

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF KANSAS**

TRACI BRANNON, LINDSEY RIZZO, and,  
JAMIE HERR, individually and on behalf of  
all others similarly situated,

Plaintiffs,

v.

EXPRESS SCRIPTS HOLDING COMPANY,  
EXPRESS SCRIPTS, INC.,  
UNITEDHEALTH GROUP, INC.,  
OPTUMRX, INC., and,  
PRIME THERAPEUTICS, LLC,

Defendants.

CASE NO. 17-CV-2497

**CLASS ACTION COMPLAINT**

## TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	PARTIES .....	2
A.	Plaintiffs .....	2
B.	Defendants .....	3
III.	JURISDICTION AND VENUE .....	6
IV.	FACTUAL ALLEGATIONS .....	7
A.	Allergies, Anaphylaxis, and Epinephrine .....	7
B.	The Development of Epinephrine Injectors and Mylan’s Acquisition of the EpiPen .....	9
C.	Mylan’s Relentless EpiPen Price Increases .....	11
D.	The Role of Pharmacy Benefit Mangers (PBMs) in the Pharmaceutical Industry and Prescription Drug Prices .....	13
E.	Pharmacy Benefit Mangers and the Epinephrine Auto-injector Market .....	18
F.	Testimony and Statements Regarding Mylan’s Payments to PBMs .....	20
G.	The Cost to Consumers in the EpiPen Auto-injector Supply Chain .....	26
V.	ERISA ALLEGATIONS .....	30
A.	The PBM Defendants are Fiduciaries and Parties in Interest. ....	30
B.	The PBM Defendants’ ERISA Duties. ....	39
C.	The PBM Defendants Breached Their Duties. ....	44
VI.	TOLLING THE STATUTE OF LIMITATIONS .....	47
A.	Plaintiffs and the Class are Entitled to Tolling Due to Fraud or Concealment .....	47
B.	Estoppel.....	49

VII.	CLASS ACTION ALLEGATIONS .....	49
VIII.	CLAIMS FOR RELIEF .....	52
	COUNT I — PURSUANT TO ERISA § 502(A)(3), 29 U.S.C. § 1132(A)(3) FOR VIOLATIONS OF ERISA § 406(b), 29 U.S.C. § 1106(b).....	52
	COUNT II — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) FOR VIOLATIONS OF ERISA § 404, 29 U.S.C. § 1104.....	55
	COUNT III — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) FOR VIOLATIONS OF ERISA § 702, 29 U.S.C. § 1182 .....	57
	COUNT IV — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3) FOR KNOWING PARTICIPATION IN VIOLATIONS OF ERISA.....	60
IX.	JURY DEMAND .....	62

## I. INTRODUCTION

1. Plaintiffs Traci Bannon, Lindsey Rizzo, and Jamie Herr, by and through their undersigned attorneys, bring this action individually and on behalf of all others similarly situated against Defendants Express Scripts Holding Company, Express Scripts, Inc. (together, “Express Scripts”), UnitedHealth Group, Inc. (“UnitedHealth”), OptumRx, Inc. (“OptumRx”), and Prime Therapeutics, LLC (“Prime”) (collectively, “Defendants”) to recover hundreds of millions of dollars improperly paid to Defendants as a result of the creation, maintenance, and concealment of a multi-tiered fraudulent scheme designed to deceive consumers through the marketing and sale of the EpiPen epinephrine injector (the “EpiPen”).<sup>1</sup> The EpiPen is a life-saving device manufactured and sold by Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. (collectively “Mylan”) to treat and prevent anaphylaxis associated with certain severe allergic reactions.

2. As more fully described below, Defendants’ scheme, which served to artificially inflate the cost of the EpiPen in order to facilitate Mylan’s payment of so-called “rebates,” fees, or other payments to Express Scripts, Prime and OptumRx (together the “PBM Defendants”) in exchange for favorable formulary placement, constitutes a breach of Defendants’ fiduciary duties under the Employee Retirement Income Security Act of 1974 (“ERISA”).

3. In Defendants’ scheme, the PBM Defendants “never take physical possession of the drug” but still “negotiate payments from manufacturers as a reward for choosing those

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<sup>1</sup> For simplicity, this Complaint uses the term “EpiPen” to refer to the EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, EpiPen Jr. 2-Pak®, My EpiPen®, LIFE HAPPENS®, EpiPen4Schools®, Never-See-Needle®, and Be Prepared® (collectively or individually, the “EpiPen”).

manufacturers' drugs for their formularies," ultimately resulting in higher list prices and co-pays for life-saving medications.<sup>2</sup>

4. Plaintiffs' allegations are based on their own experience and personal knowledge, research, the research of counsel, publicly available articles, studies, reports, and other sources, a reasonable inquiry under the circumstances, and on information and belief. Plaintiffs' allegations are likely to have further evidentiary support after a reasonable opportunity for further investigation and discovery arising out of this matter and other related cases proceeding against Mylan N.V. and its subsidiaries proceeding in this District.<sup>3</sup>

## II. PARTIES

### A. Plaintiffs

1. **Plaintiff Traci Brannon** is a resident of Oklahoma and has needed to purchase EpiPen products, specifically the EpiPen Jr. 2-Pak, for the treatment of her child's allergies for years. Plaintiff Brannon most recently purchased an EpiPen Jr. 2-Pak from CVS Pharmacy #06010 on January 18, 2016, which she paid a \$30.00 co-pay.

2. Plaintiff Brannon is and, for all relevant time periods, has been enrolled in an employer-provided welfare benefit health plan governed by ERISA through Blue Cross Blue Shield of Oklahoma for which Defendant Prime Therapeutics, LLC administers pharmacy benefits. Plaintiff Brannon used Blue Cross Blue Shield of Oklahoma's prescription drug benefit administered by Prime to make at least some of the EpiPen epinephrine injector purchases described above.

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<sup>2</sup> Cost of Health Care News, *The Truth About PBMs* (May 11, 2017), <http://www.cost-of-health-carenews.com/our-blog/the-truth-about-pbms>.

<sup>3</sup> See *In Re: EpiPen Auto-Injection Litigation*, No. 2:16-02711-DDC-KGG (2016).

3. **Plaintiff Lindsey Rizzo** is a resident of Connecticut and has needed to purchase EpiPen products for years, specifically the EpiPen Jr., for the treatment of her son's severe food allergies. Plaintiff Rizzo, most recently, purchased EpiPen Jr. products from a CVS Pharmacy located in Waterbury, Connecticut, in December, 2016; November, 2016; October, 2016; and February, 2016, where she paid a co-pay pursuant to the terms of her employer-provided welfare benefit health plan. Plaintiff Rizzo has also purchased EpiPen Jr. products from a CVS Pharmacy located in Pasadena, California on at least two occasions in 2015, four occasions in 2014, and one occasion in 2013, and paid a co-pay pursuant to the terms of her employer-provided welfare benefit health plan for each of those purchases.

4. Plaintiff Rizzo is and, for all relevant time periods, has been enrolled in an employer-provided welfare benefit health plan governed by ERISA through Anthem Blue Cross for which Defendant Express Scripts administers pharmacy benefits. Plaintiff Rizzo used Anthem Blue Cross's prescription drug benefit administered by Express Scripts to make at least one of the EpiPen epinephrine injector purchases described above.

5. **Plaintiff Jamie Herr** is a resident of New Jersey and has needed to purchase EpiPen products for years for the treatment of her son's allergies to insect bites.

6. Plaintiff Herr is and, for all relevant time periods, has been enrolled in an employer-provided welfare benefit health plan governed by ERISA through Defendant United Healthcare for which Defendant OptumRx administers pharmacy benefits. Plaintiff Herr used United Healthcare's prescription drug benefit administered by OptumRx to make at least some of the EpiPen epinephrine injector purchases described above.

## **B. Defendants**

7. **Defendant Express Scripts Holding Company** is a Delaware corporation. Its principal place of business is at 1 Express Way, St. Louis, Missouri, 63121.

8. **Defendant Express Scripts, Inc.** is a corporation organized under the laws of Delaware and headquartered at 1 Express Way, St. Louis, Missouri, 63121. Express Scripts is a pharmacy benefit manager and, as such, contracts on behalf of health plans and insurers with Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. for the purchase of EpiPen epinephrine injectors. As the largest pharmacy benefit management organization in the United States, Defendant Express Scripts Inc. covers 79 million lives<sup>4</sup> and the company reported \$96.5 billion in revenue in 2016.<sup>5</sup> Defendant Express Scripts, Inc. is a subsidiary of Defendant Express Scripts Holding Company. Defendant Express Scripts, Inc., and Defendant Express Scripts Holding Company collectively are referred to as “Express Scripts.”

9. Express Scripts maintains substantial contacts in Kansas, including offices located in Overland Park, Kansas.

10. **Defendant UnitedHealth Group, Inc.** (“UnitedHealth”) is a Delaware corporation with its principal place of business at 9900 Bren Road East, Minnetonka, Minnesota, 55343. UnitedHealth is a diversified managed healthcare company. In 2015, UnitedHealth Group reported revenue in excess of \$157 billion, and the company is currently ranked sixth on the Fortune 500 list. UnitedHealth offers a spectrum of products and services including health insurance plans through its wholly owned subsidiaries and prescription drugs through its pharmacy benefit manager (“PBM”): OptumRx.

11. **Defendant OptumRx, Inc.** is a corporation organized under the laws of California and headquartered at 2300 Main St., Irvine, California, 92614. OptumRx is a

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<sup>4</sup> Ed Kaplan & Wendy Pongracz, *Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans*, Strafford (June 21, 2016), <http://media.straffordpub.com/products/negotiating-and-drafting-pharmacy-benefit-managercontracts-for-self-funded-plans-2016-06-21/presentation.pdf>.

<sup>5</sup> Express Scripts Holding Company, Annual Report (Form 10-K) (Dec. 31, 2016).

pharmacy benefit manager (“PBM”) and, as such, contracts on behalf of health plans and insurers with Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. for the purchase of EpiPen epinephrine injectors. As one of the largest pharmacy benefit management companies in the United States, OptumRx covers 65 million lives<sup>6</sup> and reported approximately \$48.2 billion in revenue in 2015; and over \$60.44 billion in 2016.<sup>7</sup>

12. OptumRx is registered to do business in Kansas<sup>8</sup> and maintains the headquarters for its mail-order service in Overland Park, Kansas which houses nearly 2,000 employees.<sup>9</sup>

13. **Defendant Prime Therapeutics, LLC** is a corporation organized under the laws of Delaware and headquartered at 1305 Corporate Center Drive, Eagan, Minnesota, 55121. Prime Therapeutics, LLC is a pharmacy benefit manager (“PBM”) and, as such, contracts on behalf of health plans and insurers with Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. for the purchase of EpiPen epinephrine injectors. Prime Therapeutics, LLC provides comprehensive prescription benefit management services to more than 20 million plan participants.

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<sup>6</sup> Ed Kaplan & Wendy Pongracz, *Negotiating and Drafting Pharmacy Benefit Manager Contracts for Self-Insured Plans*, Strafford (June 21, 2016), <http://media.straftfordpub.com/products/negotiating-and-drafting-pharmacy-benefit-managercontracts-for-self-funded-plans-2016-06-21/presentation.pdf>.

<sup>7</sup> UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2016).

<sup>8</sup> Kansas Business Center, *Business Entity Search*, <https://www.kansas.gov/bess/flow/main?execution=e2s5> (last accessed 08/09/2017).

<sup>9</sup> Kansas Department of Commerce, *OptumRx Announces Job Growth for Overland Park Facility* (Dec. 21, 2011), <http://www.kansascommerce.com/CivicAlerts.aspx?AID=355>



14. Prime Therapeutics is registered to do business in Kansas,<sup>10</sup> and maintains substantial contacts in this State where it operates as the Pharmacy Benefit Manager for Blue Cross and Blue Shield of Kansas.<sup>11</sup>

15. Together, Express Scripts, OptumRx, and Prime are referred to herein as the “PBM Defendants.”

### III. JURISDICTION AND VENUE

16. **Subject Matter Jurisdiction.** This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiffs’ claims arise under federal law. Further, 29 U.S.C. § 1132(e)(1) confers subject matter jurisdiction on this Court over claims brought under Title I of ERISA.

