UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re EpiPen ERISA Litigation, (This Document Applies to All Cases)	Case No. 0:17-1884-PAM-SER **CONSOLIDATED CLASS ACTION COMPLAINT**

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I. INTRODUCTION

1. Plaintiffs Amy M. Khan, Susan Illis, Elan and Adam Klein, Leah Weaver, and Arissa Paschalidis, by and through their undersigned attorneys, bring this action under the Employee Retirement Income Security Act of 1974 ("ERISA") individually and on behalf of all others similarly situated ("the Class") against Defendants CVS Health Corporation, CaremarkPCS Health, L.L.C., Caremark L.L.C., Caremark Rx L.L.C. (together, "CVS Caremark"), Express Scripts Holding Company, Express Scripts, Inc., Medco Health Solutions, Inc., (together, "Express Scripts"), UnitedHealth Group Incorporated, UnitedHealthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, OptumRx, Inc., (together, "Optum"), and Prime Therapeutics, LLC ("Prime").

2. Defendants in this case—CVS Caremark, Express Scripts, Optum, and Prime—are pharmacy benefit managers ("PBMs"), which manage and administer prescription drug benefits for health plans nationwide. Over the last several years, Defendants have consolidated and grown to manage and administer prescription drug benefits for the vast majority of Americans. Together these four companies control over 81% of the market and possess the market power of more than 200 million people. One of Defendants' primary roles is managing and controlling health plan formularies: lists of prescription drugs for which health plans will provide prescription drug benefits. Thus, Defendants act as gatekeepers that control which drugs will be covered by the employer-sponsored health benefit plans for which Defendants serve as PBMs.

3. This action arises out of Defendants leveraging their gatekeeping function—through their management and administration of health insurance plans'

prescription drug benefits, their control over health plan formularies, and their management of and control over their health plan clients' massive collective pool of prescription drug benefits contracts—in order to receive unprecedented rebates, fees, discounts, or other payments or financial incentives from Mylan[1] (collectively, "Kickbacks") in exchange for inclusion and/or favorable placement of the EpiPen epinephrine auto-injector drug device (the "EpiPen"[2]) on Defendants' formularies.

4. Over the last several years, as the number of filled EpiPen prescriptions increased, so too have the Kickbacks that Mylan was required to pay Defendants so Mylan could keep selling its desired volume of EpiPens and gain competitive advantage. Defendants have achieved this by inducing and/or colluding with Mylan to continuously raise the EpiPen's list price (or "sticker price"), allowing Mylan to continue paying Kickbacks—thereby increasing Defendants' profits—and to maintain EpiPen's formulary placement and market share—thus also increasing Mylan's own profits. Indeed, Mylan recently admitted to working hand in glove with the PBMs to achieve this mutually beneficial outcome. Meanwhile, the out-of-pocket cost of EpiPen continues to rise for ERISA plan participants and beneficiaries, including the Class.

5. Pharmaceutical industry experts—including the current FDA Commissioner—have recently acknowledged the perverse incentives that Defendants

[1] Mylan N.V., Mylan Specialty L.P., and/or Mylan Pharmaceuticals, Inc. (collectively, "Mylan") market and sell EpiPen.

[2] For simplicity, this Complaint uses the term "EpiPen" or "EpiPens" to refer to the EpiPen®, EpiPen 2-Pak®, EpiPen Jr.®, and EpiPen Jr. 2-Pak® (collectively or individually, the "EpiPen").

present to Mylan. The incentives worked, and this scheme has resulted in millions of dollars in profit for Defendants. Meanwhile, ERISA plan participants and beneficiaries pay substantially more money than they should for the EpiPen—a life-saving device that treats and prevents anaphylaxis associated with certain severe allergic reactions.

6. As fiduciaries to the participants and beneficiaries whose pharmacy benefits they administer and manage, Defendants owe the highest duties known to law, including the duty to act solely in the participants' and beneficiaries' interest. Defendants breached these duties by using their role in plan management and administration and their authority and control over plan assets—including with respect to formulary management, influencing the cost of EpiPens to participants and beneficiaries, and controlling their own compensation in the form of substantial and unprecedented Kickbacks—in a manner that increased the out-of-pocket payments paid by participants and beneficiaries.

7. Working with Mylan, Defendants put their self-interest above the interests of those to whom they owed fiduciary duties when they leveraged their control over their massive purchasing pool—obtained through their existing contracts with thousands of employer-sponsored welfare benefit plans. Specifically, Defendants negotiated for and obtained exorbitant Kickbacks from Mylan in exchange for Mylan's access to these participants and beneficiaries in the form of exclusive or preferred inclusion of the EpiPen in Defendants' formularies. In their quest to increase profits, Defendants and Mylan drove up the list prices of the EpiPen—the base price of which determines the amount participants and beneficiaries pay at the pharmacy counter—which in turn increased the out-of-pocket

amount that participants and beneficiaries, including the Class, have to pay before accessing the life-saving EpiPen.[3]

8. Defendants could have offered Mylan formulary placement and market share for EpiPen in exchange for *lowering* EpiPen's list price for the benefit of participants and beneficiaries. Indeed, that is the role and skill that PBMs market to their clients: driving hard bargains to keep drug costs down. For example, rather than keeping Kickbacks in their own pockets, PBMs could reduce the cost of prescription drugs by passing that money through to the plans they claim to represent. Instead, Defendants profit by retaining substantial amounts of Kickbacks for themselves. While Defendants pass through *some* rebates and fees to the plans (particularly in the case of a health insurer owning a PBM, such as with Optum), they also retain a large portion of such funds, in part through creative labeling of the various rebates and fees they receive from drug companies like Mylan. Defendants have devised separate confidential contracts with each entity in the prescription drug distribution and reimbursement chain, thereby ensuring that none of those entities has information about prescription drug pricing outside of its individual contract. As a result, Defendants are the only entities with information in what is otherwise a prescription drug pricing black box. This lack of transparency, and Defendants' central role in ensuring it, gives them authority and discretion to label the Kickbacks that they negotiate with Mylan such that they retain control over the amount of Kickbacks they keep for themselves. Thus, the hard bargains Defendants purport to drive for their clients—the plans or their

[3] *See, e.g.*, *The Truth About PBMs*, Cost of Health Care News (May 11, 2017), http://www.cost-of-health-carenews.com/our-blog/the-truth-about-pbms.

participants and beneficiaries—are, in reality, for themselves. Between the gatekeeping role they have created for themselves, their towering market share and consequent grip on the nationwide prescription drug business, Defendants have become immensely profitable.

9. Defendants' conduct has not only resulted in massive increases to the list price of EpiPen, it has had an enormous impact on EpiPen spending. According to a recent analysis published by the Journal of the American Medical Association, between 2007 and 2014, total EpiPen spending increased astronomically, nearly 1,000%. Further, the increase in EpiPen's list price, spurred by Defendants through their inducement of and/or collusion with Mylan, has caused EpiPen deductible payments to increase by ***nearly 1,600%***, and EpiPen coinsurance payments to increase by ***more than 1,500%***.

10. Plaintiffs' allegations are based on their own experience; personal knowledge and 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 discovery arising out of this matter.

II. PARTIES

A. Plaintiffs

11. **Plaintiff Amy M. Khan** is a resident and citizen of Kansas and has needed to purchase EpiPen products for the treatment of her allergic reactions and anaphylaxis associated with an immunological condition, as well as the treatment of severe allergies of five of her children (two adults, three minors).

12. Khan most recently purchased an EpiPen Jr. 2-Pak from Walgreens #6707 for one of her minor children on January 3, 2017 and again on April 10, 2017. Additionally, Khan purchased an EpiPen 2-Pak for herself from CVS Pharmacy #17502 on May 24, 2017.

13. Since at least January 2015, Khan and her five children who require the use of EpiPens have been enrolled in a high-deductible, employer-provided welfare benefit health plan governed by ERISA through Aetna for which CVS Caremark administers pharmacy benefits. Khan used Aetna's prescription drug benefit administered by CVS Caremark to make the EpiPen epinephrine injector purchases described above.

14. **Plaintiffs Elan and Adam Klein** are residents of Lake Worth, Florida. The Kleins have a six-year-old son who has severe allergies to eggs, dairy, nuts, and seeds. Since October 2013, the Kleins have been participants in an ERISA-governed health insurance plan. Prime provides pharmacy benefit management services to the Kleins under that plan.

15. On November 3, 2015, the Kleins filled a prescription for an EpiPen Jr. 2-Pak for their six-year-old son at their local pharmacy. Because they had yet to satisfy the $5,000 annual deductible under their ERISA-governed health insurance plan, they were subject to the full benchmark-related price of $468.93, pursuant to the terms of their plan. Using a pharmacy coupon, they reduced their out-of-pocket cost to $368.93.

16. On November 18, 2015, the Kleins filled another prescription for an EpiPen Jr. 2-Pak for their son at their local pharmacy. Again, they were subject to the benchmark-related price of $468.93 under the terms of their ERISA health insurance plan

because they had yet to satisfy the plan's $5,000 annual deductible. Using a pharmacy coupon, they reduced their out-of-pocket cost to $368.93.

17. On January 6, 2017, the Kleins filled two more prescriptions, each for an EpiPen, Jr. 2-Pak, for their son at their local pharmacy. This time, they were subject to the benchmark-related price of $1,227.95 (nearly $614 for each 2-Pak) under the terms of their ERISA health insurance plan because they had yet to satisfy the plan's $5,200 annual deductible. Using a pharmacy coupon, they reduced their out-of-pocket cost to $627.95.

18. **Plaintiff Leah Weaver** is a resident of Minneapolis, Minnesota. Her ten-year-old daughter has a severe tree nut allergy. Beginning in 2013 through 2014, Weaver and her daughter were participants in an ERISA-governed health insurance plan for which Medco Health Solutions, Inc. provided pharmacy benefit management services. Beginning in 2015 through 2016, Weaver and her daughter were participants in an ERISA-governed health insurance plan for which CVS Caremark provided pharmacy benefit management services. Throughout the year 2017, Weaver and her daughter were participants in an ERISA-governed health insurance plan for which Express Scripts, Inc. provides pharmacy benefit management services.

19. On or about April 18, 2013, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price of $258.65 under the terms of her high-deductible ERISA health insurance plan because she had yet to satisfy her annual deductible. She paid $258.65 for the prescription at a pharmacy in Minneapolis. Ms. Weaver's PBM for that purchase was Medco Health Solutions, Inc.

20. On or about May 24, 2014, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price of $374.72 under the terms of her high-deductible ERISA health insurance plan because she had yet to satisfy her annual deductible. Using a pharmacy coupon to reduce her out-of-pocket costs, she paid $274.72 for the prescription at a pharmacy in Minneapolis. Ms. Weaver's PBM for that purchase was Medco Health Solutions, Inc.

21. On or about April 16, 2015, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her high-deductible ERISA health insurance plan because she had yet to satisfy her annual deductible. Records of this benchmark-related price may be obtained through discovery. Using a pharmacy coupon to reduce her out-of-pocket costs, she paid $232.89 for the prescription at a pharmacy in Minneapolis. Ms. Weaver's PBM for that purchase was CaremarkPCS Health L.L.C.

22. On or about June 18, 2015, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her high-deductible ERISA health insurance plan because she had yet to satisfy her annual deductible. Records of this benchmark-related price may be obtained through discovery. Using a pharmacy coupon to offset her out-of-pocket costs, she paid $265.00 for the prescription at a pharmacy in Bemidji, Minnesota. Ms. Weaver's PBM for that purchase was CaremarkPCS Health, L.L.C.

23. On or about April 20, 2017, Ms. Weaver filled an EpiPen prescription and was subject to a benchmark-related price under the terms of her high-deductible ERISA health insurance plan because she had yet to satisfy her annual deductible. Records of this

benchmark-related price may be obtained through discovery. Using a pharmacy coupon to offset her out-of-pocket costs, she paid $317.23 for the prescription at a pharmacy in Minneapolis, Minnesota. Ms. Weaver's PBM for that purchase was Express Scripts, Inc.

24. **Plaintiff Arissa Paschalidis** is a resident of Fort Lee, New Jersey. Mrs. Paschalidis has severe allergies to tree nuts and tree pollen. From October 2013 to August 2014, Mrs. Paschalidis was a participant in an ERISA-governed health insurance plan. Prime provided pharmacy benefit management services to Mrs. Paschalidis under that plan.

25. Mrs. Paschalidis has filled EpiPen prescriptions under her ERISA health insurance plan. In doing so, she has been subject to benchmark-related prices while under the plan's $2,500 annual deductible. She has never paid the full benchmark price, however, because she is unable to afford it. Instead, she fills her EpiPen prescriptions using a drug company or pharmacy coupon that reduces her out-of-pocket cost to an amount between approximately $150 and $250. Mrs. Paschalidis has made multiple requests—both in writing and over the telephone—to her health insurer, to Prime, and to various pharmacies for her prescription drug benefit claim records in order to confirm the specific dates and out-of-pocket costs for her EpiPen purchases while under her ERISA health insurance plan, between October 2013 and August 2014. However, she has yet to receive any records. These records may be obtained in this action through discovery.

26. **Plaintiff Susan Illis** is a resident of Marietta, Georgia. Ms. Illis has a twelve-year-old daughter who has severe allergies to tree nuts. Throughout the relevant

time period, Ms. Illis has been a participant in an ERISA-governed health insurance plan. Optum provides pharmacy benefit management services to Ms. Illis under that plan.

27. On or about January 15, 2015, Ms. Illis filled a prescription for an EpiPen 2-Pak for her daughter at Walgreens. Because she had yet to satisfy the annual deductible under her ERISA-governed health insurance plan, she was subject to the full benchmark-related price of $421.57, pursuant to the terms of her plan. Using a pharmacy coupon, she reduced her out-of-pocket cost to $321.57.

28. On or about January 16, 2015, Ms. Illis filled a prescription for an EpiPen 2-Pak for her daughter at Walgreens. Because she had yet to satisfy the annual deductible under her ERISA-governed health insurance plan, she was subject to the full benchmark-related price of $421.57, pursuant to the terms of her plan.

29. On or about September 19, 2015, Ms. Illis filled a prescription for an EpiPen 2-Pak for her daughter at Walgreens. Pursuant to a coinsurance provision in her ERISA plan, she was required to pay 20% of the full benchmark-related price of $465.94. As a result, her out-of-pocket cost was $93.19.

B. Defendants

30. **Defendant CVS Health Corporation** is a retail pharmacy and healthcare company headquartered at One CVS Drive, Woonsocket, Rhode Island 02895 and incorporated in Delaware. CVS Health Corporation, through its Pharmacy Services Segment, provides pharmacy benefit management services to various health insurance entities on behalf of nearly 90 million health plan participants. In its 2016 Annual Report, CVS Health Corporation repeatedly referred to itself as a PBM, stating that it is "the

largest integrated pharmacy health care provider in the United States" and that it "provides a full range of pharmacy benefit management services." In its 2016 Annual Report, CVS Health Corporation further stated that one of its three business segments is its Pharmacy Services Segment, which provides "a full range of pharmacy benefit management ("PBM") solutions, including plan design offerings and administration, formulary management," and that approximately 60% of its 2016 revenues were derived from its Pharmacy Services Segment.

31. **Defendant CaremarkPCS Health, L.L.C.**, a Delaware limited liability corporation, formerly known as Caremark PCS Health, L.P., was incorporated in 2002 and is headquartered at 750 West John Carpenter Freeway, Irving, Texas 75039. CaremarkPCS Health, L.L.C., d/b/a CVS Caremark, provides pharmacy benefit management services to various health insurance entities. CaremarkPCS Health, L.L.C. is a wholly owned subsidiary of CVS Health Corporation.

32. **Defendant Caremark, L.L.C.**, a California limited liability company, is headquartered at 2211 Sanders Road, Northbrook, Illinois 60062-6128. Caremark, L.L.C. offers pharmacy benefit management services to various health insurance entities. Caremark, L.L.C. is a wholly owned subsidiary of CVS Health Corporation.

33. **Defendant Caremark Rx, L.L.C.**, a Delaware limited liability company, is headquartered at 211 Commerce Street, Nashville, Tennessee 37201. Caremark Rx, L.L.C. provides pharmacy benefit management services. Caremark Rx, L.L.C. is a wholly owned subsidiary of CVS Health Corporation. Caremark Rx, L.L.C. is the parent of Defendant CVS Health Corporation's pharmacy services subsidiaries and is the

immediate or indirect parent of many pharmacy benefit management subsidiaries, including Defendant CaremarkPCS Health, L.L.C.

34. Defendant CaremarkPCS Health, L.L.C. and Caremark L.L.C. are agents and/or alter egos of Defendant Caremark Rx, L.L.C., and Defendant Caremark Rx, L.L.C. is an agent and/or alter ego of Defendant CVS Health Corporation. For example, Jonathan C. Roberts, CEO of Caremark Rx, L.L.C., is Executive Vice President and Chief Operating Officer of CVS Health Corporation. Thomas S. Moffatt, Secretary of Caremark Rx, L.L.C. and Caremark, L.L.C., is a Vice President, Assistant Secretary, and Assistant General Counsel at CVS Health Corporation. Anne E. Klis, CEO of Caremark, L.L.C., is Vice President of Professional Practice and Training at CVS Health Corporation. Daniel P. Davison, CEO of CaremarkPCS Health, L.L.C., is Senior Vice President of Finance at CVS Health Corporation. Melanie K. Luker, Assistant Secretary of CaremarkPCS Health, L.L.C., is Manager of Corporate Services at CVS Health Corporation.

35. For purposes of clarity, Plaintiffs herein collectively refer to CVS Health Corporation, CaremarkPCS Health, L.L.C., Caremark L.L.C., and Caremark Rx L.L.C. as "CVS Caremark."

36. **Defendant Express Scripts Holding Company** is a full-service pharmacy benefit management and specialty managed care company headquartered at One Express Way, St. Louis, Missouri, 63121 and incorporated in Delaware. Express Scripts Holding Company provides pharmacy benefit management services through its wholly-owned subsidiaries to various health insurance entities on behalf of 83 million plan participants.

In its 2016 Annual Report, Express Scripts Holding Company repeatedly referred to itself as a PBM, stating that it is "the largest stand-alone pharmacy benefit management ('PBM') company in the United States" and that it "provides integrated pharmacy benefit management services." In its 2016 Annual Report, Express Scripts Holding Company further stated that one of its two business segments is the PBM segment and that 96.2% of its 2016 revenues were derived from its PBM operations.

37. **Defendant Express Scripts, Inc**. is a pharmacy benefit manager headquartered at One Express Way, St. Louis, Missouri 63121 and incorporated in Delaware. Express Scripts, Inc. is a subsidiary of Express Scripts Holding Company. Express Scripts, Inc. provides pharmacy benefit management services to various health insurance entities.

