IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Case No.: _____

Shawn Carstensen Hays, Individually and on Behalf of All Others Similarly Situated,

Plaintiff(s),

v.

(1) Pfizer Inc., and
(2) Meridian Medical Technologies, Inc.,

Defendant(s).

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiff Shawn Carstensen Hays ("Plaintiff"), individually and on behalf of all others similarly situated, brings this Class Action Complaint against Defendants Pfizer, Inc. and Meridian Medical Technologies, Inc. (together, "Pfizer" or "Defendants"), and alleges:

INTRODUCTION

1. This lawsuit arises from a scheme to defraud in which Defendants artificially increased the number and frequency of purchases of the widely-used EpiPen product by listing a false and misleading expiration date on the product. By doing so, Defendants forced premature refills of the EpiPen while the product was still safe to use. From this scheme to defraud, Defendants have caused at least hundreds of millions of dollars of excess purchases every year,

year after year, for over the last decade.[1]

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

3. Working together with Mylan as an enterprise since at least November 2010, Defendants have manipulated the EpiPen expiration date and engaged in deceptive practices to force consumers and purchasers to buy the EpiPen more often than is medically necessary by: (a) putting forward a shorter expiration date than is supported by either the medical literature or the studies and data Defendants provided to the U.S. Food and Drug Administration ("FDA") to support a "temporary" extension for certain EpiPen lots; (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 not only believing but also further encouraging this false annual retail purchasing cycle.

4. The truth about Defendants' scheme began to unfold in August 2018. In response to an epinephrine auto-injector shortage during back-to-school season, the FDA extended the shelf-life of certain lots of EpiPens and authorized generic EpiPens (but not EpiPen Jrs.) by four months, "based on stability data provided by Mylan and reviewed by the FDA."[2] Pfizer and Mylan jointly

[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] *FDA In Brief: FDA takes additional action to mitigate shortage of EpiPen by extending expiration date for specific lots of medication* (Aug. 21, 2018), https://wayback.archive-it.org/7993/20190423050412/https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm617724.htm (last visited May 22, 2020).

announced this extension, declaring that "[t]his announcement is based on a careful review of product stability data provided by Pfizer."[3]

5. In other words, EpiPens suddenly gained a longer shelf life without any changes to the product, device, or medicine. Indeed, this extended expiration date applied to lots of already-manufactured devices, demonstrating that the existing formulation had a longer shelf life than advertised. This four-month extension (from 20 months to 24 months) proves that Defendants and Mylan were (and still are) engaged in a scheme to defraud by passing off the expiration date as shorter than it actually was.

6. That Defendants and Mylan could suddenly expand the expiration date proves the fraud scheme and confirms 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 was unsafe, the FDA never would (or could) have approved it—temporarily or otherwise.

7. Because the actual EpiPen expiration date is apparently much longer than 12 months, Defendants and the Mylan entities have worked to deceive consumers and purchasers into obtaining a new 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.

8. Defendants were motivated to put profits and revenue ahead of lives and medicine. While much of the negative media attention in recent years has focused on Mylan's misconduct, Pfizer has been involved in Mylan's misconduct and raking in the profits ever since acquiring King

[3] https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM617733.pdf (last visited May 22, 2020).

and Meridian in 2010.[4] According to Pfizer's publicly available annual financial reports,[5] it has consistently taken in massive revenue from EpiPen sales—over one quarter of a billion annually, and well over $1 billion during the relevant time period—peaking in 2016 at $386 million:

Year	EpiPen Revenue (in Millions) to Pfizer
2012	$263
2013	$273
2014	$294
2015	$339
2016	$386
2017	$290
2018	$303
2019	$303

9. 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 Pfizer's and Mylan's executives to ensure that they would hit these earnings targets. Pfizer and Meridian manufacture and package the EpiPen devices, including applying the expiration label and date to every device. Upon information and belief, Pfizer and Meridian worked with Mylan to implement a scheme to make sure the expiration date was lower than necessary. Consumers and payors were without the data or means to ferret out the truth behind the various and secretive ways in which the early

[4] Jim Edwards, *In $3.6B King Deal, Pfizer Gets a Small but Important EpiPen Monopoly*, CBS NEWS (Oct. 12, 2010), https://www.cbsnews.com/news/in-36b-king-deal-pfizer-gets-a-small-but-important-epipen-monopoly/.

[5] https://investors.pfizer.com/financials/annual-reports/default.aspx (last visited May 26, 2020).

expiration scheme was carried out.

10. The history of the EpiPen's expiration date is telling. Until 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.[6]

11. In November 2001, Meridian (now owned by Pfizer) submitted a new stability protocol along with data to request a reduction of 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 30 days" supplemental new drug application ("sNDA").

12. Despite this change, both the device and the active pharmaceutical ingredient (epinephrine) remained the same.

13. Mylan acquired the right to market the EpiPen in the United States in 2007. Following Mylan's acquisition, the price of the EpiPen was hiked aggressively, year after year, from approximately $100 for a 2 pack of EpiPens in 2008 to over $600 per 2 pack by 2016. In addition to pursuing a pricing strategy that placed profits over public health, Defendants began to further restrict the EpiPen's expiration date as a further means to enhance their bottom line.

14. As part of the national controversy over EpiPen pricing in Fall 2016, Mylan's CEO, Heather Bresch, testified to Congress under oath on September 21, 2016, that EpiPens expire 18 months after the date of manufacture—not 20 months.[7]

15. Around this same time, Mylan and Pfizer were also telling the public that the

[6] FDA, Center for Drug Evaluation and Research, *Approval Package for 019430Orig1s015* (Apr. 16, 2002), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[7] *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 (last visited May 7, 2020) ("*Rising Price*").

EpiPen expires and should be replaced every 12 to 18 months—not 20 months.[8]

16. Then, in August 2018, Defendants and Mylan extended the shelf-life of certain lots of EpiPens and authorized generic EpiPens (but not EpiPen Jrs.) by four months.

17. The following table summarizes Defendants' ever-changing position as to the expiration of the EpiPen:

Date	**Represented Shelf Life**	**Event related to Expiration Dates**
12/22/1987	27 months	Original approval under New Drug Application #019430, with **27-month** expiration date[9]
11/21/2001	20 months	Meridian submits supplemental new drug application under Section 505(b)(2) to reduce the shelf life of the EpiPen Auto Injector from 27 to 20 months and change the stability protocols for the EpiPen and EpiPen Jr. Auto Injectors[10]
4/16/2002	20 months	FDA Center for Drug Evaluation and Research approves Meridian's supplemental new drug application proposing a reduction of the shelf life for the EpiPen and EpiPen Jr. Auto Injectors from **27 months to 20 months**[11]
9/21/2016	18 months	Mylan CEO Heather Bresch testifies that the shelf life of EpiPens is **18 months**, and that they were trying to get it to "a minimum of 24 months."[12]

[8] Carmen Heredia Rodriguez, *The need to replace EpiPens regularly adds to concerns about cost*, PBS NEWS HOUR (Oct. 2, 2016), https://www.pbs.org/newshour/health/epipens-replace-cost (last visited May 7, 2020); Ronnie Cohen, *EpiPens should work at least a while past expiration dates*, REUTERS (May 8, 2017), https://www.reuters.com/article/us-health-epipens-expiration-idUSKBN1842BW (last visited May 7, 2020).

[9] FDA, Center for Drug Evaluation and Research, *Approval Package for 019430Orig1s015* (Apr. 16, 2002), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[10] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[11] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[12] *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 (last visited May 7, 2020) ("*Rising Price*").

10/2016-5/2017	12-18 months	Julie Knell, director of specialty communications at Mylan, states that the EpiPen expiration date range is **12-18 months** and recommends that patients refill their prescriptions on those intervals [13]
8/21/2018-present	20 months (labeled) 24 months (acknowledged safe shelf life)	FDA extends the expiration date of specific lots of 0.3 mg EpiPens by four months beyond the labeled expiration date[14] • States that this **four-month extension** is "beyond the **approved 20-month shelf life**" • States that the extension is based on "stability data provided by Mylan and reviewed by the FDA" FDA continues to extend specific lots of 0.3 mg EpiPens by four months beyond the labeled expiration date[15]

18. Indeed, published medical journals show that EpiPens have a longer shelf life than Defendants and Mylan have represented.

a. A 2015 study published in the *Annals of Allergy, Asthma, and Immunology* analyzed multiple EpiPen devices that were up to 24 months past the stamped expiration date (and therefore *44 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.[16]

[13] Carmen Heredia Rodriguez, *The need to replace EpiPens regularly adds to concerns about cost*, PBS NEWS HOUR (Oct. 2, 2016), https://www.pbs.org/newshour/health/epipens-replace-cost (last visited May 7, 2020).

