect that the negotiated discounts had on the price of the EpiPen for the end payer; (d) negotiating and/or setting the list price for EpiPen products; (e) misrepresenting and/or concealing the true cost of the EpiPen; (f) publishing, reproducing, and/or distributing documents containing the list price of the EpiPen and raising those prices as necessary; (g) negotiating and/or offering preferred formulary placement for the EpiPen; (h) misrepresenting and/or concealing the true nature of the relationship and agreements between the members of the enterprise and its effect on the pricing of the EpiPen; (i) otherwise misrepresenting and/or concealing the inflated and fraudulent nature of the pricing of the EpiPen; (j) collecting discounts, revenues, and/or profits from the sale of the EpiPen; (k) ensuring that the other Defendants and members of the EpiPen Pricing Enterprise complied with and concealed the fraudulent scheme.

C. The Pattern of Racketeering: Mail Fraud, Wire Fraud, and Corruption of an Official Proceeding

652. To carry out, or attempt to carry out the scheme to defraud, the RICO Defendants and PBM Conspirators knowingly participated, directly or indirectly, in the conduct of the affairs of the EpiPen Pricing Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

653. The Mylan Defendants also engaged in corruption of an official proceeding, in violation of <u>18 U.S.C. § 1512(c)(2)</u>.

654. The RICO Defendants' predicate acts of racketeering (<u>18 U.S.C. § 1961(1)</u>) include, but are not limited to:

> a. <u>Mail Fraud</u>: The RICO Defendants violated <u>18 U.S.C. § 1341</u> by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, and omissions. In furtherance of this scheme, the Defendants used the mails.

- b. <u>Wire Fraud</u>: The RICO Defendants violated <u>18 U.S.C. § 1343</u> by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, and omissions. In furtherance of this scheme, the Defendants used the interstate wires.
- c. <u>Corruption of an Official Proceeding</u>: The RICO Defendants violation <u>18</u> <u>U.S.C. § 1512(c)(2)</u> by having Ms. Bresch falsely testify before Congress on September 21, 2016, on behalf of Mylan N.V. and Mylan Specialty and thereby corruptly influenced or disrupted an official proceeding.

1. The RICO Defendants' Engaged in Predicate Acts to Defraud Consumers and Third-Party Payors and Exclude Competitors from the Market

655. The RICO Defendants' use of the mails and wires include several examples, many

of which are set forth in more detail above in the factual allegations. These examples include but

are not limited to:

- a. On Mylan's Q1 2009 earnings call, on April 30, 2009, Ms. Bresch made several statements about Mylan's intent to add more patents on top of the existing EpiPen patents to artificially act as a "barrier" and "hurdle" to free competition from generics so that Mylan could continue to charge inflated prices to consumers.
- b. On August 24, 2011, Mylan released via interstate wire from Basking Ridge, NJ, a news release entitled, "Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively" with the sub headline: "Decision aligns with recent clinical guidelines for patients at risk for or who have experienced anaphylaxis to have immediate access to two doses of epinephrine (1)."¹⁷⁴
- c. On April 26, 2012, Mylan announced its pay for delay secret settlement (in conjunction with Pfizer) to sideline Teva from competing on the EpiPen from 2012-15. The Mylan news release (on Mylan's website with Mylan's logo on it) stated: "Mylan Inc. (Nasdaq: MYL) and Pfizer Inc. (NYSE: PFE) today announced that Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Teva that will resolve pending patent litigation related to its abbreviated new drug application (ANDA) for a generic epinephrine auto-injector."¹⁷⁵ As set forth above, this "pay for delay" settlement with Teva was vital for the EpiPen Pricing Enterprise to succeed, and once Teva was sidelined, Mylan increased the price of the EpiPen to its highest levels during the 2012 to 2015 period.

¹⁷⁴ http://newsroom.mylan.com/press-releases?item=123144.

 $^{^{175}}$ *Id.*

- d. On August 14, 2012, Mylan launched the EpiPen for Schools Program via an interstate wire from Basking Ridge, NJ, with misleading and confusing guidance about the 2-Pak but without any guidelines or directions on how to use the second EpiPen. Mylan also did not disclose that it was using the EpiPen for Schools Program to blitz the market and hook consumers on its product so it could then raise the price. http://newsroom.mylan.com/press-releases?item=122583
- e. On August 10, 2015, Mylan released via interstate wire from Pittsburgh, PA, a news release entitled, "Mylan Celebrates EpiPen4Schools Third Anniversary, Program Extension Encourages Anaphylaxis Awareness and Preparedness This Back-to-School Season."¹⁷⁶
- f. In the news release, Mylan again stated that consumers needed to have "access to two epinephrine auto-injectors, such as EpiPen Auto-Injectors, at all times." Mylan further disclosed in this wire: "Connie Trent is a spokesperson of Mylan. Dr. Ruchi Gupta is a paid spokesperson of Mylan." Mylan knew such disclosures were necessary, but intentionally omitted saying the same about its paid statements from Drs. Lieberman or Meltzer, set forth above.
- g. On September 21, 2016, in Washington D.C., before the United States Congress, Ms. Bresch provided knowingly false testimony on several material issues:
 - i. Ms. Bresch misrepresented Mylan's profit off the EpiPen as only \$50 per device when, in fact, the profit by Mylan is at least 60% higher.
- ii. Ms. Bresch misrepresented that Mylan had invested over \$1B in the EpiPen when, in fact, Mylan acquired the EpiPen in 2007 without conducting any research and development expenses.
- iii. Ms. Bresch misrepresented that Mylan provided free EpiPens to over 66,000 schools "with no strings attached" when, in fact, Mylan attached anticompetitive strings that restricted schools from purchasing competitors' devices.
- iv. By knowingly providing false testimony to Congress, Ms. Bresch not only committed wire fraud (because she acted to conceal the ongoing scheme to defraud and it was foreseeable that her false testimony would be broadcast over interstate wires), she also corruptly influenced an official proceeding.
- v. Some of Ms. Bresch's statements concealed the relationship between PBMs

¹⁷⁶ <u>http://www.prnewswire.com/news-releases/mylan-celebrates-epipen4schools-third-anniversary-program-extension-encourages-anaphylaxis-awareness-and-preparedness-this-back-to-school-season-300125960.html</u>

and the RICO Defendants who acted in concert to inflate the price of EpiPens.

- h. On January 27, 2017, Mylan CEO Heather Bresch appeared on CBS news and made additional false statements about the EpiPen pricing and offered more false pretexts for the increased price and research involved.
- i. Each shipment and sale of the EpiPen 2-Pak (since August 24, 2011) constitutes mail fraud because Mylan does not provide any medical instructions within the packing for use of the second device, and Mylan requires American consumers to purchase the 2-Pak, which is not medically necessary.
- j. Defendants' use of mail and wires in furtherance of the EpiPen Pricing Enterprise involved thousands of individual communications throughout the Class Period, including the numerous Mylan news release catalogued above; the testimony of Heather Bresch before Congress on September 21, 2016; the televised interview of Heather Bresch at the Forbes Health Summit on December 1, 2016; and the televised interview of Heather Bresch on CBS on or about January 27, 2017.
- k. Mylan also maintains the EpiPen4Schools website, which is a wire communication, and it repeatedly ships EpiPen 2-Paks to schools in coordination with BioRidge Pharma. This program relies on the mails and wires.

656. As part of an orchestrated and long-term scheme to defraud U.S. consumers and third-party payors, Mylan unleased a scorched-earth assault on its competitors. As detailed above, starting in approximately 2009, Mylan threatened, slandered, sued, and paid off its competitors; flooded the market with medically-unnecessary 2-Paks; fleeced Medicaid and the American public for hundreds of millions of dollars by lying to the government that its product was generic (while simultaneously enforcing its patent against competitors and reaping patent-level profits from the public); paid kickbacks to PBMs to secure preferred and exclusive placements on formularies, the lists of products covered by health insurance plans; and lobbied Congress to allow it sell the EpiPen to schools under contracts that expressly forbade the schools from purchasing products from its competitors.

657. The results of Mylan's efforts were staggering, at least for the RICO Defendants

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and PBM Conspirators—who concertedly raised the price of the EpiPen from \$100 in 2007 to \$608 for an EpiPen 2-Pak by 2016, all for a device that delivers a drug which costs less than \$1 a dose.

658. In doing so, the RICO Defendants and PBM Conspirators have deceived and fleeced the consumers and third-party- payors out of hundreds of millions – if not billions -- of dollars. In short, the RICO Defendants and PBM Conspirators engaged in a pharmaceutical-grade scheme to defraud U.S. consumers to pay much higher prices for the EpiPen than is reasonable or would be charged in a fair marketplace.

659. To effectuate the goals of the EpiPen Pricing Enterprise, including but not limited to maximizing profit and controlling a dominant market position, the RICO Defendants and the PBM Conspirators launched a campaign of false and misleading statements and actions to distract consumers and regulators from the reality that the RICO Defendants were raising the price of the EpiPen from \$100 to \$600:

- a. <u>Schools</u>: As alleged in detail above, despite the fact that the Mylan Defendants represented that schools could obtain EpiPens for free with "no strings attached," the reality was completely different. In fact, they carefully orchestrated nationwide lobbying efforts on state and federal levels, to create an important sub-market for epinephrine auto-injectors in the nation's public schools, and then excluded competitors from this market through exclusive dealing contracts with those schools.
- <u>Competitor Disparagement</u>: As alleged in detail above, the Mylan Defendants made repeated false statements about its competitors to stop them from gaining any market share.

- c. <u>Paying powerful PBMs to Exclude Competitors</u>: The RICO Defendants and PBM Conspirators concealed from the public the existence, nature, and amount of kickbacks paid in the form of rebates distributed to PBMs in exchange for promises to exclude competitors' products from formularies controlled by the PBMs, thereby controlling the vast majority of the epinephrine marketshare.
- d. <u>Concealed Cooperation</u>: As alleged in detail above, in furtherance of the conspiracy to hide the concerted effort of the RICO Defendants and PBM Conspirators to inflate the price of EpiPens, the RICO Defendants and PBM Conspirators concealed from the public the true nature of their relationship and its effect on the pricing of the EpiPen.
- e. <u>Pay for Delay</u>: As described in detail above, while publicly asserting that EpiPens alone could deliver epinephrine effectively to consumers, Mylan quietly paid off several competitors (including Teva, Intelliject, and Sandoz settlements) who threatened to release a competing device that would have undercut Mylan's monopoly on the epinephrine auto-injector market. All the while, Mylan concealed from consumers the true, anti-competitive aims of its pay-for-delay arrangements.
- f. <u>False Statements About Why EpiPens are Expensive</u>: As described in detail above, the RICO Defendants made material misrepresentations regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealed from the public Mylan's unfair and anticompetitive practices that permitted those price increases. For example, during a Forbes Summit interview in New York City on December 1, 2016, Bresch falsely asserted that Mylan has

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invested \$1 billion in developing the EpiPen in creating "access and awareness and improving the product."

- g. <u>False Statements About 80% Pay Nothing</u>: As described in detail above, Mylan has falsely stated that 80% of consumers with insurance pay nothing. Not only is this statement false, but it also intentionally ignores that all consumers with insurance do pay increased premiums, and third-party payors pay for the full and/or inflated price of price increases. Thus, Mylan has used a half-truth to conceal its fraudulent price increases.
- h. <u>False Statements About Mylan's Profits</u>: As described in detail above, throughout 2016 and before Congress in 2016, Mylan falsely stated that its profit off the EpiPen was much lower than it is (\$100, as alleged by Mylan).
- <u>False Statements About Coupons and Rebates</u>: As described in detail above, throughout 2016 and before Congress in 2016, Mylan misleadingly discussed its rebate and coupon programs. But the coupons and rebates offered by Mylan "are wolves in sheep's clothing," according to Leemore Dafny, a professor at Harvard Business School.

2. Agreements Between the RICO Defendants and the PBM Conspirators Served to Formalize the RICO Defendants' Fraudulent and Anti-Competitive Market Behavior

660. The PBM Conspirators and the RICO Defendants knowingly made material misstatements to third-party payors, plan members, and the general public in furtherance of the fraudulent scheme regarding: (a) the actual net prices of EpiPen products; (b) the extent to which the actual net prices departed from the published, artificially-inflated list prices; (c) the extent to which the RICO Defendants and the PBM Conspirators had negotiated the rebates discounting the list prices of the EpiPen in good faith and for a proper purpose; (d) whether the rebates were

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intended to benefit health care payers, plan members, and/or the general public; (e) whether the rebates saved health care payers, plan members, and the general public money; (f) whether the "preferred" formulary status of the EpiPen auto-injector reflected the drug's safety, efficacy, or cost-effectiveness; (g) whether the EpiPen auto-injector would have been placed in a "preferred" formulary position absent the rebates paid by the RICO Defendants; and (h) the extent to which the rebating scheme would force plan members to incur additional expenses for their EpiPen prescriptions.

661. The PBM Conspirators use of the mails and wires include, but are not limited to: (a) the transmission of marketing or other materials indicating, setting, or negotiating the price of EpiPens; (b) the transmission of marketing or other materials indicating or advertising that any of the PBM Conspirators reduce the price of the EpiPen; (c) written, telephone, or electronic communications regarding and/or negotiating the price of the EpiPen; (d) written, telephone, or electronic communications regarding and/or negotiating discounts and/or rebates for EpiPen products; (e) written, telephone, or electronic communications regarding the existence, amount, or purpose of discounts and/or rebates for EpiPen products; (f) the transmission and/or distribution of EpiPen products through the mails; and (g) the use of the mails or wires to bill for or collect discounts, revenues, and/or profits from the sale of EpiPen products.

3. The 2-Pak Arrival on the Market in 2011 Benefited the RICO Defendants and Illustrates a Piece of the EpiPen Pricing Enterprise

662. As described above, in 2011 Mylan implemented a hard switch and forced all U.S. consumers to purchase the EpiPen as a 2-Pak—or not at all. This artificially and mechanically doubled the price -- and boosted Mylan's and Pfizer's revenue -- on the EpiPen from 2011 to present.

663. The timing of the 2-Pak launch in 2011 coincided with Mylan's overall scheme to

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defraud consumers once it had sidelined its competitors. Without any concern of being undercut on price, Mylan was free to force consumers to purchase the 2-Pak—or nothing at all.

664. To advance the hard switch to the 2-Pak, Mylan issued a false press release that cited a global standard (when only in the U.S. does Mylan sell the 2-Pak) and relied on a study that did not apply to the general population. In addition, Mylan paid doctors and medical committees to endorse the 2-Pak launch of the EpiPen as medically necessary and launching the EpiPen 2-Pak (while simultaneously withdrawing the individual EpiPen in the United States).

665. Mylan usurped control from doctors and patients by forcing them to switch to buy the 2-Pak, even though individual EpiPens had been prescribed and sold in the U.S. without incident from 1987 to 2011, and even though EpiPens must be replaced annually and nearly all of them expire without being used.

666. The EpiPen 2-Pak is just two individual EpiPens literally tied together with a grey piece of cheap plastic. Mylan deceptively suggested that the 2-Pak was medically required, but this was a false pretext because the FDA did not require Mylan to sell the 2-Pak, no FDA guidelines accompanied the "hard switch" to the 2-Pak, individual EpiPens are sold in every other country but the U.S., and Mylan offers no medical instructions or guidelines in the packaging for patients to know if or when to administer the second back-up EpiPen.

667. On April 25, 2013, Mylan announced the 25th Anniversary of the FDA approval of the EpiPen, but it never listed any FDA approval of the EpiPen 2-Pak or provided any medical instructions on administering the back-up EpiPen in the 2-Pak.

668. Profits, not medicine, drove the "hard switch." Mylan and Pfizer wanted to double their revenue, so that top executives would capture tens of millions in bonuses. In fact, Mylan's top five executives paid themselves \$82 million in secret bonuses and pillaged the company for

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over \$300 million in compensation during the 2-Pak Scheme. As Ms. Bresch orchestrated the 2-Pak Scheme, her own salary jumped by 671%—from \$2.5 million in 2007 to nearly \$19 million in 2015—virtually lockstep with the soaring percentage increase in the price of EpiPen.

669. Each consumer and third-party payor was forced to overpay for the Epipen 2-Pak because the price was double what it otherwise would have been.

670. The data and history of EpiPen purchases can be compared from 1987-2011 (prehard switch to the 2-Pak) and after 2011 (post-hard switch). By comparing this data, it is easy to see how Mylan's hard switch to the 2-Pak harmed consumers and third-party payors and forced them to overpay.

671. Because most EpiPens expire before they are used (and the EpiPen 2-Pak must be purchased every year), Mylan's requirement that all consumers and third-party payors purchase a 2-Pak is particularly unfair and damaging.

4. The RICO Defendants' and PBM Conspirators' Pattern of Racketeering

672. The RICO Defendants and the PBM Conspirators participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

673. In devising and executing the illegal scheme, the RICO Defendants and the PBM Conspirators devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and the Nationwide Class or to obtain money from Plaintiffs and the Nationwide Class by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

674. For the purpose of executing the illegal scheme, the RICO Defendants and the PBM Conspirators committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

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675. This EpiPen Pricing Enterprise has remained in existence for several years, enabling its members to pursue the enterprise's purpose.

676. The above-described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and the Class.

677. Each instance of racketeering was related, had a common purpose, was carried out with similar participants and methods, and impacted Plaintiffs and the Class in the same manner. The racketeering activities therefore constitute a continuing threat to Plaintiffs and the Class.

678. The RICO Defendants and the PBM Conspirators have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of <u>18</u> <u>U.S.C. § 1962(d)</u>, the RICO Defendants conspired to violate <u>18 U.S.C. § 1962(c)</u>, as described herein. Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with the RICO Defendants in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

679. As described herein, the RICO Defendants and the PBM Conspirators engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of: generating fraudulent and deceptive sales of the EpiPen 2-Pak, to restrain competition from generic competitors, and to deceive Plaintiffs and the Class into purchasing the EpiPen 2-Pak and not resisting the "hard switch" to the 2-Pak in the United States. But for the Defendants' fraudulent scheme and racketeering, Plaintiffs and the Class would not have accepted, acquired, and purchased the EpiPen 2-Pak.

D. Causation and Damages

680. By reason of, and as a result of the conduct of the RICO Defendants and the PBM Conspirators, and in particular, their pattern of racketeering activity, Plaintiffs and Class members have been injured in their business and/or property.

681. The Consolidated Complaint includes claims on behalf of consumers and thirdparty payors, which means the RICO Defendants are not subject to duplicative claims. All the relief possibly afforded will be adjudicated and awarded in this case alone.

682. The RICO Defendants' violations of <u>18 U.S.C. § 1962(c)</u> and <u>(d)</u> have directly and proximately caused injuries and damages to Plaintiffs and Class members, and Plaintiffs and Class members are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to <u>18 U.S.C. § 1964(c)</u>.

