IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

Troy Gott, on behalf of himself and all others similarly situated, **Plaintiff,** **v.** **(1) Mylan N.V.,** **(2) Mylan Specialty L.P.,** **(3) Pfizer Inc., and** **(4) Meridian Medical Technologies, Inc.,** **Defendants.**	**Civil Case No. 20-2099** **Jury Trial Demanded**

CLASS ACTION COMPLAINT

Plaintiff Troy Gott ("Plaintiff"), individually and on behalf of all others similarly situated, brings this Class Action Complaint against Defendants Mylan N.V.; Mylan Specialty L.P. (together, "Mylan"); Pfizer, Inc.; and Meridian Medical Technologies, Inc. (together, "Pfizer," and all Defendants collectively together, Mylan and Pfizer, as "Defendants"), and alleges:

INTRODUCTION

1. This lawsuit arises from organized deception by Defendants regarding the notorious EpiPen product: a scheme to manipulate EpiPen expiration dates in order to force patients to refill EpiPen prescriptions more often. By doing so, Defendants extracted hundreds of millions of dollars of excess profits every year, year after year, for over the last decade.[1]

[1] For simplicity, this Complaint uses the term "EpiPen" to refer to the EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, and EpiPen Jr. 2-Pak® (collectively or individually, the "EpiPen") except where otherwise noted. (hereafter without ® for readability).

2. The EpiPen is an epinephrine autoinjector device for the treatment of anaphylaxis. The EpiPen is manufactured by Meridian Medical Technologies, Inc. ("Meridian"), a Pfizer subsidiary, and marketed and sold in the United States by Defendant Mylan Specialty L.P, a wholly owned subsidiary of Mylan N.V.

3. Defendants have manipulated the EpiPen shelf life and engaged in deceptive practices to force consumers and purchasers to buy the EpiPen more often than is medically necessary by (a) putting forward shelf lives that are not supported by the companies' internal data and studies; (b) aggressively pushing consumers to purchase the EpiPen every 12 months, on a cycle, in sync with the "back to school" retail season; and, (c) embarking on deceptive marketing programs (using the interstate mails and wires) to manipulate consumers and schools into encouraging and believing this false annual retail purchasing cycle.

4. Because the actual EpiPen expiration date is much longer than 12 months, Defendants worked to deceive consumers and purchasers into obtaining the EpiPen every 12 months. This scheme to defraud ensured a steady revenue stream (good for Wall Street earnings and revenue projections), more EpiPen purchases, and an easier (albeit fraudulent) marketing strategy by which Defendants could manipulate and leverage the "back to school" retail season.

5. Defendants were motivated to put profits and revenue ahead of lives and medicine. As the world has learned in recent years, Mylan is a bare-knuckled company that is willing to do and say anything to deliver more profits and dollars into the pockets of its top executives. Mylan's five top executives have been exposed by the Wall Street Journal as paying themselves $82 million in excess, windfall profits based on the inflated sales and sales price of the EpiPen:

> The drugmaker at the center of a firestorm over hefty price increases on the lifesaving EpiPen put a special incentive plan in place more than two years ago that rewards executives if they hit aggressive profit targets.
>
> In early 2014, the board of Mylan NV approved a one-time award for more than 100 employees that hinged on more than doubling the company's adjusted per-share earnings over a five-year period ending in 2018, Mylan's regulatory filings show. Meeting that goal would require 16% compound annual earnings growth—a tall order for a company that generated almost 90% of its revenue from the generally mature generic-drug business.
>
> At the time it was granted, the award was potentially worth as much as $82 million overall to the company's top five executives. But it would be worthless if the company—whose star product is the EpiPen—fails to achieve at least 90% of its 2018 earnings target.[2]

6. Artificially restricting the EpiPen expiration date and forcing more purchases of the EpiPen based on a fictitious "12-month cycle" was a perfect path for Mylan's executives to ensure that they would hit these earnings targets and personally enrich themselves. Mylan worked with Pfizer (which manufactures the EpiPen and packages it) to implement a scheme to make sure that the expiration date was lowered and consumers and payors were without the data or means to ferret out the truth behind the various and secretive ways in which the early expiration scheme was carried out.

7. As of 2001, the EpiPen had an approved 27-month shelf life from the date of manufacture until the device expired and was no longer intended for use.[3]

8. In November 2001, Meridian (now owned by Pfizer) submitted a new stability protocol along with data that reduced the EpiPen's shelf life from 27 months from the date of manufacture to only 20 months from the date of manufacture under a "Changes Being Effected in

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[2] Mark Maremont, *EpiPen Maker Tied Executive Pay to Aggressive Profit Targets*, WALL ST. JOURNAL, Sept. 1, 2016, available at: https://www.wsj.com/articles/epipen-maker-mylan-tied-executive-pay-to-aggressive-profit-targets-1472722204

[3] FDA, Center for Drug Evaluation and Research, *Approval Package for 019430Orig1s015* (Apr. 16, 2002), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf

30 days" supplemental new drug application ("sNDA").

9. The data, study, and sNDA did not recite any reason or justification at all for this 25% reduction in shelf life. The epinephrine remained the same, as did the device itself.

10. Sometime before 2016, Pfizer and then Mylan began telling doctors and patients that EpiPens expired only 18 months after the date of manufacture and presumably began printing this 18-month expiration date on every EpiPen and instructing patients that they should refill their prescription and purchase a new EpiPen after that date.

11. As part of the national controversy over EpiPen pricing in Fall 2016, Mylan's CEO, Defendant Bresch, testified to Congress under oath on September 21, 2016, that EpiPens expire 18 months after the date of manufacture.[4]

12. Finally, in August 2018, in response to an epinephrine injector shortage during back-to-school season, Pfizer and Mylan extended the shelf-life of certain lots of EpiPens and authorized generic EpiPens (but not EpiPen Jrs.) by four months, which required these companies to produce data showing these products were actually safe and effective up to 22 (or potentially 24) months after the date of manufacture, contrary to Defendants' representations to doctors, patients, and Congress over the last several years.[5] In other words, EpiPens appear to suddenly have a longer shelf life when it serves Defendants' interests. Defendants' interests were two-fold: (a) to prevent consumers from switching to a competitor; and, (b) to take advantage of the huge "back to school" annual retail selling cycle it had created.

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[4] *Reviewing the Rising Price of EpiPens: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. 28 (2016) (Testimony of Heather Bresch), https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/pdf/CHRG-114hhrg24914.pdf ("*Rising Price*").

[5] *FDA takes additional action to mitigate shortage of EpiPen by extending expiration date for specific lots of medication* (Aug. 21, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm617724.htm

13. In fact, however, the ability of Defendants to suddenly expand the expiration date proves the fraud scheme and makes clear that the "temporary" expiration date should have been (at a minimum) the "permanent" expiration date all along, for all lots of EpiPens. If the longer expiration date were not safe, the FDA never would have approved it, temporarily or not.

14. The following table reflects Defendants' ever-changing position as to the shelf life of the EpiPen:

Date	Purported EpiPen Shelf Life	Source
Before Nov. 2001	27 months	Meridian sNDA submission
Nov. 2001	20 months	Meridian sNDA submission
Sept. 2016	18 months	Defendant Bresch testimony to Congress
Sept. 2016	12-14 months	Actual shelf life reported by patients
Aug. 2018-present	22 or 24 months (only certain lots; not EpiPen Jr.)	4-month extension of some EpiPens in response to drug shortage

15. Published medical journals show that EpiPens have a longer shelf life than what is presented to doctors and patients. Specifically, a 2015 study published in the *Annals of Allergy, Asthma, and Immunology* analyzed several EpiPen devices that were up to 24 months past the stamped expiration date (and therefore *42 months from the date of manufacture*) and concluded that 100% of these devices contained at least 90% of the original dose and would therefore be considered to still be safe and effective according to FDA standards.[6]

16. Defendants' incentive to artificially reduce and otherwise manipulate the EpiPen expiration date is clear because of two distinct features of the EpiPen market:

a. Unlike other prescription drugs (for example, antibiotics), EpiPens are prescribed with the expectation they will be used *only* in the rare,

[6] Rachid, et al., *Epinephrine doses contained in outdated epinephrine auto-injectors collected in a Florida allergy practice*, 114 ANNALS OF ALLERGY, ASTHMA, AND IMMUNOLOGY, 354-56 (2015).

unexpected occurrence of a life-threatening anaphylactic emergency. That means the vast majority of EpiPens (somewhere well above 95%) expire before use. In turn, almost all patients re-purchase EpiPens based strictly on expiration dates and *not* when they have consumed or used the EpiPen—because, again, few EpiPens are ever used. Indeed, the very act of purchasing an EpiPen is *proof* that the patient knows of her allergy, which in and of itself makes it likely she will avoid exposure to the thing that necessitated the purchase of an EpiPen in the first place.

b. The EpiPen device has historically dominated the epinephrine autoinjector market, possessing approximately 95% market share as of January 2016.