38. **Defendant Medco Health Solutions, Inc**. is a pharmacy benefit manager headquartered at 100 Parsons Pond Road, Franklin Lakes, New Jersey 07417 and organized under Delaware law. Medco Health Solutions, Inc. is a subsidiary of Express Scripts Holding Company. Medco Health Solutions, Inc. provides pharmacy benefit management services to various health insurance entities.

39. Medco Health Solutions, Inc. and Express Scripts, Inc. are agents and/or alter egos of Express Scripts Holding Company. For example, David Queller, President of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President of Sales & Account Management at Express Scripts Holding Company. Christine Houston, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Executive Vice President and Chief Operations Officer at Express

Scripts Holding Company. John Mimlitz, a Vice President at both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Vice President of Tax at Express Scripts Holding Company. Timothy Smith, a Vice President and Treasurer of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Corporate Treasurer and Vice President of Finance and Indirect Procurement at Express Scripts Holding Company. Rod Fahs, the Assistant Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Assistant General Counsel at Express Scripts Holding Company. Christopher McGinnis was a Vice President at Express Scripts, Inc., and also a Vice President and Chief Accounting Officer of Express Scripts Holding Company. Martin Akins, the only member of the Board of Directors of Express Scripts, Inc. and the only member of the Board of Directors of Medco Health Solutions, Inc., and Secretary of both Express Scripts, Inc. and Medco Health Solutions, Inc., is also Senior Vice President, General Counsel, and Corporate Secretary of Express Scripts Holding Company. All of the officers of Medco Health Solutions, Inc. are also officers of Express Scripts, Inc.

40. For purposes of clarity, Plaintiffs herein collectively refer to Express Scripts Holding Company, Express Scripts, Inc., and Medco Health Solutions, Inc. as "Express Scripts."

41. **Defendant UnitedHealth Group Incorporated** is headquartered at 9900 Bren Road East, Minnetonka, Minnesota and incorporated in Delaware. UnitedHealth Group Incorporated has two main divisions: UnitedHealthcare, which provides health benefits, and Optum, which provides health services, including pharmacy benefit management services. According to its 2016 Annual Report, "UnitedHealthcare utilizes

Optum's capabilities to help coordinate patient care, improve affordability of medical care, analyze cost trends, manage pharmacy benefits, work with care providers more effectively and create a simpler consumer experience." The 2016 Annual Report further states, "OptumRx provides a full spectrum of pharmacy care services to more than 65 million people in the United States through its network of more than 67,000 retail pharmacies and multiple home delivery facilities throughout the country." In 2016, approximately one-third of the overall revenues of UnitedHealth Group Incorporated came from OptumRx, Inc., and OptumRx, Inc.'s revenues almost doubled between 2014 and 2016, from $32 billion to $60 billion.

42. **Defendant UnitedHealthcare Services, Inc.** is headquartered at 9700 Health Care Lane, Minnetonka, Minnesota and incorporated in Minnesota. UnitedHealthcare Services, Inc. is a subsidiary of UnitedHealth Group Incorporated and provides pharmacy benefit management services through its subsidiaries to various health insurance entities. According to Exhibit 21.1 to UnitedHealth Group Incorporated's 2016 Securities and Exchange Commission ("SEC") Form 10-K, UnitedHealthcare Services, Inc. also does business as Optum, Inc.

43. **Defendant Optum, Inc.** is a PBM headquartered at 11000 Optum Circle, Eden Prairie, Minnesota and incorporated in Delaware. Optum, Inc. is a subsidiary of UnitedHealthcare Services, Inc., which provides pharmacy benefit management services through its subsidiaries to various health insurance entities on behalf of more than 65 million plan participants.

44. **Defendant OptumRx Holdings, LLC**, a Delaware limited liability corporation, is headquartered at 2300 Main Street, Irvine, California. OptumRx Holdings, LLC is a PBM and a subsidiary of Optum, Inc. OptumRx Holdings, LLC provides pharmacy benefit management services through its subsidiaries to various health insurance entities.

45. **Defendant OptumRx, Inc.** is a PBM headquartered at 2300 Main Street, Irvine, California and incorporated in California. OptumRx, Inc. is a subsidiary of OptumRx Holdings, LLC. OptumRx, Inc. changed its name from Prescription Solutions, Inc. to OptumRx, Inc. in 2012. OptumRx, Inc. provides pharmacy benefit management services to various health insurance entities.

46. Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. are agents and/or alter egos of UnitedHealthcare Services, Inc. UnitedHealthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. are agents and/or alter egos of UnitedHealth Group Incorporated. OptumRx Holdings, LLC and OptumRx, Inc. are agents and/or alter egos of Optum, Inc. OptumRx, Inc. is an agent and/or alter ego of OptumRx Holdings, LLC. For example, Larry Renfro, CEO of Optum, Inc., is Vice Chairman, Office of the Chief Executive, at UnitedHealth Group Incorporated. Tom Roos, Senior Vice President and Chief Accounting Officer of UnitedHealth Group Incorporated, is Chief Financial Officer of UnitedHealthcare Services, Inc. Timothy Alan Wicks, Chief Financial Officer and Executive Vice President of Optum, Inc. is also a director of OptumRx, Inc.

47. For purposes of clarity, Plaintiffs herein collectively refer to UnitedHealth Group Incorporated, UnitedHealthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. as "Optum."

48. On March 30, 2015, Optum announced its acquisition of another large PBM, Catamaran Corporation, which at the time provided pharmacy benefit management services on behalf of 35 million plan participants. Optum announced the completion of the merger on July 23, 2015.

49. **Defendant Prime Therapeutics, LLC** is a PBM headquartered at 1305 Corporate Center Drive, Eagan, Minnesota 55121 and organized under Delaware law. Prime is owned by fourteen Blue Cross and Blue Shield health insurance entities. Prime provides pharmacy benefit management services to those fourteen Blue Cross and Blue Shield health insurance entities on behalf of more than 20 million health plan participants.

III. JURISDICTION AND VENUE

50. **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.

51. **Personal Jurisdiction.** The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed fiduciary breaches and prohibited transactions throughout the United States, including in this judicial district. Defendants' actions 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.

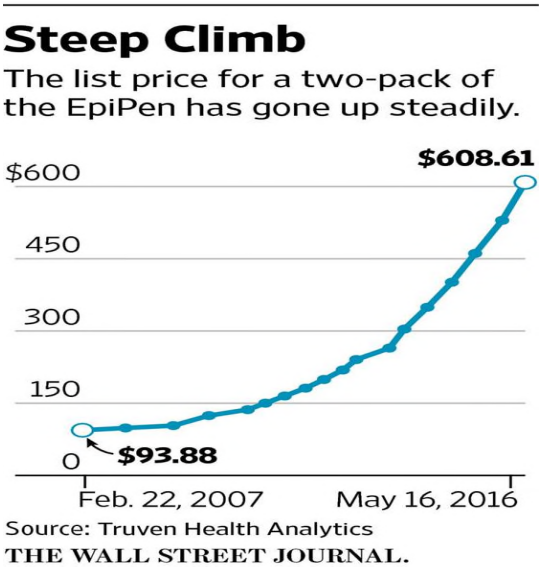
52. **Venue.** Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because Plaintiff Weaver, a Minnesotan, resides and purchased EpiPens in this District, each Defendant transacts business in, is found in, and/or has agents in this District, and because some of the actions giving 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. EpiPen

53. EpiPen is an auto-injector device designed to allow a person to easily and safely administer the appropriate dosage of epinephrine in the event of an anaphylactic episode, a potentially life-threatening reaction to one or more allergens. EpiPen can be used on oneself or on another person. EpiPen is frequently used by parents and teachers to treat children experiencing an anaphylactic episode.

54. Mylan owns the exclusive right to market and sell EpiPen.[4] Mylan acquired those rights when, in 2007, Mylan acquired Merck KGaA, Merck's generic pharmaceutical business, which owned the rights at the time. When Mylan acquired the rights to market and sell EpiPen in 2007, the list price for a 2-Pak of the drug was less than $100. By 2016, the list price for an EpiPen 2-Pak had skyrocketed to more than $608. As of September 2017, Mylan's list price for an EpiPen 2-Pak remained at $608.61.



55. EpiPen's price rose dramatically along with the number of EpiPen prescriptions filled: 3.6 million in 2015 and more than 4.1 million in 2016. Between 2013

[4] In 2011, Pfizer acquired King Pharmaceuticals, which develops, manufactures, markets, and sells branded prescription pharmaceutical products. As part of that acquisition, Pfizer also acquired Meridian Medical Technologies, Inc., which develops and manufactures the EpiPen sold by Mylan. Both King and Meridian are wholly owned subsidiaries of Pfizer. Through King and Meridian, Pfizer supplies Mylan with 100% of the EpiPens Mylan sells.

and 2016, EpiPen occupied between 85% and 96% of the epinephrine autoinjector market.

56. EpiPen users generally fill their prescriptions annually, given EpiPen's one-year expiration date. In addition, it is not uncommon for EpiPen users to fill multiple prescriptions each year in order to have an EpiPen readily available in multiple places during a given day (*e.g.*, at home, in the car, at work, at school). Approximately 70% of EpiPen prescriptions are filled using commercial health insurance with PBM-administered pharmacy benefits, the vast majority of which are ERISA health insurance plans.[5]

57. While Mylan has continuously raised the list price of EpiPen to more than $608, Mylan CEO Heather Bresch states that Mylan's "cost of goods" for an EpiPen 2-Pak is $69.[6] Industry experts estimate the cost to manufacture a single EpiPen to be approximately $20-$30.[7] Notably, in other countries, the list price of EpiPen is

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[5] *Health Insurance Coverage of the Total Population – Timeframe: 2016*, Henry J. Kaiser Fam. Found., http://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&selectedDistributions=employer--non-group&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Apr. 1, 2018).

[6] Dan Mangan, *Mylan's EpiPen 'greed is astounding ... sickening and disgusting,' rep says*, CNBC (Sept. 21, 2016), https://www.cnbc.com/2016/09/21/mylan-ceo-says-epipen-profits-no-where-near-devices-600-sticker-price.html.

[7] Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than $30*, NBC News (Sept. 6, 2016), https://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091. Others place the actual total cost of manufacturing an EpiPen 2-Pak at roughly $10. 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/2016/10/1/epipen-outrage-silicon-valley-engineers-figure-true-cost-to-make-lifesaving-auto-injector-about-10.

shockingly lower than in the U.S.—just $69 in England,[8] less than $100 in France,[9] $100 in Australia,[10] between $100 and $145 in Canada,[11] and just over $200 in Germany.[12]

B. Prescription Drug Distribution and Reimbursement

58. To understand how Defendants induced and/or colluded with Mylan to increase EpiPen list prices and profited from those list price increases, one must first understand that Defendants are at the center of the complex and opaque system of prescription drug distribution and reimbursement in the United States. This system is comprised of confidential agreements between Defendants and a variety of entities, including pharmaceutical companies, retail pharmacies, health insurers, employers, and unions. All of these agreements are separate, and their terms are kept confidential as between the various entities with which the PBMs negotiate.

1. The Prescription Drug Distribution Chain

59. *Pharmaceutical Companies*. Pharmaceutical companies, also referred to herein as "drug companies," develop, manufacture, market, and sell prescription drugs. At the beginning of the prescription drug distribution chain, pharmaceutical companies sell

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[8] James Paton & Naomi Kresge, *Why the $600 EpiPen Costs $69 in Britain*, Bloomberg (Sept. 28, 2016), https://www.bloomberg.com/news/articles/2016-09-29/epipen-s-69-cost-in-britain-shows-other-extreme-of-drug-pricing-itnvgvam.

[9] *Id.*

[10] Sophie Scott & Rebecca Armitage, *Mylan EpiPen US price hikes unlikely to be experienced in Australia, experts say*, ABC News (Aug. 24, 2016), http://www.abc.net.au/news/2016-08-25/mylan-epipen-us-prices-hikes-unlikely-to-happen-in-australia/7784700.

[11] Gillian Mohney, *EpiPen Price Hike Prompts Some US Families to Buy the Drug in Canada*, ABC News (Aug. 31, 2016), http://abcnews.go.com/Health/epipen-price-hike-prompts-us-families-buy-drug/story?id=41769704.

[12] Paton & Kresge, *supra* note 8.

prescription drugs to drug wholesalers. Mylan is the pharmaceutical company that markets and sells EpiPen. As discussed further below, Defendants entered into confidential contracts with Mylan for rebates, fees, discounts, or other payments or financial incentives ("Kickbacks") in exchange for exclusive or preferred formulary placement of the EpiPen.

60. *Wholesalers.* Drug wholesalers purchase bulk quantities of drugs directly from drug companies to distribute to pharmacies and hospitals. For example, a wholesaler may fill an order from a pharmacy for a specified quantity of drugs from one or more drug companies and deliver the order to the pharmacy. Three wholesalers—AmerisourceBergen Corporation, Cardinal Health Inc., and McKesson Corporation—account for over 85% of all drug distribution in the United States.

61. *Retail Pharmacies.* Retail pharmacies typically purchase pharmaceuticals from wholesalers to dispense to consumers. Retail pharmacies include chain pharmacies (*e.g.*, Walgreens, CVS, Walmart, and Costco), pharmacies in grocery stores and other retailers, hospitals, and independently owned pharmacies. Each Defendant has entered into contracts with chain pharmacies, pharmacies associated with grocery stores and other retailers, including Pharmacy Services Administrative Organizations ("PSAOs"),[13] as

[13] PSAOs serve as intermediaries between PBMs and independent pharmacies to negotiate reimbursement rates, among other terms. Independent pharmacies join a PSAO in the hopes that the PSAO—with membership ranging between hundreds of independent pharmacies to thousands—will be able to negotiate more favorable terms with PBMs on behalf of their members collectively than the pharmacies could alone. Nearly all independent pharmacies are members of a PSAO.

well as a small number of individual pharmacies to dispense drugs to their clients' plan participants and beneficiaries, including the Class.

62. In short, at the retail level, prescription drugs, including EpiPen, have the following chain of distribution between the drug company and the ultimate patient-consumer: (i) the drug company sells the drug to a wholesaler; (ii) the wholesaler sells the drug to a pharmacy or other drug dispensary; and (iii) the pharmacy dispenses the drug to the patient-consumer.

2. The Prescription Drug Reimbursement Chain

63. *PBMs.* At the center of the prescription drug reimbursement chain are PBMs. PBMs enter into confidential contracts with employers and other employer-related entities (like unions), health insurers, federal and state governments, municipalities, and prescription drug coalitions to manage and administer prescription drug benefits for health plan participants and beneficiaries, including the Class, in exchange for various fees. According to the Pharmaceutical Care Management Association ("PCMA"), as of 2016, PBMs administer prescription drug benefits for 266 million Americans. The four largest PBMs—CVS Caremark, Express Scripts, Optum, and Prime—administer prescription drug benefits for more than 200 million Americans.

64. *Health Insurers.* Health insurers underwrite and/or administer health insurance plans, which typically include medical and prescription drug benefits for plan participants and beneficiaries. Individuals and plan sponsors, such as employers, pay premiums and/or administrative fees to health insurers that underwrite and/or administer the plan, typically on a monthly basis.

65. *Prescription Drug Coalitions.* Prescription drug coalitions are entities that serve as intermediaries between PBMs and employers. Prescription drug coalitions are formed and managed by healthcare consulting firms, such as Willis Towers Watson, Aon, PLC, and Mercer LLC. Many employers join a prescription drug coalition—with membership ranging between dozens of employers to hundreds—in the hopes that the coalition will be able to negotiate more favorable pharmacy benefit service contracts with the PBMs on behalf of the coalition's members collectively than individual employers could negotiate on their own.

66. *Employer Health Insurance Plans.* Employers may sponsor a health insurance plan in one of two ways.[14] First, an employer may purchase health insurance policies for its plan participants from a health insurer. The health insurer then provides healthcare benefits (*i.e.*, medical and prescription drug benefits) to employees and other eligible plan beneficiaries. The plan's health insurer will contract with a specific PBM to administer the plan's prescription drug benefits. Second, an employer may set aside funds to directly provide healthcare benefits to employees, paying for their medical and prescription drug benefits itself. Such employers contract with a health insurer to administer healthcare benefits on behalf of the employer's health insurance plan. Either the plan's health insurer will contract with a PBM to administer the plan's prescription drug benefits, or the employer will contract with a specific PBM, either through a prescription drug coalition or directly, to administer the plan's prescription drug benefits.

[14] A union may sponsor a health insurance plan for its members in the same way as an employer for its employees.

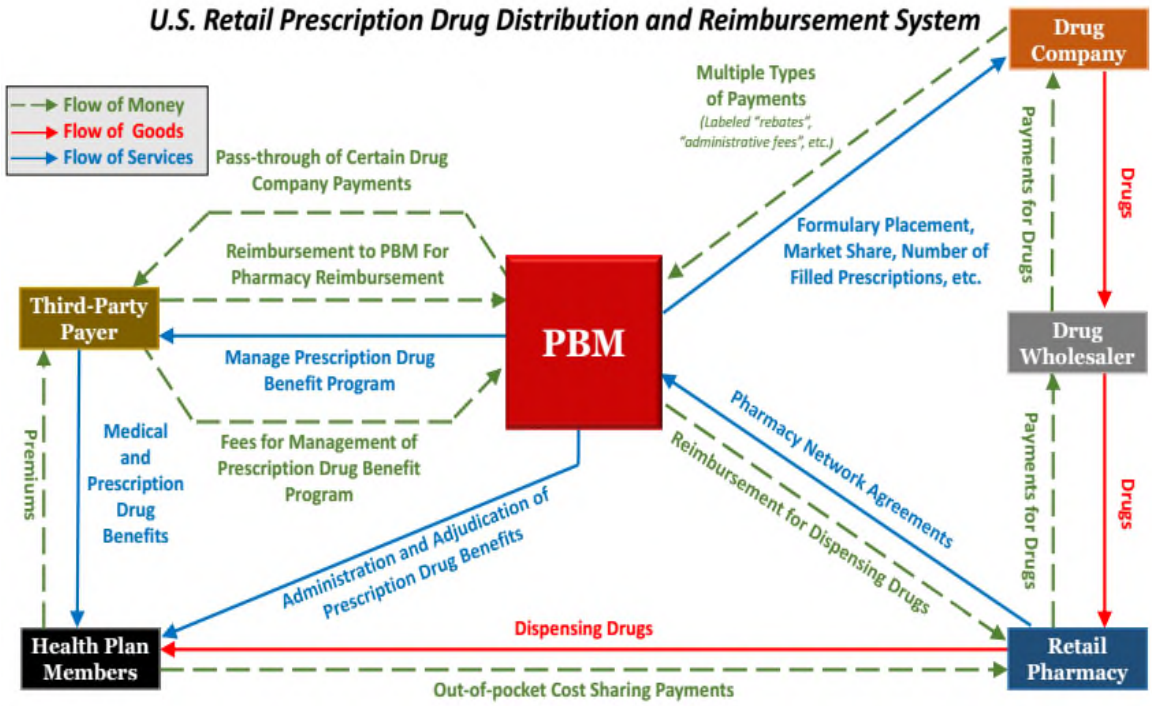
67. *Retail Pharmacies.* PBMs do not take possession or control of prescription drugs that are dispensed at retail pharmacies. Instead, PBMs create networks of retail pharmacies—for example, amongst a group of chain pharmacies, or one or more PSAOs of independent pharmacies—and contract with those networks to reimburse individual retail pharmacies for dispensing prescription drugs, like EpiPen, to health plan participants and beneficiaries with PBM-administered prescription drug benefits. PBMs mandate that these reimbursement contracts, including the rates of reimbursements to retail pharmacies for dispensing prescription drugs, be kept secret.

