

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: EpiPen Direct Purchaser Litigation

Case No. 20-cv-00827

THIS DOCUMENT RELATES TO:
All Direct Purchaser Actions

CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs Rochester Drug Co-Operative, Inc. (“RDC”) and Dakota Drug, Inc. (“Dakota Drug”) (collectively “Plaintiffs”), on behalf of themselves and all others similarly situated, for their complaint against Mylan Inc. and Mylan Specialty L.P. (collectively, “Mylan”), CVS Health Corporation, CaremarkPCS Health, L.L.C., Caremark L.L.C., and Caremark Rx L.L.C. (collectively, “CVS Caremark”), Express Scripts Holding Company, Express Scripts, Inc., and Medco Health Solutions, Inc. (collectively “Express Scripts”), and United Health Group Incorporated, United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. (“OptumRx”) (collectively, “the PBMs” or “the Defendant PBMs”), allege the following based on (a) personal knowledge, (b) the investigation of counsel, and (c) information and belief.

I. INTRODUCTION

1. Plaintiffs bring this action on behalf of a proposed class of direct purchasers of EpiPen, EpiPen Jr., EpiPen 2-Pak,¹ and EpiPen Jr. 2-Pak, and generic versions of those products (collectively or individually, “EpiPen” or “EpiPens”) from Mylan to recover overcharges due to Mylan’s and the Defendant PBMs’ illegal conduct which led to the artificial inflation of the list

¹ An EpiPen 2-Pak is a package containing two EpiPen devices. As of August 2011, Mylan stopped shipping single EpiPens and made EpiPens available only in 2-Paks. Mylan Press Release, “Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively,” 8/24/2011.

prices for EpiPen (and Mylan-sold generic EpiPen) in the United States.

2. Epinephrine auto-injectors (“EAI”) are devices that allow a patient to quickly self-administer a prescribed amount of the drug epinephrine through a spring-loaded needle as an emergency treatment for severe allergic reactions (including anaphylaxis). EpiPens (which are marketed and distributed by Mylan) are the best-selling EAI in the United States during the relevant events. From at least 2011 through 2017, Mylan’s branded EpiPens constituted up to 98% of the EAI market in the United States. During this time period, Mylan’s revenue from EpiPen sales has exceeded \$1 billion annually. While Mylan has shifted sales of branded EpiPen to an authorized-generic version of the product over the past several years, as of early 2019, Mylan’s combined sales of branded and generic EpiPen products constituted approximately 72% of the EAI market in the United States.

3. This action arises out of a scheme by Mylan to maintain and/or increase the volume and dollar amount of its EpiPen sales by paying bribes and kickbacks to the Defendant PBMs (pharmacy benefit managers), namely defendants Express Scripts, CVS Caremark, and OptumRx (and other, unnamed PBMs) in exchange for: (a) favorable placement of Mylan’s EpiPens on the PBMs’ formularies (and the exclusion or restriction of competing EAIs on the PBMs’ formularies); and (b) the elimination of price constraints that enabled Mylan to dramatically raise its prices without fear of PBM penalties.

4. PBMs are retained by various types of entities (such as private and public health plans², insurers and employers who create health-plans for their employees) (generally referred to

² For purposes of this Complaint, references to “health plans” include, but are not limited to, private employer self-insured and fully insured medical and prescription drug plans subject to the Employee Retirement Income Security Act (“ERISA”), so-called “Taft-Hartley” medical and prescription drug plans, Federal, state and local government medical and prescription drug plans, Medicare and Medicaid plans, individually procured medical and prescription drug insurance

herein as “clients”) to provide medical coverage for patients. The PBMs’ clients have delegated to the Defendant PBMs day-to-day authority and virtually exclusive control over various tasks that impact which drugs are covered, and how much health plans (and employers and other payors) pay for the drugs they cover for patients, including: (a) the negotiation of rebates with drug makers, including Mylan; (b) the flow of moneys to pharmacies and health plans (and how much the PBMs can keep for themselves); and (c) the structure and composition of formularies, which dictate the extent to which drugs are covered by a health plan/insurer. Because Defendant PBMs are the gatekeepers of which drugs will be covered by their clients, they have influence and/or control over which drugs will be prescribed and purchased.

5. PBMs have historically represented that they work on their clients’ behalf to reduce drug costs, and their clients rely on the PBMs to design, modify and administer formularies and negotiate rebates to reduce the clients’ drug costs. Toward that end, PBMs have historically used their formulary decisions to push patients to lower-priced drugs, which benefitted the PBMs’ clients (and patients). However, over the past several years, large, dominant PBMs (and particularly the Defendant PBMs), have been coopted by illegal manufacturer payments to use their control over formulary decisions for the PBMs’ own benefit (and the benefit of manufacturers such as Mylan who paid the Defendant PBMs illegal bribes or kickbacks) even though such conduct has been contrary to the interests of the PBMs’ clients (and other purchasers). As they have grown and consolidated, the Defendant PBMs have increased their control over formulary decisions for the vast majority of patients in the United States. Since at least 2014 (if not earlier) the Defendant PBMs have controlled formulary decisions for 180-200 million lives — which represents between 75-80% of the total number of patients covered by PBMs. Over the last several

coverage, and other insured medical and prescription drug plans or programs.

years, Mylan has made payments to the Defendant PBMs (including rebates, incentives, administrative fees, data fees, and other payments) in exchange for favorable (if not exclusive) formulary treatment for its EpiPen products.

6. The payments impacted not only the EpiPen sales volume, but also enabled Mylan to dramatically increase its prices to supra-competitive levels without losing sales. The effect of Mylan's bribes and kickbacks to the Defendant PBMs has been to corrupt the market policing mechanisms that the Defendant PBMs would otherwise perform, causing significant supra-competitive pricing inflation and market-wide harm. In the past, PBMs would penalize manufacturers who raised their prices too much by giving formulary preference to lower-priced drugs, which benefitted the PBMs' clients. Such conduct worked to limit price increases because a manufacturer that raised its prices too much risked adverse formulary treatment. However, Mylan's bribes coopted the PBMs to favor higher-priced drugs (to their clients' detriment) because Defendant PBMs retained a significant portion of the Mylan rebates and did not pass to the PBM clients many of the other fees that they received from Mylan. This created a conflict of interest, because: (a) while the PBMs' clients (such as health-plans and employers who pay for their employees' drug costs) are interested in promoting the lowest-priced drugs, (b) the PBMs benefit from generating the highest amount of rebates and fee payments, even if it results in pushing patients to higher-priced drugs to the detriment of the PBMs' clients. Indeed, because of this conflict of interest the Defendant PBMs are not simply indifferent to Mylan's large annual price increases, but they actually benefitted from such increases because the price increases inflated the amount of the bribes and kickbacks that the Defendant PBMs received from Mylan. This conflict has made the Defendant PBMs natural targets for Mylan's bribes and kickbacks because the payments incentivized them to favor the high-priced EpiPen products. In light of the fact that

PBMs would previously penalize manufacturers who raised their prices too much: (a) it would have been economically irrational for Mylan to take the aggressive price increases it did unless it recognized that the PBMs had been coopted by Mylan's payments, and (b) Mylan's aggressive price increases are a reflection of Mylan's understanding that the PBMs had been coopted because they kept a significant amount of Mylan's payments for themselves. Moreover, the fact that the Defendant PBMs did not make efforts to restrict Mylan's ability to aggressively raise prices (and/or penalize Mylan after the fact) reflects the fact that the PBMs were in fact coopted by Mylan's payments which they significantly kept for themselves.

7. Under several federal and state anti-kickback and bribery laws it is, and was, illegal for Mylan to pay rebates, fees, and other moneys to PBMs in return for formulary placement. This is especially so because some or all such moneys did not flow downstream to the PBM clients (and/or patients) as discounts. The Department of Health and Human Services (the agency responsible for implementing one federal anti-kickback statute) has made it clear that payments for formulary placement are not exempted under the anti-kickback statute as "discounts."

8. Furthermore, at all relevant times, the Defendant PBMs owed a duty of fidelity (and/or a fiduciary duty) to their clients (and/or their participants and beneficiaries), because of: (a) the contractual relationships between the PBMs and their clients; (b) the PBMs' position as agents, trustees, employees, and/or contractors for their clients; (c) the discretion, authority and control actually held and exercised by the PBMs over the management, administration and assets of such health plans; and (d) the assurances made by the PBMs that they would align their interests and/or act in the best interests of their clients.

9. The scheme, effectuated by Mylan with the respective Defendant PBMs (which began by 2012, if not earlier), had the purpose and/or effect of eliminating a check on Mylan's

ability to aggressively increase its list prices for EpiPens. Consequently, both to: (a) generate the bribe and kickback money it paid to the Defendant PBMs, and (b) profit from the decreased competition and improperly-obtained pricing power, Mylan aggressively increased its EpiPen list prices far beyond what it would have (and could have) done absent the scheme. EpiPen list prices were below \$240 at the end of 2012 and increased over the next four years to \$609 in May 2016.

10. It was improper and illegal under one or more state and federal laws for Mylan to pay bribes and kickbacks to the Defendant PBMs to act contrary to the interests of their clients and to conceal same. Because Mylan's bribes and kickbacks (and accompanying fraud in concealing that its list price increases were part and parcel of the bribes and kickbacks) enabled and caused tremendous EpiPen list price increases that would not have happened absent the misconduct alleged herein, Mylan's illegal conduct allowed it to improperly maintain and extend its monopoly pricing power in the EAI market. Mylan's conduct violated both the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* ("RICO") and Section 2 of the Sherman Act, 15 U.S.C. § 2.

11. Plaintiffs (and the other class members) are direct purchasers of Mylan's branded and generic EpiPens. They buy directly from Mylan at the list price. They were overcharged by Mylan's scheme with the respective Defendant PBMs because absent the scheme they would have paid lower list prices for the EpiPens they purchased. Plaintiffs, on behalf of themselves and other direct purchasers, seek recovery of those overcharges.

12. Plaintiffs' allegations are based on their own experience; the research of counsel; publicly available articles, studies, reports, and other sources; a reasonable inquiry under the circumstances; and on information and belief.

II. PARTIES

13. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, NY. During the Class period, as defined below, Plaintiff Rochester Drug Co-Operative, Inc. purchased branded and generic EpiPens directly from Mylan and was injured as a result of Mylan's and the Defendant PBMs' unlawful conduct.

14. Plaintiff Dakota Drug, Inc. is a corporation organized under the laws of the State of North Dakota with its principal place of business at 1101 Lund Blvd., Anoka, MN 55303. During the Class period, as defined below, Plaintiff Dakota Drug, Inc. purchased branded and generic EpiPens directly from Mylan and was injured as a result of Mylan's and the Defendant PBMs' unlawful conduct.