17. Defendants appear keenly aware of the financial significance of EpiPen expiration dates and go to extraordinary lengths to convince patients, schools, and other stakeholders to dispose of expired EpiPens and repurchase new ones at a cost of several hundred dollars every year. This is best illustrated by Mylan's "*My EpiPen Email Program*," through which Mylan emails patients to remind them when their EpiPens are about to expire so they can repurchase new ones before their devices expire.[7]

18. While annually extracting hundreds of millions of dollars from increased prescription frequency, Defendants have maliciously ignored the health risks created by their scheme to artificially reduce EpiPen expiration dates, which is that patients facing life-threatening emergencies may be reluctant to use "expired" EpiPens when these devices still provide life-saving medicine. There is at least one documented instance where a mother did not administer an EpiPen that was expired by two months to her college-aged son, who died of the anaphylactic reaction

[7] My EpiPen Email Program, https://www.epipen.com/en/my-epipen

while the EpiPen (which could have been safely used) sat dormant.[8]

19. Obviously, increased shelf life will lead to a decrease of annual sales on a per patient basis.[9] Indeed, a 33% shelf life increase would result in the same 33% decrease in sales.

20. Defendants' actions to manipulate EpiPen expiration dates are part of an illegal scheme to defraud that must be corrected under the civil damages provisions of the Racketeering and Corrupt Practices Act ("RICO")[10] and have damaged Plaintiffs' and the Class (defined below).

21. For all Defendants' actions alleged herein, Plaintiffs seek to recover all damages from December 21, 2001 through the present (the "Class Period"), trebled under RICO, along with costs, attorneys' fees, and pre- and post-judgment interest. Disgorgement of Defendants' excess profits is also an appropriate remedy under common law unjust enrichment.

PARTIES

22. **Plaintiff Troy Gott** is a resident and citizen of Kansas. He has purchased several EpiPens in Kansas at a cost of several hundred dollars each during the Class Period, and generally purchases EpiPens at or near the expiration date printed on each device. Plaintiff Troy Gott would not have purchased as many EpiPens in recent years if Mylan and Pfizer had not artificially reduced the expiration date on the EpiPen product and he thereby suffered financial injury. Mr. Gott monitored the expiration date of the EpiPens he purchased, and as the expiration date approached, he made sure that he and his family purchased new EpiPens on the cycle Defendants created and recommended so that the EpiPens would not be expired. Had Mr. Gott known that the true

[8] Karen Miller, *College Freshman with Peanut Allergy Dies After Eating a Cookie*, ABCNEWS.COM, Mar. 15, 2013, https://abcnews.go.com/Health/Allergies/college-freshman-peanut-allergy-dies-eating-cookie/story?id=18723777

[9] *See* Document produced by Mylan in *In re EpiPen MDL* in the D. Kansas as MYEP01033932.

[10] 18 U.S.C. § 1961, et seq.

expiration date was much longer, he would have followed the true expiration date and made his purchases later, only as needed and as dictated by the true expiration date.

23. Likewise, Mr. Gott's child's school required him to maintain a non-expired EpiPen at the school, a reality that millions of Americans face (despite Mylan's self-touted EpiPen4Schools program). If his child's EpiPen was expiring, he was required to make another purchase by the school.

24. All purchases made by Troy Gott were for personal, family, or household use.

25. **Defendant Mylan N.V.** is a publicly-traded corporation incorporated under the laws of the Netherlands with its principal executive offices located in Hartfield, Hertfordshire, England and its global headquarters located in Canonsburg, Pennsylvania, from where it directs the management and operations of its global pharmaceutical business. Mylan N.V. is the corporate successor to Mylan Inc. (by virtue of a 2015 transaction) and is the parent company of Mylan Specialty L.P, a wholly owned subsidiary, that markets and sells the EpiPen in the United States. Mylan N.V. is not directly registered to do business in the State of Kansas, but conducts business in the state through its wholly owned subsidiaries.

26. **Defendant Mylan Specialty L.P.** is a limited partnership organized under Delaware law with its principal offices located at 781 Chestnut Ridge Road, 3rd Floor, Morgantown, WV 26505. Mylan Specialty L.P. is a wholly owned subsidiary of Mylan N.V. and as a result is authorized to accept service on behalf of Mylan N.V.

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

28. Mylan Specialty L.P. is not registered to do business in Kansas, but it transacts business in the Kansas so it can be properly served through the Kansas Secretary of State. Mylan

Specialty L.P. purposefully directs activities to Kansas patients by shipping thousands of EpiPens to Kansas patients each year, maintaining the *My EpiPen Email Program* that directly emails Kansas patients to remind them to purchase new EpiPens, and by otherwise advertising and marketing the EpiPen directly to Kansas doctors, hospitals, schools, patients, either on its own or in coordination with Mylan N.V. and/or other wholly-owned subsidiaries. The harms allege in this Complaint arise from Mylan Specialty L.P.'s activities directed towards Kansas patients.

29. Mylan N.V. and Mylan Specialty L.P. operate as a single entity, along with other wholly-owned subsidiaries to sell and market EpiPens nationwide and specifically into the State of Kansas.

30. Together, Mylan N.V. and Mylan Specialty L.P. (including Dey, its predecessor) are referred to herein as "Mylan" or the "Mylan Defendants."

31. **Defendant Pfizer Inc.** is a publicly traded corporation organized under Delaware law with its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the parent company of Meridian Medical Technologies, Inc., which manufactures the EpiPens to be marketed and sold by the Mylan Defendants.

32. **Defendant Meridian Medical Technologies, Inc.** is corporation organized under Delaware law with its principal place of business located at 6350 Stevens Forest Road, Suite 301, Columbia, Maryland. Meridian Medical Technologies, Inc. became a wholly owned subsidiary of Pfizer by virtue of a 2011 transaction in which Pfizer acquired King Pharmaceuticals, Inc., which was the parent company of Meridian Medical Technologies.

33. Pfizer Inc. and Meridian Medical Technologies, Inc. purposefully directed activities and knew that EpiPens would be marketed and sold in Kansas.

34. Together, Pfizer, Inc. and Meridian Medical Technologies, Inc. are referred to

herein as "Pfizer" or the "Pfizer Defendants."

JURISDICTION AND VENUE

35. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1332(d) 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 28 U.S.C. §§1331.

36. 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.

37. Venue is proper in this forum pursuant to 28 U.S.C. § 1391 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

A. Allergies, Anaphylaxis, and Epinephrine

38. The EpiPen and EpiPen Jr. are disposable, prefilled automatic injection devices for the delivery of epinephrine (also known as adrenaline), used in the treatment of severe allergic reactions known as anaphylaxis.

39. Anaphylaxis is a 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.

40. Food allergens, medications, latex, exercise, and insect bites are the most common causes of anaphylaxis. Epinephrine is also used to treat anaphylaxis caused by exercise or unknown substances.

41. 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.[11]

42. Epinephrine is often effective at reducing the symptoms of anaphylaxis if administered promptly. In the vast majority of cases, an epinephrine auto-injector is the most effective device for quickly administering epinephrine.[12]

43. Patients prone to anaphylaxis are advised to carry an epinephrine auto-injector at all times, to be used in the event of a severe allergic reaction. In short, epinephrine auto-injectors can prevent suffering and save lives.

B. The EpiPen

44. The predecessor 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 immediate doses of epinephrine, thus creating the EpiPen.[13]

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[11] Selena Larson, *Outrageous EpiPen prices lead some people to make their own*, CNNBUSINESS, Sept. 24, 2016, https://money.cnn.com/2016/09/24/technology/diy-epipen-affordable-alternatives/?iid=TL_Popular

[12] Ben Popken, *Mylan's Upgraded EpiPen Torn Apart By Experts*, NBC NEWS, Sept. 20, 2016, http://www.nbcnews.com/business/consumer/mylan-says-it-upgraded-epipen-2009-so-experts-looked-inside-n652651

[13] Matt Reimann, *The Story of the EpiPen: From Military Technology to Drug-Industry Cash Cow*, TIMELINE, Aug. 20, 2016, https://timeline.com/epipen-technology-drug-industry-b28d19036dee#.seg6n7dls,

45. The FDA approved the EpiPen for sale in the United States on December 22, 1987 under New Drug Application ("NDA") #019430.[14]

46. 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.