68. Separately, PBMs enter into confidential contracts with health insurers, employers, and unions (collectively referred to as "plans") regarding reimbursement rates owed for prescription drugs from a plan to the PBM.

69. When an individual plan participant presents a prescription at a pharmacy, the pharmacy transmits the prescription information to the PBM. This is known as a prescription drug benefit claim. The PBM then sends a message back to the pharmacy indicating whether the individual is eligible for prescription drug benefits for that claim and, if so, (i) the amount the pharmacy will be reimbursed by the PBM for dispensing the drug, and (ii) the amount the pharmacy must collect from the individual.

70. In short, the PBM processes the prescription drug benefit claim and reimburses the pharmacy for that claim, pursuant to a secret reimbursement rate between the PBM and the pharmacy. The plan then reimburses the PBM for the same prescription drug benefit claim, pursuant to another secret—and separate—reimbursement rate

between the PBM and the plan. A simplified version of this reimbursement chain, as well as the previously discussed drug distribution chain, is graphically depicted below.



C. Defendants Use Their Position at the Center of Prescription Drug Distribution to Acquire Enormous EpiPen-Related Payments from Mylan

71. Defendants negotiated confidential contracts with Mylan pursuant to which Mylan made payments to Defendants in exchange for exclusive or preferred placement on Defendants' formularies, thus increasing consumer access to and/or market share for EpiPen, and directly contributing to increased out-of-pocket costs for the Class.

1. Rebates and Formularies

72. A common label assigned to one form of Kickback that PBMs receive from a drug company is a "***rebate***." Rebates are payments that PBMs obtain from drug companies for the supposed purpose of reducing consumer costs. Some of these rebates are remitted to plans but, as discussed below, *infra* § IV.H.3, PBMs retain a large portion

of such funds. In exchange for these rebates, among other things, the drug receives placement on ***"formularies."*** A formulary is a list of drugs for which PBMs' plan clients offer prescription drug benefits to plan participants and beneficiaries.

73. PBMs develop and manage formularies for their plan clients. Most formularies have multiple tiers of coverage. The tier in which a drug is placed determines the amount of prescription drug benefits a plan provides for the drug. As discussed below, plan participants and beneficiaries typically pay less out-of-pocket for drugs in preferred formulary tiers. If a PBM excludes a drug from the formulary it develops and manages for the plan, the plan generally will not provide any benefits to plan participants or beneficiaries for the drug.

74. Because formularies are determinative of plan prescription drug benefits, PBMs are able to manage the formularies applicable to the plans to steer plan-related prescription drug spending (including amounts paid by plans in prescription drug benefits as well as out-of-pocket amounts paid by plan participants and beneficiaries) toward certain brands of drugs over others. In doing so, most PBMs manage their clients' formularies pursuant to a standard set of criteria, guidelines, and practices, favoring certain drugs, and thus, certain drug companies, over others based on safety, efficacy, and, most importantly here, the amount of rebates and other payments obtained from the drug company.

a. Rebates Related to a Given Drug Are Tied to the Administration of Benefits for that Drug

75. Rebates are generally calculated as a percentage of a drug's Average Wholesale Price ("AWP") or Wholesale Acquisition Cost ("WAC"). AWP is a benchmark price that is published in pharmaceutical price indexes. WAC, a related benchmark price, is the price at which drug companies sell drugs like EpiPen to wholesalers. A given drug's AWP is based on its WAC plus an average markup of 20%.

76. Rebates are most often calculated and invoiced on a per-prescription or per-drug-unit[15] basis. PBMs generally invoice drug companies for rebate payments on a monthly or quarterly basis. To receive rebates for a given drug, the PBM provides to the drug company data indicating all instances where the drug was dispensed to health plan participants and beneficiaries.

77. As CVS Health Corporation (CVS Caremark's parent company) states in its 2016 SEC Form 10-K, "[r]ebates are recognized when prescriptions are dispensed and are generally calculated and billed to manufacturers within 30 days of the end of each completed quarter."[16] Similarly, Express Scripts states in its 2015 SEC Form 10-K that "[r]ebates and administrative fees billed to manufacturers are determinable when the drug is dispensed."[17] Likewise, Prime calculates a net cost per prescription, including

[15] A drug unit is a single unit of a given drug. For example, a single pill is a drug unit. In the case of EpiPen, a drug unit is a single EpiPen.

[16] *CVS Health Corporation Form 10-K*, U.S. Sec. and Exchange Commission (Feb. 9, 2017), https://www.sec.gov/Archives/edgar/data/64803/000006480317000006/cvs-20161231x10k.htm.

[17] *Express Scripts Holding Company Form 10-K*, U.S. Sec. and Exchange Commission (Feb. 16, 2016),

manufacturer rebates or administrative fees.[18] In its 2016 SEC Form 10-K, UnitedHealth Group, Inc. (Optum's parent company) states that Optum "accrues rebates as they are earned by its [plan] clients on a monthly basis" through dispensed prescriptions. Optum then "bill[s] these rebates to the manufacturers on a monthly or quarterly basis."[19]

78. Rebates are calculated based on dispensed prescriptions because the number of dispensed prescriptions for a given drug is indicative of that drug's market share (also referred to as "utilization"). In short, drug companies agree to pay rebates to PBMs regarding a given drug in exchange for driving a certain number of filled prescriptions for that drug. Dispensing a drug to a health plan participant or beneficiary under the terms of their health plan necessitates a prescription drug benefit claim and the administration of benefits for that drug by the PBM. This, in turn, triggers a reimbursement for the drug paid by the plan to the PBM.

79. As described further below, rebates are just the tip of the iceberg of drug company payments to PBMs—fees and other payments also are calculated based on the list price and sales volumes, and they remain a secret between the PBMs and the drug company.

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https://www.sec.gov/Archives/edgar/data/1532063/000153206316000017/esrx-12312015x10k.htm.

[18] *Looking Back Moving Forward, 2014 Report on Prescription Drugs*, Prime Therapeutics (June 2014), https://www.primetherapeutics.com/content/dam/corporate/Documents/Newsroom/PrimeInsights/2014/2014-report-on-rx-costs.pdf.

[19] *UnitedHealth Group Incorporated Form 10-K*, U.S. Sec. and Exchange Commission (Feb. 8, 2017), https://www.sec.gov/Archives/edgar/data/731766/000073176617000009/unh20161231 10-k.htm.

b. Market Consolidation and the Rise of Exclusionary Formularies

80. Over the past several years, PBMs have successfully negotiated enormous rebates from various drug companies, including Mylan, for two principal reasons. First, beginning in 2007, PBMs began consolidating into what are now four major entities—Defendants in this case, CVS Caremark, Express Scripts, Optum, and Prime—that administer prescription drug benefits for more than 200 million Americans. Consequently, for drug companies, including Mylan, the formularies established and managed by Defendants are the exclusive gateway to the vast majority of the prescription drug market.

81. Currently, Defendants generally devise and manage what are known as closed formularies. Up until 2013, Defendants generally devised and managed what are known as open formularies: formularies that offer varying degrees of plan prescription drug benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies compete to have their drugs placed by PBMs into the most favorable formulary tier possible. In recent years, though, closed formularies have become the norm. Indeed, Defendants now use closed formularies by default. For example, while plans traditionally had to opt into closed formularies, in 2014, Express Scripts made its standard closed formulary an opt-out formulary.[20]

[20] Thomas Reinke, *PBMs Just Say No to Some Drugs—But Not to Others*, Managed Care Mag. (Apr. 5, 2015), https://www.managedcaremag.com/archives/2015/4/pbms-just-say-no-some-drugs-not-others.

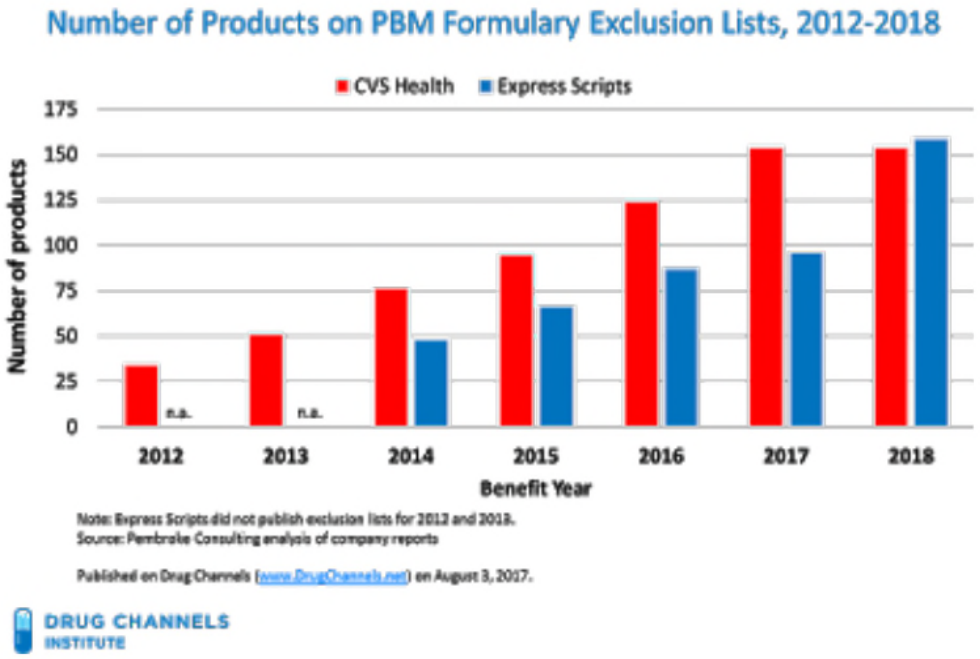
82. Like open formularies, closed formularies provide tiered benefits, but also restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit. Closed formularies cause drug companies to compete not only for favorable tier placement, but simply to have their drugs appear on the formularies, sometimes to the exclusion of their competitors, and, in turn, to have access to significant swathes of participants and beneficiaries who purchase prescription drugs through their employer-sponsored benefit plans.

83. In addition to the increase in percentage of closed formularies, beginning in approximately 2013, PBMs have increased the number of drugs excluded from their formularies year-over-year. While formulary exclusions of brand name drugs have always existed in narrowly-defined circumstances,[21] as *Managed Care Magazine* stated in its April 2015 issue, "[o]ver the past 18 months, the use of formulary exclusions has changed from being a targeted tactic to a commonly used weapon."[22] CVS Caremark's exclusions from its standard formulary increased from 72 drugs excluded in 2014 to 95 drugs excluded in 2015, 124 drugs excluded in 2016, and 154 drugs excluded in 2017 and 2018. Express Scripts's exclusions from its standard formulary increased from 48 drugs excluded in 2014 to 66 drugs excluded in 2015, 87 drugs excluded in 2016, and jumped to 159 drugs excluded in 2018. In 2014, prior to its acquisition by Optum, Catamaran

[21] For example, historically, drugs that had been found to be unsafe were excluded from formularies. In addition, certain highly specialized prescription drug plans, such as those that cover exclusively generic drugs, will inevitably exclude a significant number of drugs.

[22] Reinke, *supra* note 20.

excluded 54 drugs from its Value Formulary, and Optum's exclusions from its standard formulary increased from 77 drugs excluded in 2016 to 83 drugs excluded in 2017. Prime, which did not publish formulary exclusions until 2017, nonetheless increased exclusions over the years from its formularies. In 2017, Prime excluded 283 drugs from its standard formulary, and in 2018, Prime excluded 295. Express Scripts's and CVS Caremark's increasing exclusions are depicted in the graph below:



84. Over the last several years, Defendants have published annual lists of drug exclusions. Defendants' exclusion lists are closely analyzed by industry experts who understand that, through these lists, Defendants have the ability to both (i) drive plan participants and beneficiaries—along with the money they and their plans spend on prescription drugs—to specific drug companies; and (ii) restrict drug companies from access to plan participants and beneficiaries and the money they spend on prescription

drugs.[23] For example, in an August 2, 2016 article about CVS Caremark's and Express Scripts's 2017 formulary exclusions, *Barrons* stated:

> Make way for some waves. CVS Health (CVS) and Express Scripts (ESRX) have released their formulary exclusion list for 2017, which details which prescription drugs will not be covered by health plans.
>
> Why do we care?...The coverage list determines whether millions of privately insured individuals can easily use an insurance co-payment to buy their prescriptions. If a drug is excluded, it can dramatically hobble sales.
>
> Thus, the formulary exclusion lists can be used as a tool by insurers and PBMs—leverage you might say—to negotiate with drug makers for better prices [for PBMs and plans].[24]

85. Formulary exclusions often occur where multiple drugs are deemed therapeutically interchangeable, as has been the case with epinephrine auto-injectors like EpiPen. In a 2015 AIS Health presentation, entitled "PBM Formulary Exclusions: Bottom-Line Strategies for Health Plans" ("the AIS Presentation"),[25] Express Scripts's

[23] *See, e.g.*, Kevin McCaffrey, *PBMs unveil 2017 formularies, retain focus on exclusions*, MM&M (Aug. 2, 2016), https://www.mmm-online.com/payersmanaged-markets/pbms-unveil-2017-formularies-retain-focus-on-exclusions/article/513737/; Mark Lowery, *2016 formulary exclusions in 9 key areas*, Drug Topics: Voice of the Pharmacist (Aug. 11, 2015), http://drugtopics.modernmedicine.com/drug-topics/news/2016-formulary-exclusions-9-key-areas; Bruce Japsen, *PBMs Quietly Gain Leverage As Drug Makers Stumble On Price Hikes*, Forbes (Aug. 31, 2016), https://www.forbes.com/sites/brucejapsen/2016/08/31/pbms-quietly-gain-leverage-as-drug-makers-stumble-on-price-hikes/#554d1a3f7ffa.

[24] Johanna Bennett, *CVS Health Takes "An Audacious Step" With 2017 Drug Formularies*, Barron's (Aug. 2, 2016), https://www.barrons.com/articles/cvs-health-takes-an-audacious-step-with-2017-drug-formularies-1470169569; *see also Excluded in 2016: These Drugs Are On the Outside Looking In*, Managed Care Mag. (Sept. 10, 2015), https://www.managedcaremag.com/archives/2015/9/excluded-2016-these-drugs-are-outside-looking.

[25] David Dross & Jeff Eichholz, *PBM Formulary Exclusions: Bottom-Line Strategies for Health Plans*, AIS's (Atlantic Info. Servs., Inc.) Mgmt. Insight Series (2015), https://aishealth.com/sites/all/files/gc5p02_01-15.pdf.

Senior Director of Formulary Development and Appeals noted that in the context of "products you can clinically interchange," the company looks "at the financial aspects, including the net cost of the product [and] rebates. . . ." Similarly, the PCMA—Defendants' Washington, D.C.-based lobbying organization—states that "[i]n classes where several products may be considered therapeutically equivalent, PBMs can negotiate with drug manufacturers for higher rebates[.]"[26]

86. The threat of formulary exclusion is a major factor in rebate and other payment negotiations between Defendants and drug companies. Indeed, in April 2015, Express Scripts's Chief Medical Officer told *Managed Care Magazine* that formulary exclusions "demonstrate that PBMs could move market share."[27] He further touted that drug companies "[are] now convinced . . . that we [can] actually deliver market share when we [are] motivated to. So we went to the companies, and we told them, 'We're going to be pitting you all against each other. Who is going to give us the best price? If you give us the best price, we will move the market share to you. We will move it effectively. We'll exclude the other products.'"[28]

[26] *Drug Price Negotiations & Rebates*, Pharmaceutical Care Mgmt. Ass'n, https://www.pcmanet.org/policy-issues/drug-price-negotiations-rebates/ (last visited Apr. 1, 2018).
[27] Peter Wehrwein, *A Conversation With Steve Miller, MD: Come in and Talk With Us, Pharma*, Managed Care Mag. (April 2015), https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma.
[28] *Id.*

87. Mylan recognized Defendants' ability to direct and maintain plan-related prescription drug spending (*i.e.*, market share) to EpiPen through exclusive or preferred formulary placement. As a Mylan spokeswoman told CNBC in September 2016, "[a]s aligned with standard industry practice, we pay rebates to allow for patient access to EpiPen Auto-Injector[.]"[29] In addition, Mylan CEO Heather Bresch told investors on its earnings call for the fourth quarter of 2015 that, "in a very competitive multi-epinephrine marketplace,…we were maintaining market share. And to do so, that requires aggressive rebating."[30]

88. Industry experts also recognize Defendants' ability to steer plan-related prescription drug spending to and away from certain drugs through formulary placement. For example, a February 16, 2018 article in *STAT*, a well-known publication focused on the life sciences and pharmaceutical industries, states that Defendants—particularly CVS Caremark, Express Scripts, and Optum—"[a]s the industry's heavyweights . . . now have enormous power over the availability and pricing of essential medicines. Drug makers pay PBMs billions of dollars to ensure their products get preferred positions on formularies, drug lists used to determine which medicines are covered."[31]

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[29] Dan Mangan, *EpiPen Outrage: New pressure on Mylan as CEO Heather Bresch prepares to testify*, CNBC (Sept. 20, 2016), https://www.cnbc.com/2016/09/20/new-pressure-on-mylan-as-ceo-heather-bresch-prepares-to-testify.html.

[30] *Mylan (MYL) Earnings Report: Q4 2015 Conference Call Transcript*, TheStreet (Feb. 10, 2016), https://s.t.st/media/xtranscript/2016/Q1/13456043.pdf.