17. **Personal Jurisdiction.** The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district. ERISA § 502(e)(2) and 29 U.S.C. § 1132(e)(2) provide for nationwide service of process. This Court also has personal jurisdiction over all Defendants pursuant to Fed. R. Civ. P. 4(k)(1)(A) because they would be subject to the jurisdiction of a court of general jurisdiction in this State.

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<sup>10</sup> Kansas Business Center, Business Entity Search – Prime Therapeutics LLC, <https://www.kansas.gov/bess/flow/main?execution=e1s5> (last accessed 08/09/17)

<sup>11</sup> Prime Therapeutics, Media Resources – Clients, <https://www.primetherapeutics.com/en/news/Resources/clients.html> (last accessed: 08/09/17)

18. **Venue.** Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant transacts business in, is found in, and/or has agents in the District of Kansas, and because some of the actions giving rise to the complaint took place within this District. Venue is also proper in this District pursuant to ERISA § 502(e)(2), 29 U.S.C. § 1132(e)(2), because most Defendants reside or may be found in this District and some or all of the fiduciary breaches or other violations for which relief is sought occurred in or originated in this District.

#### IV. FACTUAL ALLEGATIONS

##### A. Allergies, Anaphylaxis, and Epinephrine

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

20. Food allergens are the most common triggers of anaphylaxis, but medications, latex, and insect bites can also cause anaphylaxis. A food allergy occurs when the body's immune system mistakenly identifies a food protein as a threat and attacks it. According to Food Allergy Research & Education—an allergy advocacy and research group—approximately 15 million people have food allergies in the United States and one out of every thirteen children in the United States has serious food allergies, the most common of which include everyday items like peanuts, milk, soy, wheat, and shellfish.<sup>12</sup>

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<sup>12</sup> Food Allergy Research & Education, *Facts and Statistics* (2017), <https://www.foodallergy.org/facts-and-stats>.

21. Around 200,000 Americans suffer anaphylaxis annually, and it is considered a life-threatening medical emergency.<sup>13</sup>

22. Epinephrine, also known as adrenaline, is a medication used for emergency treatment of severe allergic reactions, including anaphylaxis. Epinephrine is also used to treat anaphylaxis caused by exercise or unknown substances. It is available only by prescription.

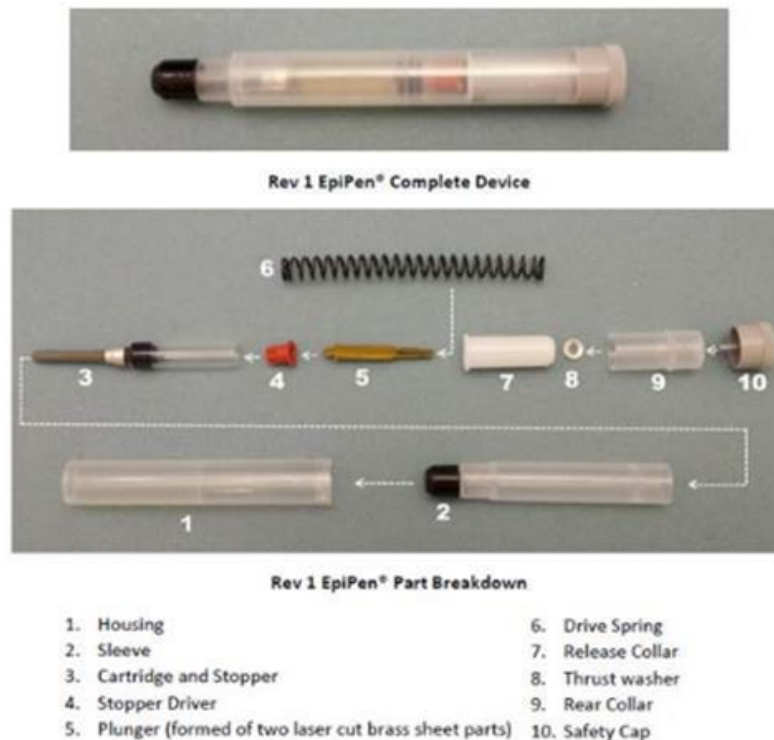
23. Epinephrine is very effective at treating anaphylaxis, but it must be administered immediately. A delay in receiving epinephrine of as little as 30 minutes can result in death.

24. In the vast majority of cases, an epinephrine auto-injector is the most effective device for quickly administering epinephrine. As shown in the below diagram, an auto-injector device injects epinephrine into a muscle through the device's spring-loaded needle.<sup>14</sup>

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<sup>13</sup> *Id.*

<sup>14</sup> 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 Jan. 31, 2017).



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

**B. The Development of Epinephrine Injectors and Mylan's Acquisition of the EpiPen**

26. The auto-injector device was first developed by Survival Technology, Inc. in the 1970s to administer a nerve agent antidote for the United States military. This original auto-injector was called the ComboPen. It was subsequently modified to deliver epinephrine, thus creating the EpiPen.<sup>15</sup>

27. The United States Food and Drug Administration approved the EpiPen on December 22, 1987, under New Drug Application 019430.

<sup>15</sup> 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-industryb28d19036dee#.seg6n7dls>, (last visited Jan. 31, 2017).

28. In 1996, Survival Technology, Inc. merged with Meridian Medical Technologies,<sup>16</sup> which one year later sold the exclusive right to market and distribute the EpiPen to Dey LP. Dey LP is a subsidiary of Merck KGaA, a German multinational pharmaceutical company.<sup>17</sup>

29. Mylan acquired Dey LP and the right to market and distribute the EpiPen line of epinephrine auto-injector devices from Merck as part of broader 2007 acquisition deal.<sup>18</sup>

30. According to Mylan, the EpiPen “is used in the treatment of severe allergic reactions” and “is an epinephrine auto-injector that has been sold in the U.S. and internationally since the mid-1980s.”<sup>19</sup>

31. The EpiPen provides a 0.3 mg dose of epinephrine, while the EpiPen Jr. contains a 0.15 mg dose. EpiPens have a one-year expiration period and patients are advised to replace them after their expiration date. The EpiPen Jr., for kids, has a retail price that is the same as the EpiPen, despite containing half the medicine (0.15 mg instead of 0.3mg) of the EpiPen. Mylan itself states that food allergies among U.S. children are “on the rise, now affecting one in 13” kids.<sup>20</sup>

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<sup>16</sup> Meridian Medical Technologies 10-K Filing (Jul. 31, 1997).

<sup>17</sup> Marilyn Case, *EpiPen Recall Points to Broader Concerns*, Wall St. J. (May, 10, 1998), <http://www.wsj.com/articles/SB895440623631960000>, (last visited Jan. 31, 2017).

<sup>18</sup> Tara Parker-Pope & Rachel Rabkin Peachman, *EpiPen Price Rise Sparks Concern for Allergy Sufferers*, N.Y. Times (Aug. 22, 2016), <http://well.blogs.nytimes.com/2016/08/22/epipen-price-risesparks-concern-for-allergy-sufferers/>, (last visited Jan. 31, 2017).

<sup>19</sup> Mylan N.V. 10-K (2015), [https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k\\_20151231x.doc.htm](https://www.sec.gov/Archives/edgar/data/1623613/000162361316000046/myl10k_20151231x.doc.htm), (last visited Jan. 31, 2017).

<sup>20</sup> *Mylan Applauds New Federal Legislation to Increase Anaphylaxis Preparedness in Schools*, Mylan Inc. (Nov. 14, 2013), <http://newsroom.mylan.com/press-releases?item=123181>, (last visited Jan. 31, 2017).

32. Mylan has worldwide rights to the EpiPen auto-injector, which is supplied to Mylan by a wholly owned subsidiary of Pfizer, Inc.

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

34. The number of patients filling a prescription for an EpiPen has grown 67 percent over the past seven years. “[F]or doctors, who write prescriptions for the name they know best, the EpiPen brand ‘is like Kleenex,’ says Robert Wood, a pediatric allergist at Johns Hopkins University School of Medicine.”<sup>21</sup>

35. By 2015, Mylan gained at least an 85% market share (and likely higher) of the epinephrine injector market. Mylan’s price hikes have left an untold number of children and adults vulnerable to dying from an allergic reaction.

**C. Mylan’s Relentless EpiPen Price Increases**

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

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

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

39. In 2010, Mylan stopped selling single EpiPens in the United States. Instead, Mylan began requiring the EpiPen be purchased in two-packs (the “EpiPen 2-Pak”), which doubled the price consumers must pay, even if they need only one EpiPen.

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

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<sup>21</sup> Cynthia Koons and Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, Bloomberg (Sep. 23, 2015), <http://www.bloomberg.com/news/articles/2015-09-23/how-marketingturned-the-epipen-into-a-billion-dollar-business>, (last visited Jan. 31, 2017).

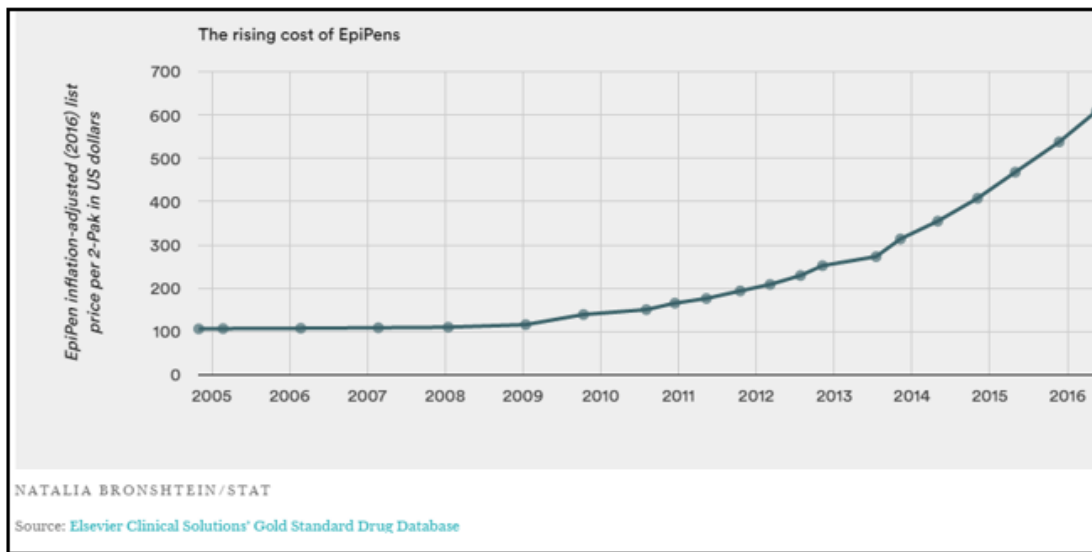
41. After four more price increases, by July 17, 2013, an EpiPen 2-Pak cost \$265.

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

43. Mylan continued to hike the price of the EpiPen 2-Pak throughout 2015 and into 2016.

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

45. The jump in the price orchestrated by Mylan is depicted in the graphic below:



46. 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), however, these increased prices cannot be explained by increased costs or new developments in technology: “the base components for each EpiPen, including the plastic cap, tube, and needle, might cost between \$2 to \$4 to purchase.”<sup>22</sup> And the EpiPen contains

<sup>22</sup> 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 Jan. 31, 2017).

“essentially [the] same core technology that [has been] there for many years.”<sup>23</sup>

47. 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,” indicating that the price of EpiPens in the United States has become completely untethered to their production cost.<sup>24</sup>

48. To fully explain these extreme increases in price, it is necessary to consider a number of other non-market forces, including radical changes that have taken place in the pharmaceutical industry and the relatively recent rise in influence of insurance industry middle-men known as Pharmacy Benefit Managers (“PBMs”).

**D. The Role of Pharmacy Benefit Mangers (PBMs) in the Pharmaceutical Industry and Prescription Drug Prices**

49. The supply chain for prescribed medical products in the United States consists of four (and sometimes three) major actors: Manufacturers, Wholesale Distributors, Pharmacies, and Consumers. Sometimes the Wholesale Distributors and Pharmacies are the same actors.

50. PBMs are a powerful gatekeeper determining what prescription drugs and medical devices flow through that supply chain to the ERISA Class.