[14] *FDA In Brief: FDA takes additional action to mitigate shortage of EpiPen by extending expiration date for specific lots of medication* (Aug. 21, 2018), https://wayback.archive-it.org/7993/20190423050412/https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm617724.htm (last visited May 22, 2020).

[15] *See* https://www.fda.gov/media/127690/download (last visited May 26, 2020) (last relevant lot to expire October 2020).

[16] 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).

b. Similarly, another study published in the *Annals of Internal Medicine* in 2017 found that all of the EpiPens studied that were up to 29 months past the stamped expiration date (and therefore *49 months from the date of manufacture*) contained at least 90% of the original dose and would therefore be considered to still be safe and effective according to FDA standards.[17]

c. Again, strikingly similar results were reported in 2019 in a study in *The Journal of Allergy and Clinical Immunology: In Practice*. The authors discovered that all of the EpiPens studied that were up to 33 months past the stamped expiration date (and therefore *53 months from the date of manufacture*) contained at least 90% of the original dose and would therefore be considered to still be safe and effective according to FDA standards.[18]

19. 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, unanticipated 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,

[17] F. Lee Cantrell, Patricia Cantrell, Anita Wen, *Epinephrine Concentrations in EpiPens After the Expiration Date*, 166 ANNALS OF INTERNAL MEDICINE 918, 918-19 (June 20, 2017).

[18] Lynn Kassel, Caroline Jones, Abebe Mengesha, *Epinephrine drug degradation in autoinjector products*, 7 J. ALLERGY & CLINICAL IMMUNOLOGY: IN PRACTICE 2491, 2491-2493 (2019).

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 auto-injector market, possessing approximately 95% market share as of January 2016.

20. Defendants appear keenly aware of the financial significance of their represented EpiPen expiration dates and go to extraordinary lengths to warn 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 when their EpiPens are about to expire and reminds them to repurchase new ones before their devices expire.[19]

21. 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 while the EpiPen (which could have been safely used) sat dormant.[20]

22. Obviously, a longer shelf life decreases the annual sales on a per patient basis. Thus, the temptation for Defendants to falsely shorten the expiration date is undeniable, and their sudden ability to extend the expiration date by several months creates a common-sense inference that

[19] My EpiPen Email Program, https://www.epipen.com/en/my-epipen (last visited May 7, 2020).

[20] 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 (last visited May 7, 2020).

Defendants have engaged in a years-long scheme to defraud via expiration date manipulation.

23. It was not until the recent extension of this expiration date that Defendants' and Mylan's fraud scheme became clear. Defendants and Mylan were able to conceal the true expiration date from consumers and third-party payors until their 2018 submissions to the FDA.

24. Defendants' actions to manipulate EpiPen expiration dates, with Mylan, 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")[21] and have damaged the business or property of Plaintiff and the Class (defined below).

25. For all Defendants' actions alleged herein, Plaintiff seeks to recover RICO damages caused by the pattern of racketeering from November 1, 2010 through the present (the "Class Period"), during which time Pfizer, Meridian, and the Mylan entities were engaged in an association-in-fact enterprise within the meaning of RICO.

PARTIES

26. **Plaintiff Shawn Carstensen Hays** is a resident and citizen of Colorado. During the Class Period, Plaintiff Carstensen Hays has purchased several EpiPen devices in Colorado. Plaintiff Carstensen Hays generally purchases EpiPens annually at or near the expiration date printed on each device, including but not limited to a purchase of one EpiPen 2-Pak 0.3 MG/0.3 ML on December 18, 2015, followed by the purchase of a new EpiPen 2-Pak 0.3 MG/0.3 ML on December 29, 2016.[22] The 2015 and 2016 purchases came at an out-of-pocket cost of $30 to Plaintiff, plus an additional amount billed to her insurance, which results in higher premiums to

[21] 18 U.S.C. § 1961, *et seq.*

[22] Plaintiff Carstensen Hays is gathering additional records on her annual purchases, but this record collection has been delayed by the closure of one of her primary pharmacies.

her and others. Plaintiff 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. Plaintiff monitored the expiration date of the EpiPens she purchased, and as the expiration date approached, she made sure that she and her family purchased new EpiPens on the cycle Defendants created and recommended so that her EpiPens would not be expired. Had Plaintiff known that the true expiration date was much longer, she would have followed the true expiration date and made her purchases later, only as needed and as dictated by the true expiration date.

27. All purchases made by Plaintiff were for personal, family, or household use.

28. **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 entities.

29. Pfizer is the biggest U.S. drug maker by revenue, and bought a Boulder, Colorado company (Array Biopharma) in 2019 for $11.4 Billion.[23]

30. **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 transaction in October 2010 in which Pfizer acquired King Pharmaceuticals,

[23] The Associated Press, *Pfizer Plunks Down $11.4B for Boulder-Based Array BioPharma,* CPR News (June 17, 2019), https://www.cpr.org/2019/06/17/pfizer-plunks-down-11-4b-for-boulder-based-array-biopharma/ (last visited May 7, 2020).

Inc., which was the parent company of Meridian Medical Technologies.[24]

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

32. Mylan N.V. is a member of the RICO enterprise but is not named separately as a defendant (in part, among other reasons, because it will soon merge with Pfizer and become part of Upjohn). It is a publicly-traded corporation incorporated under the laws of the Netherlands. Mylan N.V. is the corporate successor to Mylan Inc. (by virtue of a 2015 transaction) and is the parent company of another member of the RICO enterprise, Mylan Specialty L.P., a wholly owned subsidiary, that markets and sells the EpiPen in the United States.

JURISDICTION AND VENUE

33. 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 and 18 U.S.C. § 1964(c).

34. 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, has purposefully availed itself of the privilege of conducting business in this state by mailing, selling, marketing, and distributing thousands of EpiPens every month, and Plaintiff's claims arise out of Defendants' conduct in this District.

[24] See Press Release, Pfizer, Pfizer to Acquire King Pharmaceuticals, Inc. (Oct. 11, 2010), https://www.pfizer.com/news/press-release/press-release-detail/pfizer_to_acquire_king_pharmaceuticals_inc (last accessed April 30, 2020).

35. 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

36. 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.

37. 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.

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

39. 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 13 children in the United States has serious food allergies. Each year, allergic reactions account for about 200,000 emergency room visits.[25]

40. Epinephrine is often effective at reducing the symptoms of anaphylaxis if

[25] 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 (last visited May 7, 2020).

administered promptly. In the vast majority of cases, an epinephrine auto-injector is the most effective device for quickly administering epinephrine.[26]

41. 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

42. 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.[27]

43. The FDA approved the EpiPen for sale in the United States on December 22, 1987 under New Drug Application ("NDA") #019430.[28]

44. 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.

45. 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

[26] 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 (last visited May 7, 2020).

[27] 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 (last visited May 7, 2020).

[28] U.S. Food & Drug Administration, Drugs@FDA, NDA 019430, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430 (last visited May 7, 2020).

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."[29]

46. 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.[30] The current EpiPen label (revised 2018[31]) describes the company's relationship with regards to the EpiPen as follows:

> 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.
>
> Copyright © 2018 Meridian Medical Technologies. All rights reserved.

47. 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:

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[29] *See What is Epinephrine?*, Epipen.com, https://www.epipen.com/about-epipen/what-is-epinephrine (emphasis in original) (last visited May 7, 2020).

[30] EpiPen Label (rev. 2/2017), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019430s074lbl.pdf (last visited May 7, 2020).

[31] *Id.*

Date	Manufacturing	Sales and Marketing[32]
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

48. 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.

49. The number of patients filling a prescription for an EpiPen has grown 67% 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

[32] Mylan, *27th Annual JP Morgan Healthcare Conference Presentation*, Jan. 13, 2009, slide 7, http://i.bnet.com/blogs/mylan-ir-jan-09.pdf (last visited May 7, 2020).