[31] Casey Ross, *Washington is taking aim at drug industry middlemen. But can it break their grip on a captive market?*, STAT (Feb. 16, 2018), https://www.statnews.com/2018/02/16/washington-pharmacy-benefit-managers/.

89. Industry experts have further highlighted that the threat of formulary exclusion has yielded substantial rebates for PBMs from drug companies. In the AIS Presentation, Arthur Shinn of Pharmacy Consultants, LLC states that "[t]he exclusion strategy is a big rebate revenue generator."[32]

90. As PBMs have negotiated larger and larger rebates from drug companies over the last several years, their revenues have soared. CVS Caremark's Pharmacy Services Segment saw revenues climb from $76 billion in 2013 to more than $120 billion in 2016. Between 2010 and 2016, Express Scripts's revenue jumped from approximately $45 billion to north of $100 billion. Optum's revenue increased from roughly $32 billion in 2014 to more than $60 billion in 2016. And Prime's revenues rose from $1.8 billion in 2012 to $4.73 billion in 2016.

91. Despite their massive revenues, Defendants purport to have relatively slim profit margins. According to a March 31, 2017 article in *Bloomberg*,[33] CVS Caremark, Express Scripts, and Optum, "[t]he three big middlemen for prescription drugs, . . . had operating-profit margins last year of 4 percent to 7 percent." However, "[w]ere they to tally their revenue the way many middlemen in other industries do, their margins would more than double." Industry experts told *Bloomberg* that "booking revenue in a way that shows lower margins might have helped the companies deflect criticism of their pricing

[32] Dross & Eichholz, *supra* note 25.

[33] Tom Metcalf & Neil Weinberg, *Drug Middlemen Have Slim Profit Margins—Just Ask Them*, Bloomberg (Mar. 31, 2017), https://www.bloomberg.com/news/articles/2017-03-31/drug-middlemen-have-slim-profit-margins-just-ask-them.

practices. 'It hides a lot. It's as simple as that,' said Ravi Mehrotra, a partner at the MTS Health Partners investment bank."[34]

92. Moreover, the SEC recently asked Express Scripts why it did not break out payments it received from drug companies in its public filings. Instead, Express Scripts disclosed drug company receivables together with receivables from its plan and other clients. In a September 29, 2017 letter to Express Scripts, the SEC stated, "Rule 5-02.3 of Regulation S-X requires separate disclosure of receivables from customers (trade) and others. It is unclear why you believe accounts receivable from pharmaceutical manufacturers are a component of customer receivables considering that pharmaceutical manufacturers do not appear to be your customer." In its October 12, 2017 response, Express Scripts agreed to break out drug company receivables. As of December 31, 2017, Express Scripts reported annual drug company payments of $2.58 billion, representing approximately 37% of its total net receivables. According to Professor Ed Ketz of Penn State, given the significant percentage of total net receivables from drug companies, "we can start thinking of the pharmaceutical companies as customers. They're not just bystanders in this equation."[35]

[34] *Id.*

[35] Linette Lopez, *The Feds just asked a huge healthcare company who their real clients are and the answer is totally unsatisfying*, Bus. Insider (Dec. 7, 2017), http://www.businessinsider.com/sec-looks-into-express-scripts-rebates-from-pharmaceutical-firms-2017-12.

c. Defendants' Management of Plan Formularies

93. Despite the fact that drug companies, industry experts, and even one Defendant have recognized Defendants' discretionary authority to exclude drugs from formularies and drive prescription drug benefits to certain drugs by placing them on formularies, Defendants often tout that their clients have "final" or "ultimate" authority over the formulary. But once a plan adopts a formulary, the PBM generally retains discretionary authority to alter it at any time, including with respect to tiering and drug exclusions. Indeed, Cottingham & Butler, a national insurance broker, noted in a client presentation regarding the dynamics between PBMs and health plans that PBMs have "unilateral control . . . over formularies and tiering—driving greater profits for PBMs through rebates[.]"[36]

94. Moreover, where plans retain discretionary authority over the formulary, it is limited—Defendants typically give their plan clients very short timeframes, sometimes as little as two weeks—in which to adopt or reject formulary exclusions. According to well-known pharmacy benefits consultant David Dross, this "tactic makes plan sponsors feel like the PBMs are mandating plan coverage rules."[37]

95. In addition, in general, if a plan adopts formulary exclusions for a given year, its contract with Defendants makes it difficult to opt out of exclusions in subsequent

[36] Nancy Daas - Presenter, *Prescription Drug Plan Strategies*, Cottingham & Butler (2017), http://www.cottinghambutler.com/wp-content/uploads/2017/03/Prescription-Drug-Strategies.pdf.

[37] Dross & Eichholz, *supra* note 25 at 81.

years. As Express Scripts spokesperson David Whitrap noted in the AIS Presentation, opting out "would require a contract addendum and readjusted rebate guarantees."[38]

96. Moreover, plans typically contractually outsource the development and/or management of their formularies to their PBM. As Dross noted during the AIS Presentation, "[b]ecause most employers don't have clinicians on staff, they don't even question their PBM's formulary, much less design their own."[39]

2. Inflation Protection Rebates

97. More recently, contracts between PBMs, including Defendants, and drug companies have included what are known as "inflation protection" rebates or "price protection" rebates. These provisions allow Defendants to collect large amounts of money when a drug company increases the list price of a given drug beyond a certain threshold.

98. For example, an inflation or price protection rebate provision might set a 5% threshold. If the drug company raises the list price for a drug by less than 5% within a particular timeframe (for example, one year), the drug company need not pay anything additionally to the PBM. However, if the drug company raises the list price by more than 5%, the drug company is then required to pay a specific percentage of the revenue it earns from that list price increase to the PBM.[40]

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[38] *Id.*
[39] *Id.* at 93.
[40] Craig Metz, *What is Price Protection*, High Point Solutions (May 16, 2017), http://blog.highpointsolutions.com/what-is-price-protection.

99. Similar to the relationship between rebates and formulary placement or market share, inflation or price protection rebates are generated based on the number of filled prescriptions for the specific drug. And although inflation or price protection rebates are not directly tied to formulary placement, Defendants nonetheless obtain these rebates from drug companies because Defendants possess authority and control over plan formularies.

3. Administrative Fees

100. In addition to rebates, drug companies often pay PBMs substantial amounts of various "administrative fees" in exchange for, among other things, ensuring a given drug's formulary placement and transmitting data about a drug's utilization.[41] This information provides useful market data to drug companies, including whether their financial agreements with PBMs, including formulary placement, are in fact increasing a drug's market share.

101. As CVS Health Corporation (CVS Caremark's parent company) states in its 2016 SEC Form 10-K, it "receives fees from pharmaceutical manufacturers for administrative services."[42] Likewise, in its 2016 SEC Form 10-K, Express Scripts states

[41] Henry C. Eickelberg, *The Prescription Drug Supply Chain "Black Box" – How it Works and Why You Should Care*, Am. Health Pol'y Inst. (2015), http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf; *see also* Linda Cahn, *It's Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition (NPCC), http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/ (last visited Apr. 1, 2018).

[42] *CVS Health Corporation Form 10-K*, *supra* note 16.

that it receives "administrative fees [from drug companies] earned for the administration of our rebate programs, performed in conjunction with claims processing services[.]" Express Scripts's 2016 10-K also notes that it receives administrative fees from drug companies "in conjunction with formulary management services."[43] Similarly, in its 2016 SEC Form 10-K, UnitedHealth Group, Inc. (Optum's parent company) states that it derives revenues from, *inter alia*, "fees from management, administrative, technology and consulting services."[44] In its 2014 SEC Form 10-K, Catamaran (now controlled by Optum) states that it "administers rebate programs through which it receives rebates and administrative fees from pharmaceutical manufacturers[.]"[45] In a 2014 press release issued by Prime to tout its low net cost per prescription, "Prime defines net cost per prescription as the total amount paid for drugs, including manufacturer rebates and administrative fees[.]"[46]

102. Like rebates, the dollar amount of administrative fees that drug companies pay Defendants are not fixed amounts for a fixed service, but instead are calculated as a

[43] *Express Scripts Holding Company Form 10-K*, U.S. Sec. and Exchange Commission (Feb. 14, 2017), https://www.sec.gov/Archives/edgar/data/1532063/000153206317000004/esrx-12312016x10k.htm.

[44] *UnitedHealth Group Incorporated Form 10-K*, *supra* note 19.

[45] *Catamaran Corp. Form 10-K*, U.S. Sec. and Exchange Commission (Feb. 27, 2015), https://www.sec.gov/Archives/edgar/data/1363851/000136385115000013/ctrx10k123114.htm.

[46] Press Release, *Prime Therapeutics' 2013 overall net cost per prescription of $58.99 is industry-low for third consecutive year*, Prime Therapeutics (June 17, 2014), https://www.primetherapeutics.com/content/dam/corporate/Documents/Newsroom/Pressreleases/2014/Press_Release_-_Prescription_Cost_Report_FINAL.pdf.

percentage of the AWP or WAC of each drug processed by the PBM for their client plans. Thus, when a drug's list price increases, so does the dollar amount in "administrative fees" that Defendants collect, although Defendants perform no additional administrative work.

103. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to Dross, who has been cited in Senate testimony, administrative fees can amount to 25%-30% of total payments from drug companies like Mylan.[47]

D. Recent Data Demonstrates That Rebates Negotiated by PBMs, and Agreed to by Drug Companies, Account for the Bulk of List Price Increases for Brand Name Drugs Like EpiPen

104. Rebates negotiated by PBMs like Defendants, and agreed to by drug companies like Mylan, now account for the vast majority of drug list price increases. A study conducted by the non-profit, non-partisan Center for Medicine in the Public Interest[48] estimates that, from 2011-2015, rebates paid to PBMs grew as a percentage of total manufacturer list price increases from 6.5% to an astounding 77.4%. In 2016, these rebates accounted for 79% of total manufacturer list price increases.[49]

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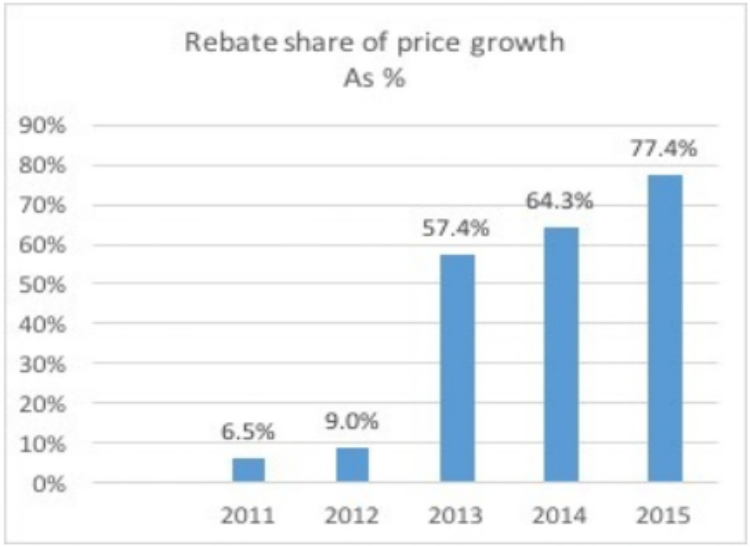
[47] David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business?*, Mercer (July 31, 2017), https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html.

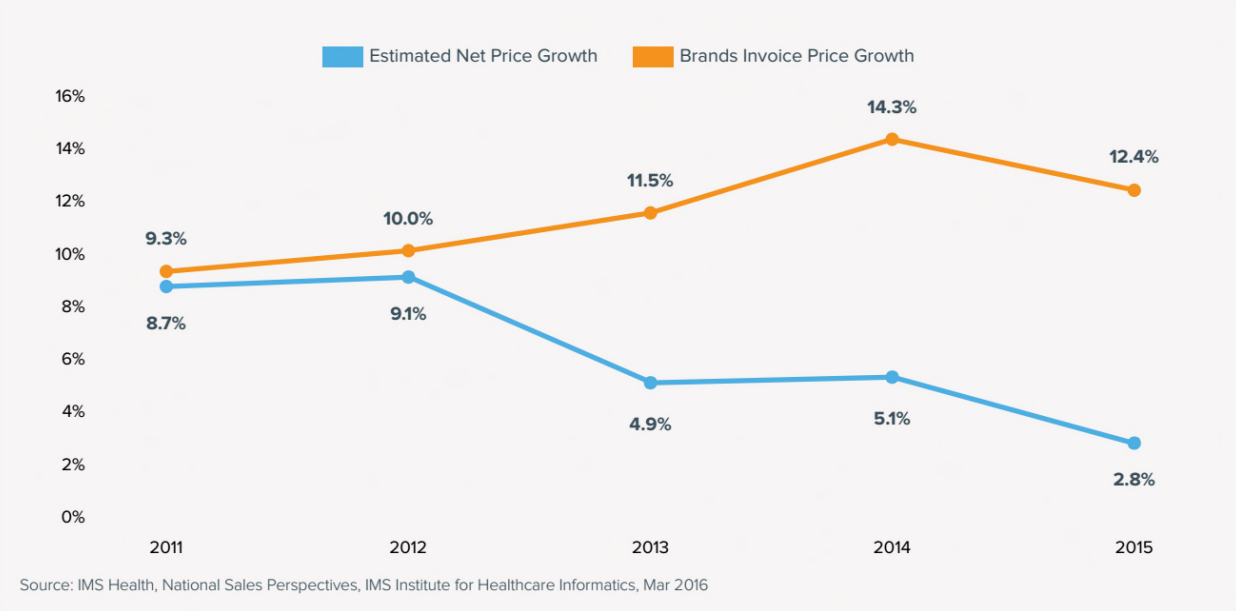
[48] Robert Goldberg, Ph.D., *Most of the Increase in Drug Spending Pocketed By PBMs and Insurers: What the Media Missed in Covering the IMS Drug Cost Study*, DrugWonks.com (Apr. 15, 2016), http://drugwonks.com/blog/most-of-the-increase-in-drug-spending-pocketed-by-pbms-and-insurers.

[49] *See* Robert Goldberg, *Reduce Drug Prices by Cutting Out PBM Rebates*, DrugWonks.com (Apr. 15, 2016), http://drugwonks.com/blog/reduce-drug-prices-by-cutting-out-pbm-rebates.



105. An April 2016 study conducted by the IMS Institute for Healthcare Informatics compared brand drug companies' "invoice price growth" (*i.e.*, benchmark prices) with the estimated "net price growth" (factoring in invoice price growth minus rebates paid to PBMs) for brand drugs over a five-year period. As reflected in the graph below, invoice prices climbed from 2013 to 2015 between 11.5% and 14.3% per year, while net price growth fell from roughly 5% to 2.8% during the same period.[50] Notably, in these three years, PBMs successfully obtained enormous rebates from drug companies through the use of formulary exclusions.

[50] *Medicines Use and Spending in the U.S., A Review of 2015 and Outlook to 2020*, IMS Inst. for Healthcare Informatics (Apr. 2016), https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf.



E. Increases in EpiPen's List Price Are Caused by Increasing Kickbacks from Mylan

1. Mylan States That Payments of EpiPen-Related Kickbacks to PBMs Cause Increased List Prices for EpiPen

106. On September 21, 2016, Mylan CEO Heather Bresch testified before Congress about the high list price of EpiPen. According to Bresch, $334 of the $608 list price for an EpiPen 2-Pak can be attributed directly to payments to PBMs and other channel vendors.[51] While testifying, Bresch held up the following chart:

[51] *Testimony of Mylan CEO Heather Bresch*, U.S. House of Representatives (Sept. 21, 2016), https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf.

107. Moreover, a few weeks before Bresch's Congressional testimony, Brian Sullivan of CNBC asked Bresch why Mylan will not simply lower EpiPen's list price. Knowing that Mylan was making significant payments to PBMs for EpiPen's exclusive formulary access and placement, thereby also causing a high list price for EpiPen, Bresch responded: "Brian, here's the perverse thing. Had we reduced the list price, I couldn't ensure that everyone who needs an EpiPen gets one."[52]

[52] *CNBC Transcript: Mylan CEO Heather Bresch Sits Down with CNBC's Brian Sullivan Today on "Squawk Box,"* CNBC (Aug. 25, 2016), https://www.cnbc.com/2016/08/25/first-on-cnbc-cnbc-transcript-mylan-ceo-heather-bresch-sits-down-with-cnbcs-brian-sullivan-today-on-squawk-box.html.

2. Industry Experts Similarly State That Defendants' Negotiation of Increasing Kickbacks Cause Drug Companies to Increase List Prices

108. Pharmaceutical industry experts have recently noted that Defendants' negotiation of increasing Kickbacks from drug companies directly contributes to increased drug company list prices. A May 2017 white paper issued by the Pacific Research Institute states that PBMs "[c]reate pricing uncertainty by incentivizing higher list prices for medicines that enable large rebates and discounts (which are particularly valuable for PBMs)."[53]

109. Similarly, Robert Galvin, M.D. and CEO of an HMO, and Roger Longman, CEO of a healthcare analytics company, published a December 1, 2015 article in the Harvard Business Review stating that "pharmaceutical companies don't deserve all of the blame for high drug prices," because "lots of other actors in purchasing, distribution, and brokerage [such as PBMs] have greater incentives to keep prices high than to lower prices or choose drugs that reduce longer-term medical and business costs[.]"[54] The Harvard Business Review article goes on to note that PBMs incentivize and prefer higher list prices because they result in increased rebates.[55]

110. Likewise, Howard Deutsch, a consultant at ZS Associates who advises drug companies on working with PBMs and other entities, was recently quoted in *The Wall*

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[53] Wayne Winegarden, Ph.D., *The Economic Costs of Pharmacy Benefit Managers: A Review of the Literature,* Pac. Res. Inst. Issue Brief at *3 (May 2017), http://www.pacificresearch.org/wp-content/uploads/2017/06/PBM_Lit_Final.pdf.

[54] Robert Galvin, M.D. & Roger Longman, *Who Has the Power to Cut Drug Prices? Employers,* Harv. Bus. Rev. (Dec. 1, 2015), https://hbr.org/2015/12/who-has-the-power-to-cut-drug-prices-employers.