47. The EpiPen has two important 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."[15]

48. EpiPens are currently manufactured by Meridian Medical Technologies, a subsidiary of Pfizer, but are marketed and sold in the United States by Mylan, through its subsidiary: Mylan Specialty L.P.[16]

49. The current EpiPen label describes the company's relationship with regards to the EpiPen as follows:

[14] Drugs@FDA, NDA 019430, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430

[15] *See What is Epinephrine?*, Epipen.com, https://www.epipen.com/about-epipen/what-is-epinephrine (emphasis in original)

[16] EpiPen Label (rev. 2/2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019430s074lbl.pdf

> Manufactured for Mylan Specialty L.P., Morgantown, WV 26505, U.S.A. by Meridian Medical Technologies, Inc., Columbia, MD 21046, U.S.A., a Pfizer company
>
> EpiPen® and EpiPen Jr® are registered trademarks of Mylan Inc. licensed exclusively to its wholly-owned affiliate, Mylan Specialty L.P. of Morgantown, WV 26505, U.S.A.
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50. Unlike most pharmaceutical products that are manufactured, sold, and marketed to the public by a single company, the EpiPen manufacturing, sales, and marketing functions have been split between two companies (now, Mylan and Pfizer) through various mergers and acquisitions:

Date	Manufacturing	Sales and Marketing[17]
1996	Longtime EpiPen manufacturer, Survival Technology, Inc. merges with Meridian Medical Technologies, Inc.	
1997		Dey Pharma L.P. obtains exclusive rights to market EpiPen in the US from Meridian Medical Technologies, Inc.
2002	Meridian Medical Technologies, Inc. acquired by King Pharmaceuticals Inc.	
2004		Dey Pharma L.P. becomes part of Merck KGaA
2007		Mylan Inc. acquires Merck KGaA including Dey Pharma L.P. and the EpiPen
2010	Pfizer Inc. acquires King Pharmaceuticals Inc. including Meridian Medical Technologies, Inc. and the EpiPen, which continues to manufacture the EpiPen until today	
2012-Present		Mylan Inc. changes the name of Dey Pharma L.P. to Mylan Specialty L.P. in line with the Mylan brand, which continues to market the EpiPen until today

[17] Mylan, *27th Annual JP Morgan Healthcare Conference Presentation*, Jan. 13, 2009, slide 7, http://i.bnet.com/blogs/mylan-ir-jan-09.pdf

51. The EpiPen provides a 0.3 mg dose of epinephrine, while the EpiPen Jr. contains a 0.15 mg dose. The EpiPen Jr., intended for children, has a retail price that is the same as the EpiPen, despite containing half the medicine (0.15 mg instead of 0.3 mg) of the EpiPen. Mylan claims that food allergies among U.S. children are "on the rise, now affecting one in 13" kids.[18]

52. 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."[19]

53. As of January 2016, the EpiPen controlled approximately 95.2% of the epinephrine auto-injector market.[20]

54. 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."[21] And the EpiPen contains "essentially [the] same core technology that [has been] there for many years."[22]

55. In fact, two engineering industry experts peg the total cost of making an EpiPen

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[18] *Mylan Applauds New Federal Legislation to Increase Anaphylaxis Preparedness in Schools*, MYLAN INC. (Nov. 14, 2013), http://newsroom.mylan.com/press-releases?item=123181

[19] Cynthia Koons and Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG (Sept. 23, 2015), http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business

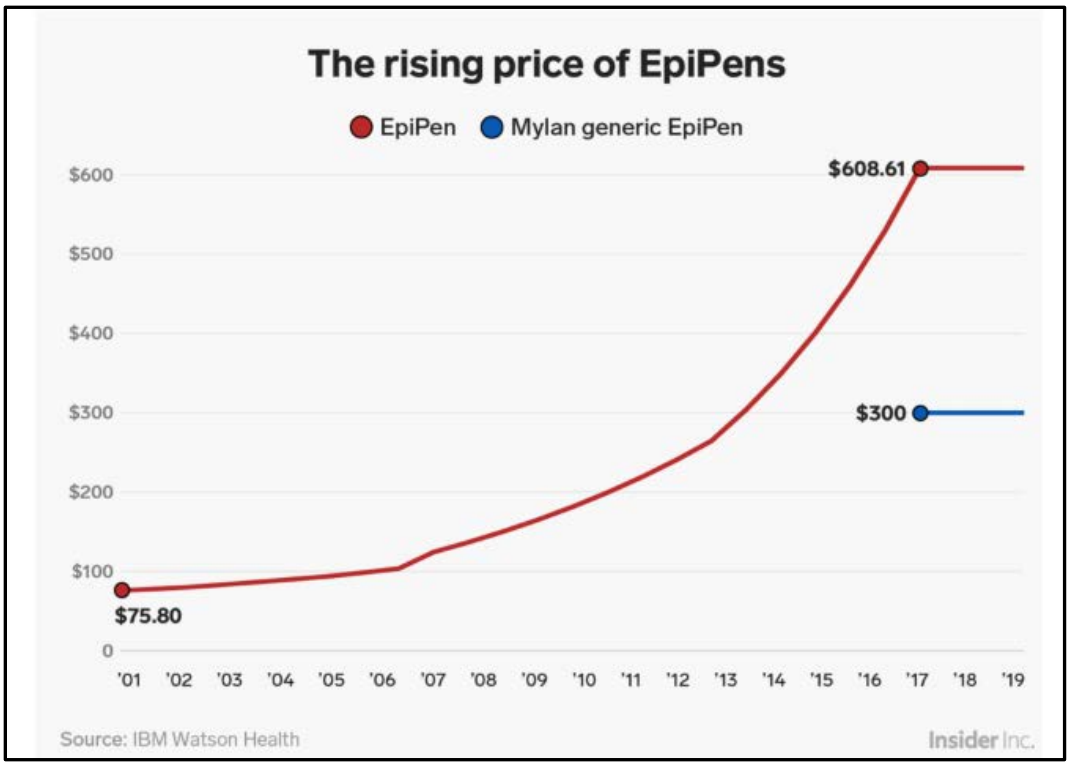
[20] Sy Mukherjee, *Mylan's EpiPen is Bleeding Market Share to Its Rivals*, FORTUNE (Mar. 6, 2017), http://fortune.com/2017/03/06/mylan-epipen-competitors-surge/ (last visited Jan. 3, 2019)

[21] Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than $30*, NBC NEWS (Sep. 6, 2016), http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091

[22] *Id.*

2-Pak at between $8.02 and $10.03, and that "even include[s] the bright-yellow box."[23]

56. In August 2016, a national controversy erupted over the price of EpiPens, which had risen from $93.88 per two-pack in 2007, when Mylan acquired the EpiPen franchise, to $608.61 as of May 16, 2016—an increase of more than 500% over nine years.[24] The rise in price from the time Mylan and Heather Bresch took over the EpiPen is jarring:



C. Existing EpiPen Litigation

57. Mylan and Heather Bresch have been dismantled by the national media for engaging in price gouging while lying about access to medicine and the United States Congress

[23] Tracy Seipel, *EpiPen Outrage: Silicon Valley Engineers Figure Real Cost to Make Lifesaving Auto-Injector Two-Pack — about $8*, MERCURY NEWS (Oct. 1, 2016), http://www.mercurynews.com/2016/10/01/epipen-outrage-silicon-valley-engineers-figure-true-cost-to-make-lifesaving-auto-injector-about-10/

[24] Lydia Ramsey and Andy Kierz, *An EpiPen is 500% more expensive than it was in 2007 – here's how that happened*, BUSINESS INSIDER (Aug. 24, 2016), https://www.businessinsider.com/epipen-price-increases-2016-8.

(both the U.S. House and Senate) for lying under oath about the EpiPen..

58. Pfizer's role, while less public, has also been exposed in various media articles, including the fact that Mylan and Pfizer have a splintered and overlapping role in the ownership of the IP surrounding the EpiPen and Mylan and Pfizer jointly work together on key EpiPen decisions, including price. Pfizer shares proportionally in the EpiPen's sales in the United States.

59. Several lawsuits have already been filed to remedy Defendants' and pharmaceutical intermediaries' bad acts regarding the EpiPen.

60. From July 2010 until March 2017, Mylan knowingly submitted false statements to state and federal Medicaid programs that incorrectly classified the EpiPen as a "noninnovator multiple source" drug (i.e. a generic drug) rather than a "single source" or "innovator multiple source" drug (i.e. a brand drug) in order to reduce the rebate percentage that Mylan owed from 23.1% to 13%, thereby earning Mylan hundreds of millions of dollars in illegal, excess profits. In August 2017, Mylan entered a settlement agreement in which they agreed to pay the government $465 million to resolve False Claims Act liability related to misclassification of EpiPens for purposes of the Medicaid drug rebate program.[25]

61. Mylan, Pfizer, and Heather Bresch have also been sued for their actions regarding the EpiPen in *In re EpiPen Mktg., Sales Practices & Antitrust Litig.*, No: 2:17-md-02785-DDC-TJJ (MDL No. 2785) (D. Kan.), in which Plaintiffs allege that Defendants violated antitrust laws, RICO, and state consumer protection statutes by carrying out a multi-faceted scheme to illegally

[25] 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, https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates/; *United States ex rel. Sanofi-Aventis US LLC v. Mylan Inc., et al.*, No. 16-CV-11572 (D. Mass.), Settlement Agreement.

maintain its monopoly of the epinephrine auto-injector market and coerce and deceive patients into paying inflated prices.