COUNT VIII

Violation of State Consumer Protection Laws (on behalf of Plaintiffs and the State Antitrust and Consumer Protection Class)

683. Plaintiffs repeat and re-allege every allegation above and below as if set forth in full herein.

684. As alleged throughout this Complaint, Mylan engaged in unfair methods of competition; unfair or deceptive acts or practices; and/or unconscionable acts or practices in violation of the following state consumer protection laws by taking the following actions, including but not limited to:

- a. making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases;
- b. making material misrepresentations, as detailed above, to the public and media outlets regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases, including statements made in a December 1, 2016 interview indicating that Mylan invested more than \$1 billion in developing the

EpiPen and increasing access to the product;

- c. failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market through misleading and deceptive statements and studies;
- d. making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States, including an August 24, 2011 news release asserting the medical necessity of the 2-Pak;
- e. failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists used as a pretext for Mylan to start selling the EpiPen only as a 2-Pak in the United States;
- f. exploiting its dominant market position to unreasonably increase the price of the EpiPen from 2009 to present;
- g. selling the EpiPen exclusively as a 2-Pak in the United States, which doubles the already-inflated price paid by every consumer;
- h. making material misrepresentations regarding Mylan's EpiPen4Schools program, including a September 21, 2016 statement to Congress that EpiPens are provided to schools with 'no strings attached' as described above;
- i. failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program;
- j. failing to disclose and/or concealing from the public the extent to which selection of the EpiPen for stockpiling at schools and other places of accommodation reflected Mylan's lobbying efforts and payment of rebates instead of the drug's safety, efficacy, or cost-effectiveness;
- k. making material misrepresentations, as detailed above, to the public and the House Oversight Committee on September 21, 2016 regarding Mylan's reasons for increasing the price of the EpiPen, CEO Heather Bresch's compensation, improvements made to the EpiPen, the medical need for the EpiPen, Mylan's profits and taxes, the amount that consumers would pay for the EpiPen, as well as Mylan's role in reducing healthcare costs in the United States;
- 1. making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen, including the statement that 80% of consumers with insurance pay nothing for the EpiPen;

- m. making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers;
- n. making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers, including but not limited to publishing, setting, or distributing the list price of the EpiPen products described herein and saturating the market with misrepresentations, misinformation and omissions suggesting that the pricing was fair and reflected the development costs of the EpiPen;
- o. failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen products described herein;
- p. making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs in exchange for the state's promise to provide exclusive formulary placement for the EpiPen on state-based Medicaid formularies;
- q. making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to pharmacy benefit managers and/or negotiated by pharmacy benefit managers in exchange for the pharmacy benefit managers' promise to give Defendants' EpiPen products exclusive and/or favorable formulary placement;
- r. making material misrepresentations regarding and/or failing to disclose the portion of discounts, rebates, and/or other payments from Defendants that are retained by pharmacy benefit managers in exchange for the pharmacy benefit managers' promise to give EpiPen products exclusive or at least favorable, formulary placement;
- s. making material misrepresentations regarding, concealing, and/or failing to disclose the effect that discounts, rebates, and/or other payments to pharmacy benefit managers had on the price of the EpiPen;
- t. failing to disclose and/or concealing from the public the extent to which EpiPen's preferred and/or exclusive formulary status reflected the drug's safety, efficacy, or cost-effectiveness;
- u. misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen;
- v. engaging in misleading, false, unfair and/or deceptive acts or practices by selling

and/or facilitating the sale of EpiPen products described herein at a grossly inflated and/or fraudulently obtained price point;

- w. engaging in advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen;
- x. engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein;
- y. submitting studies and citizens' petitions to the FDA that include misleading and deceptive statements regarding the effectiveness of products developed by Mylan's competitors, as described above;
- z. creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors, as described above, including a study entitled "Auvi-Q versus EpiPen Auto-Injectors," a 2013 statement by Mylan CEO Health Bresch that the Auvi-Q might be confused with a Blackberry, and marketing materials suggesting that the Auvi-Q was excluded from certain drug formularies for medical and/or safety reasons unrelated to rebates paid to pharmacy benefit managers;
- aa. failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and
- bb. falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.
- 685. By doing so, Mylan:
 - a. took advantage of its unequal bargaining power and exploited the vulnerability of consumers who suffered from a "physical infirmity" (severe allergies and/or children with allergies);
 - b. exploited children and their parents, among other consumers, who have no choice but to purchase the EpiPen 2-Pak (instead of an individual EpiPen) given Mylan's monopoly and extensive lobbying efforts to ensure that Mylan's products are promoted and its competitors' products never reach store shelves so they can be sold for a lower price;

- c. induced a transaction that was excessively one-sided in favor of Mylan, particularly given the monopoly created by Mylan, the lack of any other comparable device approved by the FDA, and the dependency on the EpiPen brand artificially created by Mylan by its exploitative and well-funded lobbying campaign that targeted American consumers;
- d. made materially misleading statements of opinion suggesting that its price gouging and unconscionable list price was not excessive, when in fact Mylan's pricing was excessive and Mylan executives stood to gain huge personal windfalls based on a direct correlation to EpiPen sales;
- e. materially misrepresented the scope and efficacy of its consumer assistance programs to whitewash public scrutiny and downplay its corporate greed and price gouging; and
- f. sold the EpiPen at a list price that grossly exceeded the previous price that the EpiPen was sold for before 2009 (and the costs of production have not risen substantially), and at a price that grossly exceeds the list price of the generic EpiPen (also an excessive price), which proves that Mylan has doubled the price of its own product.

686. Whether or not consumers actually paid the full list price of over \$600 is immaterial to a consumer protection violation.

687. Whether insurance has paid some or all of the full list price is immaterial to a consumer protection violation.

688. If employers or prescription benefits or insurance companies paid any portion of the cost of the EpiPen, consumers were injured because their insurance premiums were raised as a result of Mylan's price increases of the EpiPen and employer health insurance is an employee benefit that is substituted for compensation (thus, the payments made by health insurance are actually damages suffered by the employee).

689. In the same way that auto insurance premiums are raised on consumers based on the number of accidents that occur, so too do health insurance premiums rise based on the total medical costs incurred by the insured. Pharmaceutical drug costs—which companies like Mylan

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falsely pretend are "free" to consumers when in fact they are not—are a major reason why health insurance premiums are rising so quickly.

690. In addition, consumers have been damaged because Mylan's pricing prevents consumers from gaining access to critical medicine to treat life-threatening allergies. Thousands of consumers have been forced to go without an EpiPen because of Mylan's inflated list price of the EpiPen.

691. As a result of the Mylan's practices, Plaintiffs and the State Antitrust and Consumer Protection Class have suffered damages and are entitled to recover those damages and costs, including reasonable attorneys' fees, from Mylan.

692. Plaintiffs and the State Antitrust and Consumer Protection Class are also entitled to an injunction to stop Mylan's continued deceptive and unconscionable practices of selling the EpiPen 2-Pak at an inflated price.

693. By engaging in the conduct set forth throughout this Amended Complaint, Mylan has engaged in unfair competition and unfair or deceptive acts or practices or unconscionable practices in violation of the following state consumer protection statutes:

A. VIOLATIONS OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT (Ala. Code § 8-19-1, et seq.)

694. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

695. This claim is brought by Plaintiff Kenneth Evans (for the purposes of this section, "Plaintiff") on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are residents or have been residents of the State of Alabama during the relevant period ("the Alabama members of the Class") against Mylan (for the purposes of this section, "Defendants").

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696. The Alabama Deceptive Trade Practices Act ("Alabama DTPA") declares several specific actions to be unlawful, including: "(11) Making a false or misleading statement of fact concerning the reasons for, existence of, or amounts of, price reductions"; and "(27) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce." Ala. Code § 8-19-5.

697. Plaintiff and the Alabama members of the Class are "consumers" within the meaning of Ala. Code. § 8-19-3(2).

698. Defendants, Plaintiff, and the Alabama members of the Class are "persons" within the meaning of <u>Ala. Code § 8-19-3(3)</u>.

699. Each Defendant was and is engaged in "trade or commerce" within the meaning of Ala. Code § 8-19-3(8).

700. Defendants thus violated the Alabama DTPA, at a minimum by: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for in-creasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) mak-ing material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying ef-forts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations re-garding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present;

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(g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making mate-rial misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the

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FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

701. The foregoing violations caused harm to Plaintiffs and the members of the Classes, and are likely to harm consumers in the future if Defendants' practices are not stopped.

702. Pursuant to <u>Alabama Code § 8-19-10</u>, Plaintiffs seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$100 for each plaintiff.

703. Plaintiffs also seek an order enjoining each Defendant's unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under Ala. Code. § 8-19-1, *et seq*.

704. Certain Plaintiffs will send Defendants letters complying with <u>Ala. Code § 8-</u> <u>19-10(e)</u> concurrently with the filing of this Complaint. This Count is a placeholder only and will be formally asserted 15 days after demand letters are sent if Defendants fail to remedy their unlawful conduct.

B. VIOLATIONS OF THE ARIZONA CONSUMER FRAUD ACT (Ariz. Rev. Stat. § 44-1521, et seq.)

705. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

706. Plaintiff Cassandra Bredek (for the purposes of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class

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who are residents or have been residents of the State of Arizona during the relevant period ("the Arizona members of the Class") against Mylan (for the purposes of this section, "Defendants").

707. Defendants, Plaintiff Bredek, and the Arizona members of the Class are "persons" within the meaning of the Arizona Consumer Fraud Act ("Arizona CFA"), <u>Ariz. Rev. Stat. § 44-1521(6)</u>.

708. The EpiPen auto-injector products described herein (the EpiPen, EpiPen 2-Pak, EpiPen Jr., EpiPen Jr. 2-Pak, My EpiPen, LIFE HAPPENS, EpiPen4Schools, Never-See-Needle, and Be Prepared) are "goods" within the meaning of <u>Ariz. Rev. Stat. § 44-1521(5)</u>.

709. The Arizona CFA provides that "[t]he act, use or employment by any person of any deception, deceptive act or practice, fraud, … misrepresentation, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale … of any merchandise whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice." <u>Ariz. Rev.</u> Stat. § 44-1522(A).

710. As detailed above, Defendants employed deception, deceptive acts or practices, fraud, misrepresentations, or concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in violation of the Arizona CFA by at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants'

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lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease

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the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

711. Defendants owed and continue to owe Plaintiff Bredek and the Arizona members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

712. Defendants knew or should have known that their conduct was in violation of the Arizona CFA.

713. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Bredek and the Arizona members of the Class, and continued to engage in unfair and deceptive practices in violation of the Arizona CFA.

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714. Defendants' violations present a continuing risk to Plaintiff Bredek and the Arizona members of the Class as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

715. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Bredek and the Arizona members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Bredek and the Arizona members of the Class.

716. Plaintiff Bredek and Arizona members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen products described herein, as set forth above. These material misrepresentations proximately caused Plaintiff Bredek and the Arizona members of the Class to overpay for EpiPen products. Because Defendants did not reveal the true nature of the EpiPen products and their pricing, as described herein, until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Arizona CFA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

717. Plaintiff Bredek and the Arizona members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

718. Plaintiffs Bredek and the Arizona members of the Class seek monetary relief against Defendants in an amount to be determined at trial. Plaintiff Bredek and the Arizona members of the Class also seek punitive damages because Defendants engaged in aggravated and

outrageous conduct with an evil mind.

719. Plaintiff Bredek and the Arizona members of the Class also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under the Arizona CFA.

C. VIOLATIONS OF THE ARKANSAS DECEPTIVE TRADE PRACTICE ACT (Ark. Code Ann. § 4-88-101, et seq.)

720. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

721. Plaintiff Christopher Rippy, (for the purposes of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Arkansas during the relevant time period (the "Arkansas members of the Class") against Mylan (for the purposes of this section, "Defendants").

722. Plaintiff Rippy, the members of the Arkansas Class, and Defendants are "persons" within the meaning of Arkansas Deceptive Trade Practices Act ("Arkansas DTPA"), <u>Ark. Code</u> <u>Ann. § 4-88-102(5)</u>.

723. The Arkansas DTPA prohibits "[d]eceptive and unconscionable trade practices," which include, but are not limited to, a list of enumerated items, including "(1) [k]nowingly making a false representation as to the characteristics, ingredients, uses, benefits, alterations, source, sponsorship, approval, or certification of goods or services or as to whether goods are original or new or of a particular standard, quality, grade, style, or model," and "(10) [e]ngaging in any other unconscionable, false, or deceptive act or practice in business, commerce, or trade[.]" <u>Ark. Code Ann. § 4-88-107(a)(1),(10)</u>.

724. The Arkansas DTPA also prohibits the following when utilized in connection with the sale or advertisement of any goods: "(1) The act, use, or employment by any person of any

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deception, fraud, or false pretense; or (2) The concealment, suppression, or omission of any material fact with intent that others rely upon the concealment, suppression, or omission." <u>Ark.</u> <u>Code Ann. § 4-88-108</u>.

In the course of their business, Defendants engaged in misleading, false and 725. deceptive acts in violation of the above-noted provisions of the Arkansas DTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations

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regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

726. Defendants' actions as set forth above occurred in the conduct of trade or

commerce.

727. Defendants owed and continue to owe Plaintiff Rippy and the Arkansas members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

728. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Rippy and the Arkansas members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Rippy and the Arkansas members of the Class.

729. Plaintiff Rippy and other Arkansas members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations proximately caused Plaintiff and the Arkansas members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Arkansas DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

730. Defendants knew or should have known that their conduct was in violation of the Arkansas DTPA.

731. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Rippy and other Arkansas members, and continued to engage in unfair and deceptive practices in violation of the Arkansas DTPA.

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732. Plaintiff Rippy and the Arkansas members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

733. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

734. Plaintiff Rippy and the Arkansas members of the Class seek monetary relief against Defendants in an amount to be determined at trial. Plaintiff Rippy and the Arkansas members of the Class also seek punitive damages because Defendants acted wantonly in causing the injury or with such a conscious indifference to the consequences that malice may be inferred.

735. Plaintiff Rippy and the Arkansas members of the Class also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under the Arkansas DTPA.

D. VIOLATION OF CALIFORNIA CONSUMERS LEGAL REMEDIES ACT (Cal. Civ. Code §§ 1750, et seq.)

736. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

737. Plaintiffs Elizabeth Huelsman, Kimberly Corcoran, and Nikitia Marshall (for the purposes of this section, "Plaintiffs") bring this Count on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of California at any relevant time ("California members of the Class") against Mylan (for the purposes of this section, "Defendants").

738. California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750,

et seq., proscribes "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer."

739. Defendants' EpiPen products are "goods" as defined in Cal. Civ. Code § 1761(a).

740. Plaintiffs and the other California members of the Class are "consumers" as defined

in <u>Cal. Civ. Code § 1761(d)</u>.

741. Plaintiffs, the other California members of the Class, and Defendants are "persons" as defined in <u>Cal. Civ. Code § 1761(c)</u>.

- 742. Defendants' conduct violates at least the following enumerated CLRA provisions:
 - a. <u>Cal. Civ. Code § 1770(a)(2)</u>: Misrepresenting the source, sponsorship, approval, or certification of goods or services;
 - b. <u>Cal. Civ. Code § 1770(a)(3):</u> Misrepresenting the affiliation, connection, or association with, or certification by, another;
 - c. <u>Cal. Civ. Code § 1770(a)(5):</u> Representing that goods have characteristics, uses, and benefits which they do not have;
 - d. <u>Cal. Civ. Code § 1770(a)(7):</u> Representing that goods are of a particular standard, quality, or grade, if they are of another; and
 - e. <u>Cal. Civ. Code § 1770(a)(9):</u> Advertising goods with intent not to sell them as advertised.

743. As alleged throughout this Complaint, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the CLRA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to

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disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing

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material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

744. Defendants owed and continue to owe Plaintiffs Huelsman, Corcoran, Marshall and the California members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

745. Defendants knew or should have known that their conduct was in violation of the CLRA.

746. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class, and continued to engage in unfair and deceptive practices in violation of the CLRA.

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747. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class.

748. Plaintiffs Huelsman, Corcoran, and Marshall and other California members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the CLRA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

749. Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

750. Defendants' violations present a continuing risk to Plaintiffs Huelsman, Corcoran, and Marshall as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

751. Under <u>Cal. Civ. Code § 1780(a)</u>, Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class seek monetary relief against Defendants in an amount to be

determined at trial.

752. Under <u>Cal. Civ. Code § 1780(b)</u>, Plaintiffs Huelsman, Corcoran, and Marshall seek an additional award against Defendants of up to \$5,000 for each California member of the Class who qualifies as a "senior citizen" or "disabled person" under the CLRA. Defendants knew or should have known that their conduct was directed to one or more California members of the Class who are senior citizens or disabled persons. Defendants' conduct caused one or more of these senior citizens or disabled persons to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the senior citizens or disabled person. One or more California members of the Class who are senior citizens or disabled person of more California members of the Class who are senior citizens or disabled person of more California members of the Class who are senior citizens or disabled person of more california members of the Class who are senior citizens or disabled person of more california members of the Class who are senior citizens or disabled persons are substantially more vulnerable to Defendants' conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and each of them suffered substantial physical, emotional, or economic damage resulting from Defendants' conduct.

753. For consumers with health insurance, such as Plaintiff Corcoran, Mylan's pricing results in inflated premiums and higher co-pays for consumers. As the Los Angeles Times has explained, Mylan's refusal to price the EpiPen at a reasonable amount simply "means the insurers and employers that pay the bulk of the EpiPen cost for many patients will continue to do so, contributing to higher health insurance costs. 'That's just going to come out in the premiums,' said Sabrina Corlette, a research professor at Georgetown University's Health Policy Institute."¹⁷⁷ As such, Plaintiff Corcoran has suffered a concrete and particularized injury.

754. Moreover, due to Defendants' unconscionable increase in the price of the EpiPen,

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Plaintiff Corcoran has been rendered unable to leave her employer-provided health plan which covers the EpiPen. Specifically, as a result of Defendants' conduct, and, in order to ensure that she can afford and continue to receive the life-saving treatment, she was prevented from changing her insurance in order to gain favorable terms and prevented from making a change in her employment for more favorable terms. Plaintiffs interest in her employment, the terms of her employment, the terms of her insurance, as well as the economic consequences of those terms are, among others, legally protected interests that have been infringed upon by Defendants' illegal sales practices and she maintains a personal and legally protected interest in the outcome of this matter.

755. Plaintiffs Huelsman, Corcoran, and Marshall also seek punitive damages against Defendants because they carried out reprehensible conduct with willful and conscious disregard of the rights and safety of others, subjecting Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class to potential cruel and unjust hardship as a result. Defendants intentionally and willfully deceived Plaintiffs Huelsman, Corcoran, and Marshall on life-or-death matters, and concealed material facts that only Defendants knew. Defendants' unlawful conduct constitutes malice, oppression, and fraud warranting punitive damages under <u>Cal. Civ. Code §</u> 3294.

756. Plaintiffs Huelsman, Corcoran, and Marshall further seek an order enjoining Defendants' unfair or deceptive acts or practices, restitution, punitive damages, costs of court, attorneys' fees under <u>Cal. Civ. Code § 1780(e)</u>, and any other just and proper relief available under the CLRA.

757. Certain Plaintiffs have sent a letter complying with <u>Cal. Civ. Code § 1780(b)</u>.

E. VIOLATIONS OF CALIFORNIA FALSE ADVERTISING LAW (Cal. Bus. & Prof. Code §§ 17500, et seq.)

758. Plaintiffs incorporate by reference all preceding allegations as though fully set forth

herein.

759. Plaintiffs Huelsman, Corcoran, and Marshall (for the purposes of this section, "Plaintiffs") bring this Count on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of California at any relevant time ("California members of the Class") against Mylan (for the purposes of this section, "Defendants").

760. California Bus. & Prof. Code § 17500 provides:

It is unlawful for any corporation...with intent directly or indirectly to dispose of real or personal property...to induce the public to enter into any obligation relating thereto, to make or disseminate or cause to be made or disseminated from this state before the public in any state, in any newspaper or other publication, or any advertising device, ... or in any other manner or means whatever, including over the Internet, any statement ... which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading.

761. As alleged throughout this Complaint, Defendants caused to be made or disseminated throughout California and the United States, through advertising, marketing and other publications, statements that were untrue or misleading, and which were known, or which by the exercise of reasonable care should have been known to Defendants to be untrue and misleading to consumers, including Plaintiffs and the other Class members.

762. Defendants' misrepresentations with respect to the design, cost, and efficacy of Defendants' EpiPen products were material and likely to, and did in fact, deceive reasonable consumers.

763. Plaintiffs Huelsman, Corcoran, and Marshall and the California members of the Class have suffered an injury in fact, as a result of Defendants' unfair, unlawful, and/or deceptive practices, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

764. All of the wrongful conduct alleged herein occurred, and continues to occur, in the

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conduct of Defendants' business. Defendants' wrongful conduct is part of a pattern or generalized course of conduct that is still perpetuated and repeated, both in the State of California and nationwide.

765. Plaintiffs Huelsman, Corcoran, and Marshall, individually and on behalf of the other California members of the Class, request that this Court enter such orders or judgments as may be necessary to enjoin Defendants from continuing their unfair, unlawful, and/or deceptive practices and to restore to Plaintiffs and the other Class members any money Defendants acquired by their violations of California's False Advertising law, including restitution and/or restitutionary disgorgement, and for such other relief set forth below.

F. VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW (Cal. Bus. & Prof. Code § 17200, et seq.)

766. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

767. Plaintiffs Huelsman, Corcoran, and Marshall (for the purposes of this section, "Plaintiffs") bring this Count on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of California at any relevant time ("California members of the Class") against Mylan (for the purposes of this section, "Defendants").

768. <u>California Business and Professions Code § 17200</u> prohibits any "unlawful, unfair, or fraudulent business act or practices."

769. As alleged throughout this Complaint, Mylan engaged in unfair, deceptive, and/or unlawful practices in violation of California's Unfair Competition law by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material

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misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing

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of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

770. As indicated by the below statements of California and federal policy, Mylan's grossly excessive and unfair EpiPen pricing violates public policy and is, as such, unlawful within the meaning of <u>California Business and Professions Code § 17200</u>.

771. California's Senate Joint Resolution No. 29 unequivocally condemns Mylan's course of conduct in marketing and pricing the EpiPen. In particular, the California Senate and Assembly declared that "unnecessary and unexplained increases in pharmaceutical pricing is a harm to our health care system that will no longer be tolerated."¹⁷⁸ The resolution also:

¹⁷⁸ Senate Joint Resolution No. 29, CALIFORNIA STATE LEGISLATURE (2015-2016), <u>http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SJR29</u>, (last visited Jan. 31, 2017).

- a. Urges "the Congress of the United States to investigate the impact that Mylan NV's monopoly has had on price increases for EpiPen";¹⁷⁹
- Encourages "the Congress and President of the United States to take action to limit the unrestrained ability of drug manufacturers to increase prices based on what the market can bear"; ¹⁸⁰
- c. Describes Mylan's consistent price hikes for the EpiPen even though "[t]he formula of EpiPen did not change, and it is no more effective in protecting against allergic reactions in 2016" than before the increases; ¹⁸¹
- d. Condemns Mylan's "aggressive marketing and lobbying effort to increase demand for the EpiPen"; and
- e. Lists numerous harmful effects on consumers, insurance companies, and the state, including many of those identified above.

772. California also has a statutorily-demonstrated specific public policy in favor of increasing epinephrine and epinephrine auto-injector access for children:

- a. <u>California Education Code § 49414</u> requires public schools to provide epinephrine auto-injectors to trained personnel and specifically permits nurses and trained personnel to administer auto-injectors to children experiencing an anaphylactic reaction.
- b. California public policy also recognizes the life-saving and critical nature of epinephrine auto-injectors, requiring by statute that the California Emergency Medical Services Authority establish training standards for the
- ¹⁷⁹ Id.

 $^{^{180}}$ *Id.*

 $^{^{181}}$ Id.

use of epinephrine auto-injectors. *See* <u>Cal. Health & Safety Code §</u> <u>1797.197a</u>.