[55] *Id.*

Street Journal as stating that Defendants' "incentives align more to a higher gross price and a higher discount than to truly reducing the cost to everyone involved[.]"[56]

111. Even economic experts at the White House have taken notice of PBM Kickbacks driving higher drug list prices. A February 2018 white paper issued by the White House Counsel of Economic Advisors states that, through the negotiation of secret rebates, Defendants generate enormous profits for themselves while at the same time inducing drug companies to increase their list prices:

> [T]he PBM market is highly concentrated. Three PBMs account for 85 percent of the market, which allows them to exercise undue market power against manufacturers and against the health plans and beneficiaries they are supposed to be representing, thus generating outsized profits for themselves. Over 20 percent of spending on prescription drugs was taken in as profit by the pharmaceutical distribution system. The size of manufacturer rebates and the percentage of the rebate passed on to health plans and patients are secret. The system encourages manufacturers to set artificially high list prices[.][57]

112. In an August 29, 2016 CNBC article about EpiPen pricing outrage, Scott Gottlieb, M.D. and current FDA Commissioner, explained that as PBMs "consolidated and began to exert more leverage, and as the drug market became more competitive . . . the pharmaceutical companies had to start paying bigger rebates. To make headway for bigger rebates, they've been hiking the list prices on their medicines."[58]

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[56] Jonathan D. Rockoff, *Behind the Push to Keep Higher-Priced EpiPen in Consumers' Hands*, Wall Street Journal (Aug. 6, 2017), https://www.wsj.com/articles/behind-the-push-to-keep-higher-priced-epipen-in-consumers-hands-1502036741.

[57] *Reforming Biopharmaceutical Pricing at Home and Abroad*, White House Counsel of Econ. Advisors (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (citations omitted).

[58] Scott Gottlieb, *Why drug makers charge outrageous prices*, CNBC (Aug. 29, 2016), https://www.cnbc.com/2016/08/29/why-drug-makers-charge-outrageous-prices-commentary.html.

113. Likewise, in a September 12, 2016 article discussing Bresch's congressional testimony, Commissioner Gottlieb wrote:

> The public reproach over the price of Mylan's lifesaving drug EpiPen is the latest imbroglio in a much broader debate over drug costs. At issue is the rising list price on drugs.
>
> ***
>
> Mylan pointed to a long sequence of drug supply middlemen who get a series of rebates, mostly as economic inducements for helping drug makers sell their medicines. To fund these rebates, drug makers push up the list price of their pills, only to furtively pay much of the money back to pharmacy benefit managers later.
>
> This byzantine model for selling drugs aids both parties—the drug makers who use the rebates to buy access on restrictive drug formularies, and the pharmacy benefit managers that take a cut from these rebates to improve their profit margins.[59]

114. On March 7, 2018, Commissioner Gottlieb spoke to America's Health Insurance Plans' ("AHIP") National Health Policy Conference.[60] In his speech, he discussed "misaligned incentives" where PBMs like Defendants "use their individual market power to effectively split some of the monopoly rents with large manufacturers and other intermediaries rather than passing on the saving garnered from competition to patients and employers."[61] Commissioner Gottlieb noted that "the very complexity and opacity of these schemes help to conceal their corrosion on our system – and their impact on patients."[62]

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[59] Scott Gottlieb, *How Congress Can Make Drug Pricing More Rational*, Forbes (Sept. 12, 2016), https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/#6e19d6933e3b.

[60] Scott Gottlieb, *Capturing the Benefits of Competition for Patients*, U.S. Food & Drug Admin. (March 7, 2018), https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.

[61] *Id.*

[62] *Id.*

> In the long run, the interests of patients, providers, and manufacturers are not well served by these arrangements, precisely because these practices encourage large list price increases to fuel the pricing schemes.
>
> And so, we continue to see a backlash against these Kabuki drug-pricing constructs—constructs that obscure profit taking across the supply chain that drives up costs; that expose consumers to high out of pocket spending; and that actively discourage competition.[63]

Commissioner Gottlieb further criticized PBM rebating practices, stating that "[p]atients shouldn't face exorbitant out of pocket costs, and pay money where the primary purpose is to help subsidize rebates paid to a long list of supply chain intermediaries, or is used to buy down the premium costs for everyone else."[64]

115. In STAT, Haider Warraich, M.D. discussed Commissioner Gottlieb's speech, noting that "[o]ver time, [PBMs] have gained transformative influence in the pharmaceutical supply chain."[65] "Their main goal ought to be lowering drug prices—but their current business models don't necessarily provide incentivizes to do that."[66]

> PBMs use their size to negotiate drug prices with manufacturers, passing on a certain percentage of any rebates downstream to the insurance company and keeping rest of the spread for themselves. What makes this murky is that the deals these companies strike with drug makers are kept secret, so no one besides the PBM knows how much of the rebate is actually passed on to consumers. . .Since pharmacy benefit managers profit on the spread, they have no real inventive to push pharmaceutical companies to reduce costs

[63] *Id.*
[64] *Id.*
[65] Haider Warraich, *A costly PBM trick: set lower copays for expensive brand-name drugs than for generics*, Stat News (Mar. 12, 2018), https://www.statnews.com/2018/03/12/pbm-copays-brand-name-drugs-generics/.
[66] *Id.*

since their profits increase with the list price.[67]

Warraich concluded that "as long as pharmacy benefit managers operate and negotiate prices in secret, it seems unlikely that they can be positive agents for change."[68]

116. Furthermore, a recent report on the drug industry noted that, in addition to rebates directly related to formulary access and market share, price/inflation protection rebates also incentivize list price increases. PBMs benefit by receiving price protection rebates from drug companies based on list price but not having to pass on this type of rebate to many of their client plans:

> At the whole-market level, we sense that the price protection rebate arbitrage game is driving manufacturers to higher list price increases than would otherwise occur, . . . Price protection rebates between brand manufacturers and PBMs are common, as are fixed rebate agreements between PBMs and a significant portion of their plan sponsors. When brand manufacturers' [list price] increases exceed the price protection threshold, the manufacturers rebate the difference to PBMs, who pocket the difference when these price protection rebates grow faster than the PBMs' fixed rebate commitments to plan sponsors. Thus all else equal in a given category, the product with the more rapid list price increases is more profitable to the PBM. Manufacturers, realizing this, don't want their products disadvantaged, and accordingly are driven to keep their rates of list price inflation at least as high, and ideally just a bit higher, than peers'. Durable list price inflation is the natural result. Net price inflation is unaffected, but unit volumes suffer as higher list prices directly impact consumers who have not yet met their deductibles.[69]

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[67] *Id.*

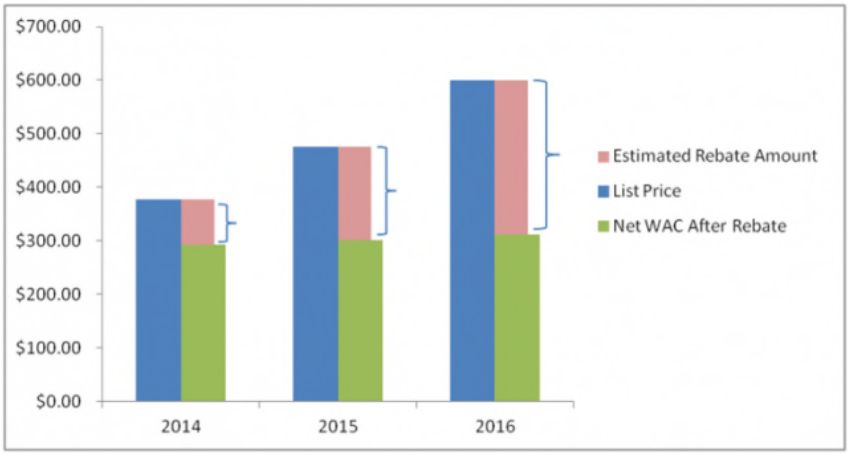
[68] *Id.*

[69] Richard Evans, Scott Hinds, & Ryan Baum, *US Rx Net Pricing Trends Thru 2Q16*, SSR LLC (Oct. 5, 2016), http://www.sector-sovereign.com/publication/us-rx-net-pricing-trends-thru-2q16/.

3. EpiPen Formulary Placement Further Demonstrates That Defendants' Negotiation of Kickbacks Leads to List Price Increases for EpiPen

117. Mylan wanted exclusive EpiPen formulary placement from the PBMs. Defendants used both (i) the threat of formulary exclusion and (ii) their ability to exclude drugs that compete with EpiPen to negotiate significant Kickbacks from Mylan, thereby significantly increasing the EpiPen list price.

118. A November 4, 2016 study by Argus Health estimated how much Mylan paid in EpiPen rebates to PBMs and health insurers between 2014 and 2016. According to this study, Mylan's payment of Kickbacks to PBMs are by far the largest component of EpiPen's list price increases.[70] As shown in the chart below, EpiPen's list price increased from $378 in 2014 to more than $600 in 2016, an increase of more than 58%, while EpiPen's net price after subtracting rebates increased less than 6%, from $294 to $311.



WAC = WHOLESALE ACQUISITION COST. ILLUSTRATIVE REBATE ANALYSIS FOR A GIVEN THREE-YEAR PERIOD

[70] *See The EpiPen Price Increase: A Deeper Look at a Complicated Story*, DST Sys., Inc., https://www.dstsystems.com/insights/epipen-price-increase (last visited Apr. 1, 2018).

119. The marked increase in the estimated rebates for EpiPen coincides with EpiPen's formulary competition with two other therapeutically interchangeable epinephrine auto-injectors: Adrenaclick and Auvi-Q. Auvi-Q was released as a brand name auto-injector by Sanofi-Aventis, U.S. LLC, in 2013. Adrenaclick was also released in 2013 by Amedra Pharmaceuticals as a generic.

120. In 2014 and 2015, Express Scripts excluded Auvi-Q from its standard formulary, while EpiPen remained. Express Scripts defended the exclusion by stating: "In 2014 and 2015, we leveraged the competition between EpiPen and Auvi-Q to earn additional discounts for our clients." Express Scripts excluded Auvi-Q again in 2017 and made EpiPen the preferred auto-injector. In doing so, Express Scripts explained that they "engaged in negotiations with various manufacturers and Mylan offered deeper discounts." Adrenaclick has never appeared on Express Scripts's standard formulary.

121. Between 2015 and 2017, CVS Caremark excluded Adrenaclick from its standard formulary. During that time, CVS Caremark listed EpiPen and Auvi-Q as the formulary options for an epinephrine auto-injector and informed plan participants and beneficiaries that if they use Adrenaclick, they "may be required to pay the full cost" and that they should ask their doctor to choose one of the "brand formulary options listed below," meaning EpiPen or Auvi-Q.

122. Likewise, since at least 2015, EpiPen was the only brand on Optum's standard formulary prescription drug lists, with Auvi-Q and Adrenaclick excluded.

123. Prime's main formularies, including Generics Plus and PrimeChoice, also listed EpiPen and excluded Auvi-Q and Adrenaclick.

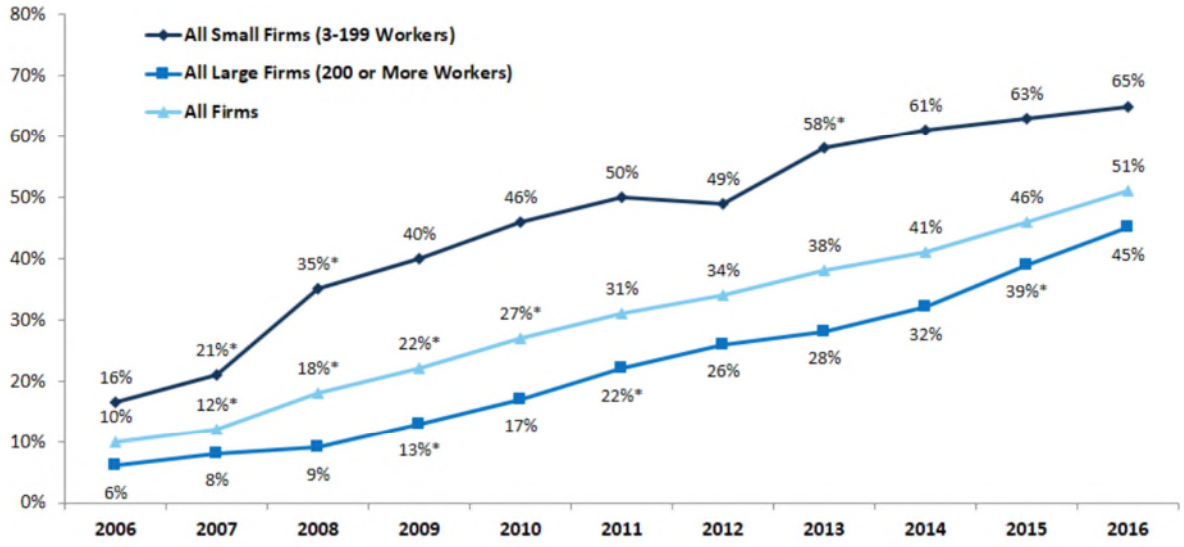
F. Out-of-Pocket Costs for Plan Participants and Beneficiaries with Prescription Drug Benefits

124. In addition to monthly or annual premiums, health plan participants and beneficiaries with prescription drug benefits often have to pay a certain amount out of pocket when filling a prescription at a pharmacy. Out-of-pocket costs come in three forms: deductibles, coinsurance, and copayment requirements.

125. *Deductibles*. The term "deductible" refers to a fixed dollar amount that a health plan participant must pay out of pocket annually for medical and/or prescription drug costs before the participant's plan will issue healthcare reimbursements, including for prescription drug purchases. For example, a given health plan might require its participants to pay $3,000 out of pocket in a given year before benefits are administered. While the health plan dictates the dollar amount of a deductible, the price the plan participant pays for a given brand name drug while under a deductible may be determined by the negotiated rate between the PBM and the pharmacy—or it may be determined by the list price. Either way, because the negotiated rate is still a function of the list price, price inflation hurts participants and beneficiaries paying for EpiPens in a deductible phase. As discussed further below, this price is a percentage of a drug's WAC and ranges between a drug's WAC and AWP (WAC + 20%). Thus, as Defendants have induced and/or colluded with Mylan to raise EpiPen's list price, which has soared to over $600, the negotiated rate paid for EpiPen by purchasers under a deductible has increased by a corresponding amount.

126. Most ERISA health plans have a deductible. According to a Kaiser Family Foundation September 2016 survey,[71] "[e]ighty-three percent of covered workers have a general annual deductible for single coverage that must be met before most services are paid for by the plan." Moreover, as reflected in the chart below, in recent years, deductibles have continuously increased for ERISA health plans, and by 2016, more than half of all covered workers had deductibles of more than $1,000.

Percentage of Covered Workers Enrolled in a Plan with a General Annual Deductible of $1,000 or More for Single Coverage, By Firm Size, 2006-2016



* Estimate is statistically different from estimate for the previous year shown ($p < .05$).

NOTE: These estimates include workers enrolled in HDHP/SO and other plan types. Average general annual health plan deductibles for PPOs, POS plans, and HDHP/SOs are for in-network services.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

THE HENRY J. KAISER FAMILY FOUNDATION

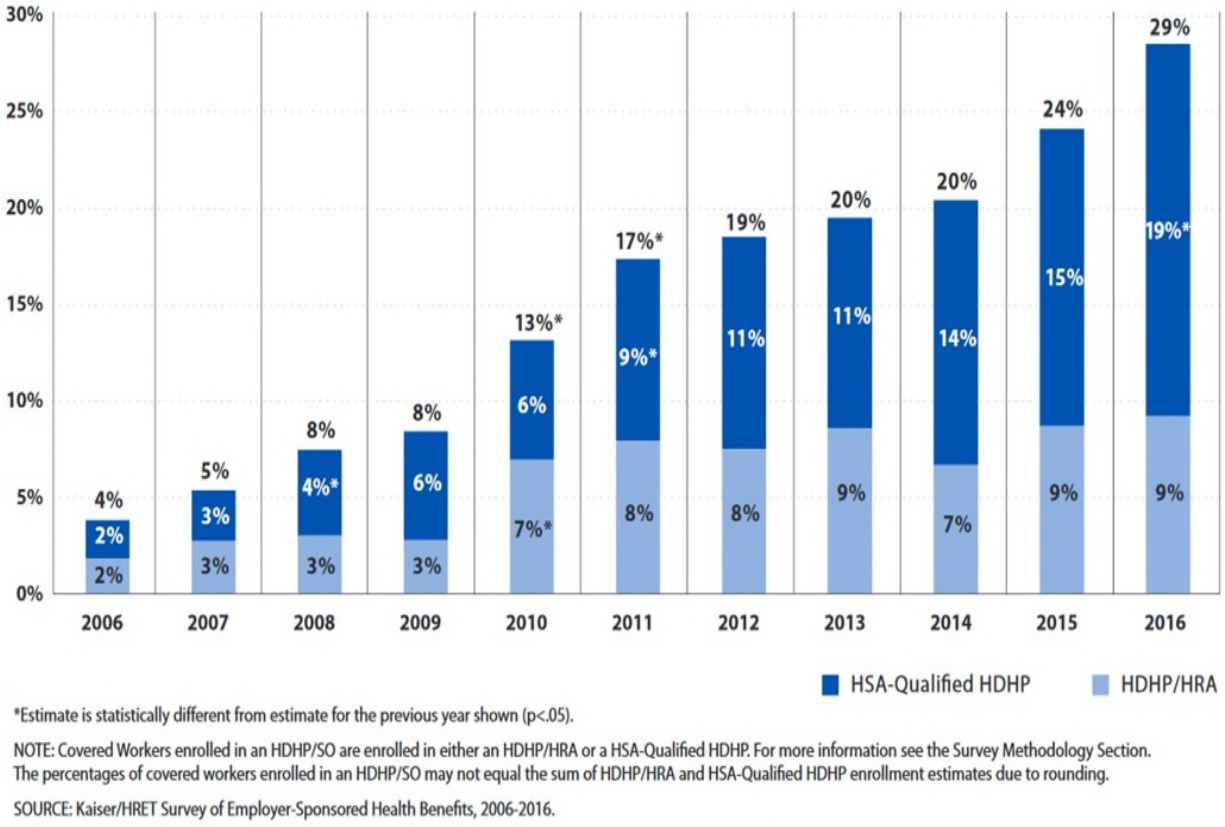
[71] *See 2016 Employer Health Benefits Survey*, Henry J. Kaiser Fam. Found. (Sept. 14, 2016), http://www.kff.org/report-section/ehbs-2016-summary-of-findings/.

127. In addition, many ERISA health plans are high-deductible health plans ("HDHPs") with multi-thousand-dollar annual deductibles.[72] According to a January 5, 2016 report from the Kaiser Family Foundation and the Journal of the American Medical Association ("JAMA"), deductibles rose 67% between 2010 and 2015. The report found that the average annual deductible for an individual enrolled in an HDHP was between $2,031 and $2,295 for individuals and $4,321 and $4,364 for families.