15. Defendant Mylan Inc. is one of the largest pharmaceutical companies in the world and has its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan owns the trademarks on the EpiPen tradenames and has worldwide rights to market and sell EpiPens. Mylan acquired these rights in 2007 through its acquisition of Merck KGaA's generics business and Dey L.P. In 2014, Mylan executed a "corporate inversion" that moved its headquarters to the Netherlands. On information and belief, Mylan moved its headquarters out of the United States to avoid paying taxes at the U.S. corporate tax rates.

16. Defendant Mylan Specialty L.P. is a Delaware limited partnership with its principal place of business at 781 Chestnut Ridge Road, West Virginia 26505. Mylan Specialty is a wholly owned subsidiary of Mylan Inc. Mylan Specialty is represented in press releases as a "specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of respiratory diseases, life-threatening allergic reactions [including EpiPen and EpiPen Jr. auto-injectors], and psychiatric disorders." Mylan

Specialty was formerly known as Dey Pharma until February 2012, when Mylan Inc. changed its name to Mylan Specialty. At all relevant times during the Class Period prior to 2013, Mylan Specialty was headquartered in Basking Ridge, New Jersey.

17. For purposes of clarity, Plaintiffs herein collectively refer to Mylan Inc. and Mylan Specialty L.P. as “Mylan.”

18. 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 [] solutions, including plan design offerings and administration, formulary management,” and that approximately 60% of its 2016 revenues were derived from its Pharmacy Services Segment.

19. 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.

20. 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.

21. 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.

22. 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.

23. 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."

24. 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 [] 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.

25. 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.

26. 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.

27. 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.

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

29. 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.

30. Defendant United Healthcare 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 Form 10-K, UnitedHealthcare Services, Inc. also does business as Optum, Inc.

31. 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.

32. 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.

33. 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.

34. Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. are agents and/or alter egos of United Healthcare Services, Inc. United Healthcare 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.

35. For purposes of clarity, Plaintiffs herein collectively refer to United Health Group Incorporated, United Healthcare Services, Inc., Optum, Inc., OptumRx Holdings, LLC, and OptumRx, Inc. as “OptumRx.”

36. The wrongful acts alleged to have been done by Mylan, CVS Caremark, Express Scripts, and OptumRx were authorized, ordered, or done by their directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of their respective affairs.

III. JURISDICTION AND VENUE

37. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because the Plaintiffs’ claims arise under federal law; this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* and Section 2 of the Sherman Act, 15 U.S.C. § 2, which are made privately actionable under 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a), respectively.

38. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) and (c) and

18 U.S.C. § 1965, because each Defendant transacts business in, is found in, and/or has agents in the District of Minnesota, and because some of the actions giving rise to this complaint took place within this District.

39. The Court has personal jurisdiction over each Defendant. Each Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including in this District. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. FACTUAL ALLEGATIONS

A. Epinephrine Auto-Injector Products

40. Anaphylaxis is a serious, life-threatening allergic reaction. It can occur in anyone at any time, and is often caused by exposure to allergens, including insect stings, certain foods (such as peanuts), pets or animals, medications, or other allergens. Studies have estimated that up to 5.1% of the U.S. population has a “probable” history of anaphylaxis.³ Mylan has stated that 43 million people in the U.S. are at risk for life-threatening allergic reactions due to allergic sensitivities, and estimated that anaphylaxis was causing 1,500 deaths annually.⁴ According to Mylan, “1 in 13 children [is] affected by food allergies.”⁵

³ Robert A. Wood, MD, et al., *Anaphylaxis in America: The Prevalence and Characteristics of Anaphylaxis in the United States*, 133 J. Allergy & Clinical Immunology 461 (2014).

⁴ See *Reviewing The Rising Price Of Epipens: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 104th Cong. 114-124 (Sept. 21, 2016) (Statement of Heather Bresch, CEO, Mylan), at 17, available at <https://docs.house.gov/meetings/GO/GO00/20160921/105373/HHRG-114-GO00-Transcript-20160921.pdf>.

⁵ Letter from Mylan to Senator Charles E. Grassley (Sept. 8, 2016), at 2, available at [https://www.grassley.senate.gov/sites/default/files/constituents/Mylan%20Response%20to%20Sen%20Grassley%209%208%2016%20\(002\).pdf](https://www.grassley.senate.gov/sites/default/files/constituents/Mylan%20Response%20to%20Sen%20Grassley%209%208%2016%20(002).pdf).

41. Epinephrine is the recognized front-line treatment for anaphylaxis. An EAI is used to self-deliver a controlled dosage of epinephrine during a life-threatening allergic reaction involving anaphylaxis. An EAI allows a person known to be at-risk for anaphylaxis to have a portable epinephrine injector present at all times in the case of anaphylaxis due to, for instance, insect, food, or animal exposure. Patients known to be at risk for anaphylaxis are recommended to always carry an EAI and to be trained in its use. EAI can also be administered by first responders or caregivers (such as parents) when a patient goes into anaphylaxis.

42. The auto-injector device was first developed by Survival Technology, Inc. in the 1970s to administer a nerve agent antidote for the United States military.⁶ It was subsequently modified to deliver epinephrine — thus creating the EpiPen product which was approved by the FDA in December 22, 1987, under NDA No. 019430.⁷ The EpiPen provides a 0.3 mg dose of epinephrine, while the EpiPen Jr. contains a 0.15 mg dose. After a series of mergers and corporate transactions, Mylan ultimately acquired the right to market and distribute the EpiPen line of EAI devices in 2007.⁸

43. Mylan has continuously dominated the EAI market since buying EpiPen in 2007. Indeed, in December 2012, Mylan touted that EpiPen “has been the number one prescribed epinephrine auto-injector for more than 20 years and constitutes more than 99% of the epinephrine

⁶ Matt Reimann, *The Story of the EpiPen: From Military Technology to Drug-Industry Cash Cow*, TIMELINE (Aug. 20, 2016), available at <https://timeline.com/epipen-technology-drug-industryb28d19036dee#seg6n7dls>.

⁷ Lydia Ramsey, *The strange history of the EpiPen, the device developed by the military that turned into a billion-dollar business and now faces generic competition between Mylan and Teva*, BUSINESS INSIDER (Aug. 17, 2018), available at <https://www.businessinsider.com/the-history-of-the-epipen-and-epinephrine-2016-8>.

⁸ *Id.*; MERIDIAN MEDICAL TECHNOLOGIES INC., Form 10-K (Jul. 31, 1997), at 6.

auto-injector market.”⁹ However, in or about January 2013, EpiPen began to face significant new competition from two products: (a) Auvi-Q, a competing, bioequivalent, branded EAI device sold by Sanofi; and (b) Adrenaclick which was sold by Impax as a generic product at prices that were much lower than EpiPen. Auvi-Q’s and Adrenaclick’s presence on the market should have placed price-disciplining pressures on Mylan, but as alleged below Mylan was able to use bribes and kickbacks — rather than price reductions — to maintain favorable (if not exclusive) formulary status for EpiPen. As a result, Mylan’s use of bribes and kickbacks for favorable formulary status has reduced (if not eliminated) any pressures on it to lower its prices and/or curb its price increases. The result has been rampant, unchecked price increases for EpiPen products that are the direct result of Mylan’s bribery and kickback scheme, and which direct purchasers like Plaintiffs have paid to Mylan in the form of overcharges.

B. The Prescription Drug Selection And Distribution System

1. The Prescription Drug Distribution Chain

44. Pharmaceutical companies develop, manufacture, market, and sell prescription drugs. At the beginning of the prescription drug distribution chain, pharmaceutical companies sell prescription drugs to drug wholesalers (such as Plaintiffs), which then re-sell the drug products to a pharmacy or other drug dispensary, which dispenses the drug to the patient. The drug is ultimately paid for by: (a) the patient (if it is a cash patient lacking insurance), (b) a third-party payor (such as an employer that is paying for its employees’ medical costs, or a commercial or government insurer or health plan that covers the drug cost); or (c) a combination of the patient and health plan, if the patient’s health plan requires some type of co-payment.

⁹ Mylan Specialty Press Release, “Mylan Specialty Offers Tips for Parents of Children with Life-Threatening Allergies to Help Prepare for Seasonal Celebrations” (Dec. 18, 2012), <http://newsroom.mylan.com/pressreleases?item=123064>.

45. Wholesalers pay directly to Mylan the published list price for EpiPens, which is frequently called the Wholesale Acquisition Cost (“WAC”). The direct purchaser may obtain a small percentage discount off of WAC for paying its invoice early.

46. Average Wholesale Price (“AWP”) is an “index” price that is a calculated derivative of WAC and is used by PBMs to determine pharmacy reimbursements for sales to insured patients. It is typically set as WAC plus 20%.

47. The price that patients pay for drugs like EpiPens at the pharmacy counter varies based on whether they have insurance and the nature of their coverage. According to a September 8, 2016 Mylan letter to Senator Charles Grassley, at least 85% of EpiPen patients are covered by either a government or private (commercial) insurer or health plan. EpiPen patients who are uninsured pay the “cash” price, which is a price that has been marked-up from the pharmacist’s purchase or acquisition cost.¹⁰ For the 85% (or more) of patients whose EpiPen purchases are covered by an insurer or health plan, which specific products are covered (and the scope of that coverage) is governed by the insurer and health plans’ formulary decisions.

48. Formularies are lists that define which drugs are covered by an insurer or health plan, and the scope or restrictions for such coverage. Most formularies have multiple tiers of coverage. The formulary tier in which a drug is placed impacts whether a drug is covered, and what co-pay amounts the patient will be required to pay at the pharmacy counter. Branded drugs

¹⁰ Patients who have insurance coverage under a plan that imposes a “deductible” will pay the cash price for each prescription until they meet the deductible amount under their insurance or health plan, at which point the insurer or health plan pays for some or all of the remaining covered purchases over the course of the year. Finally, separate and aside from deductibles, patients often have “coinsurance obligations,” pursuant to which the health plan or insurer will pay for the majority of the prescription cost, but the patients are required to pay part of the price referred to as the “co-pay” amount. Patients pay either a fixed percentage of the drug’s cost, or a set dollar amount depending on the drug’s formulary placement and whether the drug is preferred or not.

that are covered by a health plan or insurer are typically covered in Tier 2 or higher. In addition, formularies may also impose restrictions or limitations on drug coverage, which provide that a drug is only covered under certain conditions. This has the effect of completely eliminating a health plan's coverage of a drug under certain conditions and requiring the patient to pay the full cash cost of the drug if certain conditions or restrictions are not met.