School of Medicine."[33]

50. Mylan claimed in 2013 that food allergies among U.S. children are "on the rise, now affecting one in 13" kids.[34]

51. As of January 2016, the EpiPen controlled approximately 95.2% of the epinephrine auto-injector market.[35]

52. 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."[36] And the EpiPen contains "essentially [the] same core technology that [has been] there for many years."[37]

53. 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."[38]

In August 2016, a national controversy erupted over the price of EpiPens, which had risen from

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[33] 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 (last visited May 7, 2020).

[34] Press Release, Mylan Inc., *Mylan Applauds New Federal Legislation to Increase Anaphylaxis Preparedness in Schools* (Nov. 14, 2013), http://newsroom.mylan.com/press-releases?item=123181 (last visited May 7, 2020).

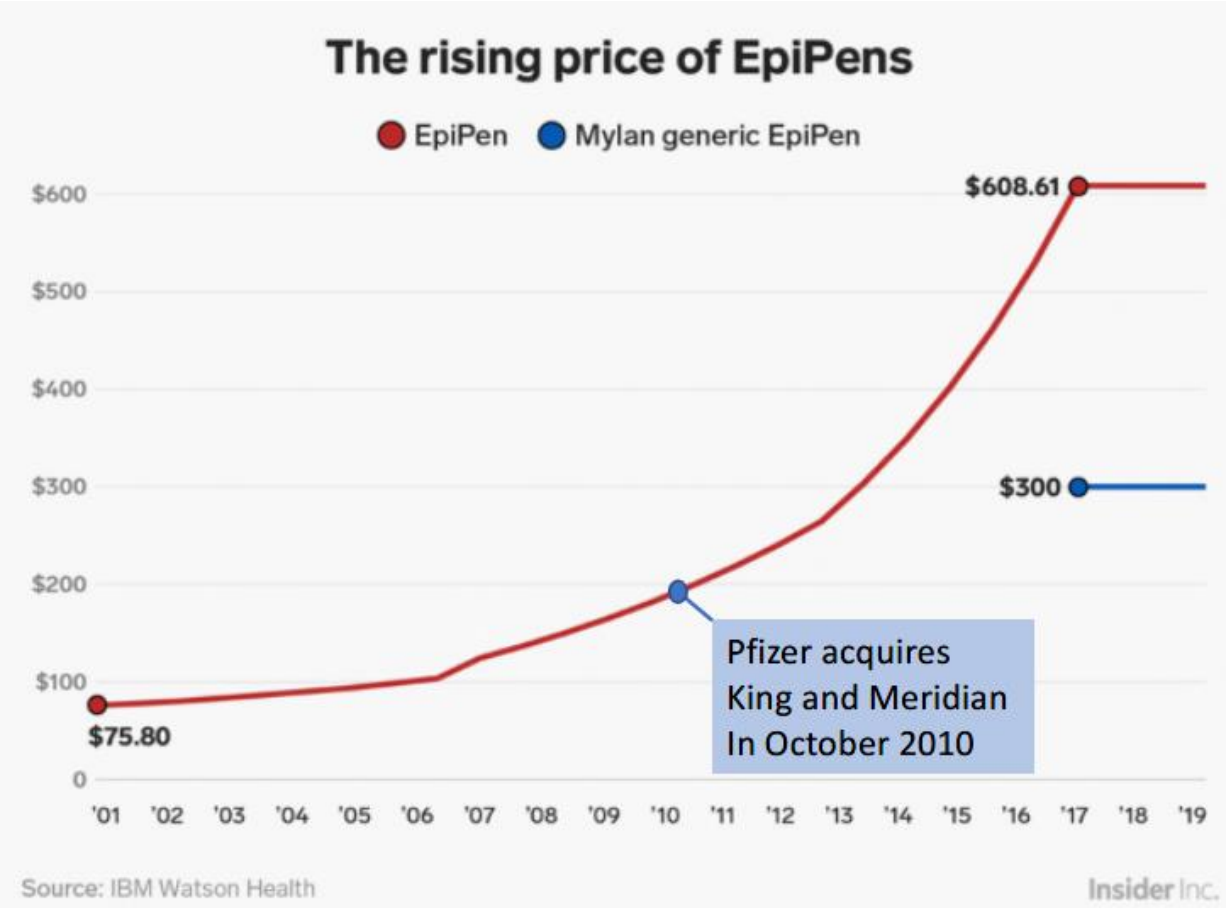
[35] Sy Mukherjee, *Mylan's EpiPen is Bleeding Market Share to Its Rivals*, FORTUNE (Mar. 6, 2017), http://www.fortune.com/2017/03/06/mylan-epipen-competitors-surge/ (last visited Jan. 3, 2019).

[36] 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 (last visited May 7, 2020).

[37] *Id.*

[38] 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/ (last visited May 7, 2020).

$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.[39] The rise in price from the time Pfizer acquired King and Meridian in 2010 has been equally jarring:



54. Pfizer and Mylan have a pattern and practice of EpiPen wrongdoing. First, 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 Medicaid from 23.1% to 13%,

[39] 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 (last visited May 7, 2020).

thereby earning Mylan hundreds of millions of dollars in illegal, excess profits. In August 2017, Mylan entered a settlement agreement in which it agreed to pay $465 million to resolve False Claims Act liability related to misclassification of EpiPens for purposes of the Medicaid drug rebate program.[40] Second, Mylan, Pfizer, and Heather Bresch have been sued for an EpiPen Pricing Scheme in *In re EpiPen Mktg., Sales Practices & Antitrust Litig.*, No: 2:17-md-02785-DDC-TJJ (MDL No. 2785) (D. Kan.) (RICO class and indirect purchaser antitrust class certified).[41]

FACTUAL ALLEGATIONS

A. The EpiPen Sham Expiration Scheme

55. Defendants and the Mylan entities misled consumers and payors into buying more EpiPens by manipulating the expiration date for the EpiPen. The profit temptation was simple: by pinching the expiration date, the product appears to last a shorter period of time, and thus consumers and payors believe they have to purchase it more often.

Meridian and Pfizer reduce the EpiPen Shelf Life from 27 months to 20 months.

56. Prescription drug products must bear an expiration date that a manufacturer determines by appropriate stability testing to assure the product meets applicable identity, strength, quality, and purity standards when a drug product is used.[42] Before November 2001, the EpiPen

[40] Press Release, 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/ (Last visited May 7, 2020); *United States ex rel. Sanofi-Aventis US LLC v. Mylan Inc., et al*., No. 16-CV-11572 (D. Mass.), Settlement Agreement.

[41] *See, e.g., In re: EpiPen Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256 (D. Kan. 2018); *In re: EpiPen Mktg., Sales Practices & Antitrust Litig.*, 2020 WL 1873989 (D. Kan. Feb. 27, 2020).

[42] 21 CFR § 211.137(a).

had a shelf life of 27 months from the date of manufacture until the product expired.[43]

57. 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 the date of manufacture and modified the Master Stability Protocols for the EpiPen and EpiPen Jr. products.[44]

58. The November 2001 Master Stability Protocol superseded a previous stability protocol that had been approved only three years earlier on November 20, 1998.[45]

59. 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.[46]

60. On April 16, 2002, based on Meridian's certifications and representations sent using the interstate mails and wires, 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.[47]

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[43] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[44] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[45] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[46] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

[47] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

61. There was no good faith or medical basis for dropping the expiration date to 20 months.

Defendants begin publicly representing that the EpiPen expiration date was shorter.

62. At some point, Pfizer and/or Mylan further misrepresented the expiration date of the EpiPen and EpiPen Jr. products when they began telling the public that these products had an expiration date that was only 18 months after the product was manufactured.

63. To this end, in September 2016, Mylan's CEO, Heather Bresch, specifically testified to Congress that EpiPens' shelf life was 18 months, and that Mylan was then working to lengthen the product's shelf life (back) to 24 months.[48]

64. Ms. Bresch testified under oath before Congress on September 21, 2016. 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." Here is a photo of her being sworn in under oath:

65. This hearing was conducted specifically so that Congress could ask Defendants and Mylan, under oath, why the EpiPen price was so high and why consumers and purchasers were

[48] *Rising Price*, *supra*, at n.4.

paying so much money to buy the EpiPen. Thus, the pricing and expiration date of the EpiPen were not only material to the hearing being conducted, they were the only reason the hearing was being held.

66. While under oath, Ms. Bresch testified on behalf of Pfizer and Mylan that the then-current shelf life of the EpiPen was "eighteen [18] months" and that "within days" an application would be submitted to extend the shelf life to a "minimum" of "twenty four months." Ms. Bresch falsely testified that Mylan and Pfizer "also invested so that we can soon offer a longer shelf life, which means patients will go longer before needing a refill."[49]

67. Ms. Bresch made this statement about "twenty-four months" twice. Here's a relevant portion of her testimony:

[49] *Rising Price, supra*, at n.4.