128. Moreover, the percentage of covered workers enrolled in HDHPs has increased from 13% in 2010 to 29% in 2016.

[72] As of 2018, HDHPs are those with minimum annual deductibles of $1,350 for individuals and $2,700 for families. *See High Deductible Health Plan (HDHP)*, HealthCare.gov, https://www.healthcare.gov/glossary/high-deductible-health-plan/ (last visited Apr. 1, 2018).

Percentage of Covered Workers Enrolled in High-Deductible Health Plans from 2006-2016



*Estimate is statistically different from estimate for the previous year shown (p<.05).

NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information see the Survey Methodology Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

129. Rising list prices for drugs like EpiPen are particularly harmful to those in HDHPs, who often have trouble affording prescription drugs, and are even forced to forego purchasing needed prescription drugs, like a potentially lifesaving EpiPen, due to high annual out-of-pocket costs.

130. *Cost-sharing Payments.* In addition to deductible payments, most ERISA health insurance plans require participants and beneficiaries to make cost-sharing

payments for medical care and prescription drugs. These cost-sharing payments come in the form of either copayments or coinsurance.[73]

131. *Copayments.* A copayment is a fixed dollar amount, set by the health insurance plan, that plan participants and beneficiaries must pay at the time they receive medical care or prescription drugs. In the case of prescription drugs, plan participants and beneficiaries pay copayments to the pharmacy. Individuals who purchased EpiPen under a copayment scheme with fixed dollar amounts, such as the one described above, are not included in the Class unless they also incurred out-of-pocket costs under deductible or coinsurance requirements.

132. *Coinsurance.* For participants with coinsurance, instead of paying a fixed dollar amount for a particular service or drug, plan participants and beneficiaries pay a fixed *percentage* of the cost of the healthcare service or drug provided. For a prescription drug, plan participants and beneficiaries pay a percentage of the list price or the negotiated rate between the PBM and the pharmacy for the drug, which, as previously discussed, falls between the drug's WAC and AWP (WAC + 20%). As with the dollar amount of a deductible, the health plan dictates the specific percentage for coinsurance. Thus, by successfully incentivizing Mylan to increase EpiPen's list price, Defendants increase the total dollar amount that EpiPen purchasers under coinsurance are required to pay.

[73] Coinsurance payments are also known as "percentage-based copayments" or "percentage-based copays."

133. For those plan participants whose ERISA health plans have three or more tiers of cost-sharing for prescription drugs, the Kaiser Family Foundation reports that average coinsurance rates are as follows:

- 17% for first-tier drugs (typically generics);
- 25% for second-tier drugs (typically "preferred" brand drugs);
- 37% for third-tier drugs (typically "non-preferred" brand drugs); and
- 29% for fourth-tier drugs (typically extremely high-cost drugs, known as "specialty drugs").[74]

134. EpiPen is generally classified on formularies as a second-tier or third-tier drug. As a result, coinsurance payments for EpiPen can be a heavy financial burden on the Class. If a plan participant is responsible for all of her drugs' costs before she hits her deductible, she is required to pay *full, point-of-sale prices* until she meets her deductible; if she pays coinsurance, she pays for a percentage of her drugs' *point-of-sale prices*. Thus, Defendants have caused the financial burden for plan participants to increase dramatically by inducing and/or colluding with Mylan to increase EpiPen's list price to more than $600.

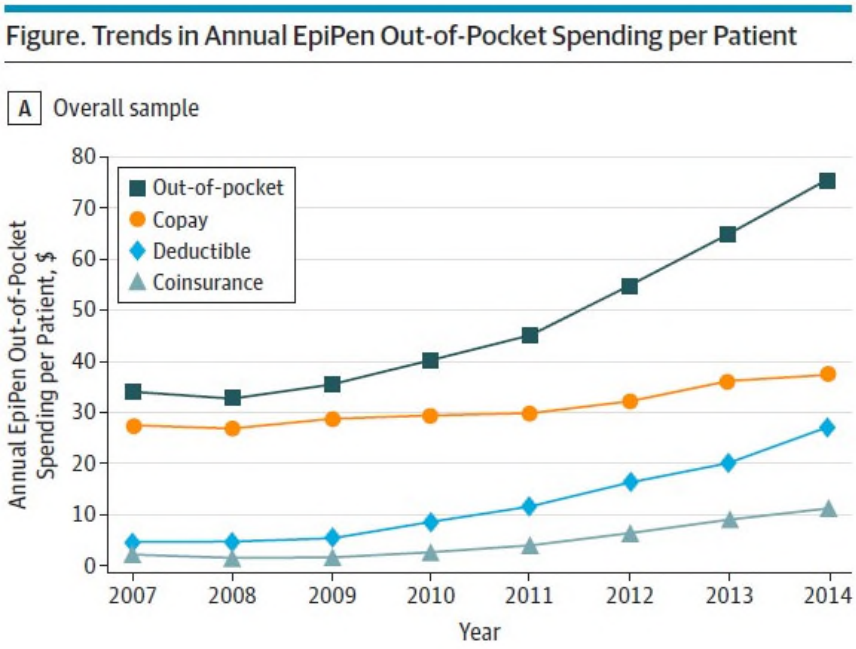
135. For example, with an EpiPen pharmacy reimbursement rate of $600, a plan participant without a deductible, or whose deductible has been satisfied, would pay, under average coinsurance rates, $150 if EpiPen were classified as a second-tier drug, or $222 if EpiPen were classified as a third-tier drug.

[74] These figures come from a 2016 Kaiser Family Foundation study of employer health benefits. *2016 Employer Health Benefits Survey*, *supra* note .

136. For those plan participants whose ERISA health insurance plans have annual deductibles, coinsurance obligations begin after the deductible is exhausted. Plans without a deductible require coinsurance contributions for every prescription drug purchase.

137. A March 27, 2017 Research Letter published by JAMA (the "2017 JAMA Research Letter") shows that, since Mylan acquired the rights to market and distribute EpiPen in 2007, patients have faced massive growth in out-of-pocket costs—including coinsurance payments and deductible payments.[75] The chart below was included in the 2017 JAMA Research Letter:

[75] Kao-Ping Chua, M.D., Ph.D.; Rena M. Conti, Ph.D., *Out-of-Pocket Spending Among Commercially Insured Patients for Epinephrine Autoinjectors Between 2007 and 2014*, JAMA Intern Med. 2017;177(5):736-739 (May 2017), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2612114?redirect=true.



138. The 2017 JAMA Research Letter concluded: "Among commercially insured patients who use EpiPen, annual EpiPen out-of-pocket spending more than doubled between 2007 and 2014. Simultaneously, the annual rate of EpiPen prescription fills barely increased, suggesting that the increased financial burden on patients was not driven by higher use."[76]

139. In addition, according to the 2017 JAMA Research Letter, the percentage of commercially insured EpiPen patients with at least $100 in annual out-of-pocket spending for EpiPen has increased between 2007 and 2014, from 3.9% to 18.0%, an increase of 365.6%. The percentage of EpiPen patients with at least $250 in annual out-of-pocket spending has increased during those years from 0.1% to 7.4%, an increase of 5,631%. Among the sampled population of people who receive private health insurance through more than 100 employers nationwide (currently more than 25 million people),

[76] *Id.*

coinsurance payments for EpiPen increased 1,532% and deductible payments increased 1,612%, disproportionately higher than the increase in total EpiPen spending of 975%.

G. Mylan's Kickback Payments to Defendants Increase Out-of-Pocket Expenses for Plan Participants and Beneficiaries

140. Given that (i) Kickbacks from Mylan related to EpiPen have inflated EpiPen's list price, and (ii) deductible and coinsurance payments by the Class are based on EpiPen's list price, Kickbacks paid to Defendants related to EpiPen have increased out-of-pocket expenses for the Class.

141. For example, the aforementioned February 16, 2018 *STAT* article states that Defendants' ability to obtain higher payments "creates an incentive for drug makers to further raise their list prices, which leaves many consumers . . . facing higher out-of-pocket costs."[77]

142. Defendants' conduct has caused the Class to pay increasing deductible and coinsurance amounts when filling prescriptions for EpiPen. While Defendants do not set the dollar amount of an annual deductible or the percentage of coinsurance, they induce (and profit from) EpiPen's inflated list price that serves as the basis for a deductible or coinsurance payment. And as their deductible and coinsurance payments continue to rise, members of the Class are negatively impacted by EpiPen's list price on an ever-increasing basis.

143. Indeed, Bresch asserted that patients are now paying list-related prices for EpiPen during a CNBC interview:

[77] Ross, *supra* note 31.

> The patient is paying twice… They're paying full retail price at the counter, and they're paying higher premiums on their insurance. It was never intended that a consumer, that the patients, would be paying list price, never. The system wasn't built for that.[78]

144. Similarly, Robert Goldberg of the Center for Medicine in the Public Interest has noted that "as the share of drug spending as a percent of rebates has soared and the contribution of net price increases to spending has declined, PBMs and insurers have increased cost sharing by more than 25% since 2010."[79] In other words, "rebates and discounts that could reduce the out of pocket cost of consumers is taken by [PBMs and] insurers . . . . And to add insult to injury, these organizations turn around and charge consumers retail price and require them to pay an increasingly greater share of that cost."[80]

145. The increasing number of patients with HDHPs and coinsurance obligations, together with the rise in deductible amounts and coinsurance percentages, has made the pain associated with the EpiPen price hikes particularly acute. Although epinephrine has been available for over a century and costs very little to produce, Defendants' greed has put EpiPen out of reach for many patients and made affording it a struggle for many others.

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[78] Dan Mangan, *Mylan CEO Heather Bresch: 'No One's More Frustrated Than Me' About EpiPen Price Furor*, CNBC (Aug. 25, 2016), https://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs.html.

[79] Robert Goldberg, Ph.D., *Drug Costs Driven By Rebates: Over $100 Billion In Price Cuts Go Directly To Insurers, Not Patients*, Ctrs. for Med. in the Pub. Int. (CMPI) at *4 (2015) http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.

[80] *Id.* at 6.

146. Unable to afford EpiPen, many patients are now facing grave risks. They have started carrying an expired EpiPen, or manually-filled syringes of epinephrine, even when they lack the medical training necessary to properly administer an injection.

147. Congress has started to acknowledge the role of PBMs in driving up prescription drug prices for plan participants and beneficiaries. On March 15, 2017, Senator Ron Wyden of Oregon introduced the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act of 2017, which would require PBMs to disclose the rebates they receive from drug companies.

148. U.S. Representative Earl L. "Buddy" Carter of Georgia recently discussed Defendants' role in driving up the price of EpiPen on the floor of the House of Representatives. Representative Carter, a pharmacist and the owner of a pharmacy, recently recalled Bresch's testimony:

> It was really interesting because, during the time that we were asking questions of the CEO, she mentioned, well, when it leaves us, it is this price right here—I am just going to use round figures—it is $150. By the time it gets to the pharmacist and by the time it is dispensed to the patient, it is $600.
>
> I asked her: What is that difference there? Where is that coming from?
>
> I don't know.
>
> I don't know either.
>
> Now, there is the beginning and the end. The beginning is the pharmaceutical [company]. She doesn't know. The end is me, the dispensing pharmacist, and I don't know.
>
> That is what I'm referring to when I talk about the man behind the curtain. That is where the PBMs come in.

> Now, they will tell you: Well, we are taking that money, and we are giving it back to the companies, to the insurance.
>
> Well, if they are, and they're not keeping any of it, then why are their profits going up so much? Why have their profits gone up over 600 percent? It's because they're keeping it. They're keeping it, and they're adding no value whatsoever to the system.

163 Cong. Rec. H1453 (daily ed. Mar. 1, 2017) (statement of Rep. Carter).

H. Defendants Not Only Profit from Exorbitant Kickbacks but Further Exploit Their Position to Profit from List Price Increases

149. As Optum's CEO once candidly admitted in an October 15, 2016 interview with *Modern Healthcare*, "the largest players" in the PBM industry "actually benefit from price increases."[81] Defendants' position at the center of prescription drug reimbursement—entering into separate, confidential agreements with plans, retail pharmacies, and drug companies—has allowed Defendants to enrich themselves in the face of list price increases for drugs like EpiPen through spread pricing, manipulating pharmacy reimbursement rates, and negotiating substantial payments from drug companies that are not passed back to plans.

1. PBM Reimbursement Contracts with Plans

150. Defendants enter into one of two types of drug reimbursement contracts with their plan clients: (i) a "Spread Pricing Contract," which allows the PBM to charge the plan a greater amount for the drug than the PBM reimburses the retail pharmacy, thereby making a profit "spread" on the drug; or (ii) a "Pass-Through Pricing Contract,"

[81] *Q&A: We don't set the price. Pharmaceutical manufacturers set the price*, Mod. Healthcare (Oct. 15, 2016), http://www.modernhealthcare.com/article/20161015/MAGAZINE/310159957.

which requires the PBM to pass through to the plan the PBM's actual rate of reimbursement to the pharmacy.

151. The amounts that PBMs reimburse pharmacies, and the amounts that plans reimburse PBMs, are kept secret.

152. In general, AWP or WAC is the starting point in determining reimbursement rates for drugs, including EpiPen. For a brand drug like EpiPen, pharmacies are generally reimbursed an amount between the drug's AWP and WAC. Under a Spread Pricing Contract, a PBM might reimburse a pharmacy for brand name drugs at AWP minus 15%, while the plan might reimburse the PBM for brand name drugs at AWP minus 12%.[82] The PBM will keep the 3% spread as profit.[83]

153. Under the same spread pricing terms, for a drug with an AWP of $360, under AWP-based reimbursement, the PBM would reimburse the pharmacy $306, the plan would reimburse the PBM $316.80, and the PBM would keep $10.80.[84] If the drug price doubled to an AWP of $720, the PBM's take would also double to $21.60 under AWP-based reimbursement.

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[82] Pharmacy reimbursements also account for plan participant cost-sharing obligations. For example, if a plan participant is required to pay $50 out-of-pocket to the pharmacy when filling a particular prescription, the PBM would reimburse the pharmacy AWP minus 15% minus $50. When a plan participant is required to pay the full pharmacy reimbursement rate while under a deductible, the pharmacy receives no reimbursement.

[83] If these reimbursements were instead based on WAC, the PBM would reimburse the pharmacy at WAC plus 6.25%, the Plan would reimburse the PBM at WAC plus 10%, and the PBM would keep the 3.75% spread as profit.

[84] Under WAC-based reimbursement, the PBM would reimburse the pharmacy $318.75, the Plan would reimburse the PBM $330, and the PBM would keep $11.25. If the drug price doubled to a WAC of $600, the PBM's take would also double to $22.50 under WAC-based reimbursement.

AWP to WAC Conversion Chart[85]

Converting from an AWP discount to a WAC based discount*

AWP Discount	WAC Plus Equivalent
12.00%	10.00%
12.50%	9.38%
13.00%	8.75%
13.50%	8.13%
14.00%	7.50%
14.50%	6.88%
15.00%	6.25%
15.50%	5.62%
16.00%	5.00%
16.50%	4.38%
17.00%	3.75%
17.50%	3.13%
18.00%	2.50%
18.50%	1.88%
19.00%	1.25%
19.50%	0.63%
20.00%	0.00%

*The conversion chart is compliments of Pharmacy Providers of Oklahoma (PPOk). http://www.ppok.com/

154. Thus, under a Spread Pricing Contract, as the list price of drugs like EpiPen increase, so too does the dollar amount of spread that Defendants keep for themselves as profit despite the PBM providing the very same service.

2. PBM Reimbursement Contracts with Retail Pharmacies

155. While Defendants enter into a single drug reimbursement contract with a given plan client, Defendants will often enter into multiple reimbursement contracts with

[85] *Converting from an AWP discount to a WAC equivalent discount*, Nat'l Community Pharmacists Ass'n, https://www.ncpanet.org/pdf/fdbinfosheet.pdf (last visited Apr. 1, 2018).

a given pharmacy network, each with varying reimbursement rates.[86] For example, one contract might reimburse the network's pharmacies at AWP minus 12% for brand name drugs like EpiPen, a second contract might reimburse the pharmacies at AWP minus 15%, and a third might reimburse the pharmacy at AWP minus 18%.

156. Defendants' pharmacy reimbursement contracts are wholly confidential and mandate that their terms not be disclosed to anyone outside the pharmacy, including Defendants' plan clients and health plan participants and beneficiaries. Indeed, the contracts themselves typically provide that disclosure of their terms is grounds for termination of the contractual relationship. Consequently, when a health plan participant fills a prescription for a drug like EpiPen at a network retail pharmacy, Defendants have the discretion to choose their reimbursement rate to the pharmacy from their various reimbursement contracts—in effect, controlling both the amount of reimbursement for drugs like EpiPen and the amount of spread that Defendants can keep for themselves.[87] When issuing reimbursements under a Spread Pricing Contract, Defendants are able to choose their pharmacy reimbursement contract with the lowest reimbursement rate (*e.g.*, AWP minus 18%), which allows Defendants to retain the largest spread.[88]

[86] Eickelberg, *supra* note 41 at 12.
[87] *See* Linda Cahn, *Eliminate All PBM Contract Loopholes*, Benefits Mag. (Oct. 2013), http://www.ifebp.org/inforequest/0164413.pdf.
[88] *Id.*

3. The Lack of Transparency in PBM Contracts with Drug Companies Allows Defendants to Retain Substantial Kickbacks as Profit

157. Defendants generally pass through some form of specified "rebates" to plans.[89] However, in their contracts with drug companies, Defendants are paid substantially more than what they pass through to their plan clients, including other types of rebates, as well as many other types of payments, fees, and discounts tied to a drug's AWP or WAC but not specifically denominated as a "rebate."

158. Similarly, Defendants sometimes pass through to their plan clients some or all of one or more forms of administrative fees paid to the PBMs by drug companies. However, given that plans have no information about Defendants' contract terms with drug companies, Defendants are free to include terms in the contracts with drug companies which simply include other categories of administrative fees or assign alternate labels to administrative fees so that Defendants can retain the payments and suffer no repercussions to their ability to conduct business with plans.

159. As a result, Defendants secretly collect—and retain—large amounts of drug company payments simply by labeling those drug company payments differently than payments which Defendants pass through to the plans. On information and belief, these payments transcend any particular plan, because they are based on total sales of a drug across a PBM's pool of plan clients.

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[89] *It's Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/ (last visited Apr. 2, 2018).

160. Moreover, participants and beneficiaries are harmed by the payment of Kickbacks and the corresponding increase in list prices *regardless* of the amount passed through to plans. This is because participants' and beneficiaries' out-of-pocket costs are calculated based on the inflated list price; any rebates or other discounts are not assessed at the point of sale. Recently, UnitedHealth Group Incorporated (Optum's parent company) and fellow industry powerhouse Aetna Inc. tacitly acknowledged this burden on the consumer, announcing that they would start passing rebates through at the point of sale.[90] But until then, participants and beneficiaries have overpaid, and will continue to overpay, for their prescription drugs.