49. A health plan or insurer's cost for a prescription is impacted by various factors. If an insurer covers a drug, then it will directly or indirectly reimburse the pharmacist for a patient's prescription based on an "ingredient cost" plus a dispensing fee. For patients in "coinsurance" plans, the reimbursement amount that the health plan pays the pharmacist will be offset or reduced by the co-pay amount that the patient pays directly to the pharmacist. The health plan or insurer's final or "net" costs for a prescription may be reduced by rebates from drug manufacturers that the health plan negotiated directly with the manufacturer or which were negotiated by a PBM (to the extent the PBM actually passes the rebates down to the health plan).

50. No matter the size of the rebate, if everything else stays the same, a health plan or insurer will always benefit from a drop in list price, and conversely, be worse off from an increase in list prices, regardless of the fact that the price changes may be partially offset by the rebates. For example, if a health plan receives a 50% rebate on a drug with a \$200 list price, the health plan's net price is \$100. If the price increases by \$100 to \$300 (and the 50% rebate stays the same) then the health plan's net price rises \$50 to \$150 (\$300 minus a \$150 rebate). Conversely, if the price drops from \$200 down to \$100 (and the 50% rebate stays the same) then the health plan's net price drops from \$100 down to \$50 (\$100 minus a \$50 rebate). Consequently, putting aside medical differences between products: (a) if there are two equivalent drugs offering the same rebate percentage, it is in a health plan's interest to drive patients to the drug with the lower list

price; and (b) it is always in a health plan's financial interest to use its power to shift patients from one drug to another to deter manufacturers from increasing drug list prices (assuming no changes in rebates). The same is true for cash patients, patients in high-deductible plans, and patients whose co-pay is set as a percentage of the drug's list price.

2. PBMs' Role In The Drug Selection And Dispensing Process

51. With the exception of their mail-order pharmacy business, PBMs are not buyers of drugs. PBMs operate as middlemen who are hired by various types of entities to design, manage, and administer prescription drug benefit programs. In a September 2013 letter to the Pennsylvania House of Representatives Committee on Health, Express Scripts stated that:

ESI contracts with Fortune 500 companies, labor unions, health insurance companies, and government entities to administer the prescription drug benefit for 109 million Americans. Our largest contract is with the United States Department of Defense - administering the pharmacy benefit for all of our country's active and retired military personnel and their families. In Pennsylvania, ESI administers pharmacy benefits for over 270 clients, or more than 6 million Pennsylvanians, such as The University of Pittsburgh Medical Center, United States Steel, Blue Cross of Northeastern Pennsylvania, ARAMARK, Tyco. Hershey, and Sunoco.

Similarly, in April 2019: (a) an Optum Rx representative testified before Congress that "OptumRx manages pharmacy benefits on behalf of customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and federal and state government employee plans,"¹¹ and (b) a Caremark representative testified in April 2019 that Caremark serves employers, unions, and government programs.

52. The PBMs' functions frequently include: (a) negotiating rebates from drug

¹¹ April 10, 2019 Written Testimony, Sumit Dutta, M.D., Chief Medical Officer, OptumRx, Before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, at 2, available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf>.

manufacturers based on the clients' drug purchases, (b) designing and revising the health plan/insurers' (and other clients') benefit rules (such as copay levels, deductibles, and formulary specifics) and determining coverage eligibility and copayments, and (c) designing, developing and managing formularies and formulary compliance programs.¹² Regardless of the nominal control that some insurers and health plans may formally retain over these functions, in reality many (if not most) of the insurers and health plans have delegated to PBMs the day-to-day control over these functions.

53. As alleged in more detail below, the Defendant PBMs understand and have acknowledged that: (a) they are supposed to be negotiating rebates on behalf of their clients, for their clients' benefit, (b) the PBMs' rebate negotiations and formulary decisions are supposed to be consistent, and in accordance with, their clients' larger, overall interests of reducing drug costs, and (c) the PBMs' clients rely on the PBMs to perform their functions in the clients' interests.

a) PBMs' Role In Negotiating Rebates With Manufacturers

54. While manufacturers pay PBMs fees for certain administrative services that the PBMs provide, the payments at issue in this Complaint do not result or flow from the PBMs' inherent, stand-alone power or services they provide. Rather the payments at issue flow from (and are inextricably linked to) the health plans' (and other clients') collective purchasing power – power that the PBMs wield and leverage for their own benefit. Manufacturers make the payments at issue to influence the PBMs' clients' purchase and coverage decisions – i.e. to maintain or improve the insurance coverage that a health plan gives to a manufacturer's drug, and thereby maintain or increase the amount of the drug that is used by patients and paid for by the health plan

¹² Robert F. Atlas, "The Role of PBMs In Implementing The Medicare Prescription Drug Benefit," Medicare Drug Benefit (Oct. 28, 2004), at W4-505-506, available at <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.W4.504>

(or employer). The manufacturers would not make the payments at issue to the PBMs but for the health plans' collective purchasing power that the PBMs manipulate. Indeed, in its 2013 Annual Report Express Scripts stated that "We manage the cost of the drug benefit by . . . leveraging purchasing volume to deliver discounts to health benefit providers." Similarly, in an August 2013 letter to the Pennsylvania House of Representatives Committee on Health, the PBMs' trade association — the Pharmaceutical Care Management Association ("PCMA") — stated that:

PBMs aggregate the buying clout of millions of enrollees through their clients, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and the efficiencies of mail-service pharmacies

Thus, without the ability to represent the health plans (and their purchasing power), with whom the PBMs purport to align their interests, the PBMs would not receive and retain the payments at issue.

55. PBMs became a major force in the late 1980s, expanding from pharmacy claims processing to a business model that forced drug manufacturers to engage in price negotiation in several drug categories. PBMs typically selected one brand among several brand drugs in a therapeutic class as the "preferred" choice and negotiated payments from that manufacturer called "rebates." So long as those rebates were passed back to the health plan, that approach could lower the net cost of that brand to health plans.¹³

56. PBMs gained even more prominence — and recognition from the federal government — in 2003 with the passage of the Medicare Modernization Act (MMA). This law implemented the Medicare Part D outpatient drug benefit using plans that competed for customers based on their advertised ability to negotiate favorable drug prices, create formularies, and hold

¹³ Health Affairs, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Policy Brief Series (Sept. 2017) at 1.

down premiums. PBMs generally represent the Part D plans in these negotiations.¹⁴

57. PBMs' effectiveness as negotiators with pharmaceutical manufacturers grew as PBMs grew in size and grew in terms and the number of covered lives they represented in negotiations. The more covered lives (insured patients) represented by a PBM, the more likely that manufacturers will offer rebates in return for preferred formulary coverage, which in turn would cause increased sales of the manufacturer's drug. According to the PBMs' trade association, the PCMA, as of January 2019, PBMs administered prescription drug benefits for more than 266 million Americans.¹⁵ In 2018, the top six PBMs handled more than 95% of total U.S. prescription claims.¹⁶

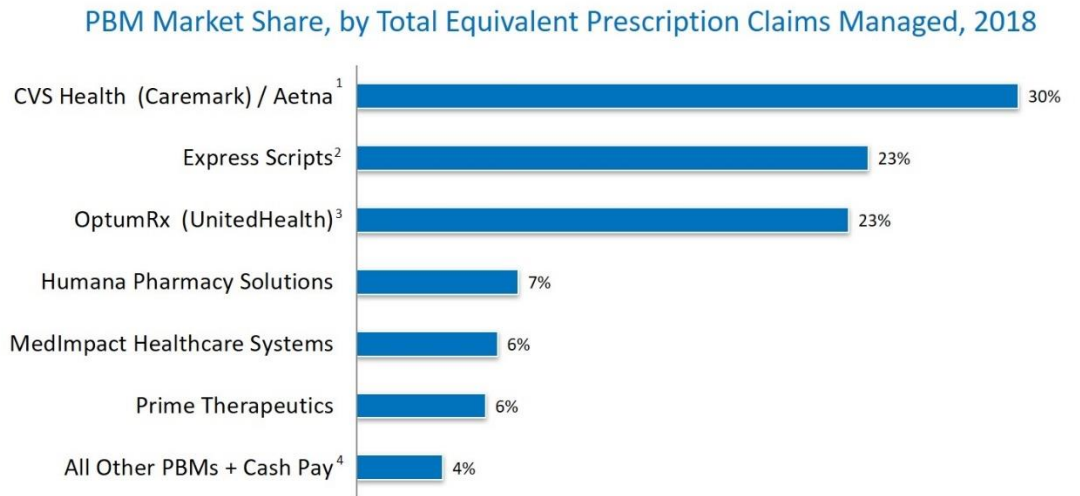
58. Because increased size gives an individual PBM increased negotiating leverage there has been dramatic consolidation in the PBM industry during the past decade. In 2012, when the Federal Trade Commission approved Express Scripts' acquisition of Medco, the agency found

¹⁴ *Id.* at 2.

¹⁵ PCMA, "Increased Competition Key to Reducing Prescription Drug Costs" (Jan. 28, 2019), available at <https://www.pcmanet.org/pcma-offers-policy-solutions-to-reduce-prescription-drug-costs/>.

¹⁶ "CVS, Express Scripts, and the Evolution of the PBM Business Model," Drug Channels (May 29, 2019), available at <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>. 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, including plan design and administration, formulary management. Express Scripts Holding Company is a full-service PBM and specialty managed care company which 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 "the largest stand-alone [PBM] company in the United States" and that it "provides integrated pharmacy benefit management services." Medco Health Solutions, Inc. is a subsidiary of Express Scripts Holding Company. Optum, Inc. provides pharmacy benefit management services through its subsidiaries to various health insurance entities on behalf of more than 65 million plan participants. Prime Therapeutics, LLC 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.

there were “at least ten significant competitors” in the PBM segment.¹⁷ However, by 2014, the top three PBMs (the Defendant PBMs) managed over 180 million lives — about 80 percent of the total number of patients covered by PBMs, evidencing recent consolidation.¹⁸ According to a May 2019 industry article,¹⁹ at the end of 2018, the Defendant PBMs continued to control over 75% of the covered lives:



1. Includes pro forma combination of claims processed by Aetna. Excludes double counting of network claims for mail choice claims filled at CVS retail pharmacies.
 2. Includes Anthem. During 2019, Anthem claims will be transitioning to IngenioRx.
 3. Includes Cigna. By the end of 2020, Cigna claims will transition to Express Scripts.
 4. Figure includes some cash pay prescriptions that use a discount card processed by one of the 6 PBMs shown on the chart.
 Source: Drug Channels Institute research and estimates. Total equivalent prescription claims includes claims at a PBM’s network pharmacies plus prescriptions filled by a PBM’s mail and specialty pharmacies. Includes discount card claims. Note that figures may not be comparable with those of previous reports due to changes in publicly reported figures of equivalent prescription claims. Total may not sum due to rounding.