- c. In order to promote the quick administration of epinephrine, the California legislature has also provided that trained personnel who administer an auto-injector in good faith and without compensation are exempt from liability for civil damages. *See* Cal. Civ. Code § 1714.23.
- d. Finally, effective January 1, 2017, California law allows pharmacies to prescribe epinephrine auto-injectors directly to "authorized entities." Cal. Bus. & Prof. Code § 4119.4.
- 773. Those policies are echoed by similar federal statutes:
 - a. The U.S. School Access to Emergency Epinephrine Act, 42 U.S.C. 280g(d), exhibits a federal public policy to promote access to epinephrine by giving preference to states that require public schools to maintain a supply of epinephrine and permit school personnel to administer epinephrine.
 - b. <u>21 U.S.C. § 2205</u>, entitled "Food Allergy and Anaphylaxis Management," requires the development of guidelines to "manage the risk of food allergy and anaphylaxis in schools"

774. Unsurprisingly, California public policy is also in favor of promoting children's access to health care:

a. California has extended its "Medi-Cal" program to individuals under the age of 19, even if they are unable to establish "satisfactory immigration status."
 See Cal. Welf. & Inst. Code § 14007.8.

b. In enacting that statute, the California legislature declared that "No child in California should endure suffering and pain due to a lack of access to health care services." Cal. Stats. 2015 ch. 709.

775. California has a strong public policy favoring the fair and reasonable pricing of health care:

- a. Section 1374.21 of the California Health and Safety Code requires that individuals and small business owners be notified if regulators find that the premium for their health care plan is "unreasonable" or "unjustified."
- b. The California Health and Safety Code contains an entire chapter focused on fair pricing policies for hospitals and emergency physicians. *See* Cal. Health & Safety Code, Division 107, Part 2, Chapter 2.5 "Fair Pricing Policies".
- c. In <u>California Business & Professions Code § 657</u>, the legislature declared that:
- i. "Health Care should be affordable and accessible to all Californians," and
- ii. "The public interest dictates that uninsured Californians have access to basic, preventative health care at affordable prices."
- d. Article 6.2 of the California Health and Safety Code provides for state review of rate increases for health care service plan contracts (with some exceptions). See Cal. Health & Safety Code § 1385.02.

776. The California Unfair Competition Law <u>exhibits</u> a public policy in favor of providing increased protection from unfair practices that harm persons who have a "physical... impairment that substantially limits one or more life activities." Cal. Bus. & Prof.

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Code § 17206.1. There is no question that children who are vulnerable to potentially fatal allergic reactions are deserving of that protection.

777. Defendants' unfair, unlawful and/or deceptive activity alleged herein caused Plaintiffs and the California members of the Class to purchase EpiPen products at inflated prices. Accordingly, Plaintiffs Corcoran, Huelsman, Marshall, and the California members of the Class have suffered injury in fact including lost money or property as a result of Defendants' misrepresentations and omissions.

778. Plaintiffs request that this Court enter such orders or judgments as may be necessary to enjoin Defendants from continuing their unfair, unlawful, and/or deceptive practices and to restore to Plaintiffs and members of the Class any money Defendants' acquired by unfair competition, including restitution and/or restitutionary disgorgement, as provided in <u>Cal. Bus. & Prof. Code § 17203</u> and <u>Cal. Bus. & Prof. Code § 3345</u>; and for such other relief set forth below.

G. VIOLATIONS OF THE COLORADO CONSUMER PROTECTION ACT (Col. Rev. Stat. § 6-1-101, et seq.)

779. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

780. Plaintiffs Svites and Nordstrum (for the purposes of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are residents or have been residents of Colorado during the relevant period (the "Colorado members of the Class") against Mylan (for the purposes of this section, "Defendants").

781. Plaintiffs and the Colorado members of the Class purchased the EpiPen primarily for personal, family or household purposes, as alleged herein.

782. Defendants are "person[s]" under § 6-1-102(6) of the Colorado Consumer Protection Act ("Colorado CPA"), Col. Rev. Stat. § 6-1-101, *et seq*.

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783. The Colorado Consumer Protection Act, C.R.S. 6-1-101, *et seq.*, prohibits "deceptive trade practices," which include, but are not limited to, a list of enumerated items, including: "(b) Knowingly mak[ing] a false representation as to the source, sponsorship, approval, or certification of goods, services, or property; (c) Knowingly mak[ing] a false representation as to affiliation, connection, or association with or certification by another; . . . (l) Mak[ing] false or misleading statements of fact concerning the price of goods, services, or property or the reasons for, existence of, or amounts of price reductions; . . . (u) Fail[ing] to disclose material information concerning goods, services, or property which information was known at the time of an advertisement or sale if such failure to disclose such information was intended to induce the consumer to enter into a transaction." Col. Rev. Stat § 6-1-105.

784. As detailed above, Defendants engaged deceptive trade practices in violation of the above-noted provisions of the Colorado Consumer Protection Act by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the united States; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present;

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(g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the

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FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

785. Defendants knowingly engaged in false, misleading, or deceptive acts or practices through the unlawful conduct alleged herein, in violation of C.R.S. 6-1-105(1).

786. Defendants owed and continue to owe Plaintiffs and the Colorado members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

787. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Colorado members of the Class, and continued to engage in unfair and deceptive practices in violation of the Colorado CPA.

788. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Colorado members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the Colorado members of the Class.

789. Plaintiffs and the Colorado members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material

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misrepresentations by Defendants proximately caused Plaintiff and the Colorado members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Colorado CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

790. Plaintiffs and the Colorado members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

791. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

792. Pursuant to Colo. Rev. Stat. § 6-1-113, Plaintiff, individually and on behalf of the Colorado Class, seeks monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and a discretionary trebling of such damages, or (b) statutory damages in the amount of \$500 for each Colorado member of the Class.

793. Plaintiffs also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under the Colorado CPA.

H. VIOLATIONS OF CONNECTICUT UNLAWFUL TRADE PRACTICES ACT (Conn. Gen. Stat. § 42-110A, et seq.)

794. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

795. Plaintiffs Lauren Coale, Rachel Fernandez, and Local 282 (for the purposes of this

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section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Connecticut during the relevant period (the "Connecticut members of the Class") against Mylan (for the purposes of this section, "Defendants").

796. The Connecticut Unfair Trade Practices Act ("Connecticut UTPA") provides: "No person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a).

797. Defendants are "person[s]" within the meaning of Conn. Gen. Stat. § 42-110a(3).

798. Defendants are and were engaged in "trade or commerce" within the meaning of Conn. Gen. Stat. § 42-110a(4) during all relevant periods by, at a minimum, advertising, offering for sale, and selling the EpiPen auto-injector products described herein in Connecticut, to Connecticut members of the Class, and throughout the United States.

799. Plaintiffs and Connecticut members of the Class purchased goods or services primarily for personal, family or household purposes as alleged herein.

800. The Connecticut Consumer Protection Act prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. Ann. § 42-110b.

801. In the course of their business, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Connecticut UTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made

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to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in

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setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

802. Defendants owed and continue to owe Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

803. Defendants knew or should have known that their conduct was in violation of the Connecticut UTPA.

804. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class, and

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continued to engage in unfair and deceptive practices in violation of the Connecticut UTPA.

805. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Coale, Fernandez, and the Connecticut members of the Class.

806. Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Connecticut UTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

807. Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

808. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

809. Defendants acted with a reckless indifference to another's rights or wanton or intentional violation to another's rights and otherwise engaged in conduct amounting to a particularly aggravated, deliberate disregard of the rights and safety of others.

810. Plaintiffs Coale, Fernandez, Local 282, and the Connecticut members of the Class are entitled to recover their actual damages, punitive damages, and attorneys' fees pursuant to Conn. Gen. Stat. § 42-110g.

I. VIOLATIONS OF THE DELAWARE CONSUMER FRAUD ACT (6 Del. Code § 2513, et seq.)

811. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

812. Plaintiff Raymond Buchta (for the purpose of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or have been residing in the State of Delaware (the "Delaware members of the Class") against Mylan (for the purposes of this section, "Defendants").

813. Defendants are "person[s]" within the meaning of <u>6 Del. Code § 2511(7)</u>.

814. The Delaware Consumer Fraud Act ("Delaware CFA") prohibits the "act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale, lease or advertisement of any merchandise, whether or not any person has in fact been misled, deceived or damaged thereby." <u>6 Del. Code § 2513(a)</u>.

815. As detailed above, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Delaware CFA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the

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EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in

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setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

816. Defendants owed and continue to owe Plaintiff Buchta and the Delaware members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

817. Defendants knew or should have known that their conduct was in violation of the Delaware CFA.

818. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Buchta and the Delaware members of the Class, and continued to engage in unfair and deceptive practices in violation of the Delaware CFA.

819. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Buchta and the Delaware members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Buchta and the Delaware members of the Class.

820. Plaintiff Buchta and the Delaware members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Delaware members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Delaware CFA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

821. Plaintiff Buchta and the Delaware members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

822. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

823. Plaintiff Buchta and the Delaware members of the Class seek damages under the Delaware CFA for injury resulting from the direct and natural consequences of Defendants' unlawful conduct. *See, e.g., Stephenson v. Capano Dev., Inc.,* <u>462 A.2d 1069, 1077</u> (Del. 1983).

824. Plaintiff Buchta and the Delaware members of the Class also seek an order

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enjoining Defendants' unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under the Delaware CFA.

825. Defendants engaged in gross, oppressive or aggravated conduct justifying the imposition of punitive damages.

J. VIOLATIONS OF FLORIDA'S UNFAIR & DECEPTIVE TRADE PRACTICES ACT (Fla. Stat. § 501.201, et seq.)

826. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

827. Plaintiffs Lee Seltzer and Local 282 (for the purpose of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Florida at any relevant time (the "Florida members of the Class") against Mylan (for the purposes of this section, "Defendants").

828. Defendants are engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8) during all relevant periods by, at a minimum, advertising, offering for sale, and selling the EpiPen auto-injector products described herein in Florida, to Florida members of the Class, and throughout the United States.

829. The FUDTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce …" Fla. Stat. § 501.204(1).

830. As detailed above, in the course of their business, Defendants engaged in unfair, unconscionable and deceptive acts or practices in violation of the above-noted provisions of the FUDTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price

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increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit

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managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

831. Defendants owed and continue to owe Plaintiffs Seltzer, Local 282, and the Florida members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

832. Defendants knew or should have known that their conduct was in violation of the FUTPA.

833. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding

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the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Seltzer, Local 282, and the Florida members of the Class, and continued to engage in unfair and deceptive practices in violation of the FUTPA.

834. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Seltzer and the Florida members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Seltzer, Local 282, and the Florida members of the Class.

835. Plaintiffs Seltzer, Local 282, and the Florida members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Seltzer, Local 282, and the Florida members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the FUTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

836. Plaintiffs Seltzer, Local 282, and the Florida members of the Class suffered injuryin-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

837. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

838. Plaintiffs and the Florida Class are entitled to recover their actual damages under

Fla. Stat. § 501.211(2) and attorneys' fees under Fla. Stat. § 501.2105(1).

839. Plaintiffs also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under the FUDTPA.

K. VIOLATIONS OF GEORGIA'S FAIR BUSINESS PRACTICES ACT (Ga. Code Ann. § 10-1-390, et seq.)

840. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

841. Plaintiffs Kimberly Dollander and Local 282 (for the purpose of this section, "Plaintiffs") bring this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Georgia at any relevant time ("the Georgia members of Class") against Mylan (for the purposes of this section, "Defendants").

842. The Georgia Fair Business Practices Act ("Georgia FBPA") declares "[u]nfair or deceptive acts or practices in the conduct of consumer transactions and consumer acts or practices in trade or commerce" to be unlawful, Ga. Code. Ann. § 10-1-393(a), including but not limited to "(2) Causing actual confusion or actual misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) Causing actual confusion or actual misunderstanding as to affiliation, connection, or association with or certification by another"; "(5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have," "(7) Representing that goods or services are of a particular standard, quality, or grade … if they are of another," "(9) Advertising goods or services with intent not to sell them as advertised," and "(11) Making false or misleading statements concerning the reasons for, existence of, or amounts of price reductions;"

843. As detailed above, Defendants engaged in unfair and deceptive acts in violation of

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the above-noted provisions of the Georgia FBPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of

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discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

844. Defendants owed and continue to owe Plaintiffs Dollander, Local 282 and the Georgia members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

845. Defendants knew or should have known that their conduct was in violation of the

Georgia FBPA.

846. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Dollander, Local 282, and the Georgia members of the Class, and continued to engage in unfair and deceptive practices in violation of the Georgia FBPA.

847. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Dollander, Local 282, and the Georgia members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Dollander, Local 282, and the Georgia members of the Class.

848. Plaintiffs Dollander, Local 282, and the Georgia members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Dollander, Local 282, and the Georgia members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Georgia FBPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

849. Plaintiffs Dollander, Local 282, and the Georgia members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

850. Defendants' violations present a continuing risk to Plaintiff as well as to the general

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public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

851. Plaintiffs Dollander, Local 282, and the Georgia members of the Class are entitled to recover damages and exemplary damages (for intentional violations) per Ga. Code. Ann. § 10-1-399(a).

852. Plaintiffs also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under the Georgia FBPA per Ga. Code. Ann. § 10-1-399.

853. Prior to this filing, certain Plaintiffs sent a letter complying with Ga. Code. Ann. § 10-1-399(b).

L. VIOLATIONS OF GEORGIA'S UNIFORM DECEPTIVE TRADE PRACTICES ACT (Ga. Code Ann. § 10-1-370, et seq.)

854. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

855. Plaintiff Kimberly Dollander (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Georgia at any relevant time ("the Georgia members of Class") against Mylan (for the purposes of this section, "Defendants").

856. Defendants, Plaintiff Dollander, and the Georgia members of the Class are "persons" within the meaning of Georgia Uniform Deceptive Trade Practices Act ("Georgia UDTPA"), Ga. Code. Ann. § 10-1-371(5).

857. The Georgia UDTPA prohibits "deceptive trade practices," which include "(2) Caus[ing] [a] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) Caus[ing] [a] likelihood of confusion or of

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misunderstanding as to affiliation, connection, or association with or certification by another;" "(5) Represent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;" "(11) Mak[ing] false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; [and] (12) Engag[ing] in any other conduct which similarly creates a likelihood of confusion or of misunderstanding." Ga. Code. Ann. § 10-1-372(a).

858. As detailed above, Defendants engaged in deceptive trade practices in violation of the above-noted provisions of the Georgia UDTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools

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program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens'

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petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

859. Defendants owed and continue to owe Plaintiff Dollander, and the Georgia members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

860. Defendants knew or should have known that their conduct was in violation of the Georgia UDTPA.

861. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Dollander, and the Georgia members of the Class, and continued to engage in unfair and deceptive practices in violation of the Georgia UDTPA.

862. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Dollander and the Georgia members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including, Plaintiff Dollander, and the Georgia members of the Class.

863. Plaintiff Dollander and the Georgia members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Dollander and the Georgia members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute

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of limitations for filing claims against Defendants under the Georgia UDTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

864. Plaintiff Dollander and the Georgia members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

865. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

866. Plaintiffs seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under the Georgia UDTPA per Ga. Code. Ann § 10-1-373.

M. UNFAIR AND DECEPTIVE ACTS IN VIOLATION OF HAWAII LAW (Haw. Rev. Stat. § 480, et seq.)

867. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

868. Plaintiff Linda Wagner (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Hawaii at any relevant time (the "Hawaii members of the Class") against Mylan (for the purposes of this section, "Defendants").

869. Defendants are "person[s]" under <u>Haw. Rev. Stat. § 480-1</u>.

870. Plaintiff Wagner and the Hawaii members of the Class are "consumer[s]" as defined by <u>Haw. Rev. Stat. § 480-1</u>.

871. Defendants' acts or practices as set forth above occurred in the conduct of trade or commerce.

872. <u>Haw. Rev. Stat. § 480-1</u> *et seq.* (the "HUPUCA"), prohibits the use of any "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce."

As detailed above, Defendants engaged in unfair and deceptive acts in violation of 873. the HUPUCA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing,

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and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to

fund payments of rebates and/or discounts.

874. Defendants owed and continue to owe Plaintiff Wagner and the Hawaii members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

875. Defendants knew or should have known that their conduct was in violation of the HUPUCA.

876. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Wagner and the Hawaii members of the Class, and continued to engage in unfair and deceptive practices in violation of the HUPUCA.

877. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Wagner and the Hawaii members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Wagner and the Hawaii members of the Class.

878. Plaintiff Wagner and the Hawaii members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Wagner and the Hawaii members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the HUPUCA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

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879. Plaintiff Wagner and the Hawaii members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

880. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

881. Pursuant to <u>Haw. Rev. Stat. § 480-13</u>, Plaintiff and the Hawaii members of the Class seek monetary relief against Defendants measured as the greater of (a) \$1,000 and (b) threefold actual damages in an amount to be determined at trial.

882. Under <u>Haw. Rev. Stat. § 480-13.5</u>, Plaintiffs seek an additional award against Defendants of up to \$10,000 for each violation directed at a Hawaiian elder. Defendants knew or should have known that its conduct was directed to one or more Class members who are elders. Defendants' conduct caused one or more of these elders to suffer a substantial loss of property set aside for retirement or for personal or family care and maintenance, or assets essential to the health or welfare of the elder. One or more Hawaii members of the Class who are elders are substantially more vulnerable to Defendants' conduct because of age, poor health or infirmity, impaired understanding, restricted mobility, or disability, and each of them suffered substantial economic damage resulting from Defendants' conduct.

N. VIOLATIONS OF THE IDAHO CONSUMER PROTECTION ACT (Idaho Code § 48-601, et seq.)

883. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

884. Plaintiff Denya Anderson (for the purpose of this section, "Plaintiff") brings this

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action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Idaho at any relevant time (the "Idaho members of the Class") against Mylan (for the purposes of this section, "Defendants").

885. Defendants are "person[s]" under the Idaho Consumer Protection Act ("Idaho CPA"), Idaho Code § 48-602(1).

886. Defendants' acts or practices as set forth above occurred in the conduct of "trade" or "commerce" under Idaho Code § 48-602(2).

887. The Idaho CPA prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce," which include "(2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) Causing likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;" "(5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, connection, qualifications or license that he does not have;" "(11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" and "(17) Engaging in any act or practice which is otherwise misleading, false, or deceptive to the consumer." <u>Idaho Code § 48-603</u>.

888. As detailed above, Defendants engaged in unfair and deceptive acts in violation of the above-noted provisions of the Idaho CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material

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misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing

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of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

889. Defendants owed and continue to owe Plaintiff Anderson and the Idaho members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

890. Defendants knew or should have known that their conduct was in violation of the Idaho CPA.

891. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead

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regulators, Plaintiff Anderson and the Idaho members of the Class, and continued to engage in unfair and deceptive practices in violation of the Idaho CPA.

892. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Anderson and the Idaho members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Anderson and the Idaho members of the Class.

893. Plaintiff Anderson and the Idaho members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Anderson and the Idaho members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Idaho CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

894. Plaintiff Anderson and the Idaho members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

895. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

896. Pursuant to <u>Idaho Code § 48-608</u>, Plaintiff Anderson and the Idaho members of the Class seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$1,000 for each Idaho

member of the Class.

897. Plaintiff Anderson and the Idaho members of the Class also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, attorneys' fees, and any other just and proper relief available under the Idaho CPA.

898. Plaintiff Anderson and the Idaho members of the Class also seek punitive damages against Defendants because Defendants' conduct evidences an extreme deviation from reasonable standards.

O. VIOLATIONS OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES ACT (815 ILCS 505/1, *et seq.* and 720 ILCS 295/1a)

899. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

900. Plaintiff Erin Korte-Lamparter and Vishal Aggarwal (for the purpose of this section, "Plaintiffs") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Illinois at any relevant time (the "Illinois members of the Class") against Mylan (for the purposes of this section, "Defendants").

901. Defendants are "person[s]" as that term is defined in 815 ILCS 505/1(c).

902. Plaintiffs and the Illinois members of the Class are "consumers" as that term is defined in 815 ILCS 505/1(e).

903. The Illinois Consumer Fraud ("ICFDPA"), 815 ILCS 505/1 *et seq.*, prohibits the use of "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact[.]"

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904. In addition, the Illinois Deceptive Business Practices Act ("IUDTPA"), 815 ILCS 510/2 *et seq.*, prohibits the use of various deceptive trade practices, including: "(2) caus[ing] a likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) caus[ing] a likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another;" "(5) represent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;" "(11) mak[ing] false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; [and] (12) engag[ing] in any other conduct which similarly creates a likelihood of confusion or misunderstanding."

905. As detailed above, Defendants engaged in unfair and deceptive acts in violation of the ICFDPA and the IUDTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen

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exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding

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the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

906. Defendants owed and continue to owe Plaintiffs and the Illinois members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

907. Defendants knew or should have known that their conduct was in violation of the ICFDPA and the IUDTPA.

908. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Illinois members of the Class, and continued to engage in unfair and deceptive practices in violation of the ICFDPA and the IUDTPA.

909. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Illinois members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the Illinois members of the Class

910. Plaintiffs and the Illinois members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material

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misrepresentations by Defendants proximately caused Plaintiff and the Illinois members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the ICFDPA and the IUDTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

911. Plaintiff Korte-Lamparter and the Illinois members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

912. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

913. Pursuant to 815 ILCS 505/10a(a), Plaintiff and the Illinois members of the Class seek monetary relief against Defendants in the amount of their actual damages, as well as punitive damages because Defendants acted with fraud and/or malice and/or was grossly negligent.