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.

68. During this exchange, Congressperson Cummings expressed relief to Mylan's statements made under oath, saying, "Because I heard that it was a year, but I'm glad to hear it's 18 months."[50]

69. This "relief"—which halted any further inquiry into Defendants' expiration date—

[50] *Rising Price, supra*, at n.4.

was the result of trickery. Ms. Bresch's statements to Congress regarding the expiration date of the EpiPen were knowingly false when made—and were never corrected by either Pfizer or Mylan. By testifying before Congress, Ms. Bresch sought to and did in fact conceal Defendants' attempts to manipulate the expiration date of the EpiPen.

70. 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 and Pfizer.

71. 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 was longer than 18 months. In fact, 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.

72. 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 would submit "within days" and "soon" because they had been working on it "for a couple of years." It has now been over 1,000 days since Ms. Bresch testified on September 21, 2016, and there is no publicly available information that indicates an FDA submission has been made to permanently extend the expiration date for all EpiPen lots.

73. Ms. Bresch's testimony was in fact "lulling" testimony that was designed to appease Congress and to lull the members of Congress in the hearing into believing the EpiPen expiration date was going to be extended. Facing regulatory scrutiny and the possibility Congress would intervene to regulate drug prices, Mylan and Pfizer worked together to craft a message that

would make Congress think there was relief in sight. The materiality of Mylan's false testimony, in other words, was significant. Mylan and Pfizer did in fact avoid further regulatory scrutiny, and Congress did not intervene further because the Pfizer/Mylan enterprise had corrupted the official proceeding held to scrutinize the Defendants' fraudulent pricing.

74. In addition, Ms. Bresch's September 21, 2016 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.[51]

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

75. Defendants have widely promoted the false notion of an 18-month shelf life for the EpiPen and EpiPen Jr. products and specifically instruct EpiPen customers to dispose and re-purchase EpiPens before the expiration date printed on each auto-injector.

76. In the fall of 2016, right after Ms. Bresch testified before Congress, an EpiPen spokeswoman told PBS for its public reporting that "the EpiPen expires every 12 to 18 months,

[51] *FDA In Brief: FDA takes additional action to mitigate shortage of EpiPen by extending expiration date for specific lots of medication* (Aug. 21, 2018), https://wayback.archive-it.org/7993/20190423050412/https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm617724.htm (last visited May 7, 2020) (discussing "the change beyond the approved 20-month shelf life . . . based on stability data provided by Mylan and reviewed by the FDA."). *See also* Matt Novak, *EpiPen Expiration Dates Extended as Schools Face Shortage of Allergy Medicine*, Gizmodo.com (Aug. 22, 2018), https://gizmodo.com/epipen-expiration-dates-extended-as-schools-face-shorta-1828491035 (last visited May 7, 2020) ("'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."); Meg Tirrell, *FDA extends certain EpiPen expiration dates to combat shortage*, CNBC.com (Aug. 21, 2018), https://www.cnbc.com/2018/08/21/fda-extends-certain-epipen-expiration-dates-to-combat-shortage.html (last visited May 7, 2020) ("EpiPens typically have a shelf life of 20 months, according to the FDA . . . .").

but that period includes the time it takes to distribute the product and reach the patient's hands."[52]

77. The spokeswoman repeated this misrepresentation several months later in a Reuter's story and encouraged the public to refill their prescriptions every 12 to 18 months: "The expiration dates stamped on EpiPens reflect 'the final day, based on quality control tests, that a product has been determined to be safe and effective when stored under the conditions stated in the package insert,' Knell said. 'Given the life-threatening nature of anaphylaxis, patients are encouraged to refill their EpiPen Auto-Injector upon expiration, approximately every 12 to 18 months.'"[53]

78. Such representations only make sense if the EpiPens do not get into consumers' hands until many months after they leave the manufacturer—and on regular 12 to 18 month intervals. By way of example, in Canada (where the EpiPen is manufactured and sold by Pfizer Canada), Pfizer has acknowledged that it only ensures that patients have 12 months of shelf-life left on the EpiPens when they get to the pharmacy for purchase.[54] This, too, suggests that Pfizer (and Pfizer Canada, which it controls) is especially focused on limiting the shelf life of the EpiPen to align with a 12 month cycle: the exact cycle that fits with Defendants' "back to school" program and marketing campaign.

79. The expiration date is prominently displayed on every EpiPen and EpiPen Jr. carton

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[52] Carmen Heredia Rodriguez, *The need to replace EpiPens regularly adds to concerns about cost*, PBS NEWS HOUR (Oct. 2, 2016), https://www.pbs.org/newshour/health/epipens-replace-cost (last visited May 7, 2020).

[53] Ronnie Cohen, *EpiPens should work at least a while past expiration dates*, REUTERS (May 8, 2017), https://www.reuters.com/article/us-health-epipens-expiration-idUSKBN1842BW (last visited May 7, 2020).

[54] Pfizer Canada Inc., *How long does a new EpiPen® have before it expires?*, https://www.epipen.ca/en/content/how-long-does-new-epipen%C2%AE-have-it-expires1 (last visited May 7, 2020).

and each individual EpiPen device, as shown in the photograph below:

80. Mylan's current EpiPen website includes the following advice regarding the use of EpiPen and EpiPen Jr. products before the expiration date:[55]

> **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.

81. Thus, directly targeting consumers, 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

[55] *Frequently Asked Questions*, EpiPen.com, https://www.epipen.com/about-epipen-and-generic/faq (last visited May 7, 2020).

in the cycle that Mylan and Defendants dictate.[56]

Defendants submit data to extend the EpiPen shelf life for some lots to 24 months.

82. By August 2018, the scheme by Defendants and Mylan to artificially increase demand through expiration date manipulation had back-fired because an EpiPen shortage developed. At that time, the FDA announced a shortage of EpiPen and similar epinephrine auto-injector devices during the back-to-school season when many parents and schools ordinarily replace (prematurely) expired devices.

83. Only because of that shortage, Defendants submitted additional stability data to the FDA to support their request to extend the expiration date of only certain lots of EpiPens (and their authorized generic equivalent product) by an additional four months from the date of manufacture—for a total of 24 months (20 + 4, not the Congressional testimony of 18 + 4).[57] Defendants did not extend the expiration date of any EpiPen Jr. auto-injectors in response to the recall and did not extend the expiration date of all EpiPens on a permanent basis.

84. In contrast to the promise to Congress of a submission to support a longer expiration date on all lots of EpiPens, this lot-specific agreement allowed Defendants and Mylan to ease some of the pressure from the shortage while maintaining the artificially shortened labeled expiration date on all EpiPens.

85. 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

[56] https://www.epipen.com/en/my-epipen (last visited May 7, 2020).

[57] Matt Novak, *EpiPen Expiration Dates Extended as Schools Face Shortage of Allergy Medicine*, Gizmodo.com (Aug. 22, 2018), https://gizmodo.com/epipen-expiration-dates-extended-as-schools-face-shorta-1828491035 (last visited May 7, 2020).

reviewed by the FDA."[58]

86. On August 21, 2018, Mylan and Pfizer jointly 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.[59]

87. Pfizer issued a press release regarding the still-ongoing EpiPen shortage and Pfizer's decision to coordinate with FDA to extend expiration for lots of EpiPens with expiration dates between April and December 2018.[60]

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[58] *FDA In Brief: FDA takes additional action to mitigate shortage of EpiPen by extending expiration date for specific lots of medication* (Aug. 21, 2018), https://wayback.archive-it.org/7993/20190423050412/https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm617724.htm (last visited May 7, 2020).

[59] *Available at*: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM617733.pdf (last visited May 7, 2020).

[60] *Available at:* https://www.pfizer.com/news/featured_stories/featured_stories_detail/important_update_on_epipen_epinephrine_injection_usp_0_3_mg_auto_injectors (last visited May 12, 2020).

88. The Pfizer announcement 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.

89. Rather than request the FDA approve a change to the shelf life of EpiPen auto injectors that would appear on the label, Pfizer has continued its deceptive strategy of only requesting (multiple, repeated) extensions of labeled expiration dates on all current lots.