This chart appears as Exhibit 76 in *The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute. Available at <http://drugch.nl/pharmacy>



59. In contrast, the market for health plans and insurers is much less concentrated, with

¹⁷ Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc., FTC File No. 111-0210 (Apr. 2, 2012), at 2, available at https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express./120402expressscripts.pdf.

¹⁸ Health Affairs, “Prescription Drug Pricing: Pharmacy Benefit Managers,” Health Policy Brief Series (Sept. 2017) at 2.

¹⁹ “CVS, Express Scripts, and the Evolution of the PBM Business Model,” Drug Channels (May 29, 2019), available at <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>.

the 25 largest companies accounting for less than two-thirds of the business in 2014.²⁰ For brand name drug manufacturers, 13 companies account for 90% of the U.S. market.²¹ Thus, it is typical to have a large PBM negotiating with several drug manufacturers on behalf of a large number of relatively small health plans.

60. One of the key functions that PBMs perform for their clients is to negotiate rebates with drug manufacturers. However, rather than negotiating separate agreements with drug manufacturers separately and individually for each of their health plan and insurer clients, PBMs typically use their combined clout to negotiate a master agreement on behalf of all their clients. As a result, in the world of drug price negotiation, market power is most highly concentrated among PBMs, and in particular the Defendant PBMs, who have more negotiating leverage than any individual drug manufacturer or health plan on either side of a transaction.

61. Because the Defendant PBMs can negotiate better rebate deals than health plans/insurers can get on their own, they are in a strong position when negotiating contract terms and conditions with the health plans/insurers they represent. While a PBM is nominally “hired by” and “working for” a particular health plan, the Defendant PBMs are actually in the driver’s seat. While health plans/insurers may technically have the right to independently control rebate negotiations, they have delegated that power to the Defendant PBMs to exercise during the course of their relationship.

62. For example, Express Scripts’ standard, uniform contract provides that it be given

²⁰ Evi Heilbrunn, “Top Health Insurance Companies,” U.S. NEWS & WORLD REPORT (Nov. 5, 2014), available at <https://health.usnews.com/health-news/health-insurance/articles/2013/12/16/top-health-insurance-companies>; Charles Roehrig, “The Impact of Prescription Drug Rebates on Health Plans and Consumers”, Altarum (Apr. 2018) at 8, available at <https://altarum.org/publications/impact-prescription-drug-rebates-health-plans-and-consumers>.

²¹ *Id.*

full and complete control to negotiate with drug makers for the insurer/health plan client, that the client will forego any right to directly negotiate with drug makers, and if the client does negotiate on its own then the PBM may terminate the relationship or the client may have to forego all rebates:

Sponsor acknowledges that it may be eligible for Rebate amounts under this Agreement only so long as Sponsor, its affiliates, or its agents do not contract directly or indirectly with anyone else for discounts, utilization limits, rebates or other financial incentives on pharmaceutical products or formulary programs for claims processed by ESI pursuant to the Agreement, without the prior written consent of ESI. . . . To the extent Sponsor knowingly negotiates and/or contracts for discounts or rebates on claims for Covered Drugs without prior written approval of ESI, such activity will be deemed to be a material breach of this Agreement, entitling ESI to suspend payment of Rebate amounts hereunder and to renegotiate the terms and conditions of this Agreement.²²

Thus, Express Scripts will work for an insurer/health plan only so long as the sponsor/payor agrees to: (a) abstain from using its right to negotiate rebates for its purchases without Express Scripts' written permission; and (b) give Express Scripts *de facto* control over rebate negotiations. Moreover, if a health plan (or similar payor) tried to independently negotiate rebates for EpiPen or other EAI products, the foregoing provision gives Express Scripts the power to suspend any and all rebates under the agreement, creating an *in terrorem* effect that would deter health plans from actually exercising any theoretical power to negotiate rebates for themselves.

63. Similarly, as discussed above, Defendant PBMs generally represent the private plans who handle the outpatient drug benefits for Medicare Part D patients pursuant to the 2003 MMA. The MMA contains a noninterference provision, section 1860D-11(i) (42 U.S.C. § 1395w-111(i)), which restricts direct government involvement in Part D price negotiations.²³ This is

²² Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (February 27, 2015), available at <http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf>.

²³ Health Affairs, "Prescription Drug Pricing: Pharmacy Benefit Managers," Health Policy Brief Series (Sept. 2017) at 2.

further reflection and demonstration of the Defendant PBMs' exclusive control over price negotiations for their clients.

b) PBMs' Role In Designing Formularies

64. Formularies are a central tool that payors use in designing, managing and publicly identifying the extent of the coverage and benefits they provide to their members. Because formulary coverage impacts how much a patient pays for a drug, formularies can be used to steer patients toward certain drugs over others, and that is one of the key purposes and functions of formulary design, implementation and management.

65. The PBMs contend that their clients make the decisions regarding the formularies' structure and details. For example, Express Scripts stated in a September 2013 letter to the Pennsylvania House of Representatives Committee on Health, that:

Based on a client's Request for Proposals, a PBM may offer the client multiple variations of models from the more basic plan to the most comprehensive plan relying on multi-tiered co-payments, formularies developed with physicians and pharmacists, pharmacy networks, mail-service pharmacy, and other similar tools that make drugs more affordable and accessible.

Similarly, in December 2011, Express Scripts' Chairman and CEO (George Paz) testified before a Senate Committee that:

[W]e do not make decisions on behalf of our plan sponsors or consumers. We offer options. It is a plan sponsor's decision whether to promote home delivery. It is a consumer's decisions whether to use home delivery or go to a retail pharmacy. . . . We cannot walk into any plan and tell them to do something. They choose. We give them a laundry list of options and they choose what they want to do in order to save money and meet the needs of their employees, weighing access versus cost.

66. However, regardless of the nominal control over the formulary structure and administration that clients may theoretically have, in reality the Defendant PBMs have contractual authority to make day-to-day changes. The PBMs have significant discretion, control and authority over the health plans' formulary or formularies, as evidenced by the following passage

from Express Scripts’ standard, uniform contract which states: “Further, ESI and TPA each understand that market conditions, patent status and other factors may influence Formulary decisions from time to time[.]” This passage contains undefined and ambiguous phrases (e.g., “market conditions,” “other factors,” and “from time to time”) which allow Express Scripts, with its preserved power to modify the formulary “from time to time” (as set forth in Complaint Paragraph 67, below), to interpret the contract as it sees fit, and thereby effectively modify a health plan’s formulary/formularies.

67. Furthermore, the Express Scripts contract template provides that Express Scripts’ additions and/or deletions to the formulary are automatically assumed to be adopted by the health plan sponsor, unless the client takes the affirmative step of electing not to implement any such addition or deletion through the set-up form process:

“Formulary” means the list of FDA-approved prescription drugs and supplies developed by ESI’s Pharmacy and Therapeutics Committee and/or customized by Sponsor, and which is selected and/or adopted by Sponsor. The drugs and supplies included on the Formulary will be modified by ESI from time to time as a result of factors, including, but not limited to, medical appropriateness, manufacturer Rebate arrangements, and patent expirations. Additions and/or deletions to the Formulary are hereby adopted by Sponsor, subject to Sponsor’s discretion to elect not to implement any such addition or deletion through the Set-Up Form process, which such election shall be considered a Sponsor change to the Formulary.²⁴

68. Most health plan and insurer clients rely upon a Defendant PBM’s formulary recommendations. A well-known pharmacy-benefits consultant, David Dross, noted during a presentation that health plans “don’t have clinicians on staff, they don’t even question their PBM’s formulary, much less design their own.”²⁵ The PCMA — the PBM trade association — has

²⁴ Sample Form of PBM Agreement with Express Scripts, Inc., Genesee County (Flint, Michigan) Purchasing Department (February 27, 2015), available at <http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf>.

²⁵ “Employers Should ‘Ask the Hard Questions’ About PBM Formularies,” HEALTH BUSINESS DAILY (Dec. 19, 2014), available at <https://www.coleridgelaw.com/archive/nhpw120814-03>.

testified to the Pennsylvania House of Representatives that even sophisticated insurers and health plans rely on PBMs to manage their drug benefit.²⁶

69. Finally, the PBM contracts contain provisions that enable the PBM to penalize clients by reducing rebates if the clients override the PBM's formulary decisions. For example, Express Scripts' standard, uniform contract provides that:

ESI shall have the right to make an equitable adjustment to the Rebates if a Client changes its Formulary, benefit design or otherwise takes action that has the effect of lowering the amount of Rebates eligible to be earned with respect to such Client, or Rebate revenue is materially decreased because of brand products moving off-patent to generic status.

70. The Defendant PBMs' contractual authority to make changes to the formulary list that automatically take effect absent a client's objection, combined with clients' reliance on the Defendant PBMs' formulary recommendations and decisions, gives the Defendant PBMs substantial day-to-day control in managing their clients' formularies.

71. In addition to the PBMs' dominion over formularies and modifications thereto is the PBMs' related control over the administration of health plan participant benefit claims. According to Express Scripts' standard, uniform contract with health plans, health plan sponsors and third party administrators of such plans, Express Scripts is responsible for processing patients' initial benefit claims (such as requests at the pharmacy counter for insurance coverage regarding a prescription) and prior authorization requests. The PBMs' control of the claims process impacts the access that health plan members (i.e., patients) have to, for example, a certain brand (or pricing category) of EpiPen and/or other EAI products. Mylan and other EAI manufacturers whose products are included in an applicable formulary pay fees to Express Scripts and the other PBMs

²⁶ Letter from PCMA to the Matthew E. Barker, Pennsylvania House of Representatives, House Comm. On Health (Aug. 28, 2013).

for the benefit claims services that the PBMs provide and control in determining which EAI products patients have access to.

72. The PBMs also play a role in the benefit claims appeals process in situations in which a health plan member (i.e., patient) is not satisfied with the initial benefits claims determination made by the PBM. While PBMs generally do not directly involve themselves in such appeals, they do have a role in the process that involves the exercise of discretion, authority and control over health plan administration. For example, Express Scripts' standard, uniform contract provides that: (a) Express Scripts has selected the services of a given third-party claims adjudicator (in the case of one of its standard contracts, that entity is UM Company), which is responsible for conducting the appeals of denied claims for benefits, (b) Express Scripts has the authority to terminate such agreements in favor of another third-party claims adjudication vendor, and (c) Express Scripts has significant control over the ultimate decisions made by that third-party as they pertain to the frequency at which they grant or deny participants' access to certain EpiPen brands for which Express Scripts receives rebates and claims administration fees.