914. Plaintiffs also seek an order enjoining Defendants' unfair and/or deceptive acts or practices, punitive damages, and attorneys' fees, and any other just and proper relief available under 815 ILCS § 505/1 *et seq*.

P. VIOLATIONS OF THE INDIANA DECEPTIVE CONSUMER SALES ACT (Ind. Code § 24-5-0.5-3)

915. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

916. Plaintiff Alene McDaniel (for the purpose of this section, "Plaintiff") brings this

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action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Indiana at any relevant time (the "Indiana members of the Class") against Mylan (for the purposes of this section, "Defendants").

917. Defendants are "person[s]" within the meaning of Ind. Code § 24-5-0.5-2(2) and "suppliers" within the meaning of Ind. Code § 24-5-.05-2(a)(3).

918. Plaintiff McDaniel and Indiana members of the Class' purchases of the EpiPen products described herein are "consumer transactions" within the meaning of Ind. Code § 24-5-.05-2(a)(1).

919. Indiana's Deceptive Consumer Sales Act ("Indiana DCSA") prohibits a person from engaging in a "deceptive act," which includes representing: "(1) That such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits that they do not have, or that a person has a sponsorship, approval, status, affiliation, or connection it does not have; (2) That such subject of a consumer transaction is of a particular standard, quality, grade, style or model, if it is not and if the supplier knows or should reasonably know that it is not; ... (7) That the supplier has a sponsorship, approval or affiliation in such consumer transaction that the supplier does not have, and which the supplier knows or should reasonably know that the supplier does not have; ... [and] (c) Any representations on or within a product or its packaging or in advertising or promotional materials which would constitute a deceptive act shall be the deceptive act both of the supplier who places such a representation thereon or therein, or who authored such materials, and such suppliers who shall state orally or in writing that such representation is true if such other supplier shall know or have reason to know that such representation was false." Ind. Code § 24-5-0.5-3.

920. As detailed above, Defendants engaged in deceptive acts in violation of the Indiana

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DCSA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to

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state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

921. Defendants owed and continue to owe Plaintiff McDaniel and the Indiana members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

922. Defendants knew or should have known that their conduct was in violation of the

Indiana DCSA.

923. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff McDaniel and the Indiana members of the Class, and continued to engage in unfair and deceptive practices in violation of the Indiana DCSA.

924. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff McDaniel and the Indiana members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff McDaniel and the Indiana members of the Class.

925. Plaintiff McDaniel and the Indiana members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused McDaniel and the Indiana members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Indiana DCSA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

926. Plaintiff McDaniel and the Indiana members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

927. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such,

Defendants' unlawful acts and practices complained of herein affect the public interest.

928. Pursuant to Ind. Code § 24-5-0.5-4, Plaintiff and the Indiana members of the Class seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$500 for each Indiana member of the Class, including treble damages up to \$1,000 for Defendants' willfully deceptive acts.

929. Plaintiff also seeks punitive damages based on the outrageousness and recklessness of the Defendants' conduct and their high net worth.

Q. VIOLATIONS OF THE KANSAS CONSUMER PROTECTION ACT (Kan. Stat. Ann. § 50-623, et seq.)

930. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

931. Plaintiffs Rosetta Serrano and Lesley Huston (for the purpose of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Kansas at any relevant time (the "Kansas members of the Class") against Mylan (for the purposes of this section, "Defendants").

932. Defendants are "suppliers" under the Kansas Consumer Protection Act ("Kansas CPA"), Kan. Stat. Ann. § 50-624(1).

933. Plaintiffs and the Kansas members of the Class are "consumers," within the meaning of Kan. Stat. Ann. § 50-624(b).

934. The sale of the EpiPen products described herein to the Plaintiffs and the Kansas members of the Class were "consumer transactions" within the meaning of Kan. Stat. Ann. § 50-624(c).

935. The Kansas CPA states "[n]o supplier shall engage in any deceptive act or practice

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in connection with a consumer transaction," Kan. Stat. Ann. § 50-626(a), and that deceptive acts or practices include: (1) knowingly making representations or with reason to know that "(A) Property or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have;" and "(D) property or services are of particular standard, quality, grade, style or model, if they are of another which differs materially from the representation;" "(2) the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact;" "(3) the willful failure to state a material fact, or the willful concealment, suppression or omission of a material fact," and "(7) making false or misleading representations, knowingly or with reason to know, of fact concerning the reason for, existence of or amounts of price reductions, or the price in comparison to prices of competitors or one's own price at a past or future time." The Kansas CPA also provides that "[n]o supplier shall engage in any unconscionable act or practice in connection with a consumer transaction." Kan. Stat. Ann. § 50-627(a).

936. As detailed above, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Kansas CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the

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EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic

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versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

937. Defendants owed and continue to owe Plaintiffs Serrano and Huston, and the Kansas members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

938. Defendants knew or should have known that their conduct was in violation of the Kansas CPA.

939. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Serrano and Huston, and the Kansas members of the Class, and continued to engage in unfair and deceptive practices in violation of the Kansas CPA.

940. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Serrano and Huston, and the Kansas members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers,

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including Plaintiffs Serrano and Huston, and the Kansas members of the Class.

941. Plaintiffs Serrano and Huston, and the Kansas members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Serrano and Huston, and the Kansas members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Kansas CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

942. Plaintiffs Serrano and Huston, and the Kansas members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

943. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

944. Pursuant to Kan. Stat. Ann. § 50-634, Plaintiffs and the Kansas members in the Class seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$10,000 for each Plaintiff and each Kansas member of the Class.

945. Plaintiffs also seek an order enjoining Defendants' unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees, and any other just and proper relief available under Kan. Stat. Ann § 50-623, *et seq.*

R. VIOLATIONS OF THE KENTUCKY CONSUMER PROTECTION ACT (Ky. Rev. Stat. § 367.110, *et seq.*)

946. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

947. Plaintiff Joy Shepard (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Kentucky at any relevant time (the "Kentucky members of the Class") against Mylan (for the purposes of this section, "Defendants").

948. Defendants, Plaintiff Shepard, and the Kentucky members of the Class are "persons" within the meaning of the Ky. Rev. Stat. § 367.110(1).

949. Defendants engaged in "trade" or "commerce" within the meaning of Ky. Rev. Stat. § 367.110(2).

950. The Kentucky Consumer Protection Act (the "Kentucky CPA") prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Ky. Rev. Stat. Ann. 367.170.

951. As detailed above, Defendants engaged in unfair, misleading, false and deceptive acts in violation of the above-noted provisions of the Kentucky CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the

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market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices

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by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

952. Defendants owed and continue to owe Plaintiff Shepard and the Kentucky members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

953. Defendants knew or should have known that their conduct was in violation of the Kentucky CPA.

954. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Shepard and the Kentucky members of the Class, and continued to engage in unfair and deceptive practices in violation of the Kentucky CPA.

955. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Shepard and the Kentucky members of the Class, and

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were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Shepard and the Kentucky members of the Class.

956. Plaintiff Shepard and the Kentucky members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Shepard and the Kentucky members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Kentucky CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

957. Plaintiff Shepard and the Kentucky members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

958. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest

959. Pursuant to Ky. Rev. Stat. Ann. § 367.220, Plaintiff Shepard and the Kentucky members of the Class seek to recover actual damages in an amount to be determined at trial; an order enjoining Defendants' unfair, unlawful, and/or deceptive practices; declaratory relief; attorneys' fees; and any other just and proper relief available under Ky. Rev. Stat. Ann. § 367.220.

S. VIOLATIONS OF THE LOUISIANA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW (La. Rev. Stat. § 51:1401, et seq.)

960. Plaintiffs incorporate by reference each preceding paragraph as though fully set

forth herein.

961. Plaintiff Eileen Montet (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Louisiana at any relevant time (the "Louisiana members of the Class") against Mylan (for the purposes of this section, "Defendants").

962. Defendants, Plaintiff Montet, and the Louisiana members of the Class are "persons" within the meaning of the La. Rev. Stat. § 51:1402(8).

963. Plaintiff Montet and the Louisiana members of the Class are "consumers" within the meaning of La. Rev. Stat. § 51:1402(1).

964. Defendants engaged in "trade" or "commerce" within the meaning of <u>La. Rev. Stat.</u> <u>§ 51:1402(10)</u>.

965. The Louisiana Unfair Trade Practices and Consumer Protection Law ("Louisiana CPL") makes unlawful "deceptive acts or practices in the conduct of any trade or commerce." <u>La.</u> <u>Rev. Stat. § 51:1405(A)</u>.

966. In the course of their business, Defendants engaged in deceptive acts or practices in violation of the Louisiana CPL by, at a minimum: (a) making material misrepresentations regarding the reason(s) for increasing the price of the EpiPen products described herein; (b) making material misrepresentations regarding the reason(s) EpiPen products are sold only in two packs; (c) causing confusion or misunderstanding regarding the National Institute of Allergy and Infectious Diseases' advice regarding certain EpiPen products described herein, including the EpiPen 2-Pak; (d) causing confusion or misunderstanding regarding the approval of doctors and panelists regarding certain EpiPen products described herein, including the EpiPen 2-Pak, by failing to disclose that Defendants provided financial incentives for their testimony, which was

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later used as a pretext for Mylan to start selling the EpiPen only as a 2-Pak in the United States; (e) misstating or making misleading statements to the public about the reasons for, existence of, or amounts of, price reductions achieved by the EpiPen4Schools program, EpiPen rebates, EpiPen coupons, and generic EpiPen, including the statement that 80% of consumers with insurance pay nothing for the EpiPen; (f) exploiting a dominant market position to unconscionably and unfairly increase the price of the EpiPen products described herein from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States, which doubles the already-inflated price paid by every consumer; (h) misrepresenting and/or creating confusion regarding the medical necessity of the EpiPen 2-Pak; and, as detailed above, and (i) providing false testimony to Congress in September 2016 and at the Forbes Health Summit in December 2016.

967. Defendants owed and continue to owe Plaintiff Montet and the Louisiana members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

968. Defendants knew or should have known that their conduct was in violation of the Louisiana CPL.

969. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Montet and the Louisiana members of the Class, and continued to engage in unfair and deceptive practices in violation of the Louisiana CPL.

970. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Montet and the Louisiana members of the Class, and

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were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Montet and the Louisiana members of the Class.

971. Plaintiff Montet and the Louisiana members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Montent and the Louisiana members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Louisiana CPL did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

972. Plaintiff Montet and the Louisiana members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

973. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

974. Pursuant to La. Rev. Stat. § 51:1409, Plaintiff Montet and the Louisiana members of the Class seek to recover actual damages in an amount to be determined at trial; treble damages for Defendants' knowing violations of the Louisiana CPL; an order enjoining Defendants' unfair, unlawful, and/or deceptive practices; declaratory relief; attorneys' fees; and any other just and proper relief available under La. Rev. Stat. § 51:1409.

T. MAINE UNFAIR TRADE PRACTICES ACT (MUTPA) AND UNIFORM DECEPTIVE TRADE PRACTICES ACT (MUDTPA)

(5 M.R.S.A. § 205-A et seq., 5 M.R.S.A. § 1211 et seq.)

975. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

976. Plaintiff Lorraine Wight (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Maine at any relevant time (the "Maine members of the Class") against Mylan (for the purposes of this section, "Defendants").

977. Defendants, Plaintiff Wight, and the Maine members of the Class are "persons" within the meaning of Me. Rev. Stat. Ann. Tit. 5, § 206(2).

978. Defendants are engaged in "trade" or "commerce" within the meaning of Me. Rev. Stat. Ann. Tit. 5, § 206(3).

979. The Maine Unfair Trade Practices Act (the "MUTPA") makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce...." Me. Rev. Stat. Ann. Tit. 5 § 207.

980. In addition, the Maine Uniform Deceptive Trade Practices Act (the "MUDTPA"), 5 M.R.S.A. § 1211 *et seq.*, prohibits the use of various deceptive trade practices, including: "Caus[ing] [a] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services; Caus[ing] [a] likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another," "Represent[ing] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have, or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;" "Mak[ing] false or misleading statements of fact concerning the reasons for, existence of or amounts of, price reductions;" and "Engag[ing]

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in any other conduct which similarly creates a likelihood of confusion or of misunderstanding."

As detailed above, Defendants engaged in deceptive acts in violation of the 981. MUTPA and the MUDTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by

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Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

982. Defendants owed and continue to owe Plaintiff Wight and the Maine members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

983. Defendants knew or should have known that their conduct was in violation of the MUTPA and the MUDTPA.

984. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Wight and the Maine members of the Class, and continued to engage in unfair and deceptive practices in violation of the MUTPA and the MUDTPA.

985. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Wight and the Maine members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Wight and the Maine members of the Class.

986. Plaintiff Wight and the Maine members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff Wight and the Maine members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the MUTPA and the MUDTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

987. Plaintiff Wight and the Maine members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of

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increased and unfair prices paid for the EpiPen products described herein.

988. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

989. Pursuant the MUTPA and the MUDTPA, Plaintiff Wight and the Maine members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the MUTPA and the MUDTPA.

990. Prior to this filing, certain Plaintiffs sent a letter complying with Me. Rev. Stat. Ann. Tit. 5, § 213(1-A). Because Defendants failed to remedy their unlawful conduct within the requisite time period, Plaintiff seeks all damages and relief to which Plaintiffs and the Maine members of the Class are entitled.

U. VIOLATIONS OF THE MARYLAND CONSUMER PROTECTION ACT (Md. Code Com. Law § 13-101, et seq.)

991. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

992. Plaintiff Teia Amell (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Maryland at any relevant time (the "Maryland members of the Class") against Mylan (for the purposes of this section, "Defendants").

993. Defendants, Plaintiff, and the Maryland members of the Class are "persons" within the meaning of Md. Code Com. Law § 13-101(h).

994. The Maryland Consumer Protection Act ("Maryland CPA") provides that a person may not engage in any unfair or deceptive trade practice in the sale of any consumer good. Md.

Code Com. Law § 13-303.

995. Md. Code Ann., Com. Law § 13-101 *et seq.*, prohibits the use of any "unfair or deceptive trade practices" including any "(1) False, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers; (2) Representation that: (i) Consumer goods, consumer realty, or consumer services have a sponsorship, approval, accessory, characteristic, ingredient, use, benefit, or quantity which they do not have; (ii) A merchant has a sponsorship, approval, status, affiliation, or connection which he does not have;" "(3) Failure to state a material fact if the failure deceives or tends to deceive;" "(6) False or misleading representation of fact which concerns [t]he reason for or the existence or amount of a price reduction;" and "(9) Deception, fraud, false pretense, false premise, misrepresentation, or knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same in connection with [t]he promotion or sale of any consumer goods, consumer realty, or consumer service." *Id.*

996. In the course of their business, Defendants engaged in unfair and deceptive acts in violation of the Maryland CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent,

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deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general

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public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

997. Defendants owed and continue to owe Plaintiff Amell and the Maryland members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

998. Defendants knew or should have known that their conduct was in violation of the Maryland CPA.

999. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Amell and the Maryland members of the Class, and continued to engage in unfair and deceptive practices in violation of the Maryland CPA.

1000. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Amell and the Maryland members of the Class, and

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were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Amell and the Maryland members of the Class.

1001. Plaintiff Amell and the Maryland members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Maryland members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Maryland CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1002. Plaintiff Amell and the Maryland members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1003. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1004. Pursuant to Md. Code Com. Law § 13-408, Plaintiff and the Maryland Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Maryland CPA.

V. DECEPTIVE ACTS OR PRACTICES PROHIBITED BY MASSACHUSETTS LAW (Mass. Gen. Laws Ch. 93a, § 1, et seq.)

1005. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1006. Plaintiff Todd Beaulieu (for the purpose of this section, "Plaintiff") brings this

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action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or have been Massachusetts residents at any relevant time (the "Massachusetts members of the Class") against Mylan (for the purposes of this section, "Defendants").

1007. Defendants, Plaintiff Beaulieu, and the Massachusetts members of the Class are "persons" within the meaning of Mass. Gen. Laws ch. 93A, § 1(a).

1008. Defendants engaged in "trade" or "commerce" within the meaning of Mass. Gen. Laws ch. 93A, § 1(b).

1009. Massachusetts law (the "Massachusetts CPA") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, § 2.

1010. As detailed above, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Massachusetts CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the united states; (b) failing to disclose and/or concealing from the public the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material

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misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by

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Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1011. As alleged throughout this Complaint, Mylan also engaged in unfair and unscrupulous practices by raising the price of life-saving medication without justification and limiting patient access to alternatives resulting in substantial harm.

1012. Mylan's conduct offends public policy and is immoral, unethical, oppressive, unscrupulous, or substantial injurious to consumers.

1013. Additionally, Mylan's conduct was deceptive because it caused Plaintiff and the Massachusetts members of the Class to act differently from the way they would have otherwise acted.

1014. Defendants owed and continue to owe Plaintiff Beaulieu, and the Massachusetts members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1015. Defendants knew or should have known that their conduct was in violation of the Massachusetts CPA.

1016. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Beaulieu, and the Massachusetts members of the Class, and continued to

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engage in unfair and deceptive practices in violation of the Massachusetts CPA.

1017. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Beaulieu, and the Massachusetts members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Beaulieu, and the Massachusetts members of the Class

1018. Plaintiff Beaulieu, and the Massachusetts members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Massachusetts members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Massachusetts CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1019. Plaintiff Beaulieu, and the Massachusetts members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1020. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1021. Pursuant to Mass. Gen. Laws ch. 93A, § 9, Plaintiff Beaulieu and the Massachusetts members of the Class seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$25 for

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Plaintiff and each Massachusetts member of the Class. Because Defendants' conduct was committed willfully and knowingly, Plaintiff is also entitled to recover, for each Massachusetts member of the Class, up to three times actual damages, but no less than two times actual damages.

1022. Plaintiff Beaulieu and the Massachusetts members of the Class also seek an order enjoining Defendants' unfair and/or deceptive acts or practices, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Massachusetts CPA.

1023. Prior to the date of this filing, certain Plaintiffs sent a letter complying with Mass. Gen. Laws ch. 93A, § 9(3). Because Defendants failed to remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiff and the Massachusetts members of the Class are entitled.

W. VIOLATIONS OF THE MICHIGAN CONSUMER PROTECTION ACT (Mich. Comp. Laws § 445.903, et seq.)

1024. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1025. Plaintiffs Anastasio Johnston and Annette Sutorik (for the purposes of this section, "Plaintiffs") bring this count on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Michigan at any relevant time (the "Michigan members of the Class") against Mylan (for the purposes of this section, "Defendants").

1026. Plaintiffs Johnston and Sutorik, and the Michigan members of the Class are "person[s]" within the meaning of the Mich. Comp. Laws § 445.902(1)(d).

1027. At all relevant times, Defendants were "persons" engaged in "trade or commerce" within the meaning of the Mich. Comp. Laws § 445.902(1)(d) and (g).

1028. The Michigan Consumer Protection Act ("Michigan CPA") specifically prohibits "[c]harging the consumer a price that is grossly in excess of the price at which similar property or services are sold." Mich. Comp. Laws § 445.903(z)

1029. Defendants acted in violation of § 445.903(z), as noted in detail above, by selling EpiPen products at a price that is grossly in excess of competing branded epinephrine injector products sold both in the United States and internationally, competing generic epinephrine injector products, and even Defendants' own generic epinephrine injector product.

1030. The Michigan CPA also prohibits "[u]nfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce" including: "(a) Causing a probability of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services," "(c) Representing that goods or services have ... characteristics ... that they do not have;" "(e) Representing that goods or services are of a particular standard ... if they are of another;" "(i) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" "(s) Failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer;" "(bb) Making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is;" and "(cc) Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner." Mich. Comp. Laws § 445.903(1).

1031. As detailed above, Defendants engaged in unfair, unconscionable, and deceptive acts in violation of the above-noted provisions of the Michigan CPA by, at a minimum: ((a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the

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EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in

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setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1032. Defendants owed and continue to owe Plaintiffs and the Michigan members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1033. Defendants knew or should have known that their conduct was in violation of the Michigan CPA.

1034. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Michigan members of the Class, and continued to engage in unfair and deceptive practices in violation of the Michigan CPA.

1035. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs the Michigan members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the Michigan members of the Class.

1036. Plaintiffs and the Michigan members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs and the Michigan members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Michigan CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1037. Plaintiffs and the Michigan members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1038. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1039. Plaintiffs and the Michigan members of the Class seek injunctive relief to enjoin Defendants from continuing their unfair and deceptive acts; monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of \$250 for Plaintiffs and each Michigan member of the Class; reasonable attorneys' fees; and any other just and proper relief available under Mich. Comp. Laws § 445.911.

1040. Plaintiffs and the Michigan members of the Class also seek punitive damages against Defendants because they carried out despicable conduct with willful and conscious disregard of the rights and safety of others.

X. VIOLATIONS OF MINNESOTA PREVENTION OF CONSUMER FRAUD ACT (Minn. Stat. § <u>325f.68</u>, *et seq.*)

1041. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1042. Plaintiff Heather DeStefano (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or who have been residents of Minnesota at any relevant time (the "Minnesota members of the Class") against Mylan (for the purposes of this section, "Defendants").