90. In June 2019, Pfizer and Mylan again posted through the FDA that they were extending the expiration dates by four months on all lots of EpiPen 0.3 mg auto-injectors.[61] The extension was based on the product stability data provided by Meridian.

91. Pfizer has recently used this same tactic of temporary, lot-specific expiration date

[61] *Available at:* https://www.fda.gov/media/127690/download (last visited May 7, 2020).

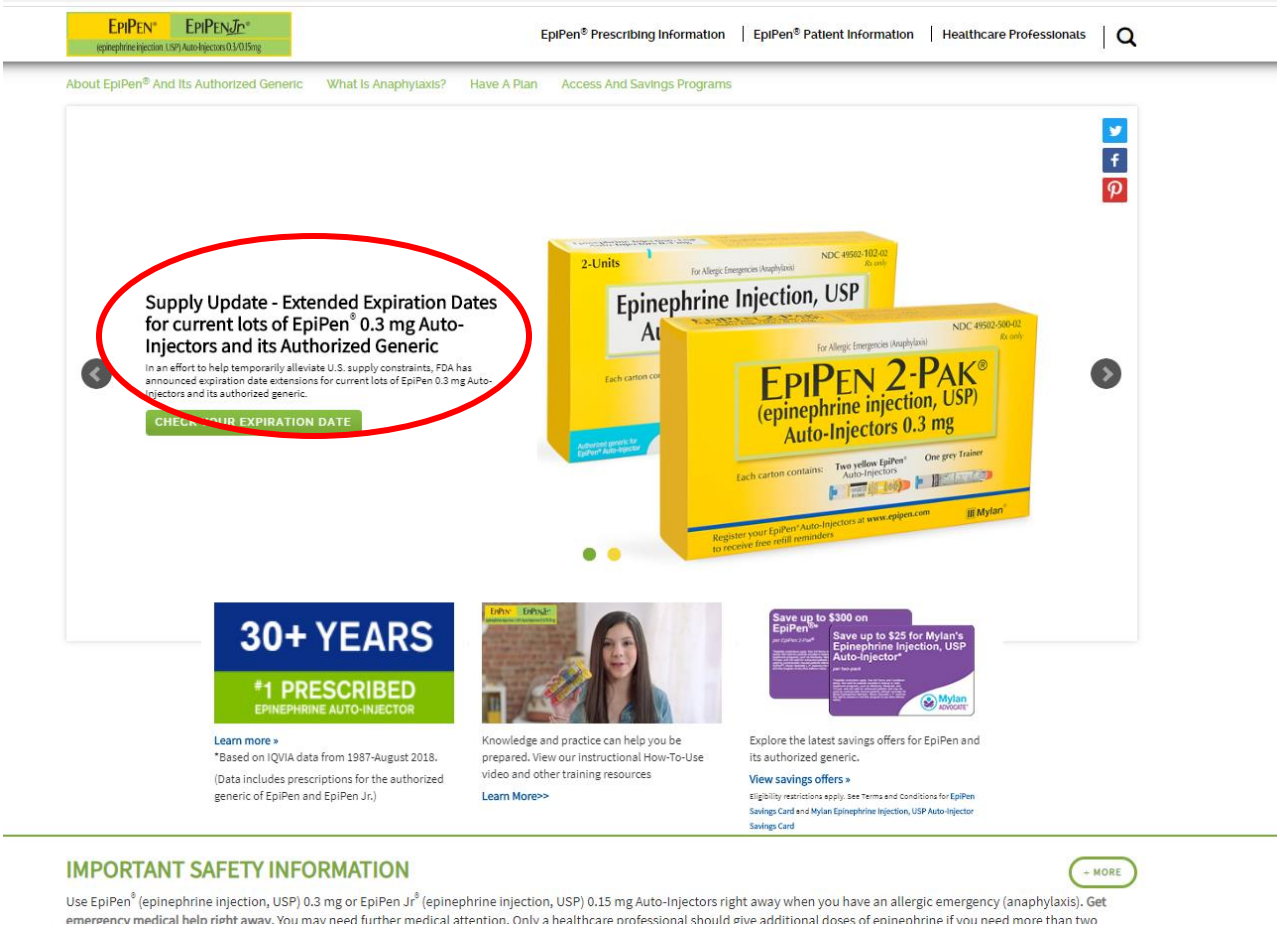
extensions – but not a labeled expiration date change – with another of its epinephrine products. In 2017, Pfizer (through its subsidiary Hospira) sought an extension of the shelf life for its Abboject epinephrine pre-filled syringe. That product had a 21-month labeled expiration date. But Pfizer submitted data showing that all of the samples of the epinephrine tested for at least 12 additional months were within the FDA-required specifications.[62] The FDA has granted (and, like EpiPen, continues to grant) Pfizer's requested 12-month expiration date extension for all lots of this product.[63] But, just as with the EpiPen product, Pfizer never submitted this data to support a permanent change to the *labeled* shelf life.

92. There is no doubt that Pfizer, Meridian, and Mylan understand that expiration dates are critically important to consumers. The current EpiPen home page has the expiration date extension as the main item, front and center, which it uses to directly target consumers and purchasers across the nation:

[62] Letter from Hospira: A Pfizer Company to CDER FDA Drug Shortage Staff re Emergency Syringe Expiration Date Extension (June 1, 2017) (attached as Exhibit 1); *see also* Announcement: https://wayback.archive-it.org/7993/20171102190121/https://www.fda.gov/Drugs/DrugSafety/ucm563378.htm;

Tables showing lot-specific extensions: https://wayback.archive-it.org/7993/20171101121403/https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm563360.htm

[63] U.S. Food & Drug Administration, *Search List of Extended Use Dates to Assist with Drug Shortages*, https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages, search for "epinephrine" and review of entries for epinephrine products with National Drug Code number NDC 0409-4921-34 (last visited April 29, 2020).



Published Sources Support a Longer Shelf-Life Than 18 Months

93. The fact that EpiPen has a longer shelf life than Defendants disclose and represent to the public is supported not only by the "temporary" extension that Pfizer and Mylan obtained for certain lots (which standing alone is sufficient to show that the expiration date should be extended at least by four months), but also by ample, published medical literature.

94. 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.[64] The study found that the epinephrine content 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 is greater than the potential risk of suboptimal epinephrine dose or of no epinephrine treatment at all."

95. 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.[65] Because this study was conducted in 2015, the EpiPens used were presumably labeled with an expiration date 20 months from the date of manufacture in accordance with Meridian's 2001 approved request to the FDA to reduce the labeled shelf life to 20 months. This study concluded that 100% of EpiPens tested up to 24 months past the labeled expiration date (*i.e.*, EpiPens that were up to 44 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, Meridian, and Mylan disseminated to the public and the 20-month shelf life placed on every EpiPen device. It further verifies why the "temporary" four-month extension of shelf life was so easily obtained from the FDA.

96. Similarly, in June 2017, the *Annals of Internal Medicine* published a letter

[64] F.E.R. Simons, Xiaochen Gu, Keith Simons, *Outdated EpiPen and EpiPen Jr. autoinjectors: Past their prime?*, 105 J. ALLERGY & CLINICAL IMMUNOLOGY 1025, 1025-30 (May 2000).

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

regarding another study on the effectiveness of expired EpiPen devices.[66] 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 23 out of 25 (92%) of EpiPen and EpiPen Jr. devices tested that were up to 29 months past the labeled expiration 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, Meridian, and Mylan.

97. Again, in 2019, another group of researchers found strikingly similar results when evaluating the potential extension of shelf life for EpiPen devices.[67] The researchers concluded that "the expiration date of EAIs was set considerably short of the point at which epinephrine in the EAI drops below the FDA's required 90%. . . [M]ost of the EAIs studied here retained a high enough percentage of epinephrine, above the requirements by the FDA, to question their true expiration dating." Notably, the study found that all 20 EpiPen and EpiPen Jr. devices tested that were up to 29 months past the labeled expiration date contained 90% of the original dose. This evidence also supports a longer shelf life than the 18-month date disseminated by Pfizer, Meridian, and Mylan.

Defendants obtained windfall profits by artificially reducing the shelf life of the EpiPen and EpiPen Jr.

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

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[66] F. Lee Cantrell, Patricia Cantrell, Anita Wen, *Epinephrine Concentrations in EpiPens After the Expiration Date*, 166 ANNALS OF INTERNAL MEDICINE 918, 918-19 (June 20, 2017).