161. Drug companies have no interest in whether PBMs pass rebates through to their plan clients or which categories the PBMs, like Defendants here, assign to the payments they receive from drug companies. Drug companies are concerned with the total amount they ultimately have to pay PBMs. For example, a drug company like Mylan has no interest in whether a given PBM labels its payment as a "formulary rebate," "market share rebate," "performance rebate," "price protection rebate," "manufacturer administrative fee," "purchase money discount," "health management fee," or "data sales fee." Conversely, PBMs, like Defendants here, have every interest in how a drug

[90] *UnitedHealthcare Launches Expansion of Direct-to-Consumer Pharmacy Discounts to Millions of Americans*, UnitedHealth Group (Mar. 6, 2018), http://www.unitedhealthgroup.com/Newsroom/Articles/Feed/UnitedHealthcare/2018/0306DirecttoConsumerPharmacyDiscounts.aspx?r=9; *Aetna to Provide Pharmacy Rebates at Time of Sale, Encourages Transparency from Drug Manufacturers*, Aetna Inc. (Mar. 27, 2018), https://news.aetna.com/news-releases/aetna-to-provide-pharmacy-rebates-at-time-of-sale-encourages-transparency-from-drug-manufacturers/.

company payment is categorized because that categorization determines whether they can retain the payment or are expressly required to pass it through to their plan clients.

162. In recent years, industry experts have confirmed these practices. For example, Linda Cahn of Pharmacy Benefit Consultants, a well-known PBM consultant to plans, noted that PBMs routinely play a "Rebate Re-Labeling Game" in their client contracts, wherein PBMs define drug company rebates in narrow terms in order to remit only a fraction of the amounts received from drug companies to their plan clients.[91] The Burchfield Group, a PBM auditing company based in Saint Paul, Minnesota, has echoed this concern.[92]

163. Likewise, the American Health Policy Institute has found that PBMs have responded to plan demands that PBMs pass back 100% of drug company rebates by relabeling payments received from drug companies:

> [T]he [PBM] industry has moved to 'reclassifying' the rebate dollars as 'purchase order discounts' or 'administrative fees'. Since the plan sponsor is often only contractually entitled to those things specifically defined in the contract as a 'rebate,' the PBM will pocket the purchase order discounts. Thus, while a plan sponsor may believe that it has negotiated a fully 'transparent' PBM deal (receiving 100 percent of the revenue coming from the manufacturer), what the plan sponsor doesn't realize is that some portion

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[91] *Message from Mylan: It's Time For Every Health Plan To Address Rebate Issues*, Nat'l Prescription Coverage Coalition, http://nationalprescriptioncoveragecoalition.com/message-from-mylan-its-time-for-every-health-plan-to-address-rebate-issues/ (last visited Apr. 2, 2018).

[92] Chris Hanson-Ehlinger, *Receive full value from your PBM rebates*, Burchfield Group (Nov. 20 2014), http://www.burchfieldgroup.com/pharmacy-benefit-blog/bid/203233/Receive-full-value-from-your-PBM-rebates; Brett McCabe, *Getting Your Fair Share: 5 Tips for Optimizing PBM Rebates*, Burchfield Group (Apr. 26, 2017), http://www.burchfieldgroup.com/pharmacy-benefit-blog/getting-your-fair-share-5-tips-for-optimizing-pbm-rebates.

> of the rebates have been carved-off and paid to the PBM as a purchase order discounts or admin fee etc.[93]

164. In addition, on October 17, 2017, Lori M. Reilly of the Pharmaceutical Research and Manufacturers of America testified before the Senate Health, Education, Labor, and Pensions ("HELP") Committee that plans "may not benefit from all of the price concessions the PBM has negotiated with manufacturers, particularly if the PBM decides not to define certain fees or other concessions as 'rebates.'"[94] She further testified that "[l]ack of transparency in contracts between employers and PBMs has led many plan sponsors to question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates."[95]

165. Similarly, *Managed Care Magazine* Senior Contributing Editor Timothy Kelley highlighted transparency concerns raised at the October 2017 Senate HELP Committee hearing, which featured key healthcare and pharmaceutical industry players—including the president of the PBM lobbying group, the PCMA.[96] "When Tennessee Republican Sen. Lamar Alexander, the committee chair, asked simply whether rebates are necessary—wouldn't simply lowering prices be more transparent?—nobody really

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[93] Eickelberg, *supra* note 41.
[94] *Testimony of Lori M. Reilly, Executive Vice President, Pharmaceutical Research and Manufacturers of America*, U.S. Senate (Oct. 17, 2017), https://www.help.senate.gov/imo/media/doc/Reilly2.pdf.
[95] *Id.*
[96] Timothy Kelley, *Drug Prices, Why so high and why so #&*! complicated*, Managed Care Mag. (Dec. 1, 2017), https://www.managedcaremag.com/archives/2017/12/drug-prices.

had an answer."[97] According to Ian Reynolds, an associate manager with the Drug Spending Research Initiative at the Pew Charitable Trusts, "A growing emphasis is now placed on what patients pay out of pocket. That, Reynolds believes, is one takeaway from the recent Senate hearing. 'A central question,' he says, 'is how much of the discounts that [PBMs] negotiate with manufacturers is being passed along to plan sponsors and how much they're keeping.'"[98]

166. As discussed in its correspondence with the SEC, Express Scripts does not quantify rebates received from drug companies in its SEC filings. Instead, it records rebates as a reduction of cost of revenues, claiming that breaking out rebates separately "would be misleading to investors" and would put Express Scripts "at a competitive disadvantage."[99] According to one comment on the SEC correspondence:

> This recent exchange of correspondence again emphasizes the great lengths Express Scripts and other PBMs have engaged in to conceal information relating to rebates received [from] drug manufacturers. More importantly, by its correspondence to Express Scripts, the SEC is taking a meaningful step toward exposing, and hopefully eliminating, covert PBM-drug manufacturer financial arrangements and how they impact patient healthcare.[100]

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[97] *Id.*
[98] *Id.*
[99] Letter from Eric R. Slusser, Executive Vice President and Chief Financial Officer, Express Scripts, to SEC Division of Corporation Finance (June 26, 2017), available at https://www.sec.gov/Archives/edgar/data/1532063/000119312517213574/filename1.htm.
[100] Jonathan Swichar, Bradley Wasser, *SEC Begins to Knock Down Wall of Secrecy Between PBMs and Drug Manufacturers*, Temple 10-Q (Feb. 1, 2018), https://www2.law.temple.edu/10q/sec-begins-knock-wall-secrecy-pbms-drug-manufacturers/.

167. Notably, even where a plan is aware of these PBM relabeling practices, it is nonetheless unable to determine the total dollar or percentage amounts of drug company payments that the PBM retains. Indeed, Defendants refuse to disclose such information to any plan client.[101]

168. From time to time, plans seek an audit of drug company payments that were passed through to them in order to ascertain whether their PBM is passing through the expected amount of drug company payments. During these audits, Defendants ensure that their clients remain in the dark, unable to learn the *true* cost of any specific drug, including EpiPen. For example, Defendants require all auditors to execute an Auditor Confidentiality Agreement. These Auditor Confidentiality Agreements uniformly preclude the auditor from sharing with its (and the PBM's) plan client any drug-by-drug rebate information or the terms of any drug company rebate contract (including Defendants' contracts with Mylan). The auditor is only allowed to share the aggregate "rebate" amount the auditor ultimately concludes is owed to the plan client.[102]

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[101] Stephan Barlas, *Employers and Drugstores Press for PBM Transparency, A Labor Department Advisory Committee Has Recommended Changes*, Pharmacy and Therapeutics (Mar. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/; *Understanding Your PBM Contract*, Pharmacy Benefit Consultants, http://pharmacybenefitconsultants.com/understand-your-pbm-contract/ (last visited Apr. 1, 2018); David Contorno, *Lawsuit Sheds Light on PBM Fees*, Insurance Thought Leadership at *1-2 (Sept. 1, 2017), http://insurancethoughtleadership.com/lawsuit-sheds-light-on-pbm-fees/pdf/.

[102] Cahn, *Eliminate All PBM Contract Loopholes, supra* note 83; *Testimony of Susan Hayes, Hearing on PBM Compensation and Fee Disclosure*, U.S. Dep't of Labor (Aug. 20, 2014), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/AChayes082014.pdf; *PBM Compensation and Fee Disclosure*, Report to Thomas E. Perez, U.S. Secretary of Labor, U.S. Dep't of Labor (Nov. 2014), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-

169. Moreover, PBMs, including Defendants, are so secretive about their collection and distribution of drug company payments that, during an audit, Defendants uniformly (i) require preapproval of the client's chosen auditor; (ii) restrict the number of drug company contracts that can be reviewed to a very limited number (typically ten); (iii) similarly restrict the number of claims and time period that can be reviewed; (iv) refuse to allow any drug company contract to be copied; (v) require a PBM representative to sit with every auditor that is reviewing a drug company contract; and (vi) refuse to allow any auditor to copy by hand the terms of any drug company contract, among other things.[103] Audits are more like spot checks—with little chance of being fulsome or independent of restrictions imposed by PBMs.

170. In addition to Defendants' recognized ability to label drug company payments in the manner most profitable to them, Defendants also profit from drug company payments in exchange for taking measures to ensure that plan participants and beneficiaries fill prescriptions only for drugs that appear on their formulary. These payments, often termed "formulary compliance payments," are almost never passed through to plans.

council/2014ACreport1.pdf; Robert Shelley & Brian Anderson - Presenters, *PBM Contracts: How to Use Audits and Market Checks to Improve Your Bottom Line*, Atlantic Info. Servs., Inc. (Jan. 28, 2014), https://aishealth.com/sites/all/files/file_downloads/c4p04f_012814.pdf.

[103] *Id.*

V. ERISA ALLEGATIONS

A. Defendants Are Fiduciaries.

171. Plaintiffs and the members of the Class (as defined below) are participants in and beneficiaries of employee welfare benefit plans, as that term is defined in ERISA § 3(1)(A), 29 U.S.C. § 1002(1)(A) (collectively the "ERISA Plans"). Each Defendant provides or has provided PBM services to these ERISA Plans during the relevant period.

172. 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).

173. ERISA treats as fiduciaries not only persons explicitly named as fiduciaries under ERISA § 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.

174. Defendants are fiduciaries to the ERISA Plans and participants and beneficiaries for which they provided PBM services in that, as described below, Defendants exercise discretionary authority or control over the management of the ERISA Plans, ERISA § 3(21)(A)(i), 29 U.S.C. § 1002(21)(A)(i), exercise *any* control or authority over ERISA Plan assets, *id.*, and have discretionary authority or discretionary responsibility in the administration of the ERISA Plans, ERISA § 3(21)(A)(iii), 29 U.S.C. § 1002(21)(A)(iii).

175. Defendants have discretionary control, and exercise such control, over plan management and administration. Defendants' ability to determine which prescription drugs will be included in, or excluded from, the formularies applicable to the ERISA Plans gives them the ongoing authority and control over which prescription drugs are covered by the ERISA Plans and thus ongoing control and authority over the ability of participants and beneficiaries to receive prescription drug benefits for a particular drug under their ERISA Plans.

176. For example, if Defendants decide to exclude the EpiPen from their formularies, participants and beneficiaries will be unable to use their ERISA Plans to purchase the EpiPen. Additionally, because the amounts ERISA Plan participants and beneficiaries pay in coinsurance increase or decrease depending upon the formulary tier in which a particular drug is classified, Defendants' ability to dictate and/or change the formulary tier in which drugs like the EpiPen are classified gives Defendants authority and control over the *amounts* participants and beneficiaries pay for the EpiPen and other prescription drugs obtained through the ERISA Plans. If Defendants decide to place

EpiPen in a less favorable formulary tier, participants and beneficiaries will receive lower levels of prescription drug benefits for the EpiPen from their ERISA Plans and will pay more in coinsurance payments.

177. Defendants also exercise control and authority over plan assets. Defendants' contracts with the ERISA Plans to provide PBM services constitute "plan assets" within the meaning of ERISA. Additionally, the insurance policies and/or administrative-services-only ("ASO") contracts underpinning the ERISA Plans are "plan assets" within the meaning of ERISA. The formularies applicable to the ERISA Plans are also plan assets, because they are a necessary part of the contracts governing prescription benefits.

178. Defendants exercise control and authority over these plan assets by using them as leverage to negotiate Kickbacks from Mylan. Defendants' pre-existing PBM contracts with the ERISA Plans and their pre-existing authority and control over the insurance policies, agreements, and formularies applicable to the ERISA Plans allow them to serve as gatekeepers between Mylan and a massive purchasing pool of millions of plan participants and beneficiaries. Mylan knows it would be deprived of millions of potential purchases of EpiPen if Defendants exclude the EpiPen from, or provide it with less favorable placement on, the formularies applicable to the ERISA Plans. Defendants leverage their control over this massive purchasing pool to induce and/or collude with Mylan to pay Defendants Kickbacks in exchange for the inclusion and favorable placement of the EpiPen on Defendants' formularies.

179. By so acting, Defendants also have and exercise fiduciary control and authority over the amount that participants, beneficiaries, *and* the ERISA Plans collectively

pay for the EpiPen. Although Mylan sets the list price of the EpiPen, because Defendants successfully dangle the worm of formulary inclusion or preferred formulary placement in exchange for the payment of Kickbacks, Defendants induce and/or collude with Mylan to artificially inflate the list price of the EpiPen to at least partially offset the amount of the Kickbacks. Defendants then permit the EpiPen to remain in the formularies applicable to the ERISA Plans—or even moved the EpiPen to a more favorable position in such formularies—despite these higher list prices. In effect, Defendants leverage their control and authority over the formularies to obtain ever larger Kickbacks for themselves. As a result, the amounts collectively paid by the Class (in deductible payments and/or coinsurance payments) and their ERISA Plans has inevitably increased.

180. The coinsurance and high deductible payments that Defendants require pharmacies to collect from the Class are "plan assets" within the meaning of ERISA, as are the amounts paid by the ERISA Plans themselves. Thus, by inducing and/or colluding with Mylan to artificially inflate the list price and thus increasing the amounts paid by both the Class and their ERISA Plans, Defendants also exercise fiduciary control and authority over ERISA Plan assets.

181. Defendants have and exercise discretion as to the price participants and beneficiaries pay for prescription drugs in another way: by choosing the pharmacy reimbursement rate for those drugs, thus determining the Class's out-of-pocket costs where participants' and beneficiaries' cost-sharing amounts are a function of the negotiated price.

182. Defendants' negotiations with Mylan and/or pharmacies are not mere business decisions independent of the ERISA Plans, as Defendants may claim. Instead,

Defendants' negotiations are based on leverage obtained from Defendants' *pre-existing relationships with the ERISA Plans*, including their pre-existing authority and control over ERISA Plan assets—including the PBM contracts, insurance policies, agreements, and/or formularies, which underpin the ERISA Plans' prescription drug benefits—as well as their pre-existing discretionary authority and control over plan management and administration. Pharmacy benefits require management and administration, and for the plans that have hired them, it is Defendants who fulfill this critical role. Defendants make decisions and engage in negotiations that are essential to the Class's realization of prescription benefits and which supply *inputs* that determine participants' and beneficiaries' access to the EpiPen and the prices paid by the Class and their ERISA Plans, as well as Defendants' own compensation for these services, as discussed further below. Defendants have leveraged and continue to leverage this fiduciary authority and control to obtain Kickbacks for their own benefit.

183. Defendants also cannot claim that their conduct is somehow immunized by the contracts they negotiated with the ERISA Plans. Defendants retain ongoing control and authority over those contracts, and exercise ongoing discretionary control and authority over plan management and administration, by virtue of their control over the formularies applicable to the ERISA Plans. Even if plan reimbursement rates or participant cost sharing payment formulas are defined by contract, Defendants exercise ongoing discretionary control and authority over the *inputs* to the negotiated plan formulas by using their control over formularies to, for example, induce and/or collude with Mylan to pay Defendants Kickbacks, which drive up the list price of the EpiPen.

This, in turn, increases the collective amounts paid by the ERISA Plans and the Class, as alleged above. Thus, neither the *price* of the EpiPen nor the *cost* to the Class and their ERISA Plans is set by contract—these are matters within or affected by the discretion of the PBMs, and the results are a function of their abuse of fiduciary power in dealing with Mylan, the entity that sets the price. Mylan's price setting and agreements with Defendants for Kickbacks and formulary treatment determine the out-of-pocket costs to the Class, the amounts paid by their ERISA Plans and the levels of Defendants' own compensation.

184. A final facet of Defendants' fiduciary status is their ability to affect and determine their own compensation for providing PBM services to the ERISA Plans. A service provider to an ERISA Plan that has discretionary control and authority over its own compensation, including control over the inputs to its compensation, is a functional fiduciary by virtue of such control and authority. This fiduciary control and authority arises by virtue of Defendants' ability to both negotiate the size of the Kickbacks and to assign various labels to portions of the Kickbacks. The label Defendants apply to a particular Kickback, or portion thereof, determines the amount retained by Defendants for their own accounts as opposed to the amount, if any, remitted to the plans. Even if Defendants take the position that they pass 100% of certain "rebates" through to the ERISA Plans, upon information and belief, Defendants have applied different labels to certain Kickbacks to conceal and retain a significant portion of the total Kickbacks they receive from Mylan, which are hidden from or undisclosed to the ERISA Plans. By

dictating the amount of Kickbacks they receive from Mylan related to EpiPen, and ultimately keep for themselves, Defendants set their own compensation for services.

185. Moreover, because Defendants have the discretion to choose the pharmacy reimbursement rate for certain drugs, they further control the compensation they receive and retain, as well as the out-of-pocket costs paid by the Class.

186. Notably, the foregoing powers and activities confer fiduciary status on 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 only administrative services—because these ERISA Plans all utilize PBMs in the same manner. Thus, Defendants owe fiduciary duties to all participants and beneficiaries in ERISA Plans of whatever type, and these participants and beneficiaries may bring claims for their own personal losses caused by Defendants' breaches and prohibited transactions, as set forth below.

B. Defendants' ERISA Duties.

187. **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 . . . (A) for the exclusive purpose of: (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan; (B) 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; (C) 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 (D) 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].

188. **Duty of Loyalty.** ERISA § 404(a)(1)(A), 29 U.S.C. § 1104(a)(1)(A), 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.