51. Prescription medical products “originate in manufacturing sites; are transferred to wholesale distributors; are stocked at retail, mail-order, and other types of pharmacies; are

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<sup>23</sup> *Id.*

<sup>24</sup> 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 Jan. 31, 2017).



subject to price negotiations and processed through quality and utilization management screens by PBMs; are dispensed by pharmacies; and ultimately are delivered to and taken by patients.”<sup>25</sup>

52. The technical function of a PBM is to administer a health coverage provider’s prescription benefit program. A PBM develops the coverage provider’s formulary (the list of prescription benefits included in coverage at various pricing “tiers”), processes claims, creates a network of retail pharmacies that provide discounts in exchange for access to a provider’s plan participants, and negotiates with manufacturers. Formularies include prescription drugs, such as EpiPen epinephrine injectors.

53. Often, PBMs are also responsible for performing drug utilization reviews and operating their own mail-order, specialty, and retail pharmacies. PBMs also contract with a network of retail and community pharmacies. Pharmacies agree to dispense prescription products to covered patients. The contract provides for a payment rate for each prescription, plus a dispensing fee. Pharmacies are also responsible for collecting patient cost-sharing payments and sending those to the PBM or reducing the PBM’s or plan’s share owed by that amount.

54. In addition, and of particular significance here, PBMs have contractual relationships with medical product manufacturers. PBMs negotiate rebates, fees, and other concessions with the manufacturers. These relationships allow PBMs to exert tremendous influence and control over what products are made available to health plans and insureds.

55. In the distribution of prescription drugs, the PBMs play a central role as the gatekeeper for drug formularies.

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<sup>25</sup> Health Strategies Consultancy LLC, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*, The Kaiser Family Foundation (Mar. 2005), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pillunderstanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>.

56. When they first came into existence in the late 1960s, PBMs provided administrative services to health plans by processing claims and maintaining formularies. Over time, they played a larger role negotiating prices with manufacturers of prescription products. Since PBMs were independent, they generally were thought to pass savings back to health plans and consumers by using their leverage to negotiate lower reimbursement rates with pharmacies and discounts with manufacturers.<sup>26</sup>

57. In the 1990s, manufacturers began acquiring PBMs, which caused an “egregious conflict[] of interest,” prompting the Federal Trade Commission to undo those deals.<sup>27</sup> The deals allowed prescription product manufacturers to coordinate pricing policies, see their competitors’ sensitive pricing information, and favor their own products over those of their competitors.<sup>28</sup>

58. In the early and late 2000s, PBMs started buying pharmacies, which has caused a similar conflict of interest that resulted from the merger of manufacturers and PBMs in the 1990s. When a PBM combines with a pharmacy, they “lose the incentive to police against pharmaceutical company schemes to steer patients to more expensive drugs. Indeed, they may collude in them.”<sup>29</sup> The power of the largest PBMs has continued to grow, and has allowed them to distort the pharmaceutical supply chain to their own financial advantage.

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<sup>26</sup> Brian Feldman, *Big pharmacies are dismantling the industry that keeps US drug costs even sort-of under control*, Quartz (Mar. 17, 2016), <https://qz.com/636823/bigpharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-undercontrol/>.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

59. Manufacturers well understand the power of PBMs.<sup>30</sup> Because of their size, and the many thousands of health plan clients they represent, PBMs can steer business from one manufacturer to another based on which one pays the larger PBM Kickback.

60. PBMs make outsize profits by exploiting the United States' complex prescription distribution system. While the role of PBMs in the supply chain is well known, the size of the rebates and other fees they extract from companies for formulary placement, and the portion of these payments they pocket (the "PBM Kickbacks") are carefully guarded secrets.<sup>31</sup>

61. PBMs depend on the lack of transparency to conduct their business and have vigorously resisted any requirement that they disclose the details of their agreements with manufacturers, and the PBM Kickbacks they receive from manufacturers—as well as their agreements with the insurers and pharmacies.<sup>32</sup>

62. The intended and direct victim of the malfeasance by the PBMs (in conjunction with the Manufacturers) is the consumer, who ends up paying an inflated price for pharmaceutical drugs and devices.

63. Although consumers are led to believe that the list price is the actual price for a prescribed product, such as EpiPens, the list price is inflated to account for PBM Kickbacks, some of which are "rebated" back to the PBMs, as shown in the following diagram. Note that the diagram is only illustrative and that insurers or other payers do not necessarily receive a large

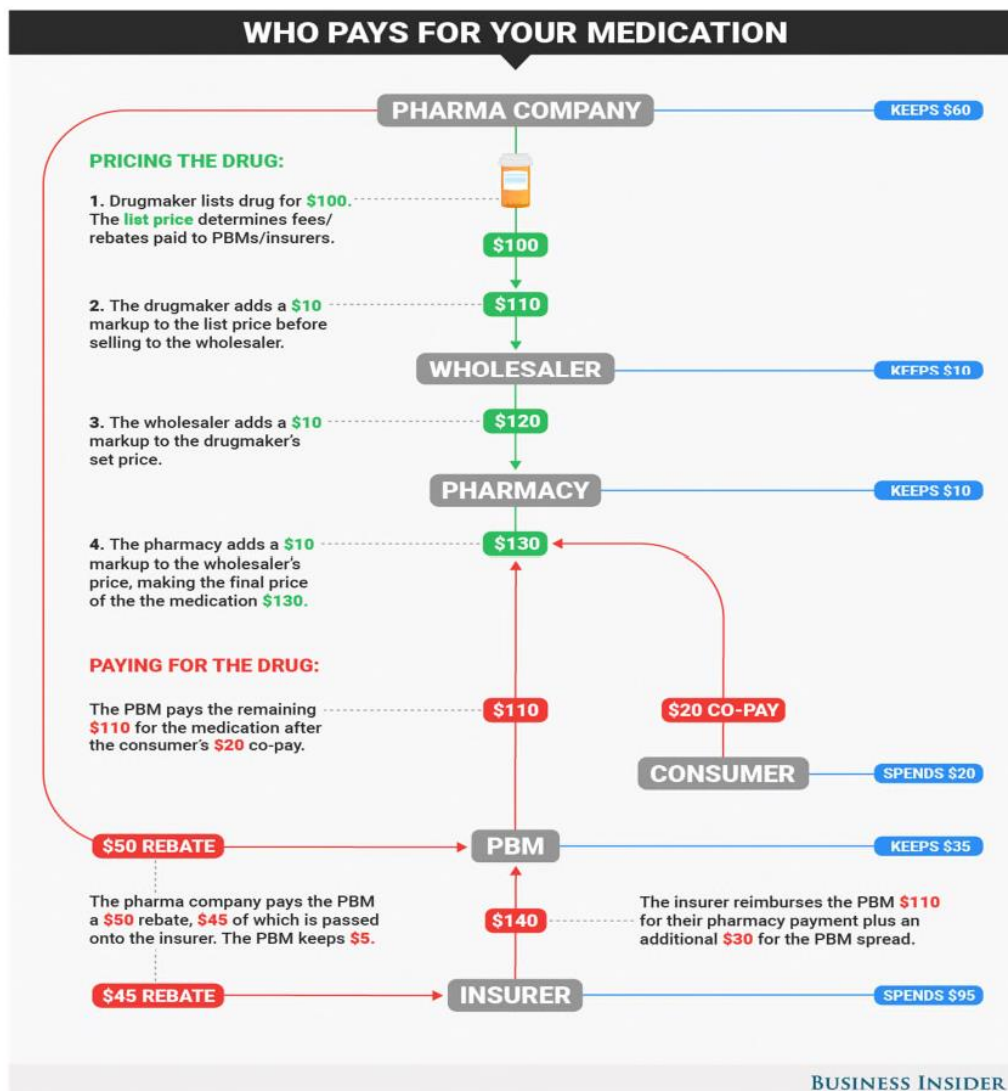
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<sup>30</sup> Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, Wall St. J., (Oct. 7, 2016, 5:46 PM), <https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764>.

<sup>31</sup> See, e.g., Lydia Ramsey, *One of the largest middlemen in the drug industry just released a video showing why it should be able to remain secretive*, Business Insider (Feb. 9, 2017), <http://www.businessinsider.com/what-pharmacy-benefit-managers-are-doing-about-trump-and-drug-pricing-2017-2>.

<sup>32</sup> *Id.*

proportion of the “rebates” back from PBMs, which may keep all or most of the payments in some instances. “Overall, nearly one-third of the total expenditures on branded pharmaceuticals were, in some way, rebated back to PBMs and payers in 2015.”<sup>33</sup> Further, the below payment diagram shows the complicated third party payments structure involved in the straightforward prescription drug distribution chain described in paragraph 52 and even the payment diagram does not depict other payments—kickbacks that are not labeled a “rebate” or that may be wholly hidden from view of others parties to the transaction, including consumers and other payers.



<sup>33</sup> Wayne Winegarden, *The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature*, Pacific Research Institute (May 2017), at 5.

**E. Pharmacy Benefit Mangers and the Epinephrine Auto-injector Market**

64. PBMs serve as gatekeepers between drug and medical supply manufacturers on the one hand, and health insurers and patients on the other. For the PBMs, business is booming. Combined, the three largest PBMs in the United States—OptumRx, ExpressScripts, and CVS Caremark—report more than \$200 billion a year in revenue.<sup>34</sup> They control close to 80% of the industry, administering and managing pharmacy benefits for over 180 million insureds.<sup>35</sup>

65. PBMs are supposed to negotiate *lower* prices for their clients, health insurers and plan administrators. Using the sheer volume of their clients as leverage, the PBM Defendants set up exclusionary tiered formularies—ranked lists of drugs, such as epinephrine injectors, where some cheaper and more effective products are supposed to be placed into lower tiers, generally with lower cost-sharing amounts due from patients.

66. Plan administrators and health insurers rely on PBMs' formularies to calculate how much of their insureds' costs for formulary products they will cover. Medical products that are in the lower, preferred, formulary tiers should be cheaper for health plan members.

67. PBMs are the gatekeepers of formularies—they can decide to exclude entirely a drug like the EpiPen if they do not receive what they view as favorable terms from the manufacturer. This gives the PBM enormous control over purchasing and leverage over manufacturers.

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<sup>34</sup> Kasia Lipska, *Break Up the Insulin Racket*, N.Y. Times (Feb. 20, 2016), <https://www.nytimes.com/2016/02/21/opinion/sunday/break-up-the-insulin-racket.html>.

<sup>35</sup> *Id.*

68. If two medical products are basically interchangeable, a PBM sometimes will exclude from its formulary the more expensive version—again, supposedly based on the price of the product for consumers.

69. Health plans that use a PBM’s formulary either will not reimburse members for the purchase price of products that are excluded from the formulary or will require members to pay a larger coinsurance amount based on the list price rather than the actual net price that the PBM paid. Thus, exclusionary formularies allow PBMs, like the PBM Defendants, to push patients toward certain brands over others, or even exclude certain brands entirely.

70. While PBMs could use this market power to drive down the prices for medical products by forcing manufacturers to lower the list price, instead they and manufacturers have figured out a way to game the system for their mutual benefit. To gain formulary access, manufacturers like Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. have inflated their list prices and then “rebate” or kick back a significant portion of the list price to the PBMs. The rebates are provided under a variety of labels—discounts, credits, concession fees, etc.<sup>36</sup> Regardless of the term used to describe them, they are a *quid pro quo* for formulary inclusion or preferential placement. The result of this rebating scheme is a vast difference between the list price reported by manufacturers and the net price obtained by the manufacturers after PBMs have taken their rebates. And even though manufacturers may not keep the entirety of the list prices they inflate to make room for kickbacks to PBMs, they too profit from the scheme—formulary inclusion translates into increased sales volumes, and increases in list price benefit the manufacturer’s bottom line as well as the PBMs.

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<sup>36</sup> See, e.g., Linda Cahn, *Don’t Get Trapped By PBMs’ Rebate Labeling Games*, Managed Care (Jan. 2009), <https://www.managedcaremag.com/archives/2009/1/don-tget-trapped-pbms-rebate-labeling-games>.

71. PBMs may pass a portion of “rebates” to their major insurer clients, some of which are owned by or affiliated with them, and pocket the rest, along with other payments with different labels. The higher the rebate or other payments, the more the PBMs can pocket. The total amount and nature of the payments, the amount that the PBM pockets, and the amount that passes through to payers are concealed from insureds and the public.