1043. The EpiPen products described herein constitute "merchandise" within the meaning of Minn. Stat. § 325F.68(2).

1044. The Minnesota Prevention of Consumer Fraud Act ("Minnesota CFA") prohibits "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby" Minn. Stat. § 325F.69(1).

1045. As detailed above, Defendants engaged in deceptive acts in violation of the Minnesota CFA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and

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permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy

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benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1046. Defendants owed and continue to owe Plaintiff DeStefano and the Minnesota members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1047. Defendants knew or should have known that their conduct was in violation of the Minnesota CFA.

1048. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding

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the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff DeStefano and the Minnesota members of the Class, and continued to engage in unfair and deceptive practices in violation of the Minnesota CFA.

1049. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff DeStefano and the Minnesota members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff DeStefano and the Minnesota members of the Class.

1050. Plaintiff DeStefano and the Minnesota members of the Class of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Minnesota members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Minnesota CFA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1051. Plaintiff DeStefano and the Minnesota members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1052. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1053. Pursuant to Minn. Stat. § 8.31(3)(a), Plaintiff and the Minnesota Class seek actual

damages, attorneys' fees, and any other just and proper relief available under the Minnesota CFA.

1054. Plaintiff also seeks punitive damages under Minn. Stat. § 549.20(1)(a) given the clear and convincing evidence that Defendants' acts show deliberate disregard for the rights or safety of others.

Y. VIOLATIONS OF MINNESOTA UNIFORM DECEPTIVE TRADE PRACTICES ACT (Minn. Stat. § 325d.43-48, *et seq.*)

1055. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1056. Plaintiff Heather Destefano (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or who have been residents of Minnesota at any relevant time (the "Minnesota members of the Class") against Mylan (for the purposes of this section, "Defendants").

1057. The Minnesota Deceptive Trade Practices Act ("Minnesota DTPA") prohibits deceptive trade practices, which occur when a person "(2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;" "(5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;" "(7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;" "(9) advertises goods or services with intent not to sell them as advertised;" "(11) makes false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" or " (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding." Minn. Stat. §

325D.44.

1058. As detailed above, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Minnesota DTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent

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nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1059. Defendants owed and continue to owe Plaintiff DeStefano and the Minnesota members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen

products described herein.

1060. Defendants knew or should have known that their conduct was in violation of the Minnesota DTPA.

1061. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff DeStefano and the Minnesota members of the Class, and continued to engage in unfair and deceptive practices in violation of the Minnesota DTPA.

1062. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff DeStefano and the Minnesota members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff DeStefano and the Minnesota members of the Class.

1063. Plaintiff DeStefano and the Minnesota members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Minnesota members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Minnesota DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1064. Plaintiff DeStefano and the Minnesota members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1065. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1066. Pursuant to Minn. Stat. § 8.31(3a) and 325D.45, Plaintiffs and the Minnesota Class seek actual damages, attorneys' fees, and any other just and proper relief available under the Minnesota DTPA.

1067. Plaintiffs also seek punitive damages under Minn. Stat. § 549.20(1)(a) give the clear and convincing evidence that Defendants' acts show deliberate disregard for the rights or safety of others.

Z. VIOLATIONS OF MISSISSIPPI CONSUMER PROTECTION ACT (Miss. Code. Ann. § 75-24-1, et seq.)

1068. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

1069. Plaintiff Elizabeth Williamson (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Mississippi at any relevant time (the "Mississippi members of the Class") against Mylan (for the purposes of this section, "Defendants").

1070. The Mississippi Consumer Protection Act ("Mississippi CPA") prohibits "unfair or deceptive trade practices in or affecting commerce." Miss. Code. Ann. § 75-24-5(1). Unfair or deceptive practices include, but are not limited to, "(b) Misrepresentation of the source, sponsorship, approval, or certification of goods or services; (c) Misrepresentation of affiliation, connection, or association with, or certification by another;" "(e) Representing that goods or

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services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;" "(g) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;" "(i) Advertising goods or services with intent not to sell them as advertised;" and "(k) Misrepresentations of fact concerning the reasons for, existence of, or amounts of price reductions." Miss. Code. Ann. § 75-24-5.

1071. As detailed above, Defendants engaged in misleading, false and deceptive acts in violation of the above-noted provisions of the Mississippi CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools

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program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens'

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petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1072. Defendants owed and continue to owe Plaintiff Williamson and the Mississippi members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1073. Defendants knew or should have known that their conduct was in violation of the Mississippi CPA.

1074. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Williamson and the Mississippi members of the Class, and continued to engage in unfair and deceptive practices in violation of the Mississippi CPA.

1075. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Williamson and the Mississippi members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Williamson and the Mississippi members of the Class.

1076. Plaintiff Williamson and the Mississippi members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Mississippi members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute

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of limitations for filing claims against Defendants under the Mississippi CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1077. Plaintiff Williamson and the Mississippi members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1078. Plaintiff seeks actual damages in an amount to be determined at trial any other just and proper relief available under the Mississippi CPA.

AA. VIOLATIONS OF MISSOURI MERCHANDISING PRACTICES ACT (MO. REV. STAT. § 407.010, ET SEQ.)

1079. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1080. Plaintiffs Shannon Clements and Local 282 (for the purpose of this section, "Plaintiffs") bring this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Missouri at any relevant time (the "Missouri members of the Class") against Mylan (for the purposes of this section, "Defendants").

1081. Defendants, Plaintiffs Clements, Local 282, and the Missouri members of the Class are "persons" within the meaning of <u>Mo. Rev. Stat. § 407.010(5)</u>.

1082. Defendants engaged in "trade" or "commerce" in the State of Missouri within the meaning of Mo. Rev. Stat. § 407.010(7).

1083. The Missouri Merchandising Practices Act ("Missouri MPA") makes unlawful the "act, use or employment by any person of any deception, fraud, false pretense, misrepresentation, unfair practice, or the concealment, suppression, or omission of any material fact in connection

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with the sale or advertisement of any merchandise." Mo. Rev. Stat. § 407.020.

1084. An "unfair practice" under Missouri law includes several types; Defendants have engaged in an "unfair practice" with the pricing of the EpiPen for several independent reasons.

1085. First, according to Missouri law, an "(1) An unfair practice is any practice which— (A) Either— 1. Offends any public policy as it has been established by the Constitution, statutes or common law of this state, or by the Federal Trade Commission, or its interpretive decisions; or 2. Is unethical, oppressive or unscrupulous; and (B) Presents a risk of, or causes, substantial injury to consumers." 15 CSR 60-8.020.

1086. Defendants' conduct constitutes an unfair practice in that Mylan sells the EpiPen for a price that is unethical, oppressive, and unscrupulous.

1087. Defendants' unjustified, inflated pricing of the EpiPen is unethical because it places a life-saving product out of reach of many consumers. The EpiPen's \$600+ price-tag is oppressive because it overcharges those consumers who are able to pay well beyond the \$300 price for the generic version of the same product (also an excessive price), causing substantial injury to consumers. The EpiPen's list price is unscrupulous because it is the result of Defendants' desire to extra maximum financial gain from a group of patients whose medical conditions do not allow them to say "No" to Defendants' ransom.

1088. Defendants' conduct is also an unfair practice because Defendants only sells the EpiPen as a 2-Pak in the United States.

1089. Even if the purchase price paid is less than \$608, Mylan's list price is price gouging that prevents critical medicine from reaching Missouri consumers.

1090. Second, according to Missouri law, an unconscionable practice is an "unfair practice." 15 CSR 60-8.080.

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1091. Defendants have engaged in an unconscionable practice by selling the EpiPen for an unconscionable list price. By doing so, Mylan took advantage of its unequal bargaining power and exploited the vulnerability of Missouri consumers.

1092. Whether or not Missouri consumers actually paid the full list price of over \$600 is immaterial to the MMPA violation. If employers or prescription benefits or insurance companies paid any portion of the cost of the EpiPen, Missouri consumers were injured because their insurance premiums were affected as a result of Mylan's price gouging and unnecessary price increases of the EpiPen.

1093. Fourth, according to Missouri law, it is "unfair practice" to sale a product and to engage in any practice that violates state or federal law intended to protect the public. 15 CSR 60-8.090.

1094. Plaintiffs and the Missouri members of the Class purchased the EpiPen for personal, family, or household purposes and thereby suffered an ascertainable loss as a result of Mylan's unlawful conduct as alleged herein, including the difference between a reasonable cost of the EpiPen and the \$600-plus list price charged by Mylan to Missouri consumers.

1095. As detailed above, Defendants also engaged in unfair, false, and deceptive practices in violation of the above-noted provisions of the Missouri MPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at

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discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's

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access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1096. Defendants conduct as described herein is unethical, oppressive, or unscrupulous and/or it presented a risk of substantial injury to consumers. Such acts are unfair practices in violation of 15 Mo. Code of State Reg. 60-8.020.

1097. Defendants owed and continue to owe Plaintiffs Clements, Local 282, and the Missouri members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1098. Defendants knew or should have known that their conduct was in violation of the Missouri MPA

1099. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead

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regulators, Plaintiffs Clements, Local 282, and the Missouri members of the Class, and continued to engage in unfair and deceptive practices in violation of the Missouri MPA.

1100. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Clements, Local 282, and the Missouri members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Clements and the Missouri members of the Class.

1101. Plaintiffs Clements, Local 282, and the Missouri members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Missouri members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Missouri MPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1102. Plaintiffs Clements, Local 282, and the Missouri members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1103. As such Defendants are liable to Plaintiffs Clements, Local 282, and the Missouri members of the Class for damages in amounts to be proven at trial, including attorneys' fees, costs, and punitive damages, as well as injunctive relief enjoining Defendants' unfair and deceptive practices, and any other just and proper relief under <u>Mo. Rev. Stat. § 407.025</u>.

BB. VIOLATIONS OF THE NEBRASKA CONSUMER PROTECTION ACT (NEB. REV. STAT. § 59-1601, ET SEQ.)

1104. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1105. Plaintiff Mark Kovarik (for the purposes of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are residents or have been residents of Nebraska during the relevant period (the "Nebraska members of the Class") against Mylan (for the purposes of this section, "Defendants").

1106. Plaintiff and the Nebraska members of the Class purchased the EpiPen primarily for personal, family or household purposes, as alleged herein.

1107. Defendants are "person[s]" within the meaning of Neb. Rev. Stat. § 59-1601(1).

1108. Defendants are engaged in "trade" or "commerce" within the meaning of Neb. Rev. Stat. § 59-1601(2).

1109. The Nebraska Consumer Protection Act ("Nebraska CPA") makes unlawful "unfair or deceptive acts or practices in the conduct of any trade or commerce." Neb. Rev. Stat. § 59-1602.

1110. In the course of their business, Defendants, through their agents, employees, and/or subsidiaries, violated the Nebraska CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent,

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deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general

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public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1111. Defendants owed and continue to owe Plaintiff Kovarik and the Nevada members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1112. Defendants knew or should have known that their conduct was in violation of the Nebraska CPA.

1113. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Kovarik and the Nebraska members of the Class, and continued to engage in unfair and deceptive practices in violation of the Nebraska CPA.

1114. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Nebraska members of the Class, and were

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likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Nebraska members of the Class.

1115. Plaintiff and Nebraska members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Nebraska members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Nebraska CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1116. Plaintiff and the Nebraska members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1117. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1118. Pursuant to Neb. Rev. Stat. § 59-1601, Plaintiffs and the Nebraska members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts and practices, actual damages, punitive damages, attorneys' fees, costs, and any other just and proper relief available under the Nebraska CPA.

CC. VIOLATIONS OF THE NEVADA DECEPTIVE TRADE PRACTICES ACT (Nev. Rev. Stat. § 598.0903, et seq.)

1119. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

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1120. Plaintiffs Miriam Clarke and Local 282 (for the purpose of this section, "Plaintiffs") bring this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of Nevada at any relevant time (the "Nevada members of the Class") against Mylan (for the purposes of this section, "Defendants").

1121. The Nevada Deceptive Trade Practices Act ("Nevada DTPA"), Nev. Rev. Stat. § 598.0903, et seq. prohibits deceptive trade practices. Nev. Rev. Stat. § 598.0915 provides that a person engages in a "deceptive trade practice" if, in the course of business or occupation, the person: "2. Knowingly makes a false representation as to the source, sponsorship, approval or certification of goods or services for sale or lease; 3. Knowingly makes a false representation as to affiliation, connection, association with or certification by another person;" "5. Knowingly makes a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease or a false representation as to the sponsorship, approval, status, affiliation or connection of a person therewith"; "7. Represents that goods or services for sale or lease are of a particular standard, quality or grade, or that such goods are of a particular style or model, if he or she knows or should know that they are of another standard, quality, grade, style or model"; "9. Advertises goods or services with intent not to sell or lease them as advertised"; "13. Makes false or misleading statements of fact concerning the price of goods or services for sale or lease, or the reasons for, existence of or amounts of price reductions." or "15. Knowingly makes any other false representation in a transaction."

1122. In the course of their business, Defendants engaged in deceptive trade practices in violation of the Nevada DTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and

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permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy

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benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1123. Defendants owed and continue to owe Plaintiffs Clarke, Local 282, and the Nevada members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1124. Defendants knew or should have known that their conduct was in violation of the Nevada DTPA.

1125. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding

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the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Clarke, Local 282, and the Nevada members of the Class, and continued to engage in unfair and deceptive practices in violation of the Nevada DTPA.

1126. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Clarke, Local 282, and the Nevada members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Clarke, Local 282, and the Nevada members of the Class.

1127. Plaintiffs Clarke, Local 282, and the Nevada members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Clarke, Local 282, and the Nevada members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Nevada DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1128. Plaintiffs Clarke, Local 282, and the Nevada members of the Class suffered injuryin-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1129. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1130. Accordingly, Plaintiffs Clarke, Local 282, and the Nevada members of the Class

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seek their actual damages, punitive damages, an order enjoining Defendants' deceptive acts or practices, costs of Court, attorney's fees, and all other appropriate and available remedies under the Nevada Deceptive Trade Practices Act. <u>Nev. Rev. Stat. § 41.600</u>.

DD. VIOLATIONS OF N.H. CONSUMER PROTECTION ACT (N.H. Rev. Stat. Ann. § 358-a:1, et seq.)

1131. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1132. Plaintiff Laura Chapin (for the purpose of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of New Hampshire at any relevant time (the "New Hampshire members of the Class") against Mylan (for the purposes of this section, "Defendants").

1133. Plaintiff Chapin, the New Hampshire members of the Class, and Defendants are "persons" under the New Hampshire Consumer Protection Act ("New Hampshire CPA"), N.H. Rev. Stat. § 358-A:1.

1134. Defendants' actions as set forth herein occurred in the conduct of trade or commerce as defined under N.H. Rev. Stat. § 358-A:1.

1135. The New Hampshire CPA prohibits a person, in the conduct of any trade or commerce, from using "any unfair or deceptive act or practice," including "but ... not limited to, the following: (II) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (III) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another; ... (V) Representing that goods or services have ... characteristics, ... uses, benefits, or quantities that they do not have;" "(VII) Representing that goods or services are of a particular standard, quality, or grade, ... if they are of another;" "(IX) Advertising goods or services with intent not to

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sell them as advertised;" "(XI) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" and "XIV. Pricing of goods or services in a manner that tends to create or maintain a monopoly, or otherwise harm competition." N.H. Rev. Stat. § 358-A:2.

1136. As detailed above, Defendants engaged in unfair and deceptive acts in violation of the New Hampshire CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by

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consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

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1137. Defendants owed and continue to owe Plaintiff Chapin and the New Hampshire members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1138. Defendants knew or should have known that their conduct was in violation of the New Hampshire CPA.

1139. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Chapin and the New Hampshire members of the Class, and continued to engage in unfair and deceptive practices in violation of the New Hampshire CPA.

1140. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Chapin and the New Hampshire members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Chapin and the New Hampshire members of the Class.

1141. Plaintiff Chapin and the New Hampshire members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the New Hampshire members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the New Hampshire CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

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1142. Plaintiff Chapin and the New Hampshire members of the Class suffered injury-infact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1143. Because Defendants' willful conduct caused injury to the New Hampshire members of the Class' property through violations of the New Hampshire CPA, the New Hampshire members of the Class seek recovery of actual damages or \$1,000, whichever is greater, treble damages, costs and reasonable attorneys' fees, an order enjoining Defendants' unfair and/or deceptive acts and practices, and any other just and proper relief under N.H. Rev. Stat. § 358-A:10.

EE. VIOLATIONS OF THE NEW JERSEY CONSUMER FRAUD ACT (N.J. Stat. Ann. §§ 56:8-1, et seq.)

1144. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1145. Plaintiffs Maria Giurland and Local 282 (for the purpose of this section, "Plaintiffs") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of New Jersey at any relevant time (the "New Jersey members of the Class") against Mylan (for the purposes of this section, "Defendants").

1146. Plaintiff Giurland, Local 282, the New Jersey members of the Class, and Defendants are persons under the New Jersey Consumer Fraud Act, <u>N.J. Stat. § 56:8-1(d)</u>.

1147. Defendants engaged in "sales" of "merchandise" within the meaning of <u>N.J. Stat.</u> <u>§ 56:8-1(c), (e)</u>.

1148. Defendants' actions as set forth herein occurred in the conduct of trade or commerce within the meaning of the New Jersey Consumer Fraud Act.

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1149. The New Jersey Consumer Fraud Act ("New Jersey CFA") makes unlawful "[t]he act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby..." N.J. Stat. § 56:8-2.

1150. In the course of their business, Defendants engaged in unfair and deceptive practices in violation of the New Jersey CFA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools

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program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens'

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petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1151. Defendants owed and continue to owe Plaintiffs Giurland, Local 282, and the New Jersey members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1152. Defendants knew or should have known that their conduct was in violation of the New Jersey CFA.

1153. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs Giurland, Local 282, and the New Jersey members of the Class, and continued to engage in unfair and deceptive practices in violation of the New Jersey CFA.

1154. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs Giurland, Local 282, and the New Jersey members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Giurland, Local 282, and the New Jersey members of the Class.

1155. Plaintiffs Giurland, Local 282, and the New Jersey members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Giurland, Local 282, and the New Jersey members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described

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herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the New Jersey CFA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1156. Plaintiffs Giurland, Local 282, and the New Jersey members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1157. As a result of the foregoing wrongful conduct of Defendants, Plaintiffs and the New Jersey members of the Class have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including, but not limited to, actual and statutory damages, treble damages, an order enjoining Defendants' deceptive and unfair conduct, costs and reasonable attorneys' fees under N.J. Stat. § 56:8-19, and all other just and appropriate relief.

FF. VIOLATIONS OF THE NEW MEXICO UNFAIR TRADE PRACTICES ACT (N.M. Stat. Ann. §§ 57-12-1, et seq.)

1158. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

1159. Plaintiff (for the purpose of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or who have been residents of the State of New Mexico at any relevant time (the "New Mexico members of the Class") against Mylan (for the purposes of this section, "Defendants").

1160. Defendants, Plaintiff and the New Mexico members of the Class are or were "person[s]" under the New Mexico Unfair Trade Practices Act ("New Mexico UTPA"), N.M. Stat. Ann. § 57-12-2.

1161. Defendants actions as set forth herein occurred in the conduct of trade or commerce

as defined under N.M. Stat. Ann. § 57-12-2.

1162. The New Mexico UTPA makes unlawful "a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services ... by a person in the regular course of the person's trade or commerce, that may, tends to or does deceive or mislead any person," including causing confusion or misunderstanding as to the source, sponsorship, but not limited to: "(2) approval or certification of goods or services; (3) causing confusion or misunderstanding as to affiliation, connection or association with or certification by another; ... (5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;" "(11) making false or misleading statements of fact concerning the price of goods or services, the prices of competitors or one's own price at a past or future time or the reasons for, existence of or amounts of price reduction;" and "(14) using exaggeration, innuendo or ambiguity as to a material fact or failing to state a material fact if doing so deceives or tends to deceive."

1163. In the course of their business, Defendants engaged in unfair and misleading acts in violation of the New Mexico UTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors

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and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading,

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false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1164. Defendants owed and continue to owe Plaintiff and the New Mexico members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1165. Defendants knew or should have known that their conduct was in violation of the New Mexico UTPA.

1166. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff and the New Mexico members of the Class, and continued to engage in unfair and deceptive practices in violation of the New Mexico UTPA.

1167. Defendants' unfair and deceptive acts or practices, omissions and

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misrepresentations were material to Plaintiff and the New Mexico members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the New Mexico members of the Class

1168. Plaintiff and the New Mexico members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the New Mexico members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the New Mexico UTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1169. Plaintiff and the New Mexico members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1170. Because Defendants' unconscionable, willful conduct caused actual harm to Plaintiff and the New Mexico Class members of the Class, they seek recovery of actual damages or \$100, whichever is greater, discretionary treble damages, punitive damages, and reasonable attorneys' fees and costs, as well as all other proper and just relief available under N.M. Stat. Ann. § 57-12-10.

GG. VIOLATIONS OF NEW YORK GENERAL BUSINESS LAW § 349 (N.Y. Gen. Bus. Law § 349)

1171. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

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1172. Plaintiffs Donna Wemple, Michael Gill, Suzanne Harwood, and Local 282 (for the purpose of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of New York at any relevant time ("New York members of the Class") against Mylan (for the purposes of this section, "Defendants").

1173. Plaintiffs, the New York Class members and all Defendants are "persons" under N.Y. Gen. Bus. Law § 349(h), the New York Deceptive Acts and Practices Act ("NY DAPA").