62. Specifically, the Plaintiffs in that case allege that Defendants: (1) paid pharmaceutical benefit managers to exclude competition; (2) used sham patent litigation to block generic epinephrine auto-injector products; (3) forced EpiPens patients to purchase two devices at a time without medical justification; and (4) made a variety of false and misleading statements to pharmaceutical stakeholders to conceal its illegal activities.[26]

D. FDA Regulation Require Drug Expiration Dates

63. Under FDA regulations, prescription drug products must bear an expiration date determined by appropriate stability testing to assure the product meets applicable identity, strength, quality, and purity standards when a drug product is used.[27]

64. Stability testing protocols are governed by CFR § 211.166, which requires a written testing program to assess the stability characteristics, appropriate storage conditions, and expiration dates for drug products and must include the following data: "(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability; (2) Storage conditions for samples retained for testing; (3) Reliable, meaningful, and specific test methods; [and] (4) Testing of the drug product in the same container closure system as that in which the drug product is marketed . . . ."[28]

65. Manufacturers are required to test an adequate number of batches of each drug

[26] *See, e.g., In re: EpiPen Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256 (D. Kan. 2018).

[27] 21 CFR § 211.137(a).

[28] 21 CFR § 211.166(a).

product to determine an appropriate expiration date and record and maintain the relevant data.[29]

66. Manufacturers are allowed to conduct accelerated stability studies to support tentative expiration dates when full shelf life studies are not available and are underway.[30] When data is taken from this type of accelerated stability study, drug sponsors are required to test the drug product at appropriate intervals until the tentative expiration date is verified or an alternative expiration date is determined.[31]

67. The relevant FDA guidance regarding stability standards define the terms 'shelf life' and 'expiration date' as follows:[32]

> **Expiration date:** The date placed on the container label of a drug product designating the time prior to which a batch of the product is expected to remain within the approved shelf life specification, if stored under defined conditions, and after which it must not be used.
> . . .
> **Shelf life (also referred to as expiration dating period):** The time period during which a drug product is expected to remain within the approved shelf life specification, provided that it is stored under the conditions defined on the container label.

68. Manufacturers must post a drug product's expiration date on both the immediate container of the drug product and the outer package, unless the expiration date is legible through the outer package or the product is a single-dose container packaged into individual cartons.[33]

69. As a whole, these regulations require drug sponsors to conduct appropriate stability

[29] 21 CFR § 211.166(b).

[30] 21 CFR § 211.166(b).

[31] 21 CFR § 211.166(b).

[32] FDA, *Guidance of Industry, Q1A(R2) Stability Testing of New Drug Substances and Products, Revision 2*, Nov. 2003, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073369.pdf

[33] 21 CFR § 201.17.

testing and then propose an expiration date for their own drug products.[34]

70. The FDA does not conduct testing or determine drug product expiration dates. Nor does the FDA regulate or establish the expiration date, or whether it is too short so as to deceptively increase sales. The FDA is limited only to evaluating patient safety and physical harm, nothing more.

FACTUAL ALLEGATIONS

A. The EpiPen Sham Expiration Scheme

71. The Defendants' efforts to mislead consumers and payors into paying more for the EpiPen depended, in part, on Defendants manipulating the expiration date for the EpiPen. The profit temptation was simple: by pinching the expiration date, the product lasts a shorter period of time, and thus consumers and payors have to purchase it more often. With this simple math in mind, Defendants were on their way to committing fraud to gin up excess profits for their bottom lines, to keep Wall Street happy, and to ensure that top executives at Mylan raked in massive bonuses year after year.

Meridian reduces the EpiPen Shelf Life from 27 months to 20 months.

72. Before November 2001, the EpiPen product had an FDA-approved shelf life of 27 months from the date of manufacture until the product expired.[35]

73. On November 21, 2001, Meridian submitted to the FDA *Changes Being Effected* in 30 days supplemental new drug application (S015) to NDA 19-430 that proposed the company reduce the shelf life of the EpiPen from 27 months from date of manufacture to 20 months from

[34]https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm605559.htm ("FDA regulations require drug applicants to provide stability testing data with a proposed expiration date and storage conditions when they submit an application for FDA approval of their drug.").

[35] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf.

the date of manufacture and modified the Master Stability Protocols for the EpiPen and EpiPen Jr. products.[36]

74. The November 2001 Master Stability Protocol superseded a previous stability protocol that had been approved only three years earlier on November 20, 1998.[37]

75. As part of the new November 2001 Master Stability Protocol, Meridian signed and agreed that any amendment to the stability protocol "must be documented and be approved by Research and Development, Regulatory Affairs and Quality" departments within Meridian and also that "FDA will be notified of all amendments" through appropriate regulatory channels.[38]

76. On April 16, 2002, the FDA responded to Meridian's *Changes Being Effected* sNDA and did not object to the company's proposed changes to the EpiPen product or Master Stability Protocols for either the EpiPen or EpiPen Jr.[39]

Defendants further reduce the EpiPen shelf life from 20 months to 18 months.

77. Sometime after 2001 and before 2016, for which discovery is needed because this information is held by Defendants, Meridian and/or Mylan further reduced the shelf life of the EpiPen and EpiPen Jr. products when it began selling and labeling these products with an expiration date that was only 18 months after the product was manufactured.

78. To this end, in September 2016, Mylan's CEO, Heather Bresch, specifically testified to Congress that EpiPens shelf life was 18 months, not 12 months as is commonly assumed, and that Mylan was then working to lengthen the product's shelf life (back) to 24

[36] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf.
[37] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf.
[38] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf.
[39] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf.

months.[40]

79. Ms. Bresch was sworn in and testified under oath before Congress on September 21, 2016, in Washington D.C. The media widely documented her raising her right hand and swearing to tell the truth to Congress during the hearing, "Reviewing the Rising Price of EpiPens."

80. While under oath, Ms. Bresch testified that the then-current shelf life of the EpiPen was "eighteen [18] months" and that Mylan was "hopeful" to reach an expiration date of "twenty-four [24] months." Here's a relevant portion of her testimony:

[40] *Rising Price*, *supra*, at n.5.

Mr. CUMMINGS. That's not what I asked you. I said, how much did you spend on R&D in 2015? And I think the hearing is about EpiPens. And I've got to tell you, I talked about in my opening statement about rope-a-doping, that's what I'm feeling like. I mean, I feel like you're not giving me answers, ma'am.

And I think, in fairness to us, you knew what this hearing was about, you knew what our concerns were, and I just, I'm asking you questions that—you're the CEO?

Ms. BRESCH. Yes, sir.

Mr. CUMMINGS. That I would think you would know. I mean, seems like this stuff would be jumping out of the top of your head.

Ms. BRESCH. Sir, as a company, Mylan spent $750 million this year, is what we're projected to spend on R&D. For EpiPen it's not broke down so much in products.

What I can tell you is that our overwhelming majority of what we've spent has been on access and awareness programs. We have, like I said, we've been developing over the years, working on smaller different devices due to patient feedback. What we have been successful in is reformulating it so it will have a longer shelf life, and that will extend the time needed between refills.

But the majority of our——

Mr. CUMMINGS. Can we stop right there, right there?

Ms. BRESCH. Sure.

Mr. CUMMINGS. Let's put a pen in that one. This longer shelf life, how are we coming with that? Right now it's about a year. Is that right?

Ms. BRESCH. Eighteen months.

Mr. CUMMINGS. Eighteen months. So how long are we trying to get it up to? Because I heard that it was a year, but I'm glad to hear it's 18 months. But go ahead.

Ms. BRESCH. So——

Mr. CUMMINGS. What are your researchers—what are you projecting?

Ms. BRESCH. Twenty-four months is what we're hopeful for, and maybe even longer, but a minimum of 24 months.

Mr. CUMMINGS. How soon will we know, do you think? What do your researchers—since you're spending all this money on it, what are your researchers telling you, how soon do they say they'll have an answer?

Ms. BRESCH. Sir, we're looking to submit it within days to the FDA. We've been working on this for a couple of years. And it will be with 24 months that you do kind of—you continue to—after you submit it to the FDA, you're able to continue to work on stability, and that there is an opportunity that it could go longer. But we, at a minimum, 24.

81. During this exchange, Congressperson Cummings expressed surprise, saying, "Because I heard that it was a year, but I'm glad to hear it's 18 months."[41]

82. Ms. Bresch's statements regarding the expiration date were knowingly false. By

[41] *Rising Price*, *supra*, at n.5.

testifying before Congress, Ms. Bresch sought to and did in fact conceal Defendants' attempts to manipulate the expiration date of the EpiPen. The September 21, 2016 hearing was expressly devoted to Mylan's price gouging and exploitation of the American public, and by being untruthful and dishonest before Congress, Ms. Bresch corrupted an official proceeding on behalf of Mylan.