72. This rebate scheme creates the best of both worlds for the Defendants, at the expense of consumers like Plaintiffs. Defendants obtain large payments from the manufacturers in exchange for granting access to the exclusionary formularies, increasing the PBM take, and manufacturers like Mylan N.V., Mylan Specialty L.P., and Mylan Pharmaceuticals, Inc. pay rebates without diminishing—and, at times, even increasing—their profits because their net profits are protected by the ever-increasing list prices, and sales are ensured through formulary placement. In this way, consumers subsidize not only Mylan’s increased profits, which are collected through the ever-increasing cost of the EpiPen set by Mylan itself, but also the kickbacks paid to the PBM Defendants which are charged to consumers, by Mylan, on top of its already exorbitant prices.

73. The result of this scheme is a wide gap between the price paid by PBMs for epinephrine auto-injectors (*i.e.*, the net realized price actually received by the manufacturer), and the publicly available manufacturer list price that directly impacts what consumers must pay.

#### **F. Testimony and Statements Regarding Mylan’s Payments to PBMs**

74. Mylan N.V., Mylan Specialty L.P., and Mylan Pharmaceuticals, Inc. (“Mylan”) have made no secret of their role in this scheme. In fact, when Mylan CEO Heather Bresch was called to testify to a Congressional committee investigating the high price of the EpiPen, she expressly admitted that Mylan’s payment of rebates and other “allowances”—whatever those are—to PBMs has directly contributed to the sky-rocking price of the EpiPen.

75. As she indicated in the below-pictured chart: “Bresch said that for every \$608 EpiPen two-pack, Mylan receives \$274. The remaining \$334 go to other players in the supply chain – middle men, including pharmacy benefit managers, or PBMs.”<sup>37</sup> What Bresch neglected to emphasize, however, is that it is Mylan that sets the price for EpiPens.



76. Going further, Bresch herself points fingers at the PBM Defendant “middlemen” to explain the exorbitant price of EpiPens: “Bresch asserted [that] Mylan had little choice but to jack up the EpiPen list price to accommodate the middlemen’s demands for rebates and fees.”<sup>38</sup> And she alleged that blaming manufacturers like Mylan for high drugs costs is unfair: “the only face that you see on that medicine is the pharmaceutical manufacturer,” Bresch said. “Where in reality . . . there’s at least five entities touching that product,”<sup>39</sup> including PBMs as indicated in

<sup>37</sup> CBS News, *Mylan CEO on EpiPen drug price controversy: “I get the outrage”* (Jan. 27, 2017), <http://www.cbsnews.com/newsepipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out.pdf>.

<sup>38</sup> Michael Hiltzik, *How ‘price-cutting’ middlemen are making crucial drugs vastly more expensive*, L.A. Times (June 9, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>.

<sup>39</sup> *Id.*



the below chart<sup>40</sup> also prepared by Mylan, who suggests the PBMs are actually in the supply chain, when in fact they are not, despite their substantial impact on the pricing of EpiPens:



77. And in the below-excerpted portion of an interview with CNBC, Ms. Bresch reiterated Mylan's position:

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

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

Bresch: My frustration is there's a list price of \$608. There is a system. There are – I laid out that there are four or five hands that the product touches and companies that it goes through before it ever gets to that patient at the counter. No one-everyone should be frustrated. I am hoping that this is an inflection point for this country. Our health care is in a crisis. It's no different than the mortgage crisis back in 2007. This bubble is going to burst.<sup>41</sup>

<sup>40</sup> Mylan, *The Entire Economic Story of the U.S. Pharmaceutical Supply Chain* (2017), [http://www.mylan.com/-/media/mylancom/images/featured\\_stories/supply-chain.jpg](http://www.mylan.com/-/media/mylancom/images/featured_stories/supply-chain.jpg).

<sup>41</sup> CNBC, *First on CNBC: CNBC Transcript: Mylan CEO Heather Bresch Sits Down with CNBC's Brian Sullivan Today on "Squawk Box"* (Aug. 25, 2016),

78. PBMs tout their market power and ability to drive down prices for prescription products, like EpiPens. They boast about the “rebates” or “discounts” for which they bargain with manufacturers, like Mylan. The story they tell is that these rebates and discounts are obtained for the benefit of patients since they purportedly result in *lower* costs. In their latest Form 10-K filed with the United States Securities Exchange Commission, for example, Defendant OptumRx reported that its PBM business helped “improve overall health system performance through optimizing care quality, reducing costs and improving consumer experience. . . .”<sup>42</sup> Similarly, Express Scripts claims, “[w]e put medicine within reach of patients while helping health benefit providers improve access to prescription drugs and make them more affordable. . . .”<sup>43</sup> And CVS Health Corp. contends, “[w]e assist our clients in designing pharmacy benefit plans that help minimize the costs to the client while helping improve health outcomes . . . .”<sup>44</sup>

79. But the story that OptumRx and other PBM Defendants tell is far from the whole truth. They obtain rebates and discounts, but neglect to reveal their large kickbacks—the portion of the manufacturers’ payments that they pocket. They also neglect to reveal that their formulary decisions are based on the amount of the spread they obtain from the rebate paid by manufacturers. And they neglect to reveal that the consequence of this scheme is higher costs for patients, whose payments at the pharmacy point of sale are calculated based on the unrebated list price of medical products, not the lower price paid by the PBMs after all rebates and other

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[www.cnbc.com/2016/08/25/first-on-cnbc-cnbc-transcript-mylan-ceo-heather-bresch-sits-down-with-cnbc-s-brian-sullivan-today-on-squawk-box.html](http://www.cnbc.com/2016/08/25/first-on-cnbc-cnbc-transcript-mylan-ceo-heather-bresch-sits-down-with-cnbc-s-brian-sullivan-today-on-squawk-box.html).

<sup>42</sup> UnitedHealth Group, Annual Report (Form 10-K) (Dec. 31, 2016).

<sup>43</sup> Express Scripts Holding Company, Annual Report (Form 10-K) (Dec. 31, 2016).

<sup>44</sup> CVS Health Corporation (Form 10-K) (Feb. 5, 2017).

financial benefits received by the PBMs from the manufacturers and other third parties are taken into account.<sup>45</sup> Indeed, PBMs, such as the PBM Defendants, misrepresent the role they play in the supply chain, and their impact on the prices actually paid by consumers. PBMs are avaricious gatekeepers, with a stranglehold on the medical supply chain. Their scheme to sell formulary access for rebates drives up the cost of prescription drugs and other medical products for the people who need to use them to stay alive.

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

81. In fact, Mylan’s scheme has inflated costs throughout the entire auto-injector market. To keep up with the rebates offered by Mylan, when competitors are able to introduce products into the market, they are forced to price their products at similarly high rates. For example, when Kaleo introduced the Auvi-Q auto-injector in 2017 it was priced at whopping \$4,500 for a two-pack. But, according to Kaleo Chief Executive Spencer Williamson, this price is due, in part, to the effect of rebates indicating that “nobody . . . will pay \$4,500” and “[t]he

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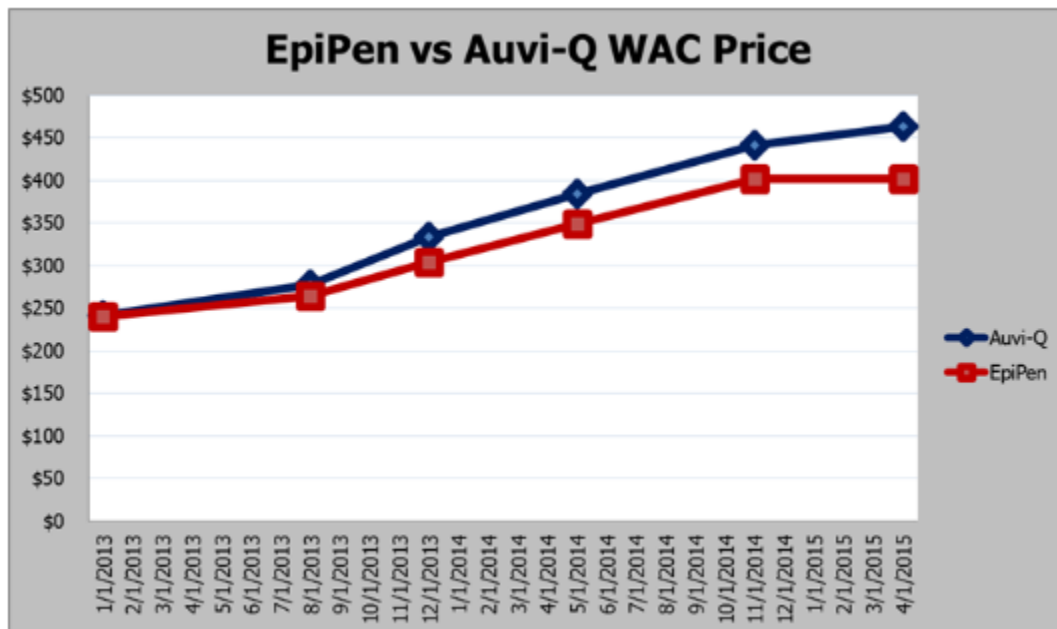
<sup>45</sup> Denise Roland & Peter Loftus, *Insulin Prices Soar While Drugmakers’ Share Stays Flat*, Wall St. J., (Oct. 7, 2016, 5:46 PM), <https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764>.

<sup>46</sup> *Id.*

reason the list price is high is it's the only way we can make sure patients have access and can get it for \$0.”<sup>47</sup>

82. According to industry analyst Ronny Gal and Michal Rea, CEO of Rx Savings Solutions, who commented on the Auvi-Q pricing announcement: “We’ve seen this pricing mechanism before. It’s the same game with a new drug.”; “The entire game is to charge an enormous amount of money to insurers and have those insurers cross-subsidize everybody else.”<sup>48</sup>

83. This is, indeed, nothing new. As indicated in the below chart,<sup>49</sup> the history of EpiPen and Auvi-Q pricing indicates only ever-increasing list prices designed to pay higher and higher rebates to ensure formulary access:



<sup>47</sup> Meg Tirrell, *EpiPen Competitor Auvi-Q Comes Back Feb. 14 With a Pricing Scheme That Will Blow Your Mind* (Jan. 19, 2017), <https://www.cnn.com/2017/01/19/epipen-competitor-auvi-q-comes-back-feb-14.html>.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

84. In contrast, auto-injector products that are traditionally excluded from formulary placement and distribute directly to retailers have been able to avoid these inflationary effects on price. For example, a little-known alternative to the EpiPen known as Adrenaclick, is sold at Walmart for as little as \$142.<sup>50</sup>

**G. The Cost to Consumers in the EpiPen Auto-injector Supply Chain**

85. Defendants' scheme to make increasing profits from EpiPen epinephrine injectors has had a devastating effect on the lives of real people. Unlike PBMs, insurers, pharmacies, health plans, and patients are directly subjected, by PBMs, to the list price artificially set by manufacturers, like Mylan N.V., Mylan Specialty L.P., and Mylan Pharmaceuticals, Inc. The Commissioner of the FDA, Dr. Scott Gottlieb, explained how this harms consumers:

[The rebates] don't necessarily help offset the costs paid by those who need a particular drug. . . . [I]f a patient needs a particular drug, they will increasingly find that they are paying the full, negotiated price at the pharmacy counter. They never see the real "net" price, after the rebate is applied much later. The rebate is paid to the health plan, not the patient buying the drug.<sup>51</sup>

Further, aside from any rebates that are passed through to plans or payers, PBMs collect substantial additional payments that are not passed through—they are pocketed by the PBMs—and may not even be disclosed to their payer clients, much less the participants and beneficiaries to whom they owe fiduciary duties. The manner and extent of the impact of price on patients depends on how patients get their prescriptions, but there is a formula for them all. They fit into the following categories:

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<sup>50</sup> Yasmin Tayag, *Adrenaclick Is the Not-So-Secret EpiPen Substitute* (Aug. 25, 2016), <https://www.inverse.com/article/20200-adrenaclick-epipen-mylan-alternative-substitute-cheaper>.

<sup>51</sup> Wayne Winegarden, *The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature*, Pacific Research Institute (May 2017), at 5.

86. **Uninsured.** First, uninsured consumers—because they are completely outside of the PBMs’ and manufacturers’ web of PBM Kickback financing arrangements through health plans—must pay the full list price for EpiPens. This is not a small population. Although the coverage rates have increased significantly lately, by the end of 2015 there were still 28.5 million nonelderly Americans who lacked insurance.<sup>52</sup>

87. **Deductibles.** Second, consumers who are in health plans suffer directly from the inflated price of EpiPens when they pay their deductibles. The deductible is the amount that an insured must pay before insurance benefits will contribute to medical and pharmacy expenses. Thus, until the deductible is met, an insured must pay out-of-pocket. Depending on the plan, consumers may be required to pay the full list price of drugs and other medical needs.