1174. Defendants' actions as set forth herein occurred in the conduct of trade or commerce under the NY DAPA.

1175. The NY DAPA makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349.

1176. New York State General Business Law Section 349 (N.Y. Gen. Bus. § 349) broadly prohibits deceptive acts or practices in the state of New York toward consumers.

1177. As detailed above, Defendants engaged in deceptive acts toward consumers in violation of New York law in connection with the EpiPen.

1178. In the course of their business, Defendants engaged in deceptive acts or practices in violation of the NY DAPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors

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and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading,

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false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1179. Defendants owed and continue to owe Plaintiffs and the New York members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1180. Defendants knew or should have known that their conduct was in violation of the NY DAPA.

1181. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs, and the New York members of the Class, and continued to engage in unfair and deceptive practices in violation of the NY DAPA.

1182. Defendants' unfair and deceptive acts or practices, omissions and

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misrepresentations were material to Plaintiffs and the New York members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the New York members of the Class.

1183. Plaintiffs Wemple, Harwood, Local 282, and the New York members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the New York members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the NY DAPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1184. Plaintiff Wemple and Harwood and the New York members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1185. As a result of the foregoing willful, knowing, and wrongful conduct of Defendants, Plaintiffs and the New York members Class have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including but not limited to actual damages, treble damages up to \$1,000, punitive damages to the extent available under the law, reasonable attorneys' fees and costs, an order enjoining Defendants' deceptive and unfair conduct, and all other just and appropriate relief available under the NY DAPA.

HH. VIOLATIONS OF THE NORTH CAROLINA UNFAIR AND DECEPTIVE TRADE PRACTICES ACT (N.C. Gen. Stat. §§ 75-1.1, et seq.)

1186. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully

set forth herein.

1187. Plaintiffs Cassandra Cobb and Local 282 (for the purposes of this section, "Plaintiff") brings this action on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of North Carolina at any relevant time (the "North Carolina members of the Class") against Mylan (for the purposes of this section, "Defendants").

1188. Plaintiffs Cobb, Local 282, and the North Carolina Class members are persons under the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. §§ 75-1.1, *et seq.* ("NCUDTPA").

1189. Defendants' acts and practices complained of herein were performed in the course of Defendants' trade or business and thus occurred in or affected "commerce," as defined in N.C. Gen. Stat. § 75-1.1(b).

1190. The NCUDTPA makes unlawful "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce[.]" The NCUDTPA provides a private right of action for any person injured "by reason of any act or thing done by any other person, firm or corporation in violation of" the NCUDTPA. N.C. Gen. Stat. § 75-16.

1191. In the course of their business Defendants engaged in unfair and deceptive acts or practices in violation of the NCUDTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors

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and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading,

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false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1192. Defendants owed and continue to owe Plaintiffs Cobb, Local 282, and the North Carolina members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1193. Defendants knew or should have known that their conduct was in violation of the NCUDTPA.

1194. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Cobb and the North Carolina members of the Class, and continued to engage in unfair and deceptive practices in violation of the NCUDTPA.

1195. Defendants' unfair and deceptive acts or practices, omissions and

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misrepresentations were material to Plaintiff Cobb and the North Carolina members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs Cobb, Local 282, and the North Carolina members of the Class.

1196. Plaintiffs Cobb, Local 282, and the North Carolina members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs Cobb, Local 282, and the North Carolina members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the NCUDTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1197. Plaintiffs Cobb, Local 282, and the North Carolina members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1198. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1199. As a result of the foregoing wrongful conduct of Defendants, Plaintiffs and the North Carolina members of the Class have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including but not limited to treble damages, an order enjoining Defendants' deceptive and unfair conduct, court costs and reasonable attorneys' fees, and any other just and proper relief available under N.C. Gen. Stat. § 75-16.

II. VIOLATIONS OF THE OHIO CONSUMER SALES PRACTICES ACT (Ohio Rev. Code §§ 1345.01, et seq.)

1200. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1201. Plaintiffs Bowersock, North, and Local 282 (for the purposes of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Ohio at any relevant time (the "Ohio members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1202. Defendants, Plaintiffs, and the Ohio members of the Class are "persons" within the meaning of Ohio Rev. Code § 1345.01(B).

1203. Defendants are "suppliers" as defined by Ohio Rev. Code § 1345.01(C).

1204. Plaintiffs and the Ohio members of the Class are "consumers" as that term is defined in Ohio Rev. Code § 1345.01(D), and their purchase of the EpiPen products described herein are "consumer transactions" within the meaning of Ohio Rev. Code § 1345.01(A).

1205. Ohio Rev. Code § 1345.02 (the "Ohio CSPA"), prohibits unfair or deceptive acts or practices in connection with a consumer transaction. The Ohio CSPA prohibits a supplier from (i) representing that goods have characteristics, uses or benefits which the goods do not have; (ii) representing that their goods are of a particular quality or grade that the product is not; and (iii) representing that the subject of a consumer transaction has been supplied in accordance with a previous representation, if it has not.

1206. In the course of their business, Defendants engaged in unfair and deceptive practices in violation of the Ohio CSPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to

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present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or

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concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1207. Defendants owed and continue to owe Plaintiffs and the Ohio members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1208. Defendants knew or should have known that their conduct was in violation of the Ohio CSPA.

1209. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding

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the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Ohio members of the Class, and continued to engage in unfair and deceptive practices in violation of the Ohio CSPA.

1210. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs North, Local 282, and the Ohio members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs North, Local 282, and the Ohio members of the Class.

1211. Plaintiffs and Ohio members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Ohio members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Ohio CSPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1212. Plaintiffs and the Ohio members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1213. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1214. Pursuant to Ohio Rev. Code § 1345.09, Plaintiffs and the Ohio members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, actual damages

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- trebled, and attorneys' fees, costs, and any other just and proper relief, to the extend available under the Ohio CSPA.

JJ. VIOLATIONS OF THE OHIO DECEPTIVE TRADE PRACTICES ACT (Ohio Rev. Code § 4165.01, et seq.)

1215. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

1216. This claim is brought by Plaintiffs Bowersock, North, and Local 282 (for the purposes of this section "Plaintiffs") on their own behalf and on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Ohio at any relevant time (the "Ohio members of the Class") against Mylan (for the purposes of this section, "Defendants").

1217. Defendants, Plaintiffs, and the Ohio members of the Class are "persons" within the meaning of Ohio Rev. Code § 4165.01(D).

1218. Defendants took the actions complained of herein in "the course of [their] business" within the meaning of Ohio Rev. Code § 4165.02(A).

1219. The Ohio Deceptive Trade Practices Act, Ohio Rev. Code § 4165.02(A) ("Ohio DTPA") provides that a "person engages in a deceptive trade practice when, in the course of the person's business, vocation, or occupation," if the person does any of the following: "(2) Causes likelihood of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (3) Causes likelihood of confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another; ... (7) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have; ... (9) Represents that goods or services are of a

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particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; ... (11) Advertises goods or services with intent not to sell them as advertised [or] (12) Makes false statements of fact concerning the reasons for, existence of, or amounts of price reductions."

1220. In the course of their business, Defendants engaged in deceptive trade practices in violation of the Ohio DPTA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by

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consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

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1221. Defendants owed and continue to owe Plaintiffs and the Ohio members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1222. Defendants knew or should have known that their conduct was in violation of the Ohio DTPA.

1223. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Ohio members of the Class, and continued to engage in unfair and deceptive practices in violation of the Ohio DTPA.

1224. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Ohio members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff North and the Ohio members of the Class.

1225. Plaintiffs and the Ohio members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Ohio members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Ohio DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1226. Plaintiffs and the Ohio members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive

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practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1227. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1228. Pursuant to Ohio Rev. Code § 4165.03, Plaintiffs and the Ohio members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Ohio DTPA.

KK. VIOLATIONS OF OKLAHOMA CONSUMER PROTECTION ACT (Okla. Stat. Tit. 15 § 751, et seq.)

1229. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1230. Plaintiff Christina James (for the purposes of this section "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are residents or have been residents of the State of Oklahoma during any relevant time period (the "Oklahoma members of the Class") against Mylan (for the purposes of this section, "Defendants").

1231. Defendants, Plaintiff and the Oklahoma members of the Class are "persons" within the meaning of Okla. Stat. Tit. 15 § 752.1.

1232. Defendants engaged in the acts alleged herein in "the course of [their] business" within the meaning of Okla. Stat. Tit. 15 § 752.3.

1233. The Oklahoma Consumer Protection Act ("Oklahoma CPA") prohibits, in the course of business: "mak[ing] a false or misleading representation, knowingly or with reason to

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know, as to the characteristics ..., uses, [or] benefits, of the subject of a consumer transaction," or making a false representation, "knowingly or with reason to know, that the subject of a consumer transaction is of a particular standard, style or model, if it is of another" or "[a]dvertis[ing], knowingly or with reason to know, the subject of a consumer transaction with intent not to sell it as advertised;" and otherwise committing "an unfair or deceptive trade practice." Okla. Stat. Tit. 15 § 753.

1234. Defendants engaged in unfair and deceptive trade practices in violation of the Oklahoma CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen

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coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise

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manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1235. Defendants owed and continue to owe Plaintiff James and the Oklahoma members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1236. Defendants knew or should have known that their conduct was in violation of the Oklahoma CPA.

1237. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff James and the Oklahoma members of the Class, and continued to engage in unfair and deceptive practices in violation of the Oklahoma CPA.

1238. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff James and the Oklahoma members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff James and the Oklahoma members of the Class.

1239. Plaintiff James and the Oklahoma members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Oklahoma members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Oklahoma CPA did not begin to accrue until the

filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1240. Plaintiff James and the Oklahoma members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1241. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1242. Pursuant to Okla. Stat. Tit. 15 § 761.1, Plaintiffs and the Oklahoma Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Oklahoma CPA.

LL. VIOLATIONS OF THE OREGON UNLAWFUL TRADE PRACTICES ACT (Or. Rev. Stat. §§ 646.605, et seq.)

1243. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1244. Plaintiff David Smith (for the purpose of this section, "Plaintiff") brings this action on behalf of himself and members of the State Antitrust and Consumer Protection Class who are residents or who have been residents of the State of Oregon during the relevant time period (the "Oregon members of the Class") against Mylan (for the purposes of this section, "Defendants").

1245. Defendants, Plaintiff Smith and the Oregon members of the Class are "persons" within the meaning of <u>Or. Rev. Stat. § 646.605(4)</u>.

1246. Defendants are engaged in "trade" or "commerce" within the meaning of <u>Or. Rev.</u> Stat. § 646.605(8).

1247. The Oregon Unfair Trade Practices Act ("Oregon UTPA") prohibits "unfair or

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deceptive acts conduct in trade or commerce," including but not limited to "(b) Caus[ing] [a] likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of real estate, goods or services; (c) Caus[ing] [a] likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;" "(j) Mak[ing] false or misleading representations of fact concerning the reasons for, existence of, or amounts of price reductions;" and "(u) Mak[ing] false or misleading representations of price reductions." Or. Rev. Stat. § 646.608(1).

1248. Defendants engaged in unfair and deceptive conduct in violation of the Oregon UTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and

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unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-

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delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1249. Defendants owed and continue to owe Plaintiff Smith and the Oregon members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1250. Defendants knew or should have known that their conduct was in violation of the Oregon UTPA.

1251. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Smith and the Oregon members of the Class, and continued to engage in unfair and deceptive practices in violation of the Oregon UTPA.

1252. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Smith and the Oregon members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Smith and the Oregon members of the Class.

1253. Plaintiff Smith and the Oregon members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Oregon members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen

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products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Oregon UTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1254. Plaintiff Smith and the Oregon members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1255. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1256. Pursuant to <u>Or. Rev. Stat. § 646.638</u>, Plaintiffs and the Oregon members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Oregon UTPA.

MM. VIOLATIONS OF THE PENNSYLVANIA UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW (73 P.S. § 201-1, et seq.)

1257. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1258. Plaintiffs Lori Collins, Jae Jones, and Local 282 (for the purpose of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are residents of or who have been residents of the State of Pennsylvania during any relevant period (the "Pennsylvania members of the Class") against Mylan (for the purposes of this section, "Defendants").

1259. Defendants, Plaintiffs and the Pennsylvania members of the Class are "persons"

within the meaning of 73 <u>P.S. 201-2(2)</u>.

1260. Defendants are engaged in "trade" or "commerce" within the meaning of 73 <u>P.S. §</u> <u>201-2(3)</u> with respect to the conduct alleged herein.

1261. The Pennsylvania Unfair Trade Practices Act ("Pennsylvania UTPA") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce," including but not limited to: "(ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services; (iii) Causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by, another;" "(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he does not have;" and "(xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions." 73 P.S. § 201-2(4).

1262. Defendants engaged in unfair and deceptive acts or practices in violation of the Pennsylvania UTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak

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in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products

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that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1263. Defendants owed and continue to owe Plaintiffs and the Pennsylvania members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1264. Defendants knew or should have known that their conduct was in violation of the Pennsylvania UTPA.

1265. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Pennsylvania members of the Class, and continued to engage in unfair and deceptive practices in violation of the Pennsylvania UTPA.

1266. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Pennsylvania members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs

and the Pennsylvania members of the Class.

1267. Plaintiffs and the Pennsylvania members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs and the Pennsylvania members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Pennsylvania UTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1268. Plaintiffs and the Pennsylvania members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1269. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1270. Pursuant to 73 <u>P.S. § 201-9.2(a)</u>, Plaintiffs and the Pennsylvania members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Pennsylvania UTPA.

NN. VIOLATIONS OF THE SOUTH CAROLINA UNFAIR TRADE PRACTICES ACT (S.C. Code Ann. § 39-5-10, *et seq.*)

1271. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1272. Plaintiffs Jennifer Walton and Local 282 (for the purposes of this section,

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"Plaintiffs") bring this count on behalf of themselves and members of the State Antitrust and Consumer Protection Class who are residents of or who have been residents of the State of South Carolina during any relevant time period (the "South Carolina members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1273. Defendants, Plaintiffs and the South Carolina members of the Class are "persons" within the meaning of S.C. Code § 39-5-10(a).

1274. Defendants are engaged in "trade" or "commerce" within the meaning of S.C. Code § 39-5-10(b) with respect to the conduct alleged herein.

1275. The South Carolina Unfair Trade Practices Act ("South Carolina UTPA") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." S.C. Code § 39-5-20(a).

1276. Defendants engaged in unfair and deceptive acts in violation of the South Carolina UTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase

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the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding

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and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1277. Defendants owed and continue to owe Plaintiffs and the South Carolina members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1278. Defendants knew or should have known that their conduct was in violation of the South Carolina UTPA.

1279. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the South Carolina members of the Class, and continued to engage in unfair and deceptive practices in violation of the South Carolina UTPA.

1280. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the South Carolina members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the South Carolina members of the Class.

1281. Plaintiffs and the South Carolina members of the class relied upon Defendants'

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material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the South Carolina members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the South Carolina UTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1282. Plaintiffs and the South Carolina members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1283. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1284. Pursuant to S.C. Code § 39-5-140(a), Plaintiffs and the South Carolina Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, treble damages for willful and knowing violations, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the South Carolina UTPA.

OO. VIOLATIONS OF TENNESSEE CONSUMER PROTECTION ACT OF 1977 (Tenn. Code Ann. § 47-18-101, et seq.)

1285. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1286. Plaintiff April Sumner (for the purposes of this section, "Plaintiff") brings this count of behalf of herself and all members of the State Antitrust and Consumer Protection Class

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who are or have been residents of the State of Tennessee during any relevant time period (the "Tennessee members of the Class") against Mylan (for the purposes of this section, "Defendants").

1287. Plaintiff and the Tennessee members of the Class are "natural persons" and "consumers" within the meaning of Tenn. Code § 47-18-103(2).

1288. Defendants are "person[s]" within the meaning of Tenn. Code § 47-18-103(9).

1289. Defendants engaged in "trade" or "commerce" or "consumer transactions" within the meaning Tenn. Code § 47-18-103(9), with respect to the conduct alleged herein.

1290. The Tennessee Consumer Protection Act ("Tennessee CPA") prohibits "unfair or deceptive acts or practices affecting the conduct of any trade or commerce" including but not limited to: "(2) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services."; "(3) Causing likelihood of confusion or misunderstanding as to affiliation, connection or association with, or certification by, another."; "(5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship approval, status, affiliation or connection that such person does not have;" "(11) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions;" and "(27) Engaging in any other act or practice which is deceptive to the consumer or to any other person." Tenn. Code § 47-18-104.

1291. Defendants engaged in unfair and deceptive acts in violation of the Tennessee CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases;(b) making material misrepresentations, as detailed above, regarding the improvements that

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Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning

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the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1292. Defendants owed and continue to owe Plaintiff and the Tennessee members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1293. Defendants knew or should have known that their conduct was in violation of the Tennessee CPA.

1294. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead

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regulators, Plaintiff and the Tennessee members of the Class, and continued to engage in unfair and deceptive practices in violation of the Tennessee CPA.

1295. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Tennessee members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Tennessee members of the Class.

1296. Plaintiff and the Tennessee members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Tennessee members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Tennessee CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1297. Plaintiff and the Tennessee members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1298. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1299. Pursuant to Tenn. Code § 47-18-109, Plaintiffs and the Tennessee members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, treble damages for willful and knowing violations, pursuant to § 47-18-109(a)(3), punitive

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damages, and attorneys' fees, costs, and any other just and proper relief to the extent available under the Tennessee CPA.

PP. VIOLATIONS OF THE DECEPTIVE TRADE PRACTICES ACT – CONSUMER PROTECTION ACT (Tex. Bus. & Com. Code §§ 17.41, et seq.)

1300. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1301. Plaintiffs Meredith Krimmel and Local 282 (for the purposes of this section, "Plaintiffs") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Texas during any relevant period (the "Texas members of the Class") against Mylan (for the purposes of this section, "Defendants").

1302. The TDTPA, <u>Tex. Bus. & Com. Code Ann. § 17.41</u>, *et. seq.*, prohibits the use of any "deceptive" or "unfair" or "unconscionable" act or practice in connection with a consumer transaction.

1303. Plaintiffs and the Texas members of the Class are individuals, partnerships or corporations with assets of less than \$25 million (or are controlled by corporations or entities with less than \$25 million in assets), *see* Tex. Bus. & Com. Code § 17.41, and are therefore "consumers" pursuant to Tex. Bus. & Com. Code § 17.45(4).

1304. Defendants are "person[s]" within the meaning of <u>Tex. Bus. & Com. Code §</u> <u>17.45(3)</u>.

1305. Defendants were and are engaged in "trade" or "commerce" or "consumer transactions" within the meaning <u>Tex. Bus. & Com. Code § 17.46(a)</u> with respect to the conduct alleged herein.

1306. The Texas Deceptive Trade Practices – Consumer Protection Act ("Texas DTPA")

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prohibits "false, misleading, or deceptive acts or practices in the conduct of any trade or commerce," <u>Tex. Bus. & Com. Code § 17.46(a)</u>, and "unconscionable action[s] or course of action[s]," which means "act[s] or practice[s] which, to a consumer's detriment, takes advantage of the lack of knowledge, ability, experience, or capacity of the consumer to a grossly unfair degree." <u>Tex. Bus. & Com. Code §§ 17.45(5)</u> and <u>17.50(a)(3)</u>.

1307. Defendants engaged in false, misleading, deceptive, and unconscionable acts or practices in violation of the Texas DTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material

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misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate

Program to extract higher payments in order to fund payments of rebates and/or discounts.

1308. Defendants owed and continue to owe Plaintiffs and the Texas members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1309. Defendants knew or should have known that their conduct was in violation of the Texas DTPA.

1310. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Texas members of the Class, and continued to engage in unfair and deceptive practices in violation of the Texas DTPA.

1311. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Texas members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the Texas members of the Class.

1312. Plaintiffs and the Texas members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs and the Texas members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Texas DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

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1313. Plaintiffs and the Texas members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1314. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1315. Pursuant to <u>Tex. Bus. & Com. Code § 17.50</u>, Plaintiffs and the Texas members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, multiple damages for knowing and intentional violations, pursuant to § 17.50(b)(1), punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Texas DTPA.

1316. Prior to this filing, certain Plaintiffs sent a letter complying with <u>Tex. Bus. & Com.</u> <u>Code § 17.505(a)</u>. Because Defendants failed to remedy their unlawful conduct within the requisite time period, Plaintiffs seek all damages and relief to which Plaintiffs and the Texas members of the Class are entitled.

QQ. VIOLATIONS OF UTAH CONSUMER SALES PRACTICES ACT (Utah Code Ann. § 13-11-1, et seq.)

1317. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1318. Plaintiffs Ipson and Steinhauser (for the purpose of this section, "Plaintiffs") bring this action on behalf of himself and on behalf of all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Utah at any relevant time (the "Utah members of the Class") against Mylan (for the purposes of this section, "Defendants").

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1319. Plaintiffs and Utah members of the Class are "persons" under the Utah Consumer Sales Practices Act ("Utah CSPA"), Utah Code § 13-11-3(5).

1320. The purchases of the EpiPen products described herein are "consumer transactions" within the meaning of Utah Code § 13-11-3(2).