83. Ms. Bresch's September 21, 2016 testimony was also knowingly false because Mylan knew at the time of the hearing that the expiration date of the EpiPen is longer than 18 months. In fact, it is believed that the then FDA-approved shelf life was at least 20 months. Thus, by representing to Congress that the expiration date is 18 months and that Mylan is looking to increase the expiration date to "24 months," Ms. Bresch lied to Congress and sought to legitimize the false expiration date in a public hearing.

84. Further, Ms. Bresch's testimony was knowingly false because Mylan and Pfizer never did submit an extended expiration date to the FDA, which she said Mylan was looking to submit "within days." It has now been over 1,000 days since Ms. Bresch testified on September 21, 2016, and no FDA submission has been made to extend the expiration date for all EpiPen lots. That's because Mylan knew that to extend the expiration date to 24 months would be to cut its sales in half, taking away the annual "back to school" retail cycle and making it the "every other year back to school" retail cycle. Mylan's bottom line (and Ms. Bresch's bonus pay) would have been wrecked by this change, so Mylan made sure to suppress the extended expiration date.

85. In addition, Ms. Bresch's September 21 statements are contradicted by recent FDA statements that show, at a bare minimum, EpiPen's approved shelf life is 20 months, not 18 months as stated by Ms. Bresch and apparently printed on each EpiPen device.[42]

[42] https://www.fda.gov/newsevents/newsroom/fdainbrief/ucm617724.htm ("the change beyond the approved 20-month shelf life . . . .) (Aug. 21, 2018).

Defendants mislead and falsely encourage patients to refill EpiPen prescriptions within 18 months, or sooner.

86. Defendants have widely promoted the 18-month shelf life for the EpiPen and EpiPen Jr. products and specifically instruct EpiPen customers to dispose and re-purchase EpiPens before the 18-month expiration date printed on each autoinjector.

87. The expiration date is prominently displayed on every EpiPen and EpiPen Jr. carton and each individual EpiPen device, as shown in the photograph below:

88. Mylan's current EpiPen website includes the following advice regarding the use of

---

See also, https://gizmodo.com/epipen-expiration-dates-extended-as-schools-face-shorta-1828491035 ("'Mylan submitted additional data to the FDA to show specific lot of its EpiPen product remained stable, retaining its strength, quality and purity for up to 24 months when stored according to its labeled storage conditions,' FDA spokesperson Theresa Eisenman told Gizmodo over email.").

https://www.cnbc.com/2018/08/21/fda-extends-certain-epipen-expiration-dates-to-combat-shortage.html ("EpiPens typically have a shelf life of 20 months, according to the FDA . . . .")

EpiPen and EpiPen Jr. products before the 18-month expiration date:[43]

> **Do EpiPen and EpiPen Jr AutoInjectors (or their authorized generics) expire? If so, what should I do when one expires?**
>
> Like any medication, EpiPen Auto-Injector (and its authorized generic) has an expiration date, which is printed on the side of the auto-injector. Because the effectiveness of epinephrine may decrease after the expiration date, you should promptly refill your prescription before the expiration date. You can register your auto-injectors online through the My EpiPen program and we'll send you reminders before your devices expire.

89. Mylan specifically encourages patients to sign up for the My EpiPen Email Program so that the company can send patients reminders to refill their prescription before their EpiPens expire, thereby ensuring that patients purchase new EpiPens before or at 18 months after the date of manufacture.[44]

Mylan submits data to extend the EpiPen shelf life for some lots to 24 months.

90. In August 2018, the FDA announced a shortage of EpiPen and similar epinephrine autoinjector devices during the back-to-school season when many parents and schools ordinarily replace (prematurely) expired devices.

91. In response, Defendants submitted additional stability data to the FDA that extended the shelf life of only certain lots of EpiPens (and their authorized generic equivalent product) by an additional 4 months to a total of 22 months (or potentially 24 months) from the date of manufacture.[45] Defendants did not extend the shelf life of any EpiPen Jr. auto-injectors in response to the recall and did not extend the shelf life of all EpiPens on a permanent basis.

92. The FDA announced that it had approved the additional shelf life for these lots "beyond the approved 20-month shelf life [] based on stability data provided by Mylan and

[43] https://www.epipen.com/about-epipen-and-generic/faq

[44] https://www.epipen.com/en/my-epipen

[45] https://gizmodo.com/epipen-expiration-dates-extended-as-schools-face-shorta-1828491035

reviewed by the FDA."[46]

93. On August 21, 2018, Mylan and Pfizer announced the 4-month shelf-life extension of certain lots of EpiPen based on Pfizer stability data:

Important Update on EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors from Mylan and Pfizer

Extended Expiration Dates for Select Lots of EpiPen® 0.3 mg Auto-Injectors and its Authorized Generic

To address shortages of EpiPen®, Pfizer is coordinating with FDA to extend the expiration dates of specific lots of EpiPen® 0.3 mg Auto-Injectors and its authorized generic version, after review of stability data. Patients should have confidence in using the products from these particular lots as Pfizer works to stabilize supply, which is anticipated in the fourth quarter of 2018.

This announcement is based on a careful review of product stability data provided by Pfizer. We believe the extension of the expiration date will temporarily address patients' access to and use of EpiPen® 0.3 mg Auto-Injectors, and the authorized generic, particularly during back-to-school season as demand increases.

The affected lots, which have current expiration dates between April 2018 and December 2018, are listed in tables on the following pages with their new expiration dates and can be found on FDA's website and EpiPen.com/EpiPenSupply.[47]

94. Pfizer currently maintains a website regarding the still-ongoing EpiPen shortage at https://www.pfizer.com/news/featured_stories/featured_stories_detail/important_update_on_epipen_epinephrine_injection_usp_0_3_mg_auto_injectors

95. The Pfizer website includes a link to a YouTube video in which Dr. Freda Lewis-Hall, Chief Medical Officer of Pfizer, updates patients about the EpiPen shortage and the extension of the expiration date of certain lots of EpiPen.

[46] https://www.fda.gov/newsevents/newsroom/fdainbrief/ucm617724.htm

[47] *Available at*: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM617733.pdf

Published Sources Support a Longer Shelf-Life Than 18 Months

96. The fact that EpiPen has a longer shelf life than Defendants disclose and represent to the public is supported by published medical literature.

97. In May 2000, the Journal of Allergy and Clinical Immunology published a study regarding the bioavailability and effectiveness of outdated EpiPen and EpiPen Jr. auto-injector devices, which were then labeled with an expiration date 27 months after the date of manufacture according to the then-approved stability protocol.[48] The study found that the epinephrine content

[48] F.E.R. Simons, Xiaochen Gu, Keith Simons, *Outdated EpiPen and EpiPen Jr. autoinjectors: Past their prime?,* Journal of Allergy and Clinical Immunology, Vol. 105, No. 5, pg. 1025-30 (May 2000).

of the devices generally decreased as the devices aged past 27 months, recommended that patients carry unexpired devices, and that a device older than 27 months should be used in the absence of an unexpired alternative because "the potential benefits of using it using it is greater than the potential risk of suboptimal epinephrine dose or of no epinephrine treatment at all."

98. In 2015, the Annals of Allergy, Asthma, and Immunology published a Letter regarding a study on the effectiveness of EpiPen devices collected in a Florida allergy clinic.[49] Because this study was conducted in 2015, the EpiPens used were presumably labeled with an expiration date 18 months from the date of manufacture in accordance with Mylan's then-established practice. This study concluded that 100% of EpiPens tested up to 24 months past the labeled expiration date (*i.e.*, EpiPens that were up to 42 months after the date of manufacture) "contained 90% of the labeled epinephrine dose and therefore met the current United States Pharmacopeia standards of 90% to 115% of labeled doses." This evidence strongly supports a shelf life longer than the 18 months that Pfizer and Mylan disseminated to the public and placed on every EpiPen device.

99. Similarly, in June 2017, the Annals of Internal Medicine published a letter regarding another study on the effectiveness of expired EpiPen devices.[50] This study concluded that EpiPens retain substantial amounts of epinephrine "well beyond their expiration dates" and that the authors expected that EpiPens up to 50 months after expiration would still provide a beneficial pharmacologic response. Additionally, the study results reveal the 22 out of 24 (91%) of EpiPen and EpiPen Jr. devices tested that were 25 months or less past the labeled expiration

[49] Rachid, et al., *Epinephrine doses contained in outdated epinephrine auto-injectors collected in a Florida allergy practice*, Annals of Allergy, Asthma, and Immunology, Vol. 114, pg. 354-56 (2015).