73. The Defendant PBMs' control over formulary decisions is related to (and a necessary predicate of) their ability to negotiate manufacturer rebates, because manufacturers pay rebates based on the Defendant PBMs' ability to deliver formulary placement for their drugs. Because favorable formulary status is likely to increase (or at least maintain) a drug's usage and sales, and formulary exclusion (or a downgrade in formulary position) is likely to reduce a drug's usage and sales, manufacturer rebates are often (if not always) conditioned on a drug's formulary coverage. Thus, the amount of the rebates that a drug manufacturer will pay will be impacted by a PBM's ability to deliver formulary status that will increase drug sales. As Cottingham & Butler (a national insurance broker) noted in a client presentation, PBMs have "unilateral control . . . over

formularies and tiering — driving greater profits for PBMs through rebates[.]”²⁷

74. In the past, PBMs generally devised and managed what are known as “open” formularies: formularies that offer varying degrees of plan coverage and benefits for virtually all available FDA-approved drugs. Consequently, with open formularies, drug companies compete to have their drugs placed by PBMs in the most favorable formulary tier possible. Like open formularies, “closed” formularies provide tiered benefits, but unlike open formularies, they restrict the overall number of drugs that are entitled to receive any plan prescription drug benefit. In the 2010s, PBMs, including the Defendant PBMs, started shifting to making “closed” formularies the default choice.²⁸ For example, while health plans traditionally had to opt into closed formularies, in 2014, Express Scripts’ national formulary was a closed formulary, and clients had to affirmatively opt-out of it.²⁹

75. Over the last several years, the Defendant PBMs have published annual lists of drug exclusions. PBMs’ exclusion lists are closely analyzed by industry experts who understand that, through these lists, PBMs have the ability to drive health and insurance plan participants and beneficiaries to (or away from) specific drugs.³⁰ For example, in an August 2, 2016 article about

²⁷ Nancy Daas, *Prescription Drug Plan Strategies*, Cottingham & Butler (2017).

²⁸ 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>.

²⁹ *Id.*

³⁰ *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>.

CVS Caremark's and Express Scripts' 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].³¹

76. Formulary placement (and potential exclusion) is a major factor in the Defendant PBMs' negotiations with drug companies like Mylan for rebates and other types of payments. The PCMA (the PBM trade association) states that “[i]n classes where several products may be considered therapeutically equivalent, PBMs can negotiate with drug manufacturers for higher rebates[.]”³² In April 2015, Express Scripts' Chief Medical Officer told *Managed Care Magazine* that formulary exclusions demonstrate that PBMs can move market share.³³ He further touted that drug companies “[are] now convinced . . . that [PBMs 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,

³¹ 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>.

³² Thomas Beaton, *How Pharmacy Benefit Managers Lower Prescription Drug Prices*, *Health Payer Intelligence* (Sept. 19, 2017), available at <https://healthpayerintelligence.com/news/how-pharmacy-benefit-managers-lower-prescription-drug-prices>.

³³ Peter Wehrwein, *A Conversation With Steve Miller, MD: Come in and Talk With Us, Pharma*, *Managed Care Mag.* (April 2015).

we will move the market share to you. We will move it effectively. We'll exclude the other products.”³⁴

77. Because the Defendant PBMs 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. Industry experts have further highlighted that the threat of formulary exclusion has yielded substantial drug company payments to PBMs. In a presentation, Arthur Shinn of Pharmacy Consultants, LLC stated that “[t]he exclusion strategy is a big rebate revenue generator.”³⁵

78. As alleged in more detail herein, the PBMs’ control over the formulary design and administration process means that in performing their formulary functions they are acting as either trustees and/or agents for their clients’ benefit. While PBMs have attempted to avoid fiduciary status by inserting into their contracts self-serving conclusory statements concerning their purported “non-fiduciary” status, the provisions in Express Scripts’ standard, uniform contract (and the actions of Express Scripts and the other PBMs), demonstrate multiple circumstances in which the PBMs have discretionary authority over the management of health plans, have authority and control over the administration of health plans, and exercise authority and control over the health plans’ plan assets. Such circumstances include, but are not limited to, the PBMs’ authority to manage and control (i) the applicable formulary/formularies of each health plan; (ii) each health plan’s (or other client’s) contractual rights to a share of manufacturer rebates paid to Express Scripts (and other PBMs); (iii) benefit claims from individual health plan participants, and (iv) the selection and retention of the adjudicator of health plan participants’ appeals of their denied benefit

³⁴ *Id.*

³⁵ “As the Clock Ticks for Exclusion Opt-Ins, Payers Ponder Access, Disruption, Savings”, *Drug Benefit News*, Vol. 15, Issue 26 (Sept. 12, 2014).

claim.

c) **PBMs Have Discretion, Authority And Control Over How Much Of The Manufacturer Payments They Keep, And How Much They Pass On To Health Plans And When**

79. Defendant PBMs generally pass through only *a portion* of specified “rebates” to client insurers and health plans.³⁶ Moreover, PBMs have written their contracts to retain for themselves all other payments from drug manufacturers like Mylan, including among other things discounts, “administrative or other fees,” and/or side deals, and thus, the Defendant PBMs keep substantially more of the moneys received from drug makers than they pass through. The result is that the Defendant PBMs profit handsomely from rebates.³⁷

80. Defendant PBMs generally retain discretion and control over the timing of any rebate-sharing remittances to their clients, assuming those PBMs have not exercised their discretion to apply those payments to other fees or adjustments at certain times. Indeed, the time period between the PBMs’ receipt of rebates from the manufacturers and the PBMs’ remittance of their clients’ contractual share of those rebates can extend as long as 6 months.

81. In addition to rebates, drug companies like Mylan often pay Defendant PBMs substantial amounts of various “administrative fees” in exchange for, among other things, ensuring a given drug’s formulary placement.³⁸ As Express Scripts states in its template contract with Flint,

³⁶ *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/>.

³⁷ “How to Dramatically Decrease Your MCO’s Rx Coverage Costs,” Managed Care, April 1, 2008.

³⁸ Henry C. Eickelberg, *The Prescription Drug Supply Chain “Black Box” — How it Works and Why You Should Care*, Am. Health Pol’y Inst. (2015), available at 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*

Michigan:

ESI provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price, or (ii) 5.5% of the wholesale acquisition cost of the products. In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These service fees are not part of the formulary rebates or associated administrative fees.³⁹

82. As industry expert Linda Cahn observed “[i]f a PBM enters into contracts with drug manufacturers and chooses to give rebates another name — like administrative fees or health management fees or grants — the PBM will arguably eliminate its obligation to pass through the financial benefits to its clients.”⁴⁰ Additionally, “a PBM can deprive its clients of rebates by ensuring the rebates are paid on the basis that is not attributable to the clients’ drug purchases.”⁴¹

83. PhRMA, an industry trade group of pharmaceutical manufacturers, has explained:

In addition to rebates, PBMs often *require* manufacturers to pay

Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An “Accounting” Procedure, Nat’l Prescription Coverage Coalition (NPCC), available at <http://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/>.

³⁹ Sample Form of PBM Agreement with Express Scripts, Inc., Genessee County (Flint, Michigan) Purchasing Department (February 27, 2015), available at <http://nationalprescriptioncoveragecoalition.com/wp-content/uploads/2017/07/WebPage.pdf>.

⁴⁰ Linda Cahn, “Don’t Get Trapped By PBM’s Rebate Labeling Games” *Managed Care* (Jan. 1, 2009).

⁴¹ *Id.*

administrative service fees for administering, invoicing, and collecting rebate payments. These administrative fees are intended to reimburse the PBM for services provided to the manufacturer and are not generally passed on to the PBM's client.⁴²

84. Altarum, a nonprofit research and consulting organization that works with governments and private insurers to improve health outcomes for Medicare and Medicaid beneficiaries, stated:

The concern is that PBMs, in their role as intermediaries, have diverted much of the potential savings to their own bottom lines, a concern intensified by the lack of transparency around the proprietary rebate amounts. Examples include PBMs retaining more than their agreed upon share of rebates through re-labeling rebates as fees and PBMs pressuring manufacturers to increase their list prices with a commensurate increase in rebates. This benefits PBMs doubly since they are often paid a percentage of list price and also retain a share of rebates.⁴³

85. For example, in a February 14, 2017 letter to HHS, regarding PBM practices, one pharmaceutical company, Eli Lilly, stated that:

[There] is an emerging practice by some (but certainly not all) of these [PBM] entities to condition a manufacturer's ability to bid for federal government business on the willingness of manufacturer to accept a non-negotiable suite of administrative services at a non-negotiable rate. From Lilly's perspective, this is in effect a "pay-to-play" requirement.⁴⁴

This was echoed by Eli Lilly in April 2019, when a Lilly representative stated in response to written questions from the United States Senate, that

manufacturers are often required to pay a specified administrative fee percentage, rather than permitted to freely negotiate the amount. Often, agreeing to these fee percentages is characterized as a "bid condition" by

⁴² "Follow the Dollar," PhRMA (Nov. 2017), at 8, available at <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf> (emphasis added).

⁴³ Charles Roehrig, The Impact of Prescription Drug Rebates on Health Plans and Consumers, Altarum (Apr. 2018), at 4.

⁴⁴ Letter from Josh O'Harra, Assistant General Counsel for Eli Lilly, to Patrice Drew, Office of the Inspector General, February 14, 2017, available at <https://www.regulations.gov/document?D=HHSIG-2017-0001-0002>.

the PBMs—failure to acquiesce to this condition will result in an offer being rejected as “non-compliant.” Since these are nonnegotiable terms, manufacturers have no choice but to accept them.⁴⁵

Thus, according to Eli Lilly, drug manufacturers are paying administrative fees (which do not flow to the health plans to any significant extent) to PBMs in exchange for formulary placement.

86. Administrative fees can make up a substantial portion of the total dollar amount of drug company payments to a PBM. According to Dross, the pharmacy-benefits consultant who has been cited in Senate testimony, administrative fees can amount to 25-30% of total payments from drug companies like Mylan.⁴⁶ Similarly, Express Scripts revealed in a 2017 lawsuit that it filed against one drug manufacturer that it kept 13 times more in administrative fees than it passed back to its clients through “rebates.”⁴⁷

87. That the Defendant PBMs have, in fact, retained increasing amounts of rebates and fees for themselves is demonstrated by a March 2019 Pew Center study which analyzed manufacturer rebate levels, health-plan drug expenditures and PBM revenues from drug expenditures during the period 2012-2016.⁴⁸ That study found that even though manufacturers

⁴⁵ April 10, 2019 answers by Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company, to written questions by Committee on Energy and Commerce Subcommittee on Oversight and Investigations at 14, available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Bio-MasonM-20190410-U2.pdf>.

⁴⁶ David Dross, *Will Point-of-Sale Rebates Disrupt the PBM Business?*, Mercer (July 31, 2017), available at <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>.