[67] Lynn Kassel, Caroline Jones, Abebe Mengesha, *Epinephrine drug degradation in autoinjector products*, 7 J. ALLERGY & CLINICAL IMMUNOLOGY: IN PRACTICE 2491, 2491-2493 (2019).

99. **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.

100. The fact that many EpiPens are never used before expiration is further exacerbated by Pfizer's and Mylan's recent efforts to pressure 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.

101. The overwhelming majority of these stockpiled EpiPens are never used.[68] 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.[69] San Francisco uses fewer than 10 EpiPens to treat anaphylaxis each year, but disposes of approximately 120 devices annually, which means more than 92% of these devices are replaced before they expire.[70]

102. Accordingly, 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.

103. **Second,** until very recently, and illustrated by the national furor over the rising cost

[68] Kaiser Health News, *Instead of Trashing A $600 EpiPen, Some Patients Get A Refill* (Mar. 1, 2017) https://khn.org/news/instead-of-trashing-a-600-epipen-some-patients-get-a-refill/ (last visited May 7, 2020).

[69] *Id.*

[70] *Id.* 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.

of the EpiPen, Pfizer and Mylan have stifled almost all potential competition to the EpiPen within the United States for many years and possessed approximately a 90% market share for the last decade.[71] Therefore, many patients have never had the option to select a longer-lasting epinephrine auto-injector product, which means Pfizer, Meridian, 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.

104. 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.

105. These incentives for artificially reducing shelf life have been also noted by other organizations, which bolsters the commonsense inference that Defendants have intentionally shortened the shelf life of the EpiPen to inflate sales and revenue. In 2000, the American Medical Association adopted a resolution urging the pharmaceutical industry to take action to evaluate drug expiration dates. It concluded that the "actual 'shelf life' of many pharmaceutical products might be considerably longer than the expiration date that appears on the manufacturer's container, which could result in unnecessary waste, higher pharmaceutical costs, and possibly reduced access to necessary drugs for some patients."[72]

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[71] Lydia Ramsey, *The strange history of the EpiPen*, Business Insider (Aug. 17, 2018), https://www.businessinsider.com/the-history-of-the-epipen-and-epinephrine-2016-8 (last visited May 18, 2020).

[72] Report of the Council of Scientific Affairs, *Pharmaceutical Expiration Dates*, https://www.documentcloud.org/documents/3671873-CSA-Rep-1-Pharmaceutical-Expiration-Dates-a-01.html (last visited May 7, 2020); *accord* Marshall Allen, *The Myth of Drug Expiration Dates*, ProPublica (July 18, 2017), https://www.propublica.org/article/the-myth-of-drug-expiration-dates (last visited May 7, 2020).

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

106. 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.

107. 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. and replace them when they have expired. Many patients therefore logically assume that EpiPens cannot be used beyond the printed expiration date either because the product is dangerous or would be ineffective to save someone's life during an anaphylactic emergency.

108. 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.[73]

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

Equitable Tolling, Discovery Rule, and Fraudulent Concealment.

110. 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

[73] 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 (last visited May 7, 2020)

combination and conspiracy alleged herein.

111. **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 four-month extension of the EpiPen shelf life.

112. 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.

113. Information regarding the unlawful conduct described herein, including the combination or conspiracy alleged, was not available to Plaintiff and members of the Class prior to August 21, 2018, the date that Defendants announced they possessed sufficient data to support an additional shelf life of the EpiPen. Plaintiff and members of the Class had no previous, reasonable means of obtaining the facts or information concerning the Defendants' unlawful activities, including the combination and conspiracy alleged herein, all of which were purposefully concealed by Defendants.

114. 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.

115. **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

publicly announced they internally possessed data supporting an extension of the EpiPen shelf life.

116. 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.

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

118. By their very nature, Defendants' conspiracy and fraudulent scheme were self-concealing. Plaintiff and members of the Class reasonably relied on the expiration date provided on their EpiPen devices and the representations of an 18-month shelf life 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.

119. 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.

120. 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.

121. 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.

122. **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

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

124. Pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure, Plaintiff brings this suit individually and on behalf of all others similarly situated across the United States (the "Class"), defined as:

> 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 36 months of the purchase date and for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (and not for the purpose of resale) from November 1, 2010, 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.

125. The Class consists of millions of EpiPen purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class members before this Court.

126. 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 engaged in a scheme to defraud by intentionally reducing the shelf life of the EpiPen, so that purchasers did not have the full life of the product, 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 as part of a scheme to defraud;

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

g. Whether Defendants engaged in a pattern of racketeering to defraud purchasers and users of the EpiPen regarding the shelf life and medically necessary shelf life; and

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

127. 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.

128. 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.

129. 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.

130. 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.

131. 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(c) and (d)

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

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

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

135. 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).

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

137. Since at least November 1, 2010 (after Pfizer acquired Meridian the month before), Defendants and the Mylan entities 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 and the Mylan entities engaged in illegal acts to further their EpiPen Sham Expiration Enterprise (defined below).

138. From at least November 1, 2010, to the present, Defendants and the Mylan entities have worked to manipulate the expiration date of the EpiPen by working together as an association-in-fact enterprise. These entities all 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. Through the EpiPen

Sham Expiration Enterprise, Defendants and the Mylan entities obtained illegal profits.

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

A. The EpiPen Sham Expiration Enterprise

140. At all relevant times, Defendants and the Mylan entities 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 and the Mylan entities conducted or participated, directly or indirectly, in the affairs of the EpiPen Sham Expiration Enterprise.

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

1. The Mylan Entities

142. Mylan N.V. and Mylan Specialty L.P. (previously Dey Pharma until 2012, before a name change to Mylan Specialty[74]) are distinct legal entities.

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

144. The Mylan entities 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.

145. Mylan N.V. was directly involved in nearly all of the sales, pricing, and marketing

[74] *Mylan to Change Name of Specialty Subsidiary From Dey Pharma to Mylan Specialty*, Feb. 15, 2012, available at: http://newsroom.mylan.com/press-releases?item=122962

decisions regarding the EpiPen.

146. 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 Entities: Pfizer and Meridian

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

148. 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).

149. The Pfizer entities do more than simply manufacture the EpiPen, as illustrated by the fact that Pfizer issued a joint press release regarding the August 2018 EpiPen shortage,[75] provided the product stability data to support expiration date extensions for particular lots,[76] currently maintains a website updating patients on the EpiPen shortage,[77] was the sponsor of the EpiPen NDA #019430 as of November 2001 via its Meridian subsidiary,[78] and stamps the critical expiration date on each EpiPen device as the manufacturer of the EpiPen. It also ships in interstate commerce, using the mails, every shipment of EpiPens with a falsely listed expiration date.

150. Meridian has owned the rights to the EpiPen in the United States since well before

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[75] https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM617733.pdf (last visited May 7, 2020).

[76] https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM617733.pdf (last visited May 7, 2020); Press Release, Pfizer, *Important Update on EpiPen® (Epinephrine Injection, USP) 0.3 mg Auto-Injectors* (Aug. 21, 2018), https://www.pfizer.com/news/featured_stories/featured_stories_detail/important_update_on_epipen_epinephrine_injection_usp_0_3_mg_auto_injectors (last visited May 7, 2020).

[77] Press Release, Pfizer, *Important Update on EpiPen® (Epinephrine Injection, USP) 0.3 mg Auto-Injectors* (Aug. 21, 2018), https://www.pfizer.com/news/featured_stories/featured_stories_detail/important_update_on_epipen_epinephrine_injection_usp_0_3_mg_auto_injectors (last visited May 7, 2020).

[78] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/019430Orig1s015.pdf (last visited May 7, 2020).

2010, and at all times relevant to this case has controlled the manufacturing, shipping, distribution, and labeling of the EpiPen, including the expiration date that is listed on that label.

151. Upon information and belief, Pfizer had a motivation to increase sales of the EpiPen because it manufactures the EpiPen and receives revenue from EpiPen sales. According to Pfizer's annual financial reports, Pfizer made well over $1 billion in EpiPen revenues from 2012-2019:[79]

Year	Pfizer EpiPen Revenue (in Millions)
2012	$263
2013	$273
2014	$294
2015	$339
2016	$386
2017	$290
2018	$303
2019	$303

152. The removal of the single EpiPen from the United States market in August 2011 forced all consumers and purchasers to buy EpiPens in packages of two (a 2-Pak), or not all. This 2-Pak hard switch amplified the EpiPen Expiration Scheme by doubling the number of EpiPens that would expire prematurely.