[50] F. Lee Cantrell, Patricia Cantrell, Anita Wen, *Epinephrine Concentrations in EpiPens After the Expiration Date*, Annals of Internal Medicine, Vol. 166 No. 12, June 20, 2017, pg. 918-19.

date contained 90% of the original dose, which means they still met FDA standards, and the remaining 2 devices contained 88% and 89% of the original dose. This evidence also supports a longer shelf life than the 18-month date disseminated by Pfizer and Mylan.

Defendant's obtained windfall profits by artificially reducing the shelf life of the EpiPen and EpiPen Jr.

100. There are several unique features of the EpiPen market that allow Defendants to profit from artificially reducing the shelf life of their product.

101. **First,** unlike other prescription drugs, EpiPens are prescribed by doctors with the hope they expire before use. EpiPens are only intended to be used in the relatively rare occurrence of a life-threatening anaphylactic reaction. This means most patients purchase EpiPens based on expiration dates and not when they run out of their supply of the medication, as with most prescription medications.

102. The fact that many EpiPens are never used before expiration is further exacerbated by Mylan's recent efforts to coerce institutions such as schools, theme parks, and airlines to stockpile EpiPens just in case someone experiences an anaphylactic reaction and does not have their own device.

103. It appears the overwhelming majority of these stockpiled EpiPens are never used.[51] Baltimore County Public Schools purchase approximately 400 EpiPens annually of which only approximately 17 are used to treat anaphylaxis, meaning the school system throws away approximately 95% of purchased devices upon expiration. San Francisco uses fewer than 10 EpiPens to treat anaphylaxis each year, but disposes of approximately 120 devices annually, which

[51] https://khn.org/news/instead-of-trashing-a-600-epipen-some-patients-get-a-refill/

means more than 92% of these devices are replaced before they expire.[52]

104. Accordingly, this means that the Defendants' decision to artificially decrease the shelf life of the EpiPen requires nearly all patients to refill their EpiPens earlier than they would otherwise and therefore increase the number of times they are forced to purchase Defendants' products.

105. **Second,** until very recently, and illustrated by the national furor over the rising cost of the EpiPen, Pfizer and Mylan have faced almost no competition to EpiPen within the United States and possessed more than 90% market share as of 2015. Therefore, many patients have never had the option to select a longer-lasting epinephrine auto-injector product, which means Pfizer and Mylan were able to diminish the quality of their own product without losing significant sales, as would happen in a truly free market in response to consumer preferences.

106. Combined, these features of the epinephrine auto-injector market mean Pfizer and Mylan have been able to rake in hundreds of millions of dollars in excess profits as a result of the EpiPen Expiration Scheme. But for the scheme to defraud, this money would not have flowed in.

Defendants may have caused unnecessary death or suffering by artificially reducing the shelf life.

107. In addition to the financial consequences of the artificial reduction in the EpiPen shelf life, Defendants' manipulation of shelf life and expiration dates may have physically harmed or killed patients.

108. EpiPens are used only in instances of life-threatening emergencies. Mylan specifically instructs patients to pay attention to the expiration dates printed on the EpiPen and EpiPen Jr. Many patients therefore logically assume that EpiPens cannot be used beyond the

[52] It is unclear how these use statistics are impacted by the forced purchase of the EpiPen in a package of two, which may further increase the percent of wasted product.

printed expiration date either because the product is dangerous or would be ineffective to save someone's life during an anaphylactic emergency.

109. As reported by ABC News, in March 2013, a college freshman ate a cookie that contained peanut oil and suffered a severe anaphylactic reaction that restricted his airway. The student's mother quickly reached for an EpiPen that had purportedly expired two months earlier, but was instructed by first responders not to use the recently expired device. A neighbor eventually brought over an unexpired EpiPen device, which was administered to the teen, but it was too late and the teenager died of the anaphylactic reaction. [53]

110. This case illustrates the extreme danger and recklessness of Defendants' manipulation of the EpiPen shelf life.

Equitable Tolling, Discovery Rule, and Fraudulent Concealment.

111. Plaintiff repeats and re-alleges 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.

112. **Discovery Rule:** Plaintiff and the members of the Class had no knowledge or reason to know of the combination or conspiracy alleged herein until on or about (at the earliest) August 21, 2018, the date that Defendants announced that they possessed data to support a 4-month extension of the EpiPen shelf life.

113. Plaintiff and the Class are consumers who do not have the training or means from which they could have discovered the combination and conspiracy described in this Complaint before August 21, 2018, if then.

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[53] Karen Keller, *College Freshman With Peanut Allergy Dies After Eating a Cookie*, ABCNEWS.COM, Mar 15, 2013, https://abcnews.go.com/Health/Allergies/college-freshman-peanut-allergy-dies-eating-cookie/story?id=18723777

114. No information in the public domain was available to Plaintiff and members of the Class concerning Defendants' unlawful activities, including the combination or conspiracy alleged herein, prior to August 21, 2018, the date that Defendants announced they possessed sufficient data to support an additional shelf life of the EpiPen. Further, the members of the Class 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.

115. For these reasons, the statute of limitations as to Plaintiff's and the Class' claims did not begin to run, and has been tolled with respect to the claims that Plaintiff and the members of the Class have alleged in this Complaint.

116. **Fraudulent Concealment and/or Equitable Tolling:** In the alternative, application of the doctrine of fraudulent concealment and/or equitable tolling tolled the statute of limitations on the claims asserted herein by Plaintiff and the Class. Plaintiff and the members of the Class did not discover, and could not have reasonably discovered, the existence of the conspiracy alleged herein until on or about (at the earliest) August 21, 2018, when Defendants announced they possessed data supporting an extension of the EpiPen shelf life.

117. Before that time, Plaintiff and the members of the Class were unaware of Defendants' unlawful conduct, and did not know before then that they were falsely listing the expiration date. Defendants provided no information, actual or constructive, to Plaintiff and members of the Class that the expiration dates were false.

118. The affirmative acts of Defendants alleged herein were wrongfully concealed and carried out in a manner that precluded detection.

119. By their very nature, Defendants' conspiracy and fraudulent scheme were

inherently self-concealing. Plaintiff and members of the Class reasonably relied on the 18-month expiration date provided on their EpiPen devices and widely disseminated to the public. Accordingly, a reasonable person under the circumstances would not have been alerted to begin to investigate the legitimacy of the EpiPen expiration dates before the temporary extension of the expiration date, first announced on August 21, 2018.

120. Plaintiff and the members of the Class could not have discovered the alleged unlawful activity at an earlier date 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.

121. Because the alleged unlawful conduct was self-concealing and affirmatively concealed by Defendants, Plaintiff and members of the Class 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 21, 2018.

122. For these reasons, the statute of limitations applicable to Plaintiff's and the Class' claims was tolled and did not begin to run until at least August 21, 2018.

123. **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 Plaintiff and the Class.

CLASS ACTION ALLEGATIONS

124. Plaintiff incorporates by reference all allegations above as if fully set forth herein.

125. Pursuant to Federal Rule 23(b)(3) and (2), Plaintiff brings this suit on behalf of himself and all others similarly situated across the United States (the "Class") consisting of:

> All persons or entities in the United States and its territories who paid any part of the purchase price of an EpiPen refill or replacement within 3 ½ years for

consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, and not for the purpose of resale, from December 21, 2001, when Defendants first reduced the shelf life of the EpiPen, through and until Class Notice is given (the "Class Period"). For purposes of this Class definition, persons or entities "purchased" an EpiPen if they directly paid for or reimbursed all or some of the purchase price of an EpiPen.

Excluded from the 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. The judges in this case and any members of their immediate families;

d. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and

e. All persons who are currently incarcerated.

126. The Class consists of well over 5 million EpiPen purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class members before this Court.

127. Pursuant to Rule 23(b)(3), there are numerous and substantial questions of law or fact common to all of the members of the Class that predominate over any individual issues that pertain to individual Class members, including:

a. Whether Defendants reduced the shelf life of the EpiPen without medical justification;

b. Whether Defendants misrepresented data or otherwise deceived the FDA to reduce the FDA-approved shelf life of the EpiPen;

c. Whether Defendants possess stability data indicating a different medically necessary shelf life of the EpiPen than the data presented to the FDA, doctors, payers, and patients;

d. What is the medically necessary shelf life of the EpiPen;

e. Whether Defendants deceived payers, doctors, and patients about the medically necessary shelf life of the EpiPen;

f. Whether Defendants formed an enterprise (the "EpiPen Sham Expiration Enterprise") within the meaning of RICO;

g. Whether the EpiPen Sham Expiration Enterprise engaged in a pattern of racketeering to defraud purchasers and users of the EpiPen; and

h. The quantum of aggregate class-wide damages to the Class as a result of Defendant's misconduct.

i. Whether Defendants were unjustly enriched by the excess purchases of EpiPens based on the premature expiration date they listed on the EpiPen in the United States market.

128. Plaintiff's claims are typical of those of the Class because their claims arise from the same facts and turn on the above questions of law and/or fact along with all Class members, there is a sufficient relationship between the damage to Plaintiff and Defendants' conduct similarly affecting all Class members, and Plaintiff has no interests adverse to the interests other Class members.