⁴⁷ <http://nationalprescriptioncoveragecoalition.com/express-scripts-lawsuit-should-raise-everyones-eyebrows/>. According to Express Scripts’ complaint, it entered into “rebate agreements” with the drug manufacturer, which required the manufacturer to pay Express Scripts far more in “administrative fees” than the manufacturer paid in “formulary rebates.” The administrative fees were about 13 times the rebates.

⁴⁸ *The Prescription Drug Landscape Explored, A look at retail pharmaceutical spending from 2012 to 2016*, March 2019 Pew Center Report, available at <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>.

paid greater rebates during the period 2012-2016,⁴⁹ those rebates did not actually reduce health-plan expenditures on drugs — which increased by 66% from 2012-2016.⁵⁰ The report observed that as health plans were being forced to spend more and more on drugs, PBM revenues virtually doubled because they retained increased percentages of rebates for themselves and increasingly took their payments from manufacturers in the form of “fees” that they did not share with their clients.

88. The Pew Center report estimated that

- in 2012, PBMs retained \$11.6 billion in rebates and fees related to drug expenditures (which was composed of \$5.7 billion in manufacturer rebates and \$5.9 billion in manufacturer fees), which constituted 4.6% of total Prescription Drug spending.
- by 2015 (3 years later), PBMs retained \$18.2 billion in rebates and fees related to drug expenditures (which was composed of \$7.8 billion in manufacturer rebates and \$10.4 billion in manufacturer fees), which constituted 5.6% of total Prescription Drug spending.
- by 2016 (4 years later), PBMs retained \$22.4 billion in rebates and fees related to drug expenditures (which was composed of \$5.8 billion in manufacturer rebates and \$16.6 billion in manufacturer fees), which constituted 6.6% of total Prescription Drug spending.⁵¹

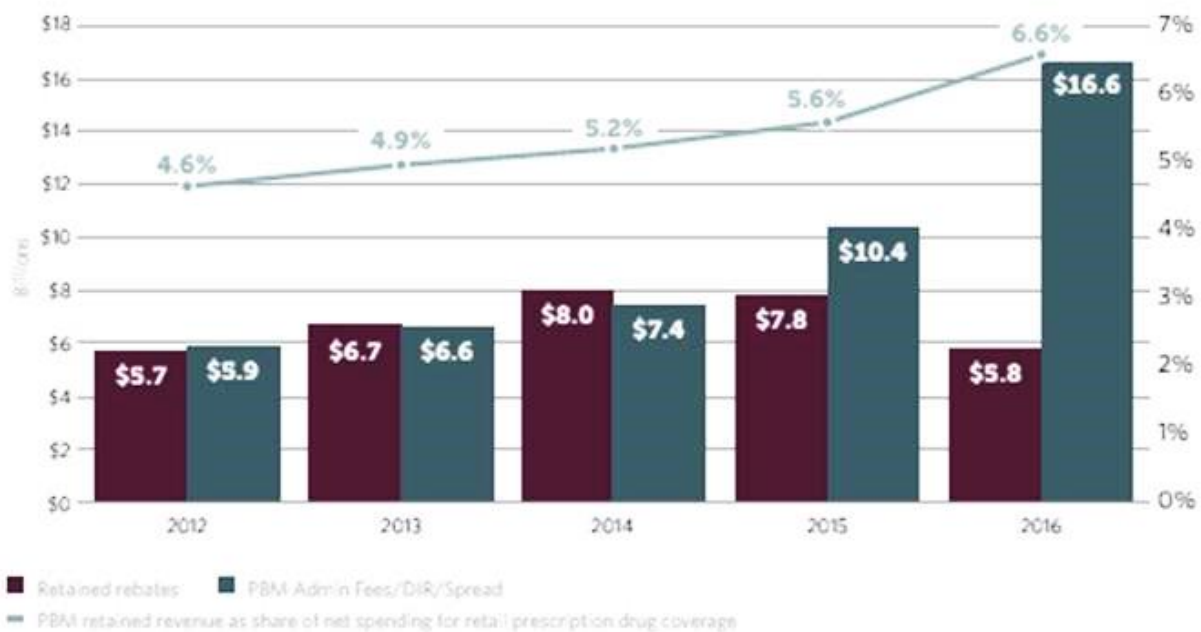
⁴⁹ Manufacturer rebates increased from \$10.2 billion in 2012 to \$29.1 billion in 2016. *Id.* at 9.

⁵⁰ In 2012, \$110.6 billion in commercial health plan premiums went to pay for retail prescription drugs, and by 2016 \$183.9 billion of commercial health plan premiums went to pay for retail prescription drugs — a 66% increase in drug expenditures over a four-year period. *Id.* at 8.

⁵¹ *Id.* at 13.

Figure 9

PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



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In the chart above from the Pew Center report, the red bars reflect rebates retained by PBMs and the grey bars reflect various types of PBM fees. The chart reflects that over a four-year period, while health-plans and consumers were forced to spend more on drug expenditures because of surging drug prices, PBM revenues virtually doubled (from \$11.6 billion to \$22.4 billion) because: (a) through 2015 PBMs retained more and more manufacturer rebates, and (b) service fees and other forms of revenue (which are not shared with health plan clients) nearly tripled. Notably, PBM-retained rebates and fees increased not only in total dollar terms, but also as an increasing percentage of total drug expenditures. Thus, at a time when health plans and consumers were forced to spend more on drug expenditures because of surging drug prices, PBMs, including Defendant PBMs, were increasing the percentage of drug expenditures they kept for themselves.

89. Thus, while Defendant PBMs pass some rebates and fees back to the plans, they also retain a large portion of such moneys, in part through misleading labeling of the various rebates and fees they receive from drug companies like Mylan. This lack of transparency, and the Defendant PBMs' central role in ensuring it, gives the PBMs authority and discretion to label the payments that they negotiate with Mylan such that they retain control over the amount of kickbacks they keep for themselves. Thus, the hard bargains Defendant PBMs purport to drive for their clients — the plans or their participants and beneficiaries — are, in reality, for the benefit of the Defendant PBMs themselves.

90. As the foregoing allegations reflect, the PBMs retain significant discretion, control and authority over the health plans' contractual rights to a share of the rebates paid to the PBMs, as evidenced by various passages from Express Scripts' standard, uniform contract, such as:

ESI will pay to TPA (or Client, if instructed in writing by TPA) an amount equal to the Rebates specified...subject to.... compliance with other reasonable, generally applicable requirements for participation in the Rebate Program, as are communicated by ESI to TPA from time to time. Further, ESI and TPA each understand that market conditions, patent status and other factors may influence Formulary decisions from time to time, and eligibility to receive payments for Rebates may change over time due to changes in laws governing prescription drug pricing (including Rebates, or changes in ESI's contracts with pharmaceutical manufacturers, or due to changes in interpretation of existing laws). Upon notice to TPA, ESI shall have the right to make an equitable adjustment to the Rebates if a Client changes its Formulary, benefit design or otherwise takes action that has the effect of lowering the amount of Rebates eligible to be earned with respect to such Client, or Rebate revenue is materially decreased because of brand products moving off-patent to generic status.

* * *

ESI shall have the right to apply Rebates to unpaid Fees and shall have the right to delay payment of Rebates to allow for final adjustments upon termination of this Agreement.

* * *

In the event that TPA, any Client, or any of TPA's or Client's affiliates or agents negotiates or arranges with a pharmaceutical manufacturer for rebates or similar

discounts for any Covered Drugs hereunder, but without limiting ESI's rights to other remedies, ESI may withhold Rebates earned by, but not yet paid to TPA as necessary to prevent duplicative rebates on Covered Drugs.

These passages are replete with undefined and ambiguous phrases (such as “generally applicable,” “market conditions,” “other factors,” “from time to time,” “equitable adjustment,” “materially decreased” and “otherwise takes action”) which provide Express Scripts with the ongoing discretion and authority to decrease or even nullify its contractual obligation to share rebates with the health plans.

91. PBMs also retain the discretion, control and authority whether to classify payments they receive from manufacturers as “rebates” or “fees” or some other classification. The PBMs’ power to determine how payments are classified and labeled gives the PBMs ongoing discretion and authority to substantially decrease (or even nullify) health plans’ contractual right to payments.

d) The PBMs Are Supposed To Act For Their Clients’ Benefit and Further Their Clients’ Interests in Lowering Drug Costs.

92. The Defendant PBMs understand and have acknowledged that: (a) they are supposed to be negotiating rebates on behalf of their clients, for their clients’ benefit, (b) the PBMs’ rebate negotiations and formulary decisions are supposed to be consistent, and in accordance with, their clients’ larger, overall interests of reducing drug costs, and (c) the PBMs’ clients rely on the PBMs to perform their functions in the clients’ interests.

93. Over the last decade (if not longer) the Defendants PBMs have marketed themselves to health care plans and other clients as a tool to reduce drug spend. For example, on its website, Defendant Express Scripts states that “We lower the cost of prescription drugs for our clients and members,”⁵² and in its 2016 Annual Report at page 3, Express Scripts represented that

⁵² <https://web.archive.org/web/20120717150752/http://express-scripts.com/services/becomeaclient/businessprinciples/>.

“we level the playing field, allowing smaller payers the same access to rebates as larger payers. These rebates materially drive down our clients’ drug trend and help keep healthcare affordable.” Similarly, in a September 2013 letter to the Pennsylvania House of Representatives Committee on Health, Express Scripts stated that “Our company’s mission is to make prescription drugs safer and more affordable.”

94. Likewise, in its 2013 Annual Report, CVS Caremark described its strategy, stating: “Can we give patients more while payors spend less? We are uniquely positioned to engage members and promote healthier, cost-effective behaviors. At the same time, we are helping payors to reduce health care costs and improve outcomes.” Finally, OptumRx’s parent company, United HealthCare, represented through its CEO Steve Hemsley in the 2013 Annual Report that “UnitedHealth Group’s capabilities continue to grow to serve and enable a more effective, modern health care system, and to respond to a national imperative to improve the performance of health care and reduce its costs.”

95. The Defendant PBMs have not only promoted their supposed ability to reduce drug costs, but also have also acknowledged that while they are compensated for their services: (a) they should not be negotiating rebates and making formulary decisions solely to benefit themselves; and (b) they should be acting on their clients’ behalf and consistently with their clients’ interests. For example, in 2003, Express Scripts enacted its “client pledge” pursuant to which Express Scripts promised to “always align its interests” with its clients and members. Similarly, in December 2011, the Chairman and CEO of Express Scripts (George Paz) testified before a Senate Committee that:

PBMs save plan sponsors and consumers money . . . We negotiate with the big drug manufacturers and retail pharmacies across the United States to get the best possible price for our clients. *Our business model is one of alignment. We make money when plan sponsors and consumers save money.* . . . Our mission is to reduce the costs of

prescription drugs, and that involves measured, tough negotiations with retail pharmacies and pharmaceutical manufacturers. . . .