88. Moreover, deductibles are rising, meaning that insured consumers are having to pay more out-of-pocket for medical needs, including EpiPens. The Kaiser Family Foundation found that in 2016, “deductibles rose 12% in the market group and four times faster than premiums increased.”<sup>53</sup> The higher the deductible, the more consumers have to pay full price for their prescriptions until their coverage begins.

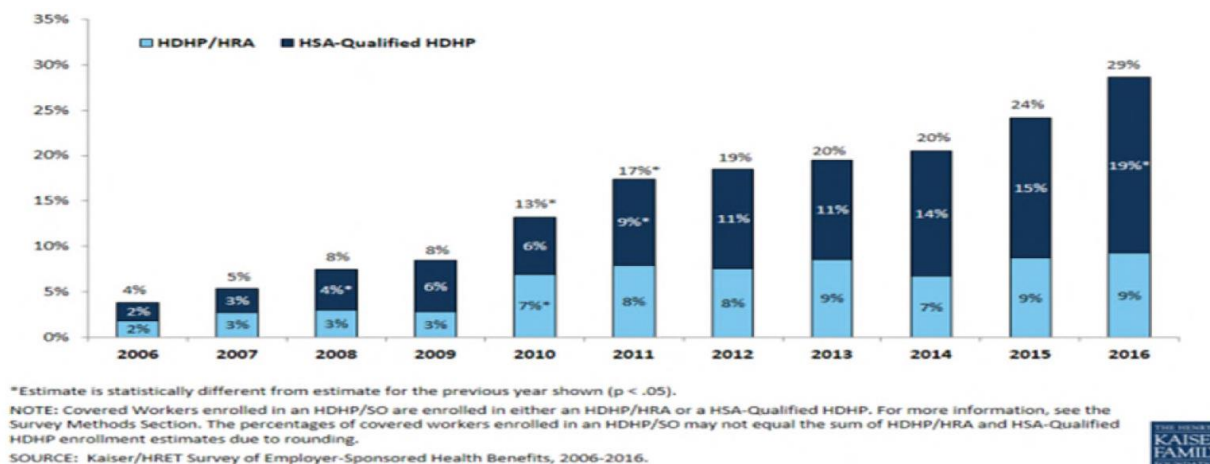
89. “Almost a quarter of all people obtaining insurance through employers are now enrolled in high-deductible-health plans (“HDHPs”), up from 4% in 2006. The average deductible amount has increased 67% since 2010. And almost half of workers are covered by

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<sup>52</sup> *Key Facts about the Uninsured Population*, The Kaiser Family Foundation (Sept. 29, 2016), <http://kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>.

<sup>53</sup> Drew Altman, *The Missing Debate Over Rising Health-Care Deductibles*, The Kaiser Family Foundation (Sept. 18, 2016), <http://kff.org/health-costs/perspective/themissing-debate-over-rising-health-care-deductibles/>.

insurance with annual deductibles of at least \$1,000 for individual coverage.”<sup>54</sup> With the surge in popularity of “high-deductible” plans among employer-sponsored health plans, deductible thresholds affect an ever-increasing number of patients, as indicated below:



90. High deductible plans require consumers to pay thousands of dollars before their coverage kicks in. Many individuals and families cannot afford to hit their high-deductible costs year after year. As a result, rising list prices for drugs and other prescription products are particularly harmful to patients in high-deductible plans, not only because they hit their deductibles annually, but because they hit their deductibles over a *shorter period of time*, resulting in significant financial burden at the start of each calendar year.

91. **Cost sharing.** Third, even after deductibles are paid, insured consumers’ prescription costs are still affected by the PBMs’ and manufacturers’ pricing scheme through copayments and coinsurance requirements. Some plans require these payments during the deductible phase, while others require payment of the full list price with copayments and coinsurance requirements only after the deductible is met.

<sup>54</sup> *Don’t Be Fooled By Eli Lilly’s & Express Scripts’ New Insulin Program*, National Prescription Coverage Association (2017), <http://nationalprescriptioncoveragecoalition.com/dont-be-fooled-by-eli-lillys-expressscripts-new-insulin-program/>.

92. Copayments are set amounts that an insured must pay for medical services, including prescriptions. Copayments vary by the prescribed product, with products in preferred formulary positions carrying a lower copay and products in a disfavored position costing the insured more. For example, if EpiPens are moved to a less preferred tier on a PBM's formulary, a patient then must spend more because of that less favorable formulary placement, which is driven by Defendants' pricing scheme.

93. Coinsurance is a percentage of the cost of a medical service or prescription product that the insured must pay. In the case of prescription products, the coinsurance amount is based on the inflated list price, not an adjusted price based on the secret rebates and kickbacks that PBMs negotiate, and not the amount that manufacturers actually collect or the PBMs actually pay.

94. To add insult to injury, the portion of prescription costs that an insured person's plan will pay is often not based on the full, inflated list price—it is based on a negotiated lower price, which will take into account some rebates, discounts, or other concessions passed through to the plan by the PBM. Thus, plans with such arrangements do not simply pay the difference between the participant's payment and the list price—they instead pay something less—and for large insurers or those that own PBMs, something much less. The burden on participants and beneficiaries of such plans is disproportionate to whatever percentages they may think they are shouldering.

95. People with severe allergies who rely on EpiPens to prevent and treat allergy-induced anaphylaxis are the victims of the Defendants' scheme. These patients are burdened with exorbitant out-of-pocket expenses for their treatment because their payment obligations are based on the list prices, not the opaque net prices provided to PBMs. This is so regardless of



whether these patients are uninsured and paying the entire list price or whether they are insured and paying large deductibles, coinsurance, or high-tier copayments. All of these patients are making payments based on the inflated list price.

96. This lawsuit alleges that Defendants breached their fiduciary duties imposed by the Employee Retirement Income Security Act of 1974 (“ERISA”), by engaging in extortion, and deceptive conduct, whose purpose is to unlawfully extract ever-larger portions of rebates and other payments—“PBM Kickbacks”—from Mylan N.V., Mylan Specialty L.P., and Mylan Pharmaceuticals, Inc.

97. Plaintiffs further allege that Mylan provided the PBM Defendants with increasingly larger kickbacks by inflating their list prices, and have further conspired to prevent disclosure of net prices to consumers—also in violation of the aforementioned laws. Defendants’ scheme directly and foreseeably causes consumers to overpay for these life-saving medications. Thus, this action is brought to redress Plaintiffs’ injuries that flow from Defendants’ scheme—which has driven up the cost of prescription drugs—and in particular EpiPen epinephrine injectors—to the substantial benefit of the PBM Defendants and Mylan—and to obtain prospective injunctive relief to curtail Defendants’ practices and provide greater transparency in pricing, as well as lower prices going forward. The causes of action asserted herein allow the remedies of monetary damages, damage multipliers, restitution, injunctive relief, and other equitable relief.

## **V. ERISA ALLEGATIONS**

### **A. The PBM Defendants are Fiduciaries and Parties in Interest.**

98. Plaintiffs Rizzo, Brannon, and Herr and the members of the ERISA Class (as defined below) are participants in employee welfare benefit plans, as that term is defined in 29

U.S.C. § 1002(1)(A), whose pharmacy benefits covering prescription medications are administered by one or more of the PBM Defendants (“ERISA Plans”).

99. ERISA requires every plan to provide for one or more named fiduciaries who will have “authority to control and manage the operation and administration of the plan.” ERISA § 402(a)(1), 29 U.S.C. § 1102(a)(1).

100. ERISA treats as fiduciaries not only persons explicitly named as fiduciaries under § 402(a)(1), 29 U.S.C. § 1102(a)(1), but also any other persons who in fact perform fiduciary functions. Thus, a person is a fiduciary to the extent “(i) he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets, (ii) he renders investment advice for a fee or other compensation, direct or indirect, with respect to any monies or other property of such plan, or has any authority or responsibility to do so, or (iii) he has any discretionary authority or discretionary responsibility in the administration of such plan.” ERISA § 3(21)(A), 29 U.S.C. § 1002(21)(A). This is a functional test. Neither “named fiduciary” status nor formal delegation is required for a finding of fiduciary status, and contractual agreements cannot override finding fiduciary status when the statutory test is met.

101. The PBM Defendants are fiduciaries of all of the ERISA Class members’ ERISA Plans for which they administered prescription drug benefits in that they exercised discretionary authority or control respecting the following plan management activities, ERISA § 3(21)(A)(i), 29 U.S.C. § 1002(21)(A)(i), and in that they had discretionary authority or discretionary responsibility in the administration of the ERISA Plans of participants and beneficiaries in the ERISA Class, ERISA § 3(21)(A)(iii), 29 U.S.C. § 1002(21)(A)(iii), because, by way of example, they did and/or could do one or more of the following with respect to the ERISA Plans:

A. negotiate with drug manufacturers for the inclusion of the drugs they manufacture on the formularies that govern prescription drug coverage through the ERISA Plans;

B. negotiate with drug manufacturers the prices that patients and the ERISA Plans will pay, including through placement of specific drugs on tiered formularies;

C. dictate whether a particular drug was covered, and if so, in which tier it was categorized;

D. dictate the prices of prescription drugs to patients and ERISA Plans;

E. negotiate with drug manufacturers the amount of rebates, discounts, fees, or other financial incentive payments (*i.e.*, PBM Kickbacks, as defined above) that they will receive from drug manufacturers upon the purchase of specific drugs by patients and health plans;

F. induce drug manufacturers to artificially inflate their list prices so that there is room enough in the drug pricing regime for the PBM Kickbacks, while drug manufacturers' net profits and sales volumes are buoyed by their drugs' inclusion on PBM formularies;

G. dictate the portion, if any, of the PBM Kickbacks that are shared with or passed through to other entities, such as health insurers, plan administrators, plan sponsors, or patients;

H. dictate the amount ultimately paid to pharmacies for prescription drugs;

I. dictate the amount pharmacies charge patients for prescription drugs;

J. manage the prescription drug benefit program, including processing and paying prescription drug claims received from pharmacies;

K. choose whether to fill a prescription from a participant, reject the prescription, or shift the participant to a different prescription medication or require the use of exclusive mail order pharmacies;

L. determine the amount of and require the collection of additional profits and compensation for services provided by the PBM Defendants pursuant to and in managing or administering the ERISA Plans;

M. set their own margin/compensation for services performed as a fiduciary by dictating the amount of PBM Kickbacks they will collect from drug manufacturers and the amount of such PBM Kickbacks they will ultimately keep for themselves in connection with prescription drug purchases;

N. unilaterally collect their own compensation for services performed as a fiduciary by collecting PBM Kickbacks;

O. set and change their own compensation with respect to the ERISA Plans by allocating the proceeds of PBM Kickbacks;

P. misrepresent, conceal, and/or fail to disclose to patients and other fiduciaries the manner in which they charge for the EpiPen products alleged above;

Q. misrepresent, conceal, and/or fail to disclose to patients and to other fiduciaries the amounts and components of PBM Kickbacks that they collect

from drug manufacturers like Mylan N.V., Mylan Specialty L.P., and Mylan Pharmaceuticals, Inc.;

R. misrepresent, conceal, and/or fail to disclose to patients and to other fiduciaries their compensation and profit collected in connection with prescription drug transactions—*i.e.*, the amount they keep for themselves;

S. improperly trade off the interests of ERISA Plan participants and beneficiaries for their own benefit in charging inflated prices to obtain excessive profits at the expense of participants and others paying amounts that are captured as PBM Kickbacks;

T. improperly trade off the interests of plan participants and beneficiaries for the benefit of third parties, including drug manufacturers like Mylan, who are able to sell more of the drugs they produce as a result of their participation in the pricing scheme described herein;

U. leverage their contractual relationships with ERISA Plans, their insurers and administrators, and the pharmacies from which the ERISA Plans and their participants and beneficiaries purchase prescription drugs to exert control over billions of dollars that flow from prescription drug purchases by ERISA Plans and their participants and beneficiaries, as well as over the ERISA Plan instruments that govern these transactions, as described further below, causing Plan participants to pay inflated prices for EpiPen auto-injectors and other drugs.