129. Plaintiff will fairly and adequately protect the interests of Class members and has retained counsel experienced and competent in the prosecution of complex class actions including complex questions that frequently arise in similar consumer protection litigation.

130. 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 method of adjudication of the 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 Class members;

b. Absent certification, Class members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants obtain further illegal profits;

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 Class members can seek compensation for the harm caused to them by Defendant.

131. Because Plaintiff seeks relief for all Class members, the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual Class members, which would establish incompatible standards of conduct for Defendants.

132. Further, bringing individual claims would overburden the courts and be an inefficient method of resolving the dispute at the center of this litigation. Adjudications with respect to individual Class members would, as a practical matter, be dispositive of the interest of other Class members 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.

CLAIM FOR RELIEF

COUNT I
Violation of The Racketeer Influenced and Corrupt Organizations Act (Civil RICO) under 18 U.S.C. § 1962

133. Plaintiff incorporates by reference all allegations above as if fully set forth herein.

134. Plaintiff brings Count I on behalf of the Class against all Defendants.

135. At all relevant times, Defendants have been "persons" under 18 U.S.C. § 1961(3).

136. 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." 18 U.S.C. § 1962(c).

137. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

138. Since 2001, Defendants have sought to extract excess profits from the sales of the EpiPen in the United States. Finding it impossible to achieve their sales goals through lawful means, Defendants engaged in illegal acts to further their EpiPen Sham Expiration Scheme (defined below).

139. From at least 2001 to the present, by virtue of their wholly owned subsidiaries, the affiliation between Mylan and Pfizer has constituted an association-in-fact enterprise: Mylan and Pfizer both participated directly or indirectly in a scheme to falsely state the medically necessary shelf life of the EpiPen and otherwise manipulate EpiPen expiration dates (the **"EpiPen Sham Expiration Enterprise"**), whose purpose was to fraudulently mislead and deceive payers and patients to purchase EpiPens more often than necessary and thereby obtain illegal profits.

140. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants illegally extracted billions of dollars from Plaintiffs and the Class. As explained in detail below, Defendants' years-long misconduct violated RICO Sections §§ 1962(c) and (d).

A. The EpiPen Sham Expiration Enterprise

141. At all relevant times, Defendants operated as an association-in-fact enterprise, which was formed for the purpose of engaging in a scheme to defraud regarding the medically necessary expiration date of the EpiPen. Each of Defendants conducted or participated, directly or indirectly, in the affairs of the EpiPen Sham Expiration Enterprise.

142. The EpiPen Sham Expiration Enterprise consists of the following entities and individuals:

1. The Mylan Defendants

143. Each of the Mylan Defendants is a "person" under 18 U.S.C. § 1961(3).

144. Mylan N.V. and Mylan Specialty L.P. are each distinct legal entities.

145. The Mylan Defendants acquired Dey and are legally responsible for its liability.

146. The Mylan Defendants operated and managed the EpiPen Sham Expiration Enterprise to inflate EpiPen sales and revenue to enrich Mylan's top executives, including Ms. Bresch, who paid themselves bonuses, among other self-serving compensation schemes.

147. 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 and millions of dollars for themselves.

148. Mylan N.V., through Ms. Bresch, was directly involved in nearly all of the sales, pricing, and marketing decisions regarding the EpiPen.

149. Ms. Bresch has made herself the face and spokesperson of the EpiPen, including through her false testimony to the U.S. Congress in September 2016, during which she expressly misled Congress about the expiration date. The media has widely documented that her career trajectory (and excessive compensation) has followed the rise of the EpiPen, which she publicly has called her "baby."

150. Mylan Specialty, L.P., is the primary entity that markets, distributes, and sells the EpiPen in the United States and is currently the holder of NDA #019430 for the EpiPen.

2. The Pfizer Defendants

151. Each of the Pfizer Defendants are a corporate "person" under 18 U.S.C. § 1961(3).

152. Each operated or managed the affairs of an enterprise, the EpiPen Sham Expiration

Enterprise, through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

153. The Pfizer and Mylan defendants are, and have been, in regular and constant communication regarding the EpiPen.

154. The shared intellectual property of the EpiPen between Mylan and Pfizer, as well as their other work together in forming an enterprise to engage in racketeering related to the EpiPen Pricing Scheme, has been demonstrated in the underlying EpiPen MDL, *In re EpiPen Marketing, Sales Practices and Antitrust Litigation*, 17-md-2785 (D. Kan.), before Judge Crabtree. That case's RICO and antitrust claims against Mylan and Pfizer were recently granted class certification by Judge Crabtree in February 2020.

155. The Pfizer Defendants do more than simply manufacture the EpiPen according to Mylan's specifications, as illustrated by the fact that Pfizer issued a joint press release regarding the August 2018 EpiPen shortage,[54] currently maintains a website updating patients on the EpiPen shortage,[55] was the sponsor of the EpiPen NDA #019430 as of November 2001 via its Meridian subsidiary,[56] and presumably stamps the critical expiration date on each EpiPen device as the manufacturer of the EpiPen.

156. Mylan and Pfizer are in the regular business of making and selling pharmaceutical drugs and devices. It is not routine for them to engage in fraudulent activities.

[54] https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM622167.pdf

[55] https://www.pfizer.com/news/featured_stories/featured_stories_detail/important_update_on_epipen_epinephrine_injection_usp_0_3_mg_auto_injectors

[56] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf

B. The EpiPen Sham Expiration Enterprise Sought to Increase Defendants Profits by Deceiving Consumers into Purchasing EpiPens More Frequently By Misstating the Expiration Date.

157. The attempt to manipulate the EpiPen expiration date began as early as November 21, 2001, when Meridian reduced the EpiPen shelf life from 27 months to 20 months without medical justification.

158. Mylan did not become involved until 2007, when it acquired the rights to the EpiPen from Merck via an acquisition that closed in 2007. But its predecessor, Dey, was involved, and Mylan's acquisition of Dey brought with it the legal obligation to cover Dey's liabilities.

159. At all relevant times, the EpiPen Sham Expiration Enterprise: (a) had an existence separate and distinct from each Defendant; (b) was separate and distinct from the pattern of racketeering in which Defendants engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Mylan Defendants, the Pfizer Defendants, other entities and individuals associated for the common purpose of increasing EpiPen sales. The EpiPen Sham Expiration Enterprise was also complimentary to the EpiPen Pricing Scheme, as alleged and set forth by Judge Crabtree in *In re: EpiPen Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256 (D. Kan. 2018).

160. Each member of the EpiPen Sham Expiration Enterprise shared in the financial windfall generated by the enterprise, and each Defendant shared in the common purpose of forcing patients and payers to repurchase EpiPens sooner than was medically necessary based on false, deceptive, and or misleading expiration dates.

161. The EpiPen Sham Expiration 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.

162. Within the EpiPen Sham Expiration Enterprise, there was a common communication network by which co-conspirators shared information using the interstate mails and wires on a regular basis.

163. Each participant in the EpiPen Sham Expiration Enterprise had a systematic linkage to the others through corporate ties, contractual relationships, financial ties, and continuing coordination of activities.

164. Through the EpiPen Sham Expiration Enterprise, Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing their revenues.

165. Defendants' ordinary business is to engage in the manufacture and sale of pharmaceutical drugs and devices. It is not part of their routine business to engage in acts of mail and wire fraud by deceiving consumers of their products about the actual expiration dates of their products.

166. While 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.

167. Defendants directed and controlled the ongoing organization necessary to implement the scheme at meetings and through communications of which Plaintiff cannot fully know at present, because such information lies in the Defendants' exclusive control.

C. The Pattern of Racketeering: Mail Fraud, Wire Fraud, and Corruption of an Official Proceeding

168. To carry out the scheme to defraud, Defendants knowingly participated, directly or indirectly, and conducted the affairs of the EpiPen Sham Expiration 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). Defendants also engaged in corruption of an official proceeding, a Congressional hearing in which Ms. Bresch was under oath and speaking on behalf of Mylan, in violation of 18 U.S.C. § 1512(c)(2).

169. Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: Defendants violated 18 U.S.C. § 1341 by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, and omissions. In furtherance of this scheme, Defendants used the mails.

- The RICO Defendants shipped, or caused to ship, via interstate mail EpiPen devices to pharmacies, patients, schools, and others bearing expiration dates that were artificially restricted to increase Defendants' profits.

- Every EpiPen that bears a false expiration date was shipped in interstate commerce using the mails, as that term is defined within the RICO statute.

- Defendants used the mails in furtherance of their scheme to defraud and, in fact, could not have accomplished their scheme to defraud without using the mails to ship the EpiPen nationwide to victims in all fifty states.

b. Wire Fraud: Defendants violated 18 U.S.C. § 1343 by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, and omissions. In furtherance of this scheme, Defendants used the interstate wires.