3. The Participation of Defendants and the Mylan entities in the EpiPen Sham Expiration Enterprise

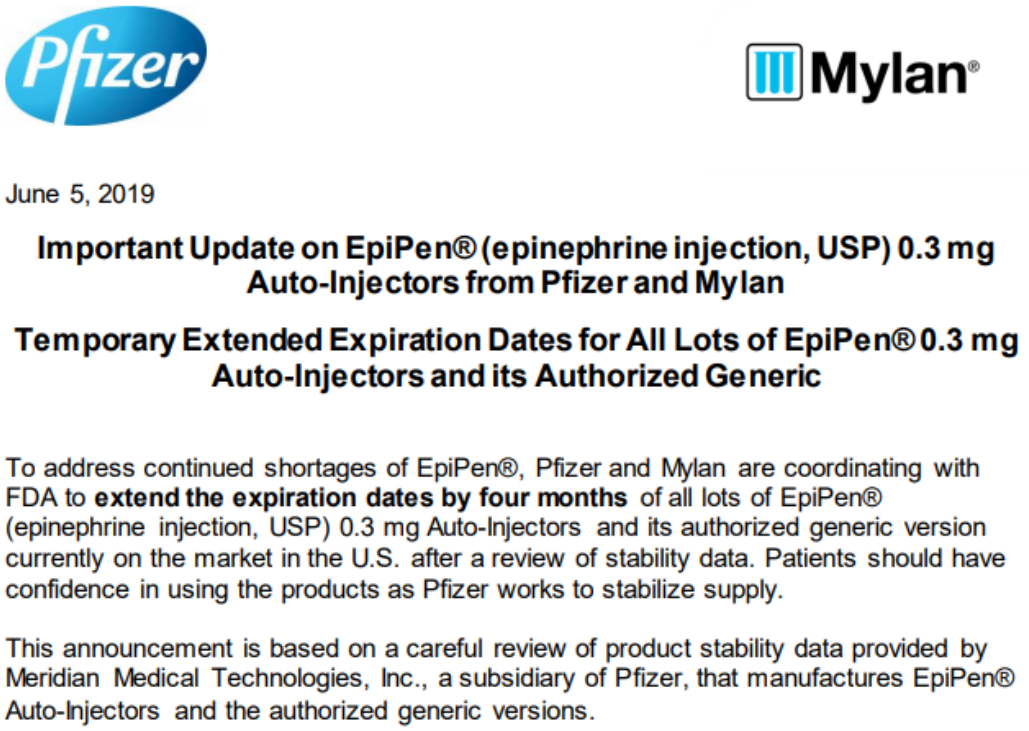
153. Upon information and belief, Defendants and the Mylan entities are, and have been,

[79] https://investors.pfizer.com/financials/annual-reports/default.aspx (last visited May 26, 2020).

in regular and constant communication regarding the EpiPen.

154. Pfizer and Mylan have jointly shared the intellectual property for the EpiPen, including rotating Orange Book sponsorship.

155. Upon information and belief, Defendants and the Mylan entities were deeply involved in the EpiPen Sham Expiration Enterprise. The June 5, 2019, press release regarding the "temporary" expiration date extension, for example, was issued jointly by Mylan and Pfizer and makes clear that Mylan and Pfizer were both "coordinating with the FDA" and that the stability data was provided by Pfizer:[80]



June 5, 2019

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

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

To address continued shortages of EpiPen®, Pfizer and Mylan are coordinating with FDA to **extend the expiration dates by four months** of all lots of EpiPen® (epinephrine injection, USP) 0.3 mg Auto-Injectors and its authorized generic version currently on the market in the U.S. after a review of stability data. Patients should have confidence in using the products as Pfizer works to stabilize supply.

This announcement is based on a careful review of product stability data provided by Meridian Medical Technologies, Inc., a subsidiary of Pfizer, that manufactures EpiPen® Auto-Injectors and the authorized generic versions.

156. The EpiPen Sham Expiration Enterprise depended upon Defendants and the Mylan entities working together in shared concert to conceal the actual expiration date. Neither of the Defendants nor any of the Mylan entities could have individually pulled off this scheme to defraud,

[80] https://www.fda.gov/media/127690/download (last visited May 26, 2020).

and it was strengthened by the fact that two major pharmaceutical companies used their prestige and logos to lull the world into believing the expiration date was accurate and not misrepresented.

157. Defendants and the Mylan entities are in the regular business of making and selling pharmaceutical drugs and devices. It is not routine for them to engage in fraudulent activities or to engage in a pattern of mail and wire fraud.

158. Defendants and the Mylan entities have worked together on the EpiPen in shared concert since at least November 2010, when Pfizer acquired King and Meridian.

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

159. At all relevant times, the EpiPen Sham Expiration Enterprise: (a) had an existence separate and distinct from each of the Defendants and the Mylan entities; (b) was separate and distinct from the pattern of racketeering in which Defendants and the Mylan entities engaged; and (c) was an ongoing and continuing organization consisting of legal entities, including the Mylan entities, the Pfizer entities, other entities and individuals associated for the common purpose of increasing EpiPen sales.

160. Pfizer and Mylan coordinated the EpiPen Sham through their "Joint Commercial Committee"—virtually the working definition of a RICO enterprise.[81]

161. Each member of the EpiPen Sham Expiration Enterprise shared in the financial windfall generated by the enterprise, and each member shared in the common purpose of forcing

[81] *See In re EpiPen* (*Sanofi v. Mylan*), 2:17-md-02785-DDC-TJJ (D. Kan.) Doc. 1814, at p. 30 of 110 (describing Joint Commercial Committee), available at https://media.snacksafely.com/wp-content/uploads/2019/08/07915399824.pdf. *See also In re EpiPen Mktg., Sales Practices & Antitrust Litig.*, No. 17-MD-2785-DDC-TJJ, 2019 WL 5424763, at *4 (D. Kan. Oct. 23, 2019) ("Mylan asserts there are no Joint Commercial Committee-related agreements it has not produced[.]").

patients and payers to repurchase EpiPens sooner than was medically necessary based on false, deceptive, and or misleading expiration dates.

162. 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.

163. 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.

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

165. Through the EpiPen Sham Expiration Enterprise, Defendants and the Mylan entities functioned as a continuing unit with the common purpose of furthering the illegal scheme and their common purposes of increasing their revenues by artificially and secretly shortening the expiration date in a matter that was at odds with and contradicted their own testing and data.

166. The ordinary business of Defendants and the Mylan entities 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.

167. While Defendants and the Mylan entities 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.

168. Defendants and the Mylan entities 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 exclusive control of Defendants and the Mylan entities.

169. This enterprise has continued for over ten years (since November 2010), and the enterprise (and pattern of racketeering) are ongoing and open-ended.

170. In fact, Defendants and the Mylan entities worked so closely on the EpiPen that they have decided to merge, with Pfizer absorbing Mylan (to obtain the EpiPen rights):

> The new company will be led by Pfizer's Michael Goettler, currently president of the Upjohn business. Mylan Chairman Robert Coury will be executive chairman, and Mylan CEO Heather Bresch will depart.
>
> [Jared Holz, health-care strategist at Jefferies] called the management shuffle a positive for the deal, noting Mylan's had "one of the most out-of-favor management teams in all of health care."
>
> Bresch was at the center of the 2016 uproar over Mylan's pricing of the EpiPen, a lifesaving medication delivery system for people with extreme allergies. The price of a pair of EpiPens had risen to $600 from $100 in 2008, and she defended the price hike. Mylan later offered a generic version for about $300.
>
> As part of the deal, Pfizer will separate its Upjohn unit in a tax-free spinoff and will simultaneously combine with Mylan.[82]

171. Once this merger occurs, which is scheduled for 2021, the association-in-fact enterprise alleged in this case will cease within the meaning of RICO because Mylan and Pfizer will be one unified corporate entity. Since 2010 until the merger, however, Defendants and the Mylan entities have functioned as the EpiPen Sham Expiration Enterprise.

[82] Meg Tirrell, *Pfizer will combine its off-patent drug business with Mylan*, CNBC (July 29, 2019), https://www.cnbc.com/2019/07/29/pfizer-to-combine-its-off-patent-drug-business-with-mylan.html (last visited May 7, 2020).

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

172. To carry out the scheme to defraud, Defendants and the Mylan entities 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 and the Mylan entities 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).