1321. Defendants are "suppliers" within the meaning of Utah Code § 13-11-3(6).

1322. The Utah CSPA makes unlawful any "deceptive act or practice by a supplier in connection with a consumer transaction." Specifically, "a supplier commits a deceptive act or practice if the supplier knowingly or intentionally: (a) indicates that the subject of a consumer transaction has sponsorship, approval, performance characteristics, accessories, uses, or benefits, if it has not" or "(b) indicates that the subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not." Utah Code § 13-11-4. "An unconscionable act or practice by a supplier in connection with a consumer transaction" also violates the Utah CSPA. Utah Code § 13-11-5.

1323. Defendants engaged in deceptive and unconscionable acts and practices in violation of the Utah CSPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak

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in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products

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that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1324. Defendants owed and continue to owe Plaintiffs and the Utah members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1325. Defendants knew or should have known that their conduct was in violation of the Utah CSPA.

1326. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs, and the Utah members of the Class, and continued to engage in unfair and deceptive practices in violation of the Utah CSPA.

1327. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Utah members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Utah members of the Class.

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1328. Plaintiffs and the Utah members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs and the Utah members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Utah CSPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1329. Plaintiffs and the Utah members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1330. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest

1331. Plaintiffs and the Utah members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, multiple damages for knowing and intentional violations, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Utah CSPA.

RR. VIOLATIONS OF VERMONT CONSUMER PROTECTION ACT (Vt. Stat. Ann. Tit. 9, § 2451 et seq.)

1332. Plaintiffs incorporate by reference each preceding paragraph as though fully set forth herein.

1333. Plaintiff John Dodge (for the purposes of this section "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who

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are or have been residents of the State of Vermont during any relevant time period (the "Vermont members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1334. Plaintiffs and the Vermont members of the Class are "consumers" within the meaning of Vt. Stat. Tit. 9, § 2451a(a).

1335. Defendants are "person[s]" within the meaning of Vt. Code R. § 100(3) (citing Vt. Stat. Tit. 9, § 2453).

1336. Defendants are engaged in "commerce" within the meaning of Vt. Stat. Tit. 9, § 2453(a), with respect to the acts and practices alleged herein.

1337. The Vermont Consumer Protection Act ("Vermont CPA") prohibits "[u]nfair methods of competition in commerce and unfair or deceptive acts or practices in commerce...." Vt. Stat. Tit. 9, § 2453(a).

1338. Defendants engaged in unfair and deceptive conduct in violation of the Vermont CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase

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the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding

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and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1339. Defendants owed and continue to owe Plaintiff Dodge and the Vermont members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1340. Defendants knew or should have known that their conduct was in violation of the Vermont CPA.

1341. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Dodge and the Vermont members of the Class, and continued to engage in unfair and deceptive practices in violation of the Vermont CPA.

1342. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Vermont members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Vermont members of the Class.

1343. Plaintiff and Vermont members of the Class relied upon Defendants' material

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misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Vermont members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Vermont CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1344. Plaintiff and the Vermont members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1345. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1346. Pursuant to Vt. Stat. Tit. 9, § 2461(b), Plaintiffs and the Vermont members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, actual damages, damages up to three times the consideration provided, punitive damages, attorneys' fees, costs, and any other just and proper relief available under the Vermont CPA.

SS. VIOLATIONS OF THE VIRGINIA CONSUMER PROTECTION ACT (Va. Code Ann. §§ 59.1-196, et seq.)

1347. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1348. Plaintiff Amie Vialet De Montbel and Plaintiff Donna Anne Dvorak (for the purposes of this section, "Plaintiffs") bring this action on behalf of themselves and all members of the State Antitrust and Consumer Protection Class who are residents of or who have been residents

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of the State of Virginia during any relevant time period (the "Virginia members of the Class") against Mylan (for the purposes of this section, "Defendants").

1349. Defendants, Plaintiffs, and the Virginia members of the Class are "persons" within the meaning of Va. Code § 59.1-198.

1350. Defendants are "suppliers" within the meaning of Va. Code § 59.1-198.

1351. The Virginia Consumer Protection Act ("Virginia CPA") makes unlawful "fraudulent acts or practices." Va. Code § 59.1-200(A).

1352. Defendants engaged in fraudulent acts or practices in violation of the Virginia CPA, at a minimum by: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public

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about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-fordelay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal

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officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1353. Defendants owed and continue to owe Plaintiffs and the Virginia members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1354. Defendants knew or should have known that their conduct was in violation of the Virginia CPA.

1355. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiffs and the Virginia members of the Class, and continued to engage in unfair and deceptive practices in violation of the Virginia CPA.

1356. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiffs and the Virginia members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiffs and the Virginia members of the Class.

1357. Plaintiffs and other Virginia members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiffs and the Virginia members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations

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for filing claims against Defendants under the Virginia CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1358. Plaintiffs and the Virginia members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1359. Defendants' violations present a continuing risk to Plaintiffs as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1360. Pursuant to Va. Code § 59.1-204(A)–(B), Plaintiffs and the Virginia members of the Class are entitled to the greater of actual damages or \$500, attorneys' fees, and costs. Because Defendants' actions were willful, Plaintiffs and the Virginia members of the Class should each receive also receive the greater of treble damages or \$1,000. *Id*.

TT. VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION ACT (Wash. Rev. Code Ann. §§ 19.86.010, et seq.)

1361. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1362. Plaintiff Connie Stafford (for the purposes of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are residents or who have been residents of the State of Washington (the "Washington members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1363. Defendants, Plaintiff, and the Washington members of the Class are "persons" within the meaning of Wash. Rev. Code § 19.86.010(2).

1364. Defendants are engaged in "trade" or "commerce" within the meaning of Wash.

Rev. Code § 19.86.010(2).

1365. The Washington Consumer Protection Act ("Washington CPA") makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020.

1366. The Washington CPA also renders it unlawful "for any person to monopolize, or attempt to monopolize or combine or conspire with any other person or persons to monopolize any part of trade or commerce." Wash. Rev. Code § 19.86.040.

1367. Defendants engaged in unfair, deceptive, and monopolistic acts and practices in violation of the Washington CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading

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statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely

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certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1368. Defendants owed and continue to owe Plaintiff Stafford and the Washington members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1369. Defendants knew or should have known that their conduct was in violation of the Washington CPA.

1370. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Stafford and the Washington members of the Class, and continued to engage in unfair and deceptive practices in violation of the Washington CPA.

1371. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Stafford and the Washington members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Stafford and the Washington members of the Class.

1372. Plaintiff Stafford and other Washington members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Washington members of the Class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute

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of limitations for filing claims against Defendants under the Washington CPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1373. Plaintiff Stafford and the Washington members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1374. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1375. Pursuant to Wash. Rev. Code § 19.86.090, Plaintiff and the Washington members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Washington CPA. Because Defendants' actions were willful and knowing, Plaintiffs' damages should be trebled. *Id*.

UU. VIOLATIONS OF THE WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT (W. Va. Code § 46A-1-101, et seq.)

1376. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1377. Plaintiff Francis Meyer (for the purposes of this section, "Plaintiff") brings this count on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of West Virginia (the "West Virginia members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1378. Defendants, Plaintiff, and the West Virginia members of the Class are "persons"

within the meaning of W. Va. Code § 46A-1-102(31).

1379. Plaintiff and the West Virginia members of the Class members are "consumers" within the meaning of W. Va. Code §§ 46A-1-102(2) and 46A-1-102(12).

1380. The West Virginia Consumer Credit and Protection Act ("West Virginia CCPA") makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." W. Va. Code § 46A-6-104.

1381. Defendants engaged in unfair and deceptive practices in violation of the West Virginia CCPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen

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coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise

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manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1382. Defendants owed and continue to owe Plaintiff Meyer and the West Virginia members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1383. Defendants knew or should have known that their conduct was in violation of the West Virginia CCPA.

1384. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff Meyer and the West Virginia members of the Class, and continued to engage in unfair and deceptive practices in violation of the West Virginia CCPA.

1385. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff Meyer and the West Virginia members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff Meyer and the West Virginia members of the Class.

1386. Plaintiff Meyer and the West Virginia members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the West Virginia members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the West Virginia CCPA did

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not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1387. Plaintiff Meyer and the West Virginia members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1388. Pursuant to W. Va. Code § 46A-6-106(a), Plaintiff and the West Virginia members of the Class seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and any other just and proper relief available under the West Virginia CCPA.

1389. Prior to this filing, at least one Plaintiff sent a letter complying with W. Va. Code § 46A-6-106(c).

VV. VIOLATIONS OF THE WISCONSIN DECEPTIVE TRADE PRACTICES ACT (WIS. STAT. § 100.18)

1390. Plaintiffs repeat and re-allege the above paragraphs as though fully set forth herein.

1391. Plaintiff Heather Ruland (for the purposes of this section, "Plaintiff") brings this action on behalf of herself and all members of the State Antitrust and Consumer Protection Class who are or have been residents of the State of Wisconsin (the "Wisconsin members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1392. Plaintiff and the Wisconsin members of the Class are members of "the public" within the meaning of Wis. Stat. § 100.18(1).

1393. Plaintiff and Wisconsin members of the Class are "persons" under the Wisconsin Deceptive Trade Practices Act ("Wisconsin DTPA"), Wis. Stat. § 100.18(1).

1394. Each Defendant is a "person, firm, corporation or association" within the meaning

of Wis. Stat. § 100.18(1).

1395. The Wisconsin DTPA makes unlawful any "representation or statement of fact which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1).

1396. Defendants acted in violation of the Wisconsin DTPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead

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consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (l) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1397. Defendants owed and continue to owe Plaintiff and the Wisconsin members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the

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true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1398. Defendants knew or should have known that their conduct was in violation of the Wisconsin DTPA.

1399. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff and the Wisconsin members of the Class, and continued to engage in unfair and deceptive practices in violation of the Wisconsin DTPA.

1400. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Wisconsin members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Wisconsin members of the Class.

1401. Plaintiff and the Wisconsin members of the class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Wisconsin members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Wisconsin DTPA did not begin to accrue until the filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1402. Plaintiff and the Wisconsin members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of

increased and unfair prices paid for the EpiPen products described herein.

1403. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1404. Plaintiff and the Wisconsin members of the Class seek damages, court costs and attorneys' fees under Wis. Stat. § 100.18(11)(b)(2), and any other just and proper relief available under the Wisconsin DTPA.

VV. VIOLATIONS OF THE WYOMING CONSUMER PROTECTION ACT (Wyo. Stat. §§ 40-12-101, et seq.)

1405. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

1406. Plaintiff Curt Palmer (for the purposes of this section, "Plaintiff") brings this action on behalf of himself and all members of the State Antitrust and Consumer Protection Class who are residents or have been residents of the State of Wyoming (the "Wyoming members of the Class"), against Mylan (for the purposes of this section, "Defendants").

1407. Plaintiff, the Wyoming members of the Class and Defendants are "persons" within the meaning of Wyo. Stat. § 40-12-102(a)(i).

1408. The EpiPen products described herein constitute "merchandise" pursuant to Wyo. Stat. § 40-12-102(a)(vi).

1409. Each sale of an EpiPen product constitutes a "consumer transaction" as defined by Wyo. Stat. § 40-12-102(a)(ii). These consumer transactions occurred "in the course of [Defendants'] business" under Wyo. Stat. § 40-12-105(a).

1410. The Wyoming Consumer Protection Act ("Wyoming CPA") prohibits unlawful deceptive trade practices, including when a seller: "(i) Represents that merchandise has a source,

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origin, sponsorship, approval, accessories, or uses it does not have; (ii) Represents that he has a sponsorship, approval or affiliation he does not have; (iii) Represents that merchandise is of a particular standard, grade, style or model, if it is not;" "(vii) Makes false or misleading statements of fact concerning the price of merchandise or the reason for, existence of, or amounts of a price reduction;" "(x) Advertises merchandise with intent not to sell it as advertised;" or "(xv) Engages in unfair or deceptive acts or practices." Wyo. Stat. §§ 40-12-105(a).

1411. Defendants engaged in unfair and deceptive acts or practices in violation of the Wyoming CPA by, at a minimum: (a) making material misrepresentations (detailed above) regarding Mylan's reasons for increasing the price of the EpiPen from 2009 to present, and concealing from the public Mylan's unfair and anticompetitive practices which lead to and permitted those price increases; (b) making material misrepresentations, as detailed above, regarding the improvements that Defendants made to the EpiPen that justified Mylan's price increases and/or the medical need for the EpiPen; (c) failing to disclose and/or concealing from the public the extent of Defendants' lobbying efforts aimed at discrediting Mylan's competitors and excluding products that compete with the EpiPen from the market; (d) making fraudulent, deceptive, and material misrepresentations regarding the reason the EpiPen is sold only as a 2-Pak in the United States; (e) failing to disclose and/or concealing from the public that Mylan tainted the testimony of the doctors and panelists; (f) unfairly exploiting a dominant market position to unreasonably increase the price of the EpiPen from 2009 to present; (g) selling the EpiPen exclusively as a 2-Pak in the United States; (h) making material misrepresentations regarding Mylan's EpiPen4Schools program and failing to disclose and/or concealing from the public the true anti-competitive and unfair purposes of the EpiPen4Schools program; (i) making misleading statements to the public about the savings to consumers through its EpiPen rebates, EpiPen

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coupons, and the generic EpiPen; (j) making material misrepresentations regarding, concealing, and/or failing to disclose Mylan's role in setting the price of the EpiPen and/or the price paid by consumers; (k) making material misrepresentations regarding the true cost of the EpiPen products described herein that had the tendency to mislead consumers and failing to disclose and concealing from the public the inflated and/or fraudulent nature of the list price(s) set and/or charged by Defendants for the EpiPen; (1) making material misrepresentations regarding or failing to disclose the existence, amount, and/or purpose(s) of discounts, rebates, and/or other payments offered by Defendants to state-based Medicaid programs and/or pharmacy benefit managers in exchange for promises to provide exclusive or formulary placement for the EpiPen; (m) misrepresenting and/or concealing from the public the true nature of the relationship between Defendants and pharmacy benefit managers and its effect on the pricing of the EpiPen; (n) engaging in false advertising concerning the role that Defendants played in setting the price paid for the EpiPen products described, including but not limited to marketing material averring that Defendants make efforts to decrease the price of and increase the public's access to the EpiPen; (o) engaging in misleading, false, unfair and/or deceptive acts or practices by foreclosing from consumers and the general public the opportunity to purchase cheaper generic versions of the EpiPen and/or cheaper products that could have competed with the EpiPen through anticompetitive practices including patent misuse, reverse 'pay-for-delay' settlements, and sham citizens' petitions as described herein; (p) creating, funding and spreading misinformation to the FDA, physicians, and the public regarding the effectiveness and safety of products developed by Mylan's competitors; (q) failing to disclose and/or concealing from the public the true purpose of Mylan's EpiPen-related patents, patent lawsuits, 'pay-for-delay' settlements, and citizens' petitions described herein; and (r) falsely certifying to federal officials that the EpiPen was a generic or non-innovator product and otherwise

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manipulating the Medicaid Medical Drug Rebate Program to extract higher payments in order to fund payments of rebates and/or discounts.

1412. Defendants owed and continue to owe Plaintiff and the Wyoming members of the Class a duty to refrain from the above-described unfair and deceptive practices and disclose the true nature of the pricing, legality, and health and safety risks of the EpiPen products described herein.

1413. Defendants knew or should have known that their conduct was in violation of the Wyoming CPA.

1414. Despite knowing the true nature of their products and practices for years, Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding the quality and characteristics of the EpiPen products described herein, with the intent to mislead regulators, Plaintiff and the Wyoming members of the Class, and continued to engage in unfair and deceptive practices in violation of the Wyoming CPA.

1415. Defendants' unfair and deceptive acts or practices, omissions and misrepresentations were material to Plaintiff and the Wyoming members of the Class, and were likely to and/or did, in fact, deceive regulators and reasonable consumers, including Plaintiff and the Wyoming members of the Class.

1416. Plaintiff and other Wyoming members of the Class relied upon Defendants' material misrepresentations and omissions regarding the EpiPen, as set forth above. These material misrepresentations by Defendants proximately caused Plaintiff and the Wyoming members of the class to overpay for the EpiPen. Because Defendants did not reveal the true nature of the EpiPen products and their pricing as described herein until this lawsuit was filed, the statute of limitations for filing claims against Defendants under the Wyoming CPA did not begin to accrue until the

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filing of this lawsuit. Defendants either concealed or failed to reveal the facts until this filing.

1417. Plaintiff and the Wyoming members of the Class suffered injury-in-fact, ascertainable loss and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for the EpiPen products described herein.

1418. Defendants' violations present a continuing risk to Plaintiff as well as to the general public, who in many cases are unable to afford or gain access to life-saving treatment. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

1419. Pursuant to Wyo. Stat. § 40-12-108(a), Plaintiffs and the Wyoming members of the Class seek damages as determined at trial, and any other just and proper relief available under the Wyoming CPA, including but not limited to court costs and reasonable attorneys' fees as provided in Wyo. Stat. § 40-12-108(b).

1420. Prior to this suit, certain Plaintiffs sent a letter complying with Wyo. Stat. § 40-12-109.

COUNT IX Unjust Enrichment (on behalf of Plaintiffs and the Nationwide Class)

1421. Plaintiffs repeat and re-allege every allegation above as if set forth herein in full.

1422. Plaintiffs bring this claim under the common law of all 50 states and territories.

1423. By reason of their conduct, Defendants caused damages to Plaintiffs and to members of the Nationwide Class.

1424. By purchasing the EpiPen at an inflated price and/or as a 2-Pak in the United States, which Mylan forced them to do, Plaintiffs and the Nationwide Class Members conferred a benefit on Mylan in the form of the inflated and unconscionable list price of the product.

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1425. Mylan appreciated the benefit because, had consumers not purchased the EpiPen, Defendants would have no sales and derive no benefit from sales of the EpiPen in the aforementioned states.

1426. Mylan was directly involved in setting the price, making material misstatements, and directing the sale and distribution of the EpiPen nationwide in the United States, as well as mandating that the EpiPen be sold exclusively in a 2-Pak.

1427. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Mylan's price gouging, unconscionable sales, unlawful acts, and as set forth above.

1428. Equity cannot in good conscience permit Mylan to be economically enriched for its unjust actions at Plaintiffs and Nationwide Class Members' expense and in violation of state law, and therefore restitution or disgorgement or both of such economic enrichment is required.

DEMAND FOR JURY TRIAL

1429. Plaintiffs respectfully demand a jury trial.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully request the following relief:

- Determine that this action may be maintained as a class action pursuant to Fed. R.
 <u>Civ. P. 23(a)</u> and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Classes;
- b. Require Mylan to pay for sending notice to the certified Classes;
- c. Appoint Plaintiffs as Class Representatives and Plaintiffs' counsel as Class Counsel;
- d. Issue an injunction to enjoin Mylan from engaging in the deceptive, unfair, unconscionable, and unlawful business practices alleged in this Complaint;
- e. Award further injunctive relief, as the Court deems appropriate;

- f. Award compensatory damages to Plaintiffs and the proposed Classes in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;
- g. Award treble damages as permitted by law;
- h. Award pre- and post-judgment interest;
- i. Award punitive damages based on Mylan's reprehensible and deliberate conduct;
- j. Award reasonable attorneys' fees and costs; and,
- k. For all such other and further relief as may be just and proper.

Date: October 17, 2017

Respectfully submitted,

/s/ Rex A. Sharp

Co-Lead Counsel for Consolidated Plaintiffs

Rex A. Sharp KS #12350 REX A. SHARP, PA 5301 W. 75th Street Prairie Village, KS 66208 Tel: (913) 901-0505 Fax: (913) 901-0419 Email: rsharp@midwest-law.com

Warren T. Burns BURNS CHAREST LLP 900 Jackson, Suite 500 Dallas, TX 75202 Tel: (469) 904-4550 Fax: (469) 444-5002 Email: wburns@burnscharest.com

Paul J. Geller ROBBINS GELLER RUDMAN & DOWD LLP 120 East Palmetto Park Road, Suite 500 Boca Raton, FL 33432 Tel: (561) 750-3000 Fax: (561) 750-3364 Email: pgeller@rgrdlaw.com

Lynn Lincoln Sarko KELLER ROHRBACK L.L.P. 1201 3rd Ave. - Ste. 3200 Seattle, WA 98101 Tel: (206) 623-1900 Fax: (206) 623-3384 Email: <u>lsarko@kellerrohrback.com</u>

Liaison Counsel

Ryan C. Hudson KS #22986 REX A. SHARP, PA 5301 W. 75th Street Prairie Village, KS 66208 Tel: (913) 901-0505 Fax: (913) 901-0419 rhudson@midwest-law.com

Plaintiff Steering Committee

Elizabeth C. Pritzker (Chair) PRITZKER LEVINE LLP 180 Grand Avenue, Suite 1390 Oakland, CA 94612 Tel: (415)692-0772 Fax: (415)366-6110 Email: ecp@pritzkerlevine.com

Sharon S. Almonrode THE MILLER LAW FIRM, P.C. 950 West University Drive Suite 300 Rochester, MI 48307 Tel: (248) 841-2200 Fax: (248) 652-2852 Email: <u>ssa@millerlawpc.com</u>

W. Mark Lanier THE LANIER LAW FIRM, P.C. 6810 FM 1960 West Houston, TX 77069 Tel: (713) 659-5200 Fax: (713) 659-2204 Email: wml@lanierlawfirm.com Damien Marshall BOIES SCHILLER FLEXNER LLP 575 Lexington Avenue New York, New York 10022 Tel: (212) 446-2350 Fax: (212) 446-2350 Email: dmarshall@bsfllp.com

Rosemary Rivas LEVI & KORSINKSY, LLP 44 Montgomery Street, Suite 650 San Francisco, CA 94104 Tel: (415) 291-2420 Fax: (415) 484-1294 Email: <u>rrivas@zlk.com</u>

Steven N. Williams COTCHETT, PITRE & MCCARTHY, LLP 840 Malcolm Road, Suite 200 Burlingame, CA 94010 Tel: (650) 697-6000 Fax: (650) 697-0577 Email: <u>swilliams@cpmlegal.com</u>

CERTIFICATE OF SERVICE

I hereby certify that on this 17th day of October 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to parties and attorneys who are filing users.

s/ Rex A. Sharp

EXHIBIT A



BUSINESS DAY

Painted as EpiPen Villain, Mylan's Chief Says She's No Such Thing

By KATIE THOMAS AUG. 26, 2016

America has a new pharmaceutical villain. Her name is Heather Bresch.