- Defendants communicated with pharmaceutical payers and pharmacy benefit managers via wire regarding formulary coverage of the EpiPen without disclosing manipulation of EpiPen expiration dates to increase Defendants' profits.

- The RICO Defendants communicated with patients directly through the My EpiPen Program (including the internet and email) to instruct patients via email to replace and repurchase EpiPens more frequently than was medically necessary.

- Defendants used the interstate wires to receive and process payments from their illicit sales of the EpiPen based on the false expiration date.

c. Corruption of an Official Proceeding: Defendants violation 18 U.S.C. § 1512(c)(2) by corruptly influencing proceedings before both Congress and the FDA.

Defendants corruptly influenced Congressional proceedings when Mylan's CEO, Ms. Bresch, testified to Congress on September 21, 2016, that the then-current expiration date of the EpiPen was 18 months from the date of manufacture without disclosing that this expiration date was artificially reduced. Additionally, Defendants corruptly influenced Congressional proceedings when Ms. Bresch testified that Mylan was about to submit documents "within days" (as explained above) to the FDA that would allow a 24-month expiration date on the EpiPen product. At the time that statement was made, Ms. Bresch and Mylan knew they had no present intention to make any submission to FDA.

170. In doing so, Defendants have deceived and cheated patients and third-party payors out of billions of dollars. The full extent of the damages will be the subject of discovery.

D. Causation and Damages

171. The EpiPen Sham Expiration Enterprise directly caused consumers to overpay by forcing them to purchase EpiPens more frequently than was medically necessary and more frequently than they would have but for the fraud scheme. There is a direct and straight line from the scheme to defraud to the damages suffered.

172. There are no intervening steps or causes that could have prevented or altered or even interfered with the EpiPen Sham Expiration Enterprise.

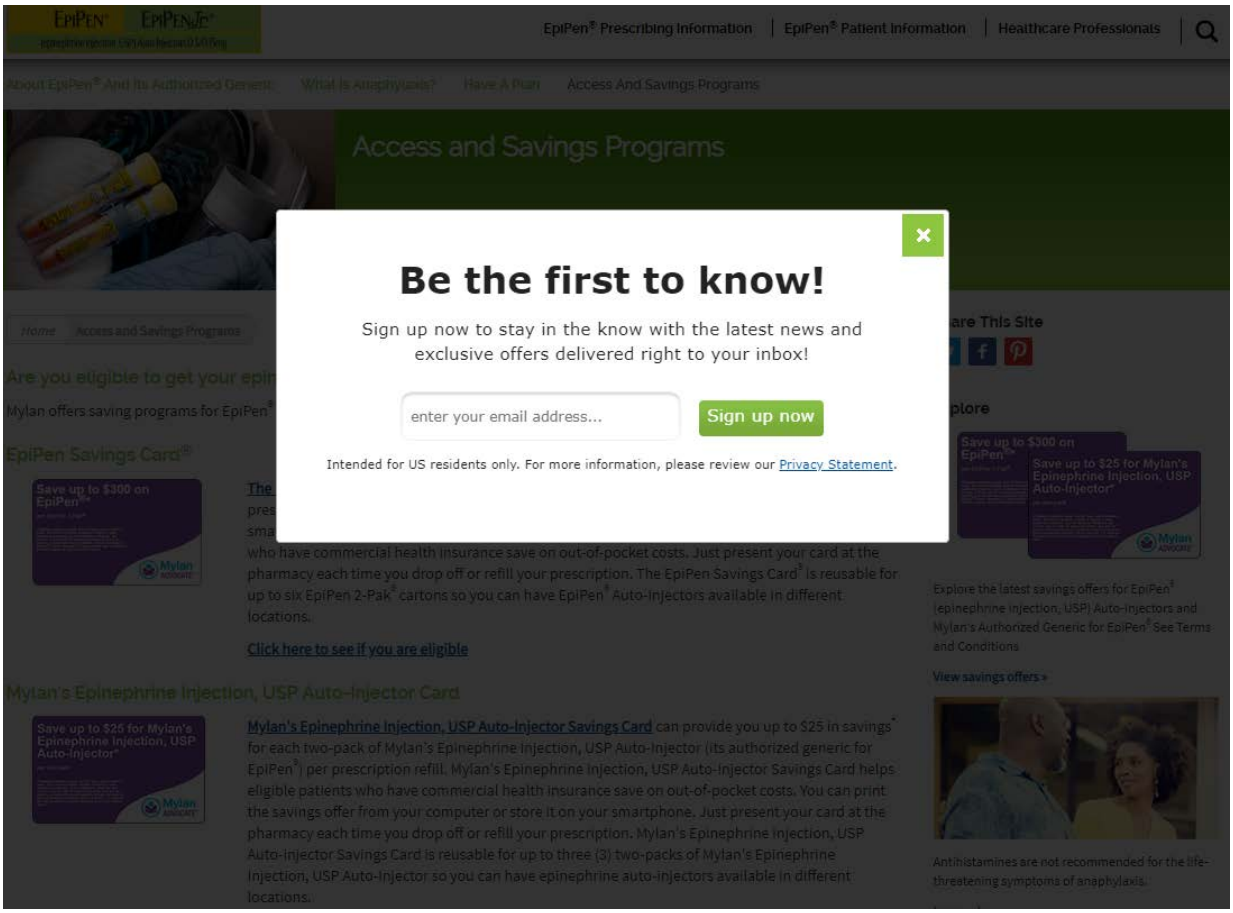
173. Consumers purchased the EpiPen in reasonable reliance upon the expiration date, and Mylan's own internal documents confirm that it was zealously focused on the buying patterns of end-consumers. Defendants knew that if they artificially manipulated the expiration date to attain a one-year purchasing cycle, then a significant portion of consumers would purchase the EpiPen exactly as Defendants intended. For example, at least 35% of consumers repurchase the

EpiPen every year, and almost every EpiPen consumer who ever repurchases an EpiPen (approximately 60%) does so within 3 years—or within the 42-month expiration date shown by recent studies.

174. The exact purchase history of consumers, at the level of the individual consumer, is available from PBMs, third-party payors (who track this information and have been proven to possess this information), and other relevant data sources, so there is no real risk that the class will include any class members who were not harmed by the EpiPen Sham Expiration Enterprise. The class will include those who purchased the EpiPen within the shortened expiration date, and, likewise, it will exclude those consumers who did not purchase the EpiPen within the shortened expiration date.

175. Defendants target individual consumers to purchase the EpiPen by encouraging them to sign up for emails and other programs, for example in this pop-up that appears:[57]

[57] *See, e.g.*, https://www.epipen.com/paying-for-epipen-and-generic (accessed March 2, 2020).



176. By reason of, and as a result of Defendants' conduct, Plaintiff and Class members have been injured in their property by overpaying more often for EpiPens than they otherwise would have. It is a commonsense inference (and one that a jury is allowed to make) that patients purchase new EpiPens once their current EpiPen expires. Thus, by falsely listing the expiration date, Defendants artificially and illegally caused patients and payors to purchase EpiPens more quickly and sooner than they would have had the accurate and true expiration date been listed.

177. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to Plaintiff and Class members, and Plaintiff and Class members are entitled to bring this action for three times their actual damages, as well as costs and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(a), (c).

DEMAND FOR JURY TRIAL

178. Plaintiff respectfully demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully requests the following relief:

a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) 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 Class;

b. Appoint Plaintiff as Class Representative and Plaintiff's counsel as Class Counsel;

c. Award compensatory damages to Plaintiff and the proposed Class in an amount to be established at trial;

d. Award treble damages under the RICO statute;

e. Award pre- and post-judgment interest;

f. Award reasonable attorneys' fees and costs; and,

g. For all such other and further relief as may be just and proper.

Respectfully submitted,

/s/ Rex A. Sharp

Rex A. Sharp K #12350
Ryan C. Hudson KS #22986
SHARP BARTON, LLP
5301 W. 75th Street
Prairie Village, KS 66208
Tel: (913) 901-0505
Fax: (913) 901-0419
Email: rex@sharpbarton.com
Email: ryan@sharpbarton.com

Warren T. Burns
Spencer Cox
BURNS CHAREST LLP
900 Jackson, Suite 500
Dallas, TX 75202
Tel: (469) 904-4550
Fax: (469) 444-5002

Paul J. Geller
Stuart Davidson
ROBBINS GELLER RUDMAN & DOWD LLP
120 East Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Tel: (561) 750-3000
Fax: (561) 750-3364

Lynn Lincoln Sarko
Gretchen Freeman Cappio
KELLER ROHRBACK L.L.P.
1201 3rd Ave. - Ste. 3200
Seattle, WA 98101
Tel: (206) 623-1900
Fax: (206) 623-3384

Counsel for Plaintiff and Proposed Class