173. The predicate acts of racketeering (18 U.S.C. § 1961(1)) engaged in by Defendants and the Mylan entities include, but are not limited to:

a. Mail Fraud: Defendants and the Mylan entities 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, in collaboration with the Mylan entities, used the mails.

- Defendants and the Mylan entities shipped, or caused to ship, via interstate mail EpiPen devices to pharmacies, patients, schools, and others bearing expiration dates on EpiPens that were manipulated by shortening the time consumers were allowed to use them before they expired.

- Every EpiPen that bears a falsely labeled expiration date was shipped in interstate commerce using the mails. Discovery is needed on how many shipments of the EpiPen have occurred, but Pfizer said in a written statement to the *Wall Street Journal* in 2017 that "between 2015 and [September 7, 2017], [Pfizer] has shipped more than 30 million EpiPen auto-injectors globally."[83]

- Defendants and the Mylan entities 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

[83] Thomas M. Burton, *FDA Warns Pfizer's Meridian Unit on EpiPen Oversight, Quality Issues*, WALL ST. J. (Sept 7, 2017), https://www.wsj.com/articles/fda-warns-pfizers-meridian-unit-on-epipen-oversight-quality-issues-1504826114 (last visited May 7, 2020).

nationwide to victims in all fifty states.

- Defendants and the Mylan entities also used the mails in correspondence with the FDA regarding the expiration date of the EpiPen, as described above in this Complaint.

b. Wire Fraud: Defendants, in collaboration with the Mylan entities, 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 and the Mylan entities used the interstate wires.

- Defendants and the Mylan entities 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 and the Mylan entities profits.

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

- Defendants, in collaboration with the Mylan entities, had Ms. Bresch testify before Congress on September 21, 2016, and falsely describe the expiration date, along with a promise that the expiration date would be extended (as described above in this Complaint).

- Defendants and the Mylan entities also used the wires in correspondence with the FDA regarding the expiration date of the EpiPen, as described above in this Complaint.

c. Corruption of an Official Proceeding: Defendants, in collaboration with the Mylan entities, violated 18 U.S.C. § 1512(c)(2) by corruptly influencing proceedings before both Congress and the FDA.

- Defendants and the Mylan entities 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 and the Mylan entities 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, Defendants, and the Mylan entities knew they

had no present intention to make any submission to FDA.

174. In doing so, Defendants and the Mylan entities have deceived and cheated patients and third-party payors out of billions of dollars for the last several years.

175. This pattern of racketeering is open-ended and remains ongoing. Only by pursuing this lawsuit and financially punishing Defendants and Mylan will the pattern of racketeering at issue here finally cease.

176. The predicate acts are all related because they were all done in furtherance of the same overall goal and common purpose of the RICO enterprise: to force consumers to refill their EpiPens earlier than was actually required.

D. Causation and Damages

177. The EpiPen Sham Expiration Enterprise directly caused consumers and purchasers 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.

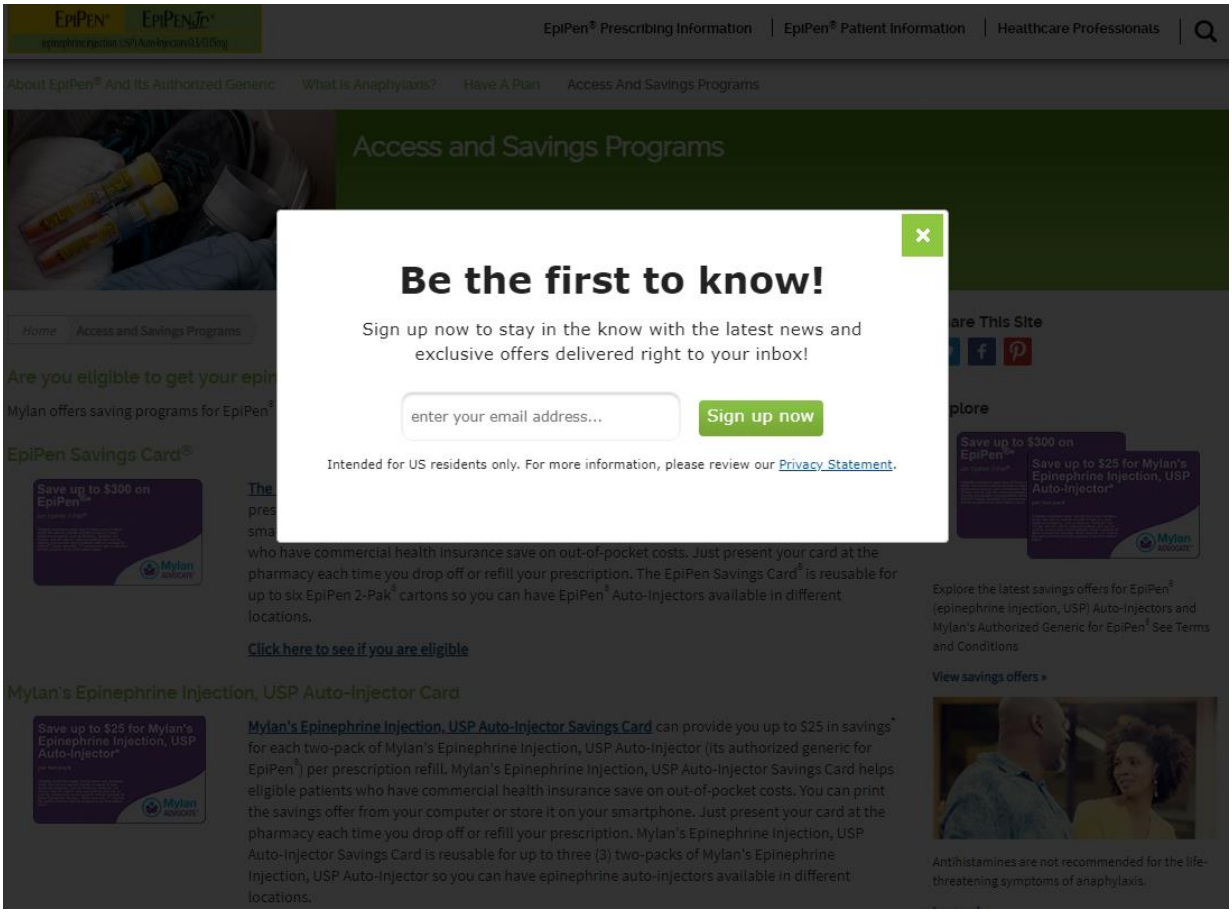
178. There are no intervening steps or causes that could have prevented or altered or even interfered with the EpiPen Sham Expiration Enterprise.

179. All purchasers of the EpiPen purchased the EpiPen in reasonable reliance upon the expiration date, and Mylan was focused on the buying patterns of end-consumers. Defendants and the Mylan entities 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 and the Mylan entities 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 three years—or within the 42-month expiration date shown by recent studies.

180. 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.

181. Defendants and the Mylan entities 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:[84]

[84] *See, e.g.*, *Access and Savings Programs*, EpiPen.com, https://www.epipen.com/paying-for-epipen-and-generic (last accessed Mar. 2, 2020).



182. The EpiPen website prominently features the expiration date on its homepage, and Defendants and the Mylan entities use the back to school mailing program to directly target end-purchasers, the focus of the scheme to defraud. Defendants and the Mylan entities have lured consumers into providing their email addresses to Mylan, which sends them reminders to renew before the false expiration date. Each email is a separate act of wire fraud that forms part of the pattern of racketeering, and each email further confirms the direct line between Defendants and the Mylan entities on one end and consumers on the other end.

183. By reason of, and as a result of the conduct of Defendants and the Mylan entities, 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 and the Mylan entities artificially and illegally caused patients and payors to purchase EpiPens more quickly and frequently than they would have had the Defendants listed the accurate and true expiration date.

184. The violations of 18 U.S.C. § 1962(c) and (d) by Defendants and the Mylan entities 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) and (c).

DEMAND FOR JURY TRIAL

185. 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), (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. Order Defendants to disgorge unlawful profits related to using misleading expiration dates on EpiPens;

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

e. Award treble damages under the RICO statute;

f. Award pre- and post-judgment interest;

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

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

Date: July 2, 2020

Respectfully submitted,

PARKER LIPMAN, LLP

A duly signed original is available at the offices of Parker Lipman, LLP

/s/ Daniel A. Lipman
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