As the chief executive of Mylan, the owner of the severe allergy treatment EpiPen, Ms. Bresch is at the center of the latest public outrage over high drug prices, excoriated for overseeing a fourfold price increase on EpiPen while taking a huge pay raise.

From talk shows to Twitter, her name is being mentioned alongside Martin Shkreli, the so-called Pharma Bro who ignited anger last fall over raising the price of the drug Daraprim, and J. Michael Pearson, the onetime McKinsey consultant who took over Valeant Pharmaceuticals International and sharply raised prices on lifesaving drugs.

But Mr. Shkreli and Mr. Pearson were outliers trying to upend the industry. At one point, the pharmaceutical industry's main lobbying group disavowed them.

Not so with Ms. Bresch. In many ways, she is an ultimate insider. Her father is a United States senator. She runs one of the largest generic drug companies in the world. She also oversees the Generic Pharmaceutical Association — the generic industry's lobbying group.

Now the question is whether her different position will give her a different result

8 ARTICLES REMAINING

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Already, Ms. Bresch, 47, has moved more quickly than they did to quell public furor over prices. On Thursday, she announced that the company was increasing financial assistance to patients to reduce their out-of-pocket costs. But the company did not say it would lower the list price — which has risen to about \$600 for a pack of two EpiPens, from about \$100 when Mylan acquired the product in 2007.

In an interview, Ms. Bresch said the price increases on EpiPen weren't even in the "same hemisphere" as what Mr. Shkreli did when he raised the price of Daraprim by 50 times overnight.

Over the years, her brash leadership style has bruised egos but also, some say, improved access to drugs and raised quality standards. Her company, Mylan, also has a reputation for bare-knuckled tactics that have angered competitors and investors alike.

"I think we mean what we say: You can do good and do well, and I think we strike that balance around the globe," Ms. Bresch said. Still, she was unapologetic that Mylan's actions were driven by profit. "I am running a business. I am a forprofit business. I am not hiding from that."

How the company, and Ms. Bresch, strikes that balance seems to be quickly changing. Generic drug companies once dealt almost exclusively in making cheap copies of pills and railed passionately against the anticompetitive tactics of brandname competitors. Now, through a series of acquisitions and mergers, the handful of large generic companies that are left are increasingly investing in expensive brandname drugs, and in doing so, are embracing many of the tactics they once scorned.

"It's like talking out of both sides of your mouth," said Dinesh Thakur, an advocate for generic drug quality. "To me, I think, it's opportunistic."

In the interview, Ms. Bresch said the company's latest actions would do the most to help patients where it mattered, by reducing their out-of-pocket costs. And she said that the \$600 list price was necessary for the company to recoup its investment in the EpiPen, which includes raising awareness for severe allergic reaction and making improvements to the way the product works.

But she also sought to shift blame away from Mylan, saying that patients are feeling the pain in part because insurers have increased the amount that customers must pay in recent years.

"What else do you shop for that when you walk up to the counter, you have no idea what it's going to cost you?" she said. "Tell me where that happens anywhere else in the system. It's unconscionable."

To some, the company's response seemed to ring hollow. "It's a real challenge to understand how a management team sits around a board table and makes a decision to raise the price of a lifesaving medication over and over and over, and when the P.R. storm hits, decides to blame someone else for that price increase," said David Maris, an analyst for Wells Fargo. He had warned investors in June that Mylan's price increases on EpiPen and other drugs could soon draw unwanted media scrutiny.

The company is not a stranger to controversy. Robert J. Coury, Mylan's chairman who served as chief executive until 2011, came under scrutiny in 2012 for using the company's corporate jet to travel to his son's music concerts. And last year, The Wall Street Journal reported that one of the board members had undisclosed ties to the land where the company built its new Pittsburgh offices.

Ms. Bresch has also weathered her share of controversy, like when it was discovered that West Virginia University awarded her a business degree 10 years after she had attended the school, even though she had completed only about half of the coursework. A report by the university later concluded that officials wrongly awarded her the degree because she was the daughter of the then-governor Joe Manchin, now a Democratic senator representing West Virginia. Mr. Manchin and Ms. Bresch have said they did nothing wrong.

The company also angered shareholders when it switched its headquarters to the Netherlands, and then used a little-known provision in Dutch law to block a takeover by the pharmaceutical giant Teva, which many investors had favored. The move to the Netherlands in 2014, called an inversion, also reduced the company's tax rate. Mylan is one of a string of pharmaceutical companies that have done inversions in recent years, prompting outcry in Washington and calls to limit the practice.

Ms. Bresch's rising salary has also fueled anger over the EpiPen price increase. Since 2007, when EpiPen was acquired and she was the company's chief operating officer, she earned about \$2.5 million in total compensation. In 2015, her compensation was nearly \$19 million. Mylan's board has said in company filings that it believes her pay is justified because she has contributed significantly to the company's growth in recent years.

Ms. Bresch, who has worked at Mylan for 25 years, said her West Virginia upbringing had informed her approach to serving as chief executive. "There is a work ethic and grit about that that allows me to help make a difference," she said.

Some of the chafing at her style, she said, is because people are resistant to change. Her top accomplishments, she said, include getting a federal law passed that required more inspections of overseas drug manufacturers, and improving access to AIDS drugs for patients overseas. "To make change happen, to make a difference, mediocrity doesn't get you there," she said.

Even as they have ruffled feathers within the industry, Ms. Bresch and Mylan have earned measured praise from consumer advocates, who said she wielded her influence in ways that helped consumers.

James Love, director of the consumers group Knowledge Ecology International, said Ms. Bresch opened doors at the Office of the United States Trade Representative when his group and others were working to change provisions in the proposed Trans-Pacific Partnership that they said would have limited access to drugs by people overseas. Mylan, as a seller of generic drugs, shared their interest, he said.

"They came in with some very talented people in the negotiations, and they knew what was going on politically," Mr. Love said.

Still, he said, he opposes their position on the EpiPen and said his group was composing a letter of complaint to the Federal Trade Commission.

"I'm appalled at the price increase," he said. "I don't want to sugarcoat that."

A version of this article appears in print on August 27, 2016, on Page B1 of the New York edition with the headline: Villain? Mylan's Chief Says She's No Such Thing.

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EXHIBIT B

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The Washington Post

The Fix

How a senator's daughter became CEO of the company at the center of the EpiPen controversy

By Amber Phillips August 24, 2016

The dramatic 400 percent rise in the cost of EpiPens is the next big flash point in the national debate over skyrocketing prescription drug prices.

It turns out that the woman at the center of this controversy has powerful political connections. My <u>colleague Catherine Ho</u> <u>reports</u> that the head of Mylan, the drug company accused of hiking the price of the pen that treats severe allergic reactions, is also the daughter of Joe Manchin, a Democratic U.S. senator from West Virginia and the state's former governor.

Heather Bresch's career has risen along with her father's, a fact that has not gone unnoticed by her critics. But Bresch's corporate rise is also a modern-day success story. Over the past quarter century, she moved from a job in the basement, literally, to the CEO's office, all while raising a family and combating what she has described as "the old-boys' club" of the corporate drug world.

This also isn't the first time Bresch's company has threatened to make her father's political life difficult.

Here's a quick timeline of Bresch's career, matched up with her father's.

1986 — 1996: Manchin is a state senator.

1992-ish: Bresch, newly married, with a college degree and a stint teaching aerobics in California, moves back to West Virginia in need of a job.

Here's how Fortune Magazine's Jen Wieczner describes how she got one:

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Her well-connected father ran into his friend Milan Puskar at a basketball game and finagled her an interview at Puskar's drug company. Dropping by Mylan's executive offices, then located in a double-wide trailer in Morgantown, Bresch walked out with a job typing labels in the factory basement.

1996: Manchin runs for governor but comes in second in a crowded Democratic primary.

2000: Manchin runs for secretary of state and wins.

2002: Bresch rises through the ranks and gets her first major job, director of government relations for Mylan (read: head lobbyist).

2003: Bresch is lobbying Congress as it passes a major Medicare overhaul. The 2003 law, among many other things, created an entitlement program for prescription drugs. A Mylan news release praised Bresch's work with the law, saying it "focused on ensuring consumers' access to affordable pharmaceuticals."

2003-2007: Bresch enters the executive world of Mylan. She served as spokeswoman, head of strategic development, head of North American Operations and chief integration officer.

2005: Manchin runs for governor to replace an outgoing Democrat and wins.

2007: Bresch is named chief operating officer of Mylan, where she is in charge of integrating the company's \$6.7 billion acquisition of German drugmaker Merck, one of the largest drugmakers in the world.

As her career soars, Bresch's first big PR problem hits. The Pittsburgh Post-Gazette reports that Bresch did not actually have enough credits for an MBA from West Virginia University, even though <u>the news release</u> announcing her new, high-profile job said she had earned one. The school, through its own investigation, found Bresch had been given grades "pulled from thin air" because of her "high profile."

Her father was finishing up his third year as governor at the time, and Bresch's critics were vocal about whether her connections led to this drama.

The school took the degree back.

This is the same year Maylan bought the rights to EpiPen.

2008: Manchin wins reelection as governor with 70 percent of the vote.

2009: Breach is named president of Mylan.

2010: Sen. Robert Byrd, at the time the longest-serving senator, dies in office. Manchin runs for the seat and wins.

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2012: Manchin wins election to his first full term as a U.S. senator.

2012: Bresch becomes CEO of Mylan. She's the only woman to ever run a Fortune 500 pharmaceutical company. (But as Fortune Magazine notes, she was kicked off 2015's list after technically headquartering her company in the Netherlands, a practice her father said should be "repealed.")

Bresch writes a mission statement to reach the entire world with Mylan's medicine, reports Fortune.

The former CEO stays on as executive chair of the company. Despite his insistence Bresch is the one "that runs his company every day," Bresch has to battle rumors that she's really his No. 2.

2012: Bresch helps draft reforms in Congress to speed up generic-drug approval by funding more FDA inspections of genericdrug factories overseas. Her outspokenness on the need for more FDA inspections of drug manufacturers abroad make her a headline name in the pharmaceutical industry. "Medicine Woman," reads the headline of a **2013** Barron's profile.

Barron's reports Bresch made hundreds of visits to Capitol Hill to get the regulatory reforms passed. "All these senators were flabbergasted when they found out she was my daughter," Manchin tells Barron's. "Of course, John Dingell wanted to adopt her."

2013: Barron's reports Bresch is "crusading for wider distribution of of EpiPens. ... She maintains they should be as widely available as cardiac defibrillators."

"I grew up in an era when generics were considered inferior," Bresch told Barron's. "People thought they were made in a bathtub."

2014: Mylan makes a deal that puts Manchin in an awkward position. The company essentially makes the Netherlands its headquarters, a move that allows its tax bill to be significantly lower. That's a practice known as inversion, and it has become a no-no in today's populist era. As my colleague Ho points out, President Obama called inversions an "unpatriotic loophole."

Manchin tells National Journal he thinks inversion should "be absolutely repealed."

2015: Yet another profile on Bresch. Fortune Magazine calls Bresch "the most powerful woman in the drug industry" as it chronicles her attempt to execute the largest hostile takeover in history of an over-the-counter drug manufacturer. (It failed.)

Fortune ranks Bresch No. 22 on its list of most powerful woman.

2016: Not only is Bresch under fire for the EpiPen price hike since 2007, but she's also weathering bad headlines for her pay spiking over the same time period. <u>NBC reports</u> her pay jumped 671 percent over the past eight years, along with other executives at the company.

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Amber Phillips writes about politics for The Fix. She was previously the one-woman D.C. bureau for the Las Vegas Sun and has reported from Boston and Taiwan. **Y** Follow @byamberphillips

EXHIBIT C

The New Hork Times https://nyti.ms/2rGQVBS

BUSINESS DAY

Outcry Over EpiPen Prices Hasn't Made Them Lower

Charles Duhigg

ADVENTURES IN CAPITALISM JUNE 4, 2017

A few weeks ago, after some particularly incompetent parenting on my part (nuts in the dessert, a rushed trip to an emergency room after my child's allergic reaction), I visited the local pharmacy to fill an EpiPen prescription.

You might recall EpiPen as last year's poster child for out-of-control drug prices. Though this simple medical device contains only about \$1 of the drug epinephrine, the company that sells it, Mylan, earned the public's enmity and lawmakers' scrutiny after ratcheting up prices to \$609 a box.

Outraged parents, presidential candidates and even both parties in Congress managed to unite to attack Mylan for the price increases. By August, the company, which sells thousands of drugs and says it fills one in every 13 American prescriptions, was making mea culpas and renewing its promise to "do what's right, not what's easy," as the company's mission statement goes.

So I was surprised when my pharmacist informed me, months after those floggings and apologies had faded from the headlines, that I would still need to pay \$609 for a box of two EpiPens.

Didn't we solve this problem?

Not quite. What's more, Mylan is back in the news. On Wednesday, regulators said the company had most likely overcharged Medicaid by \$1.27 billion for EpiPens. The same day, a group of pension funds announced that they hoped to unseat much of Mylan's board for "new lows in corporate stewardship," including paying the chairman \$97 million in 2016, more than the salaries of the chief executives at Disney, General Electric and Walmart combined.

Over the last several weeks, I've spoken with 10 former high-ranking executives at Mylan who told me that they weren't surprised EpiPen prices were still high. Nor were many startled by last week's developments.

Mylan, they said, is an example of a firm that has thrived by learning to absorb, and then ignore, opprobrium. The company has an effective monopoly on a lifesaving product, which has allowed its leaders to see public outrage as a tax they must pay, and then move on.

Mylan has been called out again and again over the years — by the company's own employees, regulators, patients, politicians and the press — and hasn't changed, even as revenue has skyrocketed, hitting \$11 billion last year. The firm is a case study in the limits of what consumer and employee activism, as well as government oversight, can achieve.

Which means this time, if we're hoping for a different outcome, something more needs to be done.

To understand Mylan's culture, consider a series of conversations that began inside the company in 2014. A group of midlevel executives was concerned about the soaring price of EpiPens, which had more than doubled in the previous four years; there were rumors that even more aggressive hikes were planned. (Former executives who related this and other anecdotes requested anonymity because they had nondisclosure agreements or feared retaliation. Aspects of their accounts were disputed by Mylan.) In meetings, the executives began warning Mylan's top leaders that the price increases seemed like unethical profiteering at the expense of sick children and adults, according to people who participated in the conversations. Over the next 16 months, those internal warnings were repeatedly aired. At one gathering, executives shared their concerns with Mylan's chairman, Robert Coury.

Mr. Coury replied that he was untroubled. He raised both his middle fingers and explained, using colorful language, that anyone criticizing Mylan, including its employees, ought to go copulate with themselves. Critics in Congress and on Wall Street, he said, should do the same. And regulators at the Food and Drug Administration? They, too, deserved a round of anatomically challenging selffulfillment.

When the executives conveyed their anxieties to other leaders, including the chief executive, Heather Bresch, these, too, were brushed off, they told me.

Those top leaders' responses are a far cry from the message on Mylan's website, which says that "we challenge every member of every team to challenge the status quo," and that "we put people and patients first, trusting that profits will follow."

But Mylan is a prime example of how easy it is for leaders to say one thing publicly and act differently in private. When we talk about consumer or employee activism, we tend to focus on firms like United Airlines, which quickly apologized and changed its policies after a video emerged of a passenger being dragged off a plane.

However, in many other cases, outrage is ineffective. Mylan's behavior persists because it is hard, and often tedious, for employees and the public to continue complaining — particularly when bosses disagree, or when some newer outrage appears on our Facebook feed.

But the costs of going silent are real. Regulators missed an opportunity to reform Mylan in 2012 when the company produced a television commercial showing a mother driving her son to a birthday party and implying that he could eat whatever he wanted, despite his nut allergy, as long as an EpiPen was nearby to counteract a reaction. The commercial also suggested that an EpiPen was a sufficient treatment on its own.

Mylan knew neither of those was true, according to executives from that period. In fact, Mylan had recently started a major lobbying effort to encourage schools to stock EpiPens by arguing that people with serious food allergies are always at risk, and that EpiPens were a necessary supplement to emergency medical treatment.

Before the birthday advertisement aired, the ad went through multiple internal review processes. Mylan executives told Ms. Bresch that the commercial was improper. One employee went so far as to send an internal email saying the advertisement would increase the frequency of allergic reactions, according to a person who saw the correspondence.

Ms. Bresch disagreed. She said it was better to act boldly, according to a former executive who participated in that conversation.

So the advertisement went on television. And a record number of consumer complaints arrived at the Food and Drug Administration. The agency ordered the commercial pulled after just a few days because it was "false and misleading," "overstates the efficacy of the drug product" and "may result in serious consequences, including death." The agency ordered Mylan to broadcast another ad, this one acknowledging that the "EpiPen cannot prevent an allergic reaction."

But regulators never investigated why Mylan's internal protocols had allowed the dangerous ad to air. And a year later, Mylan received something akin to a government endorsement. President Barack Obama signed a federal law encouraging schools to stock emergency epinephrine supplies. The White House celebrated it as the "EpiPen Law."

When I approached Mylan about these and other anecdotes, the company disputed employees' accounts. In a statement, it wrote that "any allegations of disregard for consumers who need these lifesaving drugs, government officials, regulators or any other of our valued stakeholders are patently false and wholly inconsistent with the company's culture, mission and track record of delivering access to medicine." Mr. Coury declined to be interviewed, but Ms. Bresch sat down with me last month at Mylan's Manhattan offices. She said that Mylan was "a pretty rare and unconventional company," and that it was focused on delivering low-cost drugs. A broken health care system, she said, is responsible for the inefficiencies and high prices that plague consumers.

She added that Mylan had responded promptly when the Food and Drug Administration criticized the company's advertisement in 2012, and that the EpiPen had become more expensive because Mylan had invested in public awareness and improving the device.

"Look at what we've built, and what we deliver day-in and day-out," Ms. Bresch told me, "and at the center of all of that is the patient."

But it seems hard to reconcile those comments with allegations from employees, regulators and other companies. In December, attorneys general in 20 states accused Mylan and five other firms of conspiring to illegally keep prices high on an antibiotic and a diabetes drug. In October, Mylan returned nearly a half-billion dollars to the federal authorities in an attempt to stem the investigation into overcharging that regulators cited on Wednesday. And in April, one of Mylan's competitors, Sanofi, filed a lawsuit accusing the firm of committing antitrust violations to keep an EpiPen competitor off the market.

Then there are situations that, at other firms, might have set off firings or corporate soul-searching, but that at Mylan caused neither. In 2007, reporters discovered that Ms. Bresch had not received the M.B.A. degree she claimed on her résumé. In 2012, Mr. Coury was criticized by investors and the media for repeatedly using the company plane to fly his son to music concerts. (And then there was the time, in 2013, when Mr. Coury, at a Goldman Sachs conference, indicated his dislike for hypothetical questions by saying that "if your aunt had balls, she'd be your uncle.")

In our interview, Ms. Bresch said there was nothing in Mylan's culture she would change. The company also said it had found no evidence of price-fixing or antitrust behavior, that the government overcharges had resulted from an innocent disagreement over regulatory interpretations and that Mylan's compensation policies were appropriate.

"We are a for-profit business, and we have a commitment to shareholders," Ms. Bresch told me. "But I think if there's any company out there that has demonstrated you can do good and do well, we're one of the few." For instance, Ms. Bresch noted that Mylan had recently released a generic version of EpiPen.

When I asked my pharmacist for the generic EpiPen, he told me that I would have to wait 90 minutes, until he could get my doctor on the phone to authorize the substitution. Then, he charged me \$370 for the generics.

Mylan points out there are online coupons for EpiPen customers. In fact, the company says that since it came under attack in August, nearly 90 percent of EpiPen buyers have paid less than \$100 per box because of insurance, discounts or coupons.

But for parents in urgent need of an EpiPen, or for patients who are poor, are not internet savvy or have high insurance deductibles — which are increasingly common — those programs can mean little. The most vulnerable often end up paying the highest prices, which is troubling when you consider that 15 million Americans have food allergies.

But hope springs eternal. With the recent criticisms coming on the heels of last year's controversies, Mylan will have to change, right?

Perhaps. But only if people stay angry and active. Doctors need to write different prescriptions. Pharmacists need to guide patients to alternatives. Investors should examine further efforts to elect new Mylan board members.

In the meantime, I still believe — perhaps foolishly — that sustained attention might create change. And so, as long as Mylan flouts the norms of good corporate behavior, it seems worth continuing to scrutinize what the company is doing, and questioning why EpiPens cost so much.

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