Our job is to bring down the cost both for the patient and the plan sponsor and do what is right. We are not tied to whether it's a brand or a generic. We want the lowest cost possible for our members to drive down the cost of health care. That is our most important mission.

Likewise, an Express Scripts representative testified before Congress in April 2019:

Express Scripts uses clinical expertise and scale to negotiate lower drug costs with drug manufacturers, leveraging competition *to help drive savings for clients*, which include employers, labor unions, health plans, the federal government, and states. These negotiations serve to create competition in the market for prescription drugs. The discounts negotiated in the supply chain *for our clients* ultimately benefit patients in the form of lower premiums and reduced out-of-pocket costs.”⁵³

96. Similarly, in April 2019, an Optum Rx representative testified before Congress in April 2019:

OptumRx negotiates better prices with drug manufacturers *for our customers* and consumers. OptumRx delivers value for our customers and the consumers we serve through a number of services, including negotiating lower drug costs . . . It is important to recognize that pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working *to reduce costs for their customers and the only ones able to effectively negotiate with drug companies*. OptumRx manages pharmacy benefits *on behalf of customers*, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and federal and state government employee plans.⁵⁴

Likewise, a Caremark representative testified before Congress in April 2019 that:

We negotiate the best possible discounts off the manufacturer's price *on behalf of*

⁵³ April 10, 2019 Written Testimony, Amy Bricker, Express Scripts Senior Vice President, Before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations at 4 (emphasis added), available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-BrickerA-20190410.pdf>.

⁵⁴ April 10, 2019 Written Testimony, Sumit Dutta, M.D., Chief Medical Officer, OptumRx, Before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, at 2 (emphasis added), available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf>.

employers, unions, government programs, and the beneficiaries that we serve.⁵⁵

97. Furthermore, most health plans (if not all) and other PBM clients rely upon the Defendant PBMs' formulary recommendations because, as alleged herein, they do not have clinicians on staff and/or they do not have complete information about all of the PBMs' negotiations with, and payments from, manufacturers. Consequently, they do not even question their PBM's formulary, much less design their own. As the PCMA (the PBM trade association) stated in its August 2007 presentation:

“It cannot be doubted that employer-provided ERISA plans' reliance on PBMs to provide and administer prescription drug benefits has reduced the cost of those benefits significantly.”

“PBMs perform a variety of crucial functions that employers cannot perform themselves, virtually all of which result in substantial savings in the costs of providing prescription drug benefits.”

Likewise, the PCMA testified to the Pennsylvania House of Representatives that even sophisticated insurers and health plans rely on PBMs to manage their drug benefit:

PBMs' clients are sophisticated purchasers of health care, including health plans, insurers, major employers, unions, the federal government, and state and local governments *that rely on PBMs to manage their drug benefit.*

With the rising costs of health care, *employers rely on PBMs to help keep prescription drug costs down . . .*⁵⁶

⁵⁵ April 10, 2019 Written Testimony, Thomas M. Moriarty, Executive Vice President, Chief Policy and External Affairs Officer, and General Counsel for CVS Health, Before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations at 1 (emphasis added), available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-MoriartyT-20190410.pdf>.

⁵⁶ Letter from PCMA to the Matthew E. Barker, Pennsylvania House of Representatives, House Comm. On Health (Aug. 28, 2013) (emphasis added).

Similarly, in a November 2017 slide presentation, the FTC stated that “Employers *rely* on PBMs to help them navigate drug pricing and plan benefit design.”⁵⁷

98. As alleged, herein, despite the PBMs’ acknowledgement that they are supposed to negotiate rebates and make formulary decision on behalf of their clients, for their clients’ benefit, and consistently with their clients’ interests in lowering drug costs, the PBMs have not actually done so. To the contrary, the PBMs have used their power to negotiate rebates and fees, and to control the formulary structures, to benefit themselves by favoring high-list-priced drugs (which generate larger payments much of which the PBMs have kept for themselves), even though that is contrary to their clients’ interests.

C. Mylan Paid Bribes And Kickbacks To Defendant PBMs To Impede Competition And Maintain Its Ability To Charge Supra-Competitive Prices

1. The Defendant PBMs Are Ripe Targets To Be Bribed To Use Their Formulary Control To Favor Higher-Priced Drugs

99. As alleged above, historically, PBMs that acted in their clients’ interests used their formulary power to favor lower-priced drugs in order to force down drug list prices (or slow the growth of list prices). However, during the last decade the Defendant PBMs have been bribed to eliminate the price-disciplining effects from competition. Because so much of the rebates and fees flow into the Defendant PBMs’ coffers (rather than being paid to their clients), the Defendant PBMs benefit from higher WAC prices because they result in higher rebate and fee payments that they keep for themselves (even though doing so is contrary to the interests of the PBM’s clients).

100. The rebates and administrative fees that the Defendant PBMs receive for a drug are

⁵⁷ Federal Trade Commission, “Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics”, at Slide 118, (Nov. 8, 2017), available at https://www.ftc.gov/system/files/documents/public_events/1255653/understanding_competition_in_prescription_drug_markets_workshop_slides_11-8-17.pdf

usually calculated as a percentage of the dollar value of a drug's usage based on its WAC list price — such as 30% of a drug's total unit volume purchases by the PBM's clients multiplied by the WAC list price per unit. The total amount of a drug's purchases (and thus the total amount of the rebates and fees paid to a PBM for that drug) are driven by two factors: a drug's list price (WAC or AWP, which is typically WAC plus 20%), and its sales volume. For example, the total purchase amount for 1000 units of a \$300 drug is \$300,000, and the total purchase amount for 1000 units of a \$100 drug is \$100,000. If a PBM receives a 30% rebate for both drugs, then the PBM receives \$90,000 in rebates for the \$300 drug, and \$30,000 for the \$100 drug. In that context, it is in the PBM's interest to drive sales to the higher-priced \$300 drug, even though that is contrary to the financial interests of its clients who pay the higher prices but do not receive many of the accompanying rebates and fees that are kept by the PBM.

101. Furthermore, the Defendant PBMs benefit from large, annual list price increases by drug manufacturers that occur during the life of a multi-year contract for two reasons. First, increases in a drug's list price increase the dollar-amount of the rebate and fee payments that the PBMs get to keep. For example, if a PBM receives a 30% rebate on 1000-unit sales of a \$300 drug, if the drug price increases by \$100 per unit, then the PBM's rebates increase by \$30,000 (from \$90,000 to \$120,000).

102. In addition, large drug price increases during a multi-year contract can generate additional fees and rebates to PBMs in the form of "price-protection" benefits that Defendant PBMs do not share with their health plan clients. A recent report on the drug industry noted that, in addition to rebates used to purchase formulary access and market share, price/inflation protection rebates also incentivize drug manufacturers to raise list prices and thereby compensate Defendant PBMs for formulary placement:

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.⁵⁸

As OptumRx's CEO candidly admitted in an October 15, 2016 interview with *Modern Healthcare*, "the largest players" in the PBM industry — the Defendant PBMs — "actually benefit from price increases."⁵⁹

103. This has created a perverse incentive for: (a) the Defendant PBMs to give preferential formulary status to higher-priced drugs which come with higher payments to the PBMs, even if doing so is contrary to their clients' interest in favoring lower-priced drugs; and (b) for drug manufacturers such as Mylan to use high rebate and fee payments to purchase favorable formulary status from Defendant PBMs, instead of trying to ensure favorable formulary status by lowering list prices or limiting list price increases.

104. The Defendant PBMs' interest and benefit in favoring high-priced drugs and large price increases (contrary to their clients' interests) makes them ripe targets to be bribed by brand manufacturers such as Mylan who pay kickbacks (*i.e.*, rebates that flow into the Defendant PBMs' coffers and not to the clients) to gain the ability to raise list prices without being penalized by the

⁵⁸ Richard Evans, Scott Hinds, & Ryan Baum, US Rx Net Pricing Trends Thru 2Q16, SSR LLC, 36 (Oct. 5, 2016).

⁵⁹ *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>.

PBMs. In a March 7, 2018 speech to America’s Health Insurance Plans’ (“AHIP”) National Health Policy Conference, FDA Commissioner Scott Gottlieb discussed how the PBMs have “misaligned incentives” which cause them to “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.”⁶⁰ In essence, rather than using their control over day-to-day formulary decisions to penalize manufacturers who charge excessive prices, PBMs can be bribed with a share of excessive, supra-competitive prices that flow into their pockets not just to look the other way while brand manufacturers (such as Mylan) raise list prices, but to actively encourage it.

105. In fact, PBMs actually work to discourage price reductions. As the drug-makers’ trade association, PhRMA, has stated:

Under the current system, the revenues PBMs earn on medicines could decline if the prices of medicines were to decrease. . . . **[A] hypothetical manufacturer’s unilateral decision to lower list price could result in a PBM then taking action to significantly reduce formulary access for that manufacturer’s medicine . . .**

* * *

Similarly, OIG has observed that “[t]he prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs” and that under the current system, **PBMs may have incentives to penalize manufacturers for reducing list prices, including removing medicines from the formulary or placing them on a less-preferred formulary tier. Information published by industry analysts shows that similar penalties may exist if manufacturers attempt to lower list prices without modifying their contract terms to provide a corresponding increase in the rebates received by the PBM.**⁶¹

⁶⁰ Scott Gottlieb, M.D., Capturing the Benefits of Competition for Patients (March 7, 2018), available at <https://www.fda.gov/news-events/speeches-fda-officials/capturing-benefits-competition-patients-03072018>.

⁶¹ Letter from PhRMA, to Daniel R. Levinson, Office of the Inspector General, April 8, 2019, at 15-16 (emphasis added) (citing Carolyn Y. Johnson, “In May, Trump predicted the pharmaceutical industry would cut prices in two weeks. It hasn’t happened yet.” THE

Analysts have also observed that PBMs' earnings would "take a direct hit if drug companies began to slow down on price hikes."⁶²

106. Indeed, Defendant PBMs have implemented policies that penalize drug makers who lower their list prices. For example, Defendant OptumRx informed manufacturers in a letter that OptumRx wants 18 months advance notice before a manufacturer lowers a drug's list price, and if a price reduction occurs then OptumRX wants the manufacturer to increase the rebate percentage so that OptumRx receives the same dollar rebate amount. Under Optum Rx's policy, a manufacturer that lowered a drug's list price would face a double negative financial effect – reduced revenues from a lower list price per unit, and further reduced revenues from having to pay an increased rebate percentage. This deters manufacturers from lowering their list prices. As an Eli Lilly representative stated in response to written questions from the United States Senate regarding OptumRx's letter:

some PBMs have indicated that manufacturers must maintain the total dollar amount of rebates paid to them even if the list price of a prescription medication is reduced. Indeed, the above-referenced letter proposed an alternative rebate calculation whereby Lilly would be required to pay the same amount of rebate dollars on a prescription drug with a lower list price. Such demands make it difficult for Lilly to reduce list prices and retain comparable levels of patient access on PBM formularies.⁶³

WASHINGTON POST (June 26, 2018) (pharmaceutical manufacturers "argue that PBMs that make their money off negotiating rebates may prefer a competing drug with a higher list price and a bigger rebate."); Max Nisen, "Pharma's Quieter Price War Continues," BLOOMBERG BUSINESSWEEK (Aug. 3, 2007).