102. The PBM Kickbacks are possible because of the PBM Defendants' discretion and power to do the foregoing, which makes them fiduciaries to the ERISA Plans for which they administer benefits. The PBM Defendants' *relationships with* and *access to* the ERISA Plans and

related prescription drug purchases are the source of this discretion and power. The PBM Defendants have and use their discretion and authority to set their own fees and compensation by virtue of their role with respect to the administration and/or management of the ERISA Plans for which they administer benefits—a central part of which is and was negotiating drug prices from which the PBM Defendants extract a significant cut of rebates and other payments from drug manufacturers while increasing, rather than decreasing, costs to ERISA Plan participants. Thus the PBM Defendants’ fiduciary power is, in part, the power over their own fees and compensation, because their fees and compensation flow from the drug price negotiations *only they* have the power to conduct on behalf of the ERISA Plans. The fees and compensation the PBM Defendants extract from these negotiations performed on behalf of the ERISA Plans are achieved at the substantial expense of the ERISA Plans’ participants and beneficiaries, who must pay purchase prices that result from the inflated list prices that are central to and caused by the Defendants’ pricing scheme.

103. Further, the PBM Kickbacks were additional compensation for the administration and/or management of prescription drug coverage that was collected by the PBM Defendants that was neither disclosed to nor agreed to by the participants and beneficiaries or others that were required to make these additional payments so that participants and beneficiaries could receive their covered prescription drugs. The PBM Defendants had and exercised discretion to determine the amount of and require the payment of this additional undisclosed compensation, as well as whether to disclose it—or require its concealment. ERISA § 3(21)(A)(i), (iii), 29 U.S.C. § 1002(21)(A)(i), (iii).

104. The PBM Kickbacks are an additional “premium” within the meaning of ERISA § 702, for the provision of prescription drug coverage that was collected by the PBM Defendants

that was neither disclosed to nor agreed to by the participants and beneficiaries that were required to make these additional contributions to receive their covered prescription drugs. The PBM Defendants had and exercised discretion to determine the amount of and require the payment of this additional undisclosed premium payment, as well as whether to disclose it—or require its concealment. ERISA § 3(21)(A)(i), (iii), 29 U.S.C. § 1002(21)(A)(i), (iii).

105. In addition to its fiduciary status under the foregoing provisions, the PBM Defendants are fiduciaries of all of the ERISA Class members' ERISA Plans for which they administered benefits in that they exercised *any* authority or control respecting the management or disposition of plan assets, ERISA § 3(21)(A)(i), 29 U.S.C. § 1002(21)(A)(i), because:

A. The copayments, coinsurance, and deductible payments that the PBM Defendants required pharmacies to collect from participants and beneficiaries are “plan assets” within the meaning of ERISA;

B. The contracts (*e.g.*, insurance policies and administrative-services-only (“ASO”) contracts) underpinning the plans are “plan assets” within the meaning of ERISA; and

C. Through the pricing scheme, as described above, the PBM Defendants exercised control over both (i) drug payments from participants and beneficiaries and (ii) the contracts underpinning the ERISA Plans. The PBM Defendants successfully leveraged their relationships to the ERISA Class members' ERISA Plans to benefit themselves and third parties, and their authority or control over significant plan assets and relationships with the ERISA Plans enabled them to do so. Through this scheme, the PBM Defendants caused participants to pay inflated prices for EpiPen epinephrine injectors.

106. In addition, any plan-paid amounts that were contributed to participant prescription drug transactions were “plan assets” within the meaning of ERISA. The PBM Defendants also exercised control over these plan assets, part of which became PBM Kickbacks, making the PBM Defendants fiduciaries for purposes of these transactions.

107. The PBM Defendants are able to pervert their ostensible roles as the entities that drive drug prices down—and instead induce drug manufacturers to raise prices on prescription medications to allow for PBM Kickbacks—because they have and exercise control over both ERISA Plans and ERISA plan assets. The PBM Defendants’ access to the ERISA Plans and ERISA plan assets is used as leverage in their negotiations with drug manufacturers. But for the PBM Defendants’ access to millions of insureds’ prescription drug transactions and the funds used to purchase drugs for plan participants, the PBM Defendants would not be able to negotiate and extract the PBM Kickbacks. Thus, the PBM Defendants leveraged their unique and powerful access to one of the most exploitable (and lucrative) plan assets that exists today—health insurance policies and ASO contracts—as well as their key relationships with and access to thousands of ERISA Plans.

108. In addition to the conduct described herein the PBM Defendants are fiduciaries because they exercise discretion to set the prices that the members of the ERISA Class were and are required to pay for their prescription medications. PBMs are required to act in the best interests of the members of the ERISA Class, but by allowing participants and beneficiaries of ERISA Plans to be subject to the pricing scheme described herein and participating in this scheme with Mylan, the PBM Defendants also breached their fiduciary duties to the ERISA Class, as described more below.



109. The PBM Defendants are aware of the effect the pricing scheme is having on the ERISA Class. Nevertheless, it has maximized and continue to maximize its revenues and the revenues of drug manufacturers at the expense of the ERISA Class by engaging in the illegal conduct described herein.

110. Furthermore, in negotiating and entering into a contract on behalf of an ERISA plan, a fiduciary must act prudently and negotiate terms that are reasonable and in the best interests of plan participants and beneficiaries. In these negotiations and in the contract, agreement, or arrangement that is ultimately agreed upon, a fiduciary cannot place its interests over the interests of the plan participants and beneficiaries. To the extent that the PBM Defendants negotiated agreements subject to the pricing scheme described herein, they exercised discretionary authority and control over the ERISA Plans, their management and administration, and ERISA plan assets by setting their own margins and compensation for the sale of prescription medications through rebate and other payment negotiations with drug manufacturers. As discussed further below, this same conduct breached their fiduciary duties under ERISA and constituted prohibited transactions.

111. In addition to being fiduciaries for the foregoing reasons, the PBM Defendants are parties in interest under ERISA because (a) they are fiduciaries, ERISA § 3(14)(A), 29 U.S.C. § 1002(14)(A); and/or (b) they provided plan administration and pharmacy benefit management services to Plaintiffs and the ERISA Class members' health plans, ERISA § 3(14)(B), 29 U.S.C. § 1002(14)(B).

112. As further described below, the PBM Defendants—fiduciaries and parties in interest—also received and used for its own and third parties' benefit “plan assets,” including patients' and certain ERISA Plans' contributions to prescription drug purchases and ERISA Plan

contracts under which they had access to the ERISA Plans and ERISA plan assets, and was able to impose its pricing scheme on the ERISA Class.

113. Notably, the foregoing powers and activities confer fiduciary status on the PBM Defendants for all types of ERISA Plans for which they provide pharmacy benefit services—including both insured plans and self-insured or union funded (Taft-Hartley) plans for which a health insurance company provides administrative-services-only (ASO) plan administration—because these plans all utilize PBMs in the same manner. Thus, all participants and beneficiaries in ERISA Plans of whatever type are owed fiduciary duties by the PBM Defendants, and these participants and beneficiaries may bring claims for their own personal losses caused by the PBM Defendants' breaches and prohibited transactions, as set forth below.

114. As a result of the PBM Defendants misuse of their fiduciary power, ERISA Plan participants and beneficiaries are forced to finance the PBM Kickbacks, from which the PBM Defendants and others profit. The PBM Kickbacks do not just enrich the PBM Defendants. They do so to the detriment of Plan participants, who pay inflated prices for EpiPen autoinjectors as a result of the scheme.

## **B. The PBM Defendants' ERISA Duties.**

115. **The Statutory Requirements:** ERISA imposes strict fiduciary duties upon plan fiduciaries. ERISA § 404(a), 29 U.S.C. § 1104(a), states, in relevant part, that:

[A] fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . for the exclusive purpose of providing benefit to participants and their beneficiaries; and defraying reasonable expenses of administering the plan; with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of like character and with like aims; by diversifying the investments of the plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this title and Title IV.

116. **The Duty of Loyalty.** ERISA imposes on a plan fiduciary the duty of loyalty—that is, the duty to “discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . for the exclusive purpose of . . . providing benefits to participants and their beneficiaries . . . .” The duty of loyalty entails a duty to avoid conflicts of interest and to resolve them promptly when they occur. A fiduciary must always administer a plan with an “eye single” to the interests of the participants and beneficiaries, regardless of the interests of the fiduciaries themselves or the plan sponsor.

117. **The Duty of Prudence.** Section 404(a)(1)(B) also imposes on a plan fiduciary the duty of prudence—that is, the duty “to discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man, acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. . . .”

118. **The Duty to Inform.** The duties of loyalty and prudence include the duty to disclose and inform. These duties entail: (a) a negative duty not to misinform; (b) an affirmative duty to inform when the fiduciary knows or should know that silence might be harmful; and (c) a duty to convey complete and accurate information material to the circumstances of participants and beneficiaries.

119. **Prohibited Transactions.** ERISA’s prohibited transaction rules bar fiduciaries from certain acts because they are self-interested or conflicted and therefore become per se violations of ERISA § 406(b)—or because they are improper “party in interest” transactions under ERISA § 406(a). As noted above, under ERISA, a “party in interest” includes a fiduciary as well as entities providing any “services” to a plan, among others. *See* ERISA § 3(14), 29

U.S.C. § 1002(14). ERISA's prohibited transaction rules are closely related to ERISA's duties of loyalty, which are discussed above.

120. ERISA § 406(a) provides that transactions between a plan and a party in interest are prohibited transactions unless they are exempted under ERISA § 408:

(a) Transactions between plan and party in interest

Except as provided in section 1108 of this title:

(1) A fiduciary with respect to a plan shall not cause the plan to engage in a transaction, if he knows or should know that such transaction constitutes a direct or indirect—

(A) sale or exchange, or leasing, of any property between the plan and a party in interest;

(B) lending of money or other extension of credit between the plan and a party in interest;

(C) furnishing of goods, services, or facilities between the plan and a party in interest;

(D) transfer to, or use by or for the benefit of a party in interest, of any assets of the plan; or

(E) acquisition, on behalf of the plan, of any employer security or employer real property in violation of section 1107(a) of this title.

29 U.S.C. § 1106(a).

121. ERISA § 406(b), provides:

A fiduciary with respect to a plan shall not—

(1) deal with the assets of the plan in his own interest or for his own account,

(2) in his individual or in any other capacity act in any transaction involving the plan on behalf of a party (or represent a party) whose interests are adverse to the interests of the plan or the interests of its participants or beneficiaries, or

(3) receive any consideration for his own personal account from any party dealing with such plan in connection with a transaction involving the assets of the plan.

29 U.S.C. § 1106(b).

122. **Co-Fiduciary Liability.** A fiduciary is liable not only for fiduciary breaches within the sphere of its own responsibility, but also as a co-fiduciary in certain circumstances.

ERISA § 405(a), 29 U.S.C. § 1105(a), states, in relevant part, that:

In addition to any liability which he may have under any other provision of this part, a fiduciary with respect to a plan shall be liable for a breach of fiduciary responsibility of another fiduciary with respect to the same plan in the following circumstances:

- (1) if he participates knowingly in, or knowingly undertakes to conceal, an act or omission of such other fiduciary, knowing such act or omission is a breach; or
- (2) if, by his failure to comply with section 404(a)(1) in the administration of his specific responsibilities which give rise to his status as a fiduciary, he has enabled such other fiduciary to commit a breach; or
- (3) if he has knowledge of a breach by such other fiduciary, unless he makes reasonable efforts under the circumstances to remedy the breach.

123. **The Duty to Monitor.** In addition, a fiduciary that appoints another person to fulfill all or part of its duties, by formal or informal hiring, subcontracting, or delegation, assumes the duty to monitor that appointee to protect the interests of the ERISA participants and beneficiaries. As noted above, the power to appoint, retain, and remove plan fiduciaries or service providers confers fiduciary status upon the person holding such power.

124. **The Duty Not To Discriminate.** A health insurer may not discriminate against insureds by charging excessive premiums. ERISA § 702, 29 U.S.C. § 1182, states in pertinent part:

Prohibiting discrimination against individual participants and beneficiaries based on health status.

(a) In eligibility to enroll.