189. **Duty of Prudence.** ERISA § 404(a)(1)(B), 29 U.S.C. § 1104(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."

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

191. **Prohibited Transactions.** ERISA's prohibited transaction rules bar fiduciaries from certain acts because they are self-interested or conflicted. ERISA's prohibited transaction rules are closely related to ERISA's duty of loyalty, which is discussed above.

192. ERISA § 406(b), 29 U.S.C. § 1106(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.

193. **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 under ERISA § 502(a)(3) include remedies for breaches of the fiduciary duties set forth in ERISA § 404 and for violation of the prohibited transaction rules set forth in ERISA § 406. Plaintiffs bring their ERISA claims pursuant to ERISA § 502(a)(3), as further set forth below.

C. Defendants Breached Their Duties.

194. Defendants engaged in prohibited transactions, breached their fiduciary duties, and harmed Plaintiffs and the Class by improperly leveraging their relationships with, and access to, the ERISA Plans and Defendants' control and authority over plan assets in order to induce and/or collude with Mylan to pay Kickbacks to Defendants. This Kickback scheme operated by Defendants in conjunction with Mylan drove up the EpiPen list prices set by Mylan, thereby increasing Defendants' profits (and the profits of Mylan) at the expense of the Class.

195. By acting to maximize Kickbacks for their own pecuniary gain and by failing to disclose their practices, the reasons for the high cost of the EpiPen, or the compensation they set for themselves, Defendants failed to discharge their duties "solely in the interest of the participants and beneficiaries," in violation of ERISA § 404(a)(1). By inducing and/or colluding with Mylan for exorbitant Kickbacks in exchange for formulary placement and/or inclusion, Defendants contributed to Mylan's inflation of the list price of the EpiPen, caused the amounts paid by the Class and their ERISA Plans to increase, and thus further breached their duty of loyalty, which requires that fiduciaries discharge their duties "for the exclusive purpose of (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan," ERISA § 404(a)(1)(A), and their duty of prudence, ERISA § 404(a)(1)(B), with which excessive fees are incompatible.

196. By using their authority and control over ERISA Plan assets—in the form of the PBM contracts, the underlying plan contracts, formularies, and the amounts paid by the

Class and the ERISA Plans—in order to obtain Kickbacks for their own benefit, Defendants dealt with the assets of the ERISA Plans in their own interest and for their own account, in violation of ERISA § 406(b)(1).

197. By using their relationships with, and agreements that govern, the ERISA Plans' prescription drug benefits and their control over formularies and the management and administration of prescription drug benefits to maximize Kickbacks for their own pecuniary gain while contributing to Mylan's inflation of the list price of the EpiPen, Defendants acted in transactions involving the ERISA Plans on behalf of parties (themselves, their affiliates, and Mylan) whose interests are adverse to the interests of the Class and the ERISA Plans, all in violation of ERISA § 406(b)(2). Defendants engaged in conflicted transactions each time they negotiated Kickbacks with Mylan, each time they collected Kickbacks, and each time they facilitated, required, or allowed the Class to be charged for EpiPen based on inflated list prices (*i.e.*, in each ERISA Plan-related prescription drug transaction).

198. Likewise, in so acting, Defendants received consideration for their own accounts from a party or parties dealing with the ERISA Plans (including Mylan, third parties, Plaintiffs, and the members of the Class) in connection with transactions involving ERISA Plan assets, in violation of ERISA § 406(b)(3). Defendants engaged in conflicted transactions each time they negotiated Kickbacks with Mylan, each time they collected Kickbacks, and each time they facilitated, required, or allowed ERISA Plans, participants, and beneficiaries to be charged for the EpiPen based on inflated list prices (*i.e.*, in each prescription drug transaction involving assets of the ERISA Plans).

199. As a direct result of the Kickback scheme between Defendants and Mylan, Plaintiffs and the Class were overcharged and/or paid unauthorized and excessive coinsurance and deductible payments in connection with the purchase of the EpiPen. ERISA Plan participants and beneficiaries were overcharged for coinsurance contributions in that, rather than paying a percentage of an uninflated price for EpiPen, these out-of-pocket costs were based on substantially inflated amounts. Plaintiffs and the Class were overcharged when making payments toward their deductibles in that, rather than paying an uninflated price for EpiPen, they were charged inflated amounts.

200. Defendants further misrepresented and failed to disclose to ERISA Plan participants and beneficiaries the manner in which they charged for prescription drugs as alleged above; the amounts and components of Kickbacks that they collected from Mylan; or their compensation and profit collected in connection with EpiPen transactions—*i.e.*, the amount of Kickbacks they keep for themselves. As explained further in Count II, the duty of loyalty encompasses a robust duty to disclose, particularly when a fiduciary knows or should know that nondisclosure could harm one to whom the fiduciary owes a duty.

201. Defendants abused their fiduciary power, a substantial part of which gives 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, as well as authority and control over ERISA Plan assets. Defendants' ability to wield fiduciary power—to induce and/or collude with Mylan to obtain Kickbacks from Mylan—directly and financially harmed participants and beneficiaries of the ERISA Plans. Plaintiffs and the Class were forced to pay purchase prices for EpiPen based on the very

same inflated list prices that facilitated Kickbacks and resulted from Defendants' wrongful conduct alleged herein. Had Defendants conditioned the EpiPen's formulary inclusion or placement on Mylan *lowering* the EpiPen's list price, participants' and beneficiaries' out-of-pocket costs would have been lower. Thus, Defendants' profits derived from the Kickback scheme with Mylan directly harm participants and beneficiaries who purchase EpiPen.

VI. CLASS ACTION ALLEGATIONS

202. Plaintiffs bring 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 Class.** All individuals residing in the United States and its territories who are or were participants in, or beneficiaries of, an ERISA-covered health benefit plan or health insurance plan for which one or more Defendant(s) administered/administers or managed/manages pharmacy benefits or otherwise provided/provides pharmacy benefit management services ("ERISA Plans") and who paid any portion of the purchase price for EpiPen, EpiPen Jr., EpiPen 2-Pak, or EpiPen Jr. 2-Pak in one or more transaction(s) processed through their ERISA Plan(s).
>
> 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.

Plaintiffs reserve the right to redefine the class or assert subclasses prior to or in connection with seeking class certification.

203. **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 learning the extent and length of Defendants' fraud and/or concealment.

204. 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.

205. **Numerosity.** The members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. While the exact number of members is presently unknown to Plaintiffs, on information and belief, it is likely that hundreds of thousands—if not millions—of individuals will be members of the Class and that those individuals are readily identifiable in Defendants' records. According to the PCMA, as of 2016, PBMs administer prescription drug benefits for 266 million Americans. The four largest PBMs—CVS Caremark, Express Scripts, Optum, and Prime—administer prescription drug benefits for more than 200 million Americans, with CVS Caremark administering benefits for approximately 94 million plan participants,[104] Express Scripts for 83 million,[105] Optum for 65 million,[106] and Prime for

[104] *CVS Health At A Glance*, CVS Health, https://cvshealth.com/about/facts-and-company-information (last visited Apr. 1, 2018).
[105] *2016 Annual Report*, Express Scripts Holding Co., https://expressscriptsholdingco.gcs-web.com/static-files/777166b9-6d1a-4b3f-b979-f798b856955c (last visited Apr. 1, 2018).
[106] *OptumRx Opioid Risk Management Program Leads to Better Outcomes for Patients and Clients*, Optum, Inc. (Aug. 22, 2017), https://www.optum.com/about/news/optumrx-risk-management-program-leads-to-better-outcomes.html.

20 million.[107] Moreover, according to IMS Health, more than 3.6 million EpiPen prescriptions were written in 2015. According to Mylan, nearly 70% of the prescriptions were for commercially insured patients.

206. **Typicality.** Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were and/or continue to be harmed by Defendants' same wrongful conduct—*i.e.*, as a result of Defendants' misconduct, breaches of their fiduciary duties, and/or violations of ERISA, members of the Class paid all or a portion of artificially inflated prices for EpiPen.

207. **Adequacy.** Plaintiffs will fairly and adequately protect and represent the interests of the Class. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other members of the Class. Plaintiffs have retained counsel that are competent and experienced in the prosecution of complex class action litigation, including ERISA litigation, and have particular experience with class action litigation involving health insurers, the pharmaceutical industry, and PBMs. Plaintiffs' counsel will undertake to vigorously protect the interests of the Class.

208. **Commonality.** Common questions of law and fact exist and predominate over any questions affecting individual members of the Class. Defendants have acted toward Plaintiffs and the Class in a uniform manner, raising the following common questions, among others:

[107] *Our History*, Prime Therapeutics LLC, https://www.primetherapeutics.com/en/about/history.html (last visited Apr. 1, 2018).

A. Whether Defendants' conduct violated the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*;

B. Whether Defendants acted as fiduciaries under ERISA, including—but not limited to—by using their relationships with ERISA Plans and their control over applicable formularies and/or plan assets to negotiate, collect, and/or collude to obtain Kickbacks from Mylan related to EpiPen, and by administering prescription drug benefits for EpiPen to members of the Class, based on a price inflated as a result of Kickbacks, Defendants obtained from Mylan by inducement and/or collusion;

C. Whether Defendants' conduct as alleged above breached their fiduciary duties under ERISA;

D. Whether Defendants' conduct as alleged above breached ERISA's prohibited transaction rules;

E. Whether Defendants managed formulary inclusion and/or exclusion lists pursuant to uniform guidelines and/or practices;

F. Whether Defendants used their leverage over their pools of ERISA Plan clients and ERISA Plan assets to negotiate, collect, and/or collude with Mylan to obtain Kickbacks in exchange for including or placing EpiPen on their formularies;

G. Whether Defendants induced and/or colluded with Mylan to raise the list price of the EpiPen in exchange for formulary inclusion or placement;

H. Whether Defendants had and/or exercised discretion to label Kickbacks received from Mylan as they saw fit and to determine the amount of and what portion of such Kickbacks they would retain for themselves;

I. Whether Defendants had and/or exercised discretion to choose their rate of reimbursement to retail pharmacies for EpiPen;

J. Whether Plaintiffs and the Class are entitled to monetary relief, restitution, disgorgement, and surcharge; and

K. Whether Plaintiffs and the Class are entitled to injunctive or equitable relief and, if so, the nature of that relief.

209. 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.

210. 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.

211. With respect to Rule 23(b)(1)(B), the prosecution of separate actions by each members of the Class would create a risk of adjudications with respect to individual

members, 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.

212. 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.

213. Plaintiffs reserve the right to invoke additional provisions of Rule 23 if necessary at certification, including the Court's ability to certify issue classes under Rule 23(c)(4) and subclasses under Rule 23(c)(5).

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

VII. 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)

215. 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.

216. 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.

217. As alleged above, (i) the contracts underpinning the ERISA Plans; (ii) the ERISA Plans' formularies; and (iii) prescription drug benefit payments both from the ERISA Plans and from plan participants and beneficiaries are plan assets under ERISA.

218. As alleged above, Defendants are fiduciaries to the ERISA Plans.

219. Defendants violated all three subsections of ERISA § 406(b).

220. Defendants violated § 406(b)(1) by leveraging their authority over ERISA Plan assets in order to maximize Kickbacks from Mylan related to EpiPen and in turn maximize Defendants' own profit; setting their own compensation from EpiPen prescription drug benefit payments and Kickbacks from Mylan; collecting their own compensation from those same sources; and managing pharmacy benefits in exchange for Kickbacks from Mylan. And by inducing and/or colluding with Mylan to inflate list prices for EpiPen to enable Mylan's payment of Kickbacks to Defendants, Defendants dealt with Plaintiffs, the ERISA Plans, and ERISA Plan assets in their own self-interest, rather than in the interest of ERISA Plan participants and beneficiaries.

221. Each time Defendants administered benefits for a Class member filling an EpiPen prescription, Defendants realized Kickbacks from Mylan that Defendants kept, in whole or in part, for themselves.

222. Defendants violated § 406(b)(2) by acting on behalf of themselves, their affiliates, and Mylan by using their relationships with the ERISA Plans and their attendant control over plan assets, including formularies, to maximize Kickbacks from Mylan for Defendants' own pecuniary gain, which resulted in inflation of the EpiPen list price. Because Defendants stood to profit from the inflated EpiPen prices at the expense

of Plaintiffs and the Class, Defendants had interests adverse to Plaintiffs and the Class. Further, Defendants' conduct allowed Mylan to boost its own sales volumes and profits through EpiPen's inclusion on Defendants' formularies—which Defendants facilitated by acting on behalf of Mylan, whose interests are adverse to the interests of the Class and the ERISA Plans. Defendants engaged in conflicted transactions each time they negotiated Kickbacks with Mylan, each time they collected Kickbacks from Mylan, and each time they facilitated, required, or allowed Plaintiffs and the Class to be charged for the EpiPen based on inflated list prices (*i.e.*, each prescription drug transaction involving assets of the ERISA Plans).

223. As alleged above, these transactions involve the ERISA Plans because Defendants used their existing relationships with the ERISA Plans, their control and authority over plan formularies, and their control and authority over plan assets (although involvement of plan assets is not a requirement under 406(b)(2)), to obtain Kickbacks, to induce and/or collude with Mylan to inflate the price of EpiPen, and to place and/or keep EpiPen on the formulary, all of which contributed to the inflated list price of EpiPen. These transactions further involve the ERISA Plans because Mylan's payments to Defendants are invoiced based on the number of EpiPen prescriptions filled by members of the Class, which necessarily involves Defendants' administration of prescription drug benefits for the Class on behalf of the ERISA Plans and a subsequent reimbursement for benefits administration by those ERISA Plans.

224. Defendants violated § 406(b)(3) by receiving consideration for their own personal accounts from other parties dealing with the ERISA Plans—including Mylan,

third parties, Plaintiffs, and the members of the Class—in connection with transactions involving ERISA Plan assets. Defendants engaged in conflicted transactions each time they negotiated Kickbacks with Mylan, each time they collected Kickbacks, and each time they facilitated, required, or allowed ERISA Plans, participants, and beneficiaries to be charged for the EpiPen based on inflated list prices (*i.e.*, each prescription drug transaction involving assets of the ERISA Plans).

225. Defendants' prohibited transactions described herein not only profited Defendants, but also injured Plaintiffs and the Class. Specifically, Plaintiffs' prescription transactions were necessary to and thus facilitated the excessive profits in the form of Kickbacks that Defendants received from these prohibited transactions, while their overpayments constituted monetary harm.

226. 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 Class seek to recover the portions of their coinsurance and deductible amounts paid for EpiPen at an inflated price due to the Kickbacks described herein, as well as disgorgement of unjust profits obtained via Kickbacks from Mylan.

227. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should also order equitable relief to Plaintiffs and the Class, including but not limited to the relief set forth in the Prayer for Relief below.

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

228. 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.

229. 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.

230. Defendants violated their duties to administer prescription drug benefits solely in the interests of the Class. Instead, Defendants leveraged their access to millions of dollars in EpiPen prescription drug benefits through the ERISA Plans, to which they had access and over whose assets they had or exercised authority or control, for the benefit of themselves, third parties, or adverse parties and to the detriment of the Class, as well as the ERISA Plans. Defendants' conduct allowed them to maximize Kickbacks received from Mylan, a significant portion of which they kept for themselves, and allowed Mylan to boost its profits through EpiPen's inclusion on Defendants' formularies. Defendants' conduct alleged herein directly caused the list price for EpiPen to increase, meaning Plaintiffs and the Class paid more. Defendants' conduct and control also allowed Defendants to set their own compensation. Defendants thus acted in their

own interests—not the interests of Plaintiffs or the Class. Moreover, in acting in their own self-interest and in the interest of their own corporate affiliates, as well as in the interest of Mylan, Defendants violated the "exclusive purpose" standard under ERISA.

231. The duty to disclose is part of the duty of loyalty. Defendants breached this duty by concealing and failing to disclose to the Class the fact or amount of the Kickbacks; the inflation of EpiPen list prices; and the fact that plan participants and beneficiaries were paying all or a portion of inflated EpiPen prices via their coinsurance and deductible payments. Both omissions and misrepresentations are actionable under ERISA's disclosure obligations, and those alleged here are not subject to individualized reliance requirements.

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

233. Plaintiffs and the Class have been harmed in the amount of their overpayments. Further, Plaintiffs' and the Class's prescription transactions were necessary to and thus facilitated the excessive profits in the form of Kickbacks that Defendants collected from Mylan related to these breaches.

234. Defendants knew, or reasonably should have known, that these actions would injure the Class.

235. 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."

236. Pursuant to ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), the Court should order equitable relief to the Plaintiffs and the Class, including but not limited to the relief set forth in the Prayer for Relief below.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully demand that this Court:

A. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), (b)(2), and/or (b)(1), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class, and declare Plaintiffs as the representatives of the Class, and appoint Plaintiffs' Interim Co-Lead Class Counsel as Class Counsel;

B. Enter judgments against Defendants and in favor of Plaintiffs and the Class for violations of the legal standards invoked herein;

C. Award preliminary and permanent injunctive and other equitable relief as is necessary to protect the interests of Plaintiffs and the Class, including, *inter alia*, an order: prohibiting Defendants from engaging in the unlawful acts described above; requiring Defendants or their agents to disclose the existence and/or amount of any rebates, discounts, fees, or other payments received by Defendants for including EpiPen on any formulary; and requiring Defendants or their agents to disclose the true price they are paid for EpiPen;

D. Find that Defendants are fiduciaries as defined by ERISA;

E. Find that Defendants engaged in prohibited transactions and violated their fiduciary duties to Plaintiffs and the Class;

F. Award Plaintiffs and the Class equitable relief including, but not limited to: an accounting; a surcharge; correction of the transactions; disgorgement of profits; an equitable lien; a constructive trust; restitution; full disclosure of the foregoing acts and practices; an injunction against further violations; and/or any other remedy the Court deems proper;

G. Order other such remedial relief as may be appropriate under ERISA;

H. Order Defendants to pay pre-judgment and post-judgment interest as provided for by law or allowed in equity;

I. Award the Class monetary relief in an amount to be determined by the Court;

J. Award Plaintiffs' counsel attorneys' fees, reimbursement of out-of-pocket litigation expenses, expert witness fees, and other costs pursuant to ERISA § 502(g)(1), 29 U.S.C. § 1132(g)(1), and/or the common fund doctrine;

K. Order that Defendants must notify each and every individual who paid inflated prices for EpiPen about the pendency of this action so that they may obtain relief from Defendants for their harm; and

L. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

DATED: April 2, 2018 Respectfully submitted by

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of April, 2018, I filed the above-titled documents on Pacer, which provided service to all attorneys of record and the defendants in this case.

/s/ Cari Campen Laufenberg