⁶² Linette Lopez, "These companies you've never heard of are about to incite another massive drug price outrage," BUSINESS INSIDER (Sep. 12, 2016), available at <https://www.businessinsider.com/scrutiny-express-scripts-pbms-drug-price-fury-2016-9>.

⁶³ April 10, 2019 answers by Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company, to written questions by Committee on Energy and Commerce Subcommittee on Oversight and Investigations, at 12, available at <https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Bio-MasonM-20190410-U2.pdf>.

107. These policies are evidence that in order to share in the excessive, supra-competitive prices, Defendant PBMs have derogated their duty of fidelity and/or fiduciary duty by adopting policies that are contrary to their clients' interests in lower drug list prices. Almost half of those surveyed by the National Pharmaceutical Council expressed the view that rebates contributed to misaligned incentives that put Defendant PBMs' business interests before those of their clients or patients.⁶⁴

108. The problem has grown so significant that in February 2019 HHS proposed a rule to change how PBMs are compensated. Although the proposed rule was ultimately withdrawn, the commentary from the Secretary of Health and Human Services and the Inspector General was not, and remains accurate and relevant. The Federal Register notice for comment stated, *inter alia*, as follows:

The prominence of rebate arrangements in the prescription drug supply chain has been cited as a potential barrier to lowering drug costs. For instance, **the system may create incentives for manufacturers to raise list prices and discourage manufacturers from reducing their list prices or, in some cases, penalize them if they do.**

Often, a portion of PBM compensation is derived from the savings they create, or the gap between the list price and "net price." This compensation may be derived from retaining a portion of the rebate, as well as receiving "price protection" payments from manufacturers. Rebates and price protection payments increase when list prices increase. Thus, there may be a greater incentive for a PBM to encourage the use of drugs with higher list prices, typically via preferred formulary placement, than the use of lower price drugs that would generate lower rebates or price protection payments. **A manufacturer choosing to lower the list price of a drug would be reducing the gap between list price and "net" price, which would reduce either the size of the rebate or price protection guarantee. This could result in a drug being removed from the formulary or being placed in a less-preferred formulary tier.** As a result, the current system works to the

⁶⁴ National Pharmaceutical Council, *Toward Better Value: Employer Perspectives on What's Wrong With the Management of Prescription Drug Benefits and How to Fix It* (October 2017), available at <http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf>.

disadvantage of beneficiaries, and the Federal health care programs.⁶⁵

109. The Secretary of Health and Human Service’s and Inspector General’s observations have been echoed and confirmed by various entities throughout the health-care industry. For example, the Alliance for Transparent and Affordable Prescriptions (which represents various patient and provider groups⁶⁶) stated in comments to the Proposed Rule that:

[O]ur current system is such that the patient is encouraged to use the product that provides the most rebate potential to the PBM. Throughout the proposed rule, OIG highlights that the current rebate structure may actually result in PBMs placing more expensive products in a preferred formulary position over less expensive equivalents. This is because a more expensive product generates a higher rebate. This system benefits no one but the PBM.

The current rebate system encourages pharmaceutical manufacturers to set high list prices, as these prices are just the starting point of negotiations with the PBM. OIG notes that this system is a “potential barrier to lowering drug costs.”

* * *

If net prices are flat or even declining, why do patients have more trouble than ever affording the medicines they need? The answer is that little of these savings make it to patients, because the “savings” are absorbed by the middlemen as revenue. Rebates are not savings for patients; they are income for PBMs.⁶⁷

⁶⁵ Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefits Manager Service Fees, A Proposed Rule by the Health and Human Services Department, 84 Fed. Reg. 2340 (Feb. 6, 2019) (emphasis added), available at <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

⁶⁶ American Association of Clinical Urologists, American College of Rheumatology, Association of Women in Rheumatology, California Rheumatology Alliance, Coalition of State Rheumatology Organizations, Florida Society of Rheumatology, Global Healthy Living Foundation, International Foundation for Autoimmune & Autoinflammatory Arthritis, Lupus and Allied Diseases Association, Inc., National Infusion Center Association, National Organization of Rheumatology Managers, New York State Rheumatology Society, North Carolina Rheumatology Association, Ohio Association of Rheumatology, Rheumatology Alliance of Louisiana, Rheumatology Nurses Society, South Carolina Rheumatism Society, Tennessee Rheumatology Society, and U.S. Pain Foundation.

⁶⁷ Letter from Alliance for Transparent & Affordable Prescriptions to OIG (Apr. 2, 2019) at 2-

110. Likewise, Navitus Health Solutions, a 100% pass-through PBM⁶⁸ stated in comments to the HHS Proposed Rule that:

[T]raditional PBM business models may drive up drug expenses by promoting higher cost agents in their quest to secure higher rebates from drug manufacturers because traditional PBMs often keep a portion of the rebates that they negotiate.

[R]ebates from drug manufacturers warp the incentives that PBMs are operating under, creating a market dysfunction where the goals of CMS and the Part D plans are not aligned with those of the PBMs providing services to the plans. For PBMs, the amount of rebates that are paid to Part D plans are often used as a rough measure of performance by the plans and their consultants in the process of PBM service acquisition and ongoing PBM services. However, higher rebates are not necessarily a good proxy for lower costs. ... When PBMs choose drugs with higher rebates but higher costs over comparable drugs with lower overall costs, then the total costs can be significantly higher for the plans and CMS in spite of the higher rebates.

* * *

If drug manufacturers are paying PBMs money that the PBMs keep, then the PBMs have an incentive that is not consistent with goals of lowering prices and overall costs. **Instead, PBMs would have the incentive to keep manufacturers happy in order to continue receiving such payments from manufacturers. Manufacturers have the goal of increasing overall revenue**, which normally means keeping their drugs on each formulary in a preferred status to increase sale volume for their drugs at the highest prices possible. **Allowing drug manufacturers to continue to pay PBMs will allow the manufacturers to influence PBM decisions, implicitly or explicitly, including decisions to keep overpriced drugs on the formularies and continually enabling escalating drug prices**. Regardless of what payments from manufacturers are labeled, they all impact PBMs' incentives unless they are fully passed through to the plans, Part D

3, available at

<https://static1.squarespace.com/static/593e9cb8db29d6d8538e36a1/t/5ca3d2b8c8302522a6585dae/1554240185296/ATAP+--+Rebate+Rule+Letter+2019.pdf>.

⁶⁸ Unlike most PBMs, Navitus “pass[es]-through to [its] clients all of the payments that [it] receives from drug manufacturers in the form of rebates, incentives, administrative fees, data fees, and any other amounts that [it] receives from drug manufacturers.” Testimony of Brent Eberle, R.Ph, MBA, Chief Pharmacy Officer, Navitus Health Solutions, to the U.S. House of Representatives, Energy and Commerce Committee Subcommittee on Health on May 9, 2019, at 1, available at <https://docs.house.gov/meetings/IF/IF14/20190509/109436/HHRG-116-IF14-Wstate-EberleB-20190509.pdf>.

beneficiaries, or CMS and used to reduce overall drug prices.⁶⁹

2. Mylan Paid Bribes To The Defendant PBMs To Eliminate The Price-Curbing Effects Of Competition

111. As alleged above, in early 2013, EpiPen started facing competition from Auvi-Q, a competing, bioequivalent, branded EAI device sold by Sanofi. At the time, Sanofi was already well-known in the allergy space for the drug Allegra, and it brought its resources and reputation to Auvi-Q. Sanofi spent tens of millions of dollars promoting Auvi-Q and educating physicians and key allergy awareness groups on the benefits of Auvi-Q. Sanofi also hired a large sales force to compete with Mylan.

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

113. In addition, in early 2013, Impax Laboratories started offering an EAI device at much lower prices than EpiPen. The Impax EAI was an authorized generic version of an EAI previously sold under the brand name Adrenacllick.

114. Rather than lower its prices in response to competition from Auvi-Q, Mylan aggressively increased EpiPen's list price in order to increase the rebates and administrative fees it paid to PBMs, including Defendant PBMs, in exchange for: (a) Mylan's ability to raise its prices without penalty, and/or (b) formulary exclusivity. Before the launch of Auvi-Q, EAI's were considered a "managed" product category; that is, PBMs historically did not place competing

⁶⁹ Letter from Paul M. Page, General Counsel of Navitus Health Solutions to Aaron Zajic, Office of Inspector General, Department of Health and Human Services (April 5, 2019) at 1, 3 (emphasis added).

injectors into different status tiers or otherwise “prefer” one product over another. Before the launch of the Auvi-Q, Mylan did not typically offer rebates for the EpiPen and, where it did so, Mylan’s rebates were generally low, often below 10%. After Auvi-Q launched, Mylan entered into long-term, multi-year contracts which offered much larger rebates — 30% or higher. Heather Bresch, Mylan’s former CEO, told investors on a Q4 2015 Earnings Call that “in a very competitive multi-epinephrine marketplace ... we were maintaining market share. And to do so, that required aggressive rebating.”⁷⁰

115. In a series of 2019 court filings in an antitrust suit between Mylan and Sanofi, Mylan has admitted that, starting in or about 2013: (a) Mylan was concerned about formulary placement and price competition as a result of Sanofi’s entry; and (b) Mylan paid increased rebates and fees to large PBMs in exchange for favorable (if not exclusive) formulary placement. These are the very type of payments that the Secretary of Health and Human Services has opined would violate the “Anti-Kickback Act” (42 U.S.C. § 1320a-7b(b)(2)), especially where the payments went into the PBM coffers and did not flow down to the clients.⁷¹ Mylan’s decision to obtain favorable formulary placement through payments to PBMs rather than lowering its list prices (or limiting its price increases) reflects Mylan’s understanding that the PBMs kept a significant amount of the payments for themselves and could be coopted by such payments.

116. Mylan gave these improper bribes and kickbacks to the Defendant PBMs not only to maintain EpiPen’s formulary status, but also to exclude or restrict Auvi-Q and/or the authorized

⁷⁰ Mylan Q4 2015 Earning Conference Call, Feb. 10, 2016.

⁷¹ As alleged below, the Secretary of HHS has said that there is no “safe harbor” for formulary placement payments