(1) In general. Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of

the following health status-related factors in relation to the individual or a dependent of the individual:

- (A) Health status.
- (B) Medical condition (including both physical and mental illnesses).
- (C) Claims experience.
- (D) Receipt of health care.
- (E) Medical history.
- (F) Genetic information.
- (G) Evidence of insurability (including conditions arising out of acts of domestic violence).
- (H) Disability.

(2) No application to benefits or exclusions. To the extent consistent with section 701, paragraph (1) shall not be construed—

(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) Construction. For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

(b) In premium contributions.

(1) In general. A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

**125. Rights of Action Under the Plans, for Fiduciary Breach, Prohibited**

**Transactions, and Related Claims.** ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3),

authorizes individual participants and fiduciaries to bring suit “(A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.” The remedies available pursuant to § 502(a)(3) include remedies for breaches of the fiduciary duties set forth in ERISA § 404, 29 U.S.C. § 1104, and for violation of the prohibited transaction rules set forth in ERISA § 406, 29 U.S.C. § 1106. Plaintiffs brings their ERISA claims pursuant to ERISA § 502(a)(3), as further set forth below.

**C. The PBM Defendants Breached Their Duties.**

126. The PBM Defendants committed breaches of their fiduciary duties and prohibited transactions, and harmed Plaintiffs and the ERISA Class members in the following ways:

A. Plaintiffs and the ERISA Class members were charged excessive “copayments” or “coinsurance” contributions for EpiPens as a result of the Defendants’ pricing scheme, which caused the list price of the EpiPen to be artificially inflated;

B. Through the Defendants’ pricing scheme, Plaintiffs and the ERISA Class members were charged unlawful fees and additional premiums for EpiPens;

C. Plaintiffs and the ERISA Class members were overcharged for copayment and coinsurance contributions in that rather than paying a percentage of an uninflated price for EpiPens or a flat fee based on an uninflated price for EpiPens; these cost-sharing payments were based on substantially inflated amounts;

D. Plaintiffs and the ERISA Class members were overcharged when making payments toward their deductibles or out-of-pocket maximums in that

rather than paying an uninflated price for EpiPens, they were charged inflated amounts as a result of Defendants' pricing scheme;

E. The PBM Defendants improperly leveraged their relationships with and access to the ERISA Plans and their plan assets to extract PBM Kickbacks from drug manufacturers like Mylan;

F. The PBM Defendants discriminated against patients who require the use of EpiPens as compared to those who do not;

G. The PBM Defendants misrepresented and failed to disclose to ERISA Plan participants and beneficiaries the manner in which they charged for prescription drugs as alleged above;

H. The PBM Defendants set their own compensation for services performed as fiduciaries by inducing drug manufacturers like Mylan to inflate the list price of EpiPens to facilitate the PBM Defendants' collection of PBM Kickbacks;

I. The PBM Defendants unilaterally collected their own compensation for services performed as fiduciaries by collecting PBM Kickbacks;

J. The PBM Defendants set and changed the compensation of third parties with respect to the ERISA Class members' ERISA Plans by allocating the proceeds of the PBM Kickbacks without heeding the best interests of participants and beneficiaries;

K. The PBM Defendants maximized their own profits and profits to third parties, at the expense of Plaintiffs and the ERISA Class members;



L. The PBM Defendants received improper compensation from entities doing business with the ERISA Plans whose pharmacy benefits they administered and managed;

M. The PBM Defendants knew or reasonably should have known that its actions would injure plan participants and beneficiaries of all ERISA Plans whose EpiPen epinephrine injector prices they manipulated;

N. The PBM Defendants negotiated EpiPen prices and PBM Kickbacks based on disloyal and self-interested factors and made such decisions without putting the interests of participants and beneficiaries first;

O. The PBM Defendants drove up EpiPen prices instead of driving them down, in order to increase its profits and the profits of drug manufacturers like Mylan at the expense of participants and beneficiaries of the ERISA Plans; and

P. Drug manufacturers like Mylan knowingly participated in and profit from the fiduciary breaches and prohibited transactions committed by the PBM Defendants.

127. Plaintiffs and the ERISA Class members were overcharged for and/or paid unauthorized and excessive copayments, coinsurance, and deductible payments in connection with the purchase of EpiPen epinephrine injectors.

128. Plaintiffs and the ERISA Class members were harmed by an abuse of the fiduciary power that the PBM Defendants possess—a substantial part of which gives the PBM Defendants discretion and authority over the administration and management of the ERISA plans with respect to prescription drug benefits and costs and their own fees and compensation. The

PBM Defendants' ability to wield fiduciary power to extract from drug manufacturers like Mylan, kickbacks and other benefits for themselves directly and financially harmed participants and beneficiaries of the ERISA Plans. Plaintiffs and the ERISA Class members were forced to pay purchase prices for EpiPens that were based on the very same inflated list prices that facilitated the PBM Defendants' profits from rebates and other kickbacks that drug manufacturers like Mylan paid in exchange for formulary placement and access to the EpiPen purchases of ERISA Plan participants and beneficiaries whose ERISA Plans the PBM Defendants managed and administered. Had the PBM Defendants required drug manufacturers like Mylan to *lower* their price for formulary inclusion, participants' cost sharing amounts would have been based on lower list prices. Thus, the PBM Defendants profits derived from the Defendants' pricing scheme directly harm participants and beneficiaries who must purchase EpiPen epinephrine injectors.

## **VI. TOLLING THE STATUTE OF LIMITATIONS**

### **A. Plaintiffs and the Class are Entitled to Tolling Due to Fraud or Concealment**

129. By its nature, Defendants' pricing scheme has hidden Defendants' unlawful conduct from consumers and injured parties, and its details remain hidden.

130. Plaintiffs and the members of the Class had no way of knowing about Defendants' scheme and deception with respect to the pricing of EpiPen epinephrine injectors, nor could they have reasonably discovered its existence until shortly before filing this action.

131. Within the time period of any applicable statutes of limitation, Plaintiffs and members of the proposed Class could not have discovered through the exercise of reasonable diligence that Defendants were engaged in and/or concealing the conduct complained of herein and misrepresenting the true cost of the EpiPen and the amount of PBM Kickbacks that resulted from the scheme.

132. Plaintiffs and the other members of the Class did not discover, and did not know of facts that would have caused a reasonable person to suspect, that Defendants were engaged in the pricing scheme described herein and were negotiating based on phony list prices, nor would reasonable and diligent investigation have disclosed the true facts.

133. Even today, lack of transparency in EpiPen pricing and the arrangements, relationships, and agreements between and among drug manufacturers like Mylan and the PBM Defendants that result in the PBM Kickbacks continue to hide Defendants' unlawful conduct from the members of the Class.

134. For these reasons, all applicable statutes of limitation have been tolled by operation of the discovery rule with respect to all claims identified herein.

135. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the time period relevant to this action. For example, ERISA's statute of limitations for fiduciary breach claims, ERISA § 413, 29 U.S.C. § 1113, provides that "in the case of fraud or concealment, [an] action may be commenced not later than six years after the date of discovery of such breach or violation."

136. Defendants' pricing scheme—by its nature a secret endeavor by Defendants—remains hidden from most members of the Class. Indeed, although Defendants have admitted that their pricing scheme has driven up prices, the precise amount of PBM Kickbacks remains information in Defendants' possession and largely a mystery to the members of the Class. Moreover, each Defendant actively and effectively concealed its participation in the scheme from Plaintiffs and the other members of the Class through opaque practices and secrecy policies. There is no question that Plaintiffs' claims are timely.

**B. Estoppel**

137. Defendants were under a continuous duty to disclose to Plaintiffs and the members of the Class the true price that they should have been charged for EpiPens, rather than the artificially inflated list price that resulted from the Defendants' scheme, the net price paid by the PBM Defendants for EpiPens, the existence of the Defendants' scheme, and the impact that it had on Plaintiffs and the Class' payment obligations for EpiPens. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

**VII. CLASS ACTION ALLEGATIONS**

138. Plaintiffs brings this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a), as well as (b)(3), (b)(2), and (b)(1), as representatives of the Class defined as follows:

**The ERISA Class.** All individuals residing in the United States and its territories who are or were enrolled in an ERISA-covered health benefit plan or health insurance plan for which one or more of the PBM Defendants administers or manages pharmacy benefits, who purchased an EpiPen epinephrine injector pursuant to such plans or policies and were required to pay all or a portion of the purchase price based on an inflated list price (the "ERISA Class").

Excluded from the Class are: (a) the named Defendants and any entity in which they have a controlling interest, and their legal representatives, officers, directors, assignees, and successors and (b) any co-conspirators, and their officers, directors, management, employees, subsidiaries, and affiliates.

139. **Class Period.** Plaintiffs will seek Class certification, damages, losses, and other available relief for fiduciary breaches and prohibited transactions occurring within the entire period allowable under ERISA § 413, 29 U.S.C. § 1113, including its fraud or concealment tolling provisions, and the doctrine of equitable tolling. Further, Plaintiffs reserve the right to refine the Class Period after they have learned the extent of Defendants' fraud and the length of their concealment.

140. This action is brought, and may properly be maintained, as a Class action pursuant to Fed. R. Civ. P. 23. This action satisfies the numerosity, typicality, adequacy, predominance, and superiority requirements of those provisions.

141. **Numerosity.** Upon information and belief, the Class consists of millions of purchasers residing throughout the United States. Accordingly, it would be impracticable to join all members of the Class before the Court.

142. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants—i.e., as a result of Defendants' misconduct, these purchasers paid artificially inflated prices for EpiPen epinephrine injectors.

143. **Adequacy.** Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs are coincident with, and not antagonistic to, those of the other members of the Class.

144. Counsel that represent Plaintiffs are experienced in the prosecution of Class action and ERISA litigation and have particular experience with Class action litigation involving pharmaceutical products and Pharmacy Benefit Managers.

145. **Commonality.** Questions of law and fact common to the members of the Class predominate over questions that may affect only individual members of the Class because Defendants have acted on grounds generally applicable to all members of the Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

146. Under Rule 23(b)(3), there are numerous and substantial questions of law or fact common to all of the members of the Class and which predominate over any individual issues.

Included within the common question of law or fact are:

- A. Whether the PBM Defendants were induced by PBM Kickbacks to place EpiPens on their formularies;
- B. Whether the PBM Defendants induced Mylan to raise the list price of the EpiPen in exchange for formulary inclusion;
- C. Whether Defendants' conduct violated the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*,
- D. Whether the PBM Defendants are fiduciaries under ERISA;
- E. Whether the PBM Defendants are parties in interest under ERISA;
- F. Whether the PBM Defendants breached their fiduciary duties in failing to comply with ERISA as set forth above;
- G. Whether the PBM Defendants' conduct as alleged above breached ERISA's prohibited transaction rules;
- H. Whether the PBM Defendants breached ERISA § 702;
- I. Whether Plaintiffs and the members of the Class are entitled to compensatory damages and, if so, the nature of such damages;
- J. Whether Plaintiffs and the members of the Class are entitled to exemplary or punitive damages and, if so, the nature of such damages; and
- K. Whether Plaintiffs and the members of the Class are entitled to injunctive or equitable relief and, if so, the nature of that relief.

147. Under Rule 23(b)(3), class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

148. This action is also maintainable as a class action under Rule 23(b)(2) because Defendants have acted, or refused to act, on grounds generally applicable to the Class, thereby making appropriate final injunctive relief respecting the Class as a whole.

149. With respect to Rule 23(b)(1)(B), the prosecution of separate actions by each plaintiff in the Class would create a risk of adjudications with respect to individual members of the Class which would, as a practical matter, be dispositive of the interests of the other members not parties to the actions, or substantially impair or impede their ability to protect their interests.

150. Finally, Class action status is also warranted under Rule 23(b)(1)(A) because prosecution of separate actions by the members of the Class would create a risk of establishing incompatible standards of conduct for Defendants.

151. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## **VIII. CLAIMS FOR RELIEF**

### **COUNT I — PURSUANT TO ERISA § 502(A)(3), 29 U.S.C. § 1132(A)(3) FOR VIOLATIONS OF ERISA § 406(b), 29 U.S.C. § 1106(b)**

(By Plaintiffs on Behalf of all Members of the ERISA Class, Against Defendants Express  
Scripts, OptumRx, and Prime)

152. Plaintiffs incorporate by reference all paragraphs as though fully set forth herein and, to the extent necessary, plead this cause of action in the alternative.

153. ERISA § 406(b), 29 U.S.C. § 1106(b), provides that a fiduciary shall not (1) deal with plan assets in its own interest or for its own account, (2) act in any transaction involving the plan on behalf of a party whose interests are adverse to participants or beneficiaries, or (3) receive any consideration for its own personal account from any party dealing with such plan in connection with a transaction involving the assets of the plan.

154. As alleged above, the PBM Defendants are fiduciaries to Plaintiffs' ERISA Plan and the ERISA Plans of the members of the ERISA Class. They violated all three subsections of ERISA § 406(b).

155. As alleged above, both (i) payments from participants and beneficiaries and (ii) the contracts underpinning the ERISA Class members' ERISA Plans are plan assets under ERISA.

156. First, by setting its own compensation from EpiPen epinephrine injector prescription payments from participants and beneficiaries, as well as from ERISA Plan contributions, collecting their own compensation from those same sources, and managing pharmacy benefits in their own interest or for their own account, the PBM Defendants violated ERISA § 406(b)(1). Specifically, in setting the amount of and taking undisclosed payments, often in the form of PBM Kickbacks, the PBM Defendants dealt with Plaintiffs' and the members of the ERISA Class' ERISA Plans and with the ERISA Plans' plan assets in their own interest and received plan assets and consideration for its personal accounts. Further, by inducing Mylan to inflate list prices for EpiPen epinephrine injectors to accommodate their demands for kickbacks, the PBM Defendants dealt with Plaintiffs and the members of the ERISA Class'



ERISA Plans and the plan assets of those ERISA Plans in their own self-interest, rather than in the interest of ERISA Plan participants and beneficiaries.

157. Second, by acting on behalf of Mylan, who also stood to profit from inflated EpiPen epinephrine injector prices at the expense of Plaintiffs and the members of the ERISA Class—and thus had interests adverse to the affected participants and beneficiaries—the PBM Defendants engaged in conflicted transactions each time they facilitated, required, or allowed EpiPen epinephrine injector price inflation and/or the payment of PBM Kickbacks, in violation of ERISA § 406(b)(2). Under this subsection of ERISA § 406(b), plan assets need not be involved—dealing with an ERISA Plan is enough.

158. Third, the PBM Defendants received consideration for their own personal accounts from other parties—including Mylan, third parties, Plaintiffs, and the members of the ERISA Class—that were dealing with ERISA Plans in connection with transactions involving the assets of ERISA Plans.

159. The PBM Defendants' prohibited transactions described herein not only profited the PBM Defendants, but also injured Plaintiffs and the members of the ERISA Class, who have suffered losses through the PBM Kickbacks that the PBM Defendants took through these prohibited transactions.

160. ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), authorizes a participant or beneficiary to bring a civil action: “(A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan.” Plaintiffs and the ERISA Class' § 502(a)(3) claims are on behalf of *all participants and beneficiaries* of ERISA Plans whose pharmacy benefits are managed and administered by the

PBM Defendants, regardless of the type of ERISA Plan it is and whether or not it is underwritten by an insurance contract with a health insurer, to recover the portions of their copayments, coinsurance, and deductible amounts paid for EpiPen epinephrine injector products at an inflated price due to the PBM Kickbacks described herein.

161. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should order equitable relief to the Plaintiffs and the members of the ERISA Class, including but not limited to:

- A. an accounting;
- B. a surcharge;
- C. correction of the transactions;
- D. disgorgement of profits;
- E. an equitable lien;
- F. a constructive trust;
- G. restitution;
- H. full disclosure of the foregoing acts and practices;
- I. an injunction against further violations; and/or
- J. any other remedy the Court deems proper.

**COUNT II — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3)  
FOR VIOLATIONS OF ERISA § 404, 29 U.S.C. § 1104**

(By Plaintiffs on Behalf of all Members of the ERISA Class, Against Defendants Express  
Scripts, OptumRx, and Prime)

162. Plaintiffs incorporate by reference all paragraphs as though fully set forth herein and, to the extent necessary, plead this cause of action in the alternative.

163. ERISA § 404(a)(1), 29 U.S.C. § 1104(a)(1), provides that a fiduciary shall discharge its duties with respect to a plan solely in the interest of the participants and

beneficiaries and for the exclusive purpose of providing benefits to participants and beneficiaries and defraying reasonable expenses of administering the plan, and with the care, skill, prudence and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims.

164. In leveraging its access to millions of dollars in EpiPen purchases through ERISA Plans to which they had access and over whose plan assets they had or exercised control for its own benefit or the benefit of third parties, and to the detriment of participants and beneficiaries the PBM Defendants breached their fiduciary duties of loyalty and prudence.

165. Further, in failing to put the interests of participants and beneficiaries first in managing and administering pharmacy benefits, the PBM Defendants breached their fiduciary duty of loyalty. And in acting in their own self-interest and in the interest of their own corporate affiliates, the PBM Defendants violated the “exclusive purpose” standard.

166. The duty to disclose is part of the duty of loyalty. In concealing and failing to disclose to the ERISA Class the fact or amount of the PBM Kickbacks, the inflation of list prices, or the net price of EpiPen auto-injector products for which they were being charged, and in concealing and failing to disclose to Plaintiffs and the ERISA Class that plan participants were paying inflated amounts for copayments and coinsurance, as well as deductible payments, the PBM Defendants breached this duty. Further, both omissions and misrepresentations are actionable under ERISA’s disclosure obligations, and the type that occurred here are not subject to individualized reliance requirements.

167. Finally, it is never prudent to require or allow excessive compensation in the context of an ERISA-covered plan. In so doing, the PBM Defendants violated their duty of prudence.

168. Plaintiffs and the members of the ERISA Class have been damaged and suffered losses in the amount of the PBM Kickbacks the PBM Defendants took.

169. ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), authorizes a participant or beneficiary to bring a civil action: “(A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan.”

170. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should order equitable relief to the Plaintiffs and the ERISA Class, including but not limited to:

- A. an accounting;
- B. a surcharge;
- C. correction of the transactions;
- D. disgorgement of profits;
- E. an equitable lien;
- F. a constructive trust;
- G. restitution;
- H. full disclosure of the foregoing acts and practices;
- I. an injunction against further violations; and/or
- J. any other remedy the Court deems proper.

**COUNT III — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3)  
FOR VIOLATIONS OF ERISA § 702, 29 U.S.C. § 1182**

(By Plaintiffs on Behalf of all Members of the ERISA Class, Against Defendants Express Scripts, OptumRx, and Prime)

171. Plaintiffs incorporate by reference all paragraphs as though fully set forth herein and, to the extent necessary, plead this cause of action in the alternative.

172. ERISA § 702, 29 USC § 1182, states in pertinent part:

Prohibiting discrimination against individual participants and beneficiaries based on health status.

(a) In eligibility to enroll.

(1) In general. Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

- A. Health status.
- B. Medical condition (including both physical and mental illnesses).
- C. Claims experience.
- D. Receipt of health care.
- E. Medical history.
- F. Genetic information.
- G. Evidence of insurability (including conditions arising out of acts of domestic violence).
- H. Disability.

(2) No application to benefits or exclusions. To the extent consistent with section 701, paragraph (1) shall not be construed—

(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the

benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

(3) Construction. For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

(b) In premium contributions.

(1) In general. A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

173. In setting the price for EpiPen auto-injector products and taking excessive and undisclosed rebate and other kickback payments, Defendants have required plan participants and beneficiaries who have a medical condition that requires an EpiPen subject to Defendants' artificially inflated prices and undisclosed and excessive PBM Kickbacks to pay greater premiums and contributions for their health plan benefits than those participants and beneficiaries who do not.

174. Under Defendants' scheme, Plaintiffs and members of the ERISA Class who need prescription EpiPen auto-injector products subject to Defendants' artificially inflated prices and undisclosed and excessive PBM Kickbacks were required to pay hidden additional and/or higher premiums in order to be able to use their benefits as enrollees, thus making the artificially inflated prices and payment of PBM Kickbacks a condition of continued enrollment under their ERISA Plans. Without paying inflated copayments, coinsurance, or deductible payments, above and beyond the required participant contributions set forth in their plans, Plaintiffs and members of the ERISA Class could not obtain covered prescription medications under their ERISA Plans, the effect of which is that they would not be enrolled in the Plans.

175. Plaintiffs and the ERISA Class have been damaged and suffered losses in the amount of the PBM Kickback the PBM Defendants took, which were financed by the inflated costs paid by Plaintiffs and the ERISA Class for prescription EpiPen auto-injector products.

176. ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), authorizes a participant or beneficiary to bring a civil action: “(A) to enjoin any act or practice which violates any provision of this title or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this title or the terms of the plan.”

177. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should order equitable relief to the Plaintiffs and the ERISA Class, including but not limited to:

- A. an accounting;
- B. surcharge;
- C. correction of the transactions;
- D. disgorgement of profits;
- E. an equitable lien;
- F. a constructive trust;
- G. restitution;
- H. full disclosure of the foregoing acts and practices;
- I. an injunction against further violations; and/or
- J. any other remedy the Court deems proper.

**COUNT IV — PURSUANT TO ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3)  
FOR KNOWING PARTICIPATION IN VIOLATIONS OF ERISA**

(By Plaintiffs on Behalf of all Members of the ERISA Class,  
Against all Defendants)

178. Plaintiffs incorporate by reference all paragraphs as though fully set forth herein.

179. Under ERISA, non-fiduciaries—regardless of whether they are parties in interest—who knowingly participate in a fiduciary breach may themselves be liable for certain relief under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3).

180. Accordingly, as to the ERISA claims, even for Defendants who have no fiduciary or party-in-interest status themselves, they must nevertheless restore unjust profits or fees and are subject to other appropriate equitable relief with regard to the transactions at issue in this action, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), and well established case law. Thus, even if Defendants are not fiduciaries to the ERISA Plans with regard to any transaction at issue in this action, they are nevertheless subject to equitable relief under ERISA based on their actual or constructive knowledge of the wrongdoing at issue.

181. Accordingly, Plaintiffs Rizzo, Brannon, and Herr and the ERISA Class make claims against all Defendants even if they do not have fiduciary status with respect to the ERISA Plans. Even as non-fiduciaries, they nevertheless must restore unjust profits or fees and are subject to other appropriate equitable relief, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), and pursuant to *Harris Trust & Sav. Bank v. Salomon Smith Barney Inc.*, 530 U.S. 238 (2000).

182. All Defendants had actual or constructive knowledge of and participated in and/or profited from the prohibited transactions and fiduciary breaches alleged above by the PBM Defendants, and these non-fiduciaries are liable to disgorge ill-gotten gains and/or plan assets and to provide other appropriate equitable relief, pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), and *Harris Trust*.

183. As a direct and proximate result of the fiduciary breaches and prohibited transactions alleged above and the participation therein of all Defendants, Plaintiffs Rizzo,



Brannon, and Herr and the members of the ERISA Class directly or indirectly lost millions of dollars and/or plan assets both participant pharmacy payments and Plan contracts were improperly used to generate profits for the Defendants.

184. The Defendants collected and/or paid these amounts to themselves, their affiliates, or third parties from plan assets or generated them through improper leveraging of plan assets and/or their relationships with and access to ERISA Plans.

185. The Defendants' facilitation of inflated prices for EpiPens harmed the ERISA Class, and the Defendants are liable to restore their ill-gotten gains to the ERISA Plaintiffs.

186. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should order equitable relief to Plaintiffs Rizzo, Brannon, and Herr and the ERISA Class, including but not limited to:

- A. an accounting;
- B. a surcharge;
- C. correction of the transactions;
- D. disgorgement of profits;
- E. an equitable lien;
- F. a constructive trust;
- G. restitution;
- H. full disclosure of the foregoing acts and practices;
- I. an injunction against further violations; and/or
- J. any other remedy the Court deems proper.

#### **IX. JURY DEMAND**

Pursuant to Fed. R. Civ. P. 38, Plaintiffs, on behalf of the proposed Class, demand a trial by jury on all issues so triable.

DATED: August 29, 2017

Respectfully submitted by,

/s/ Rex A. Sharp

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 29th day of August, 2017, I filed the above-titled documents on Pacer, which provided service to all attorneys of record and the defendants in this case.

/s/ Rex A. Sharp

4815-5272-5326, v. 1

# ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [Pharmacy Benefit Managers Accused of Inflating EpiPen Prices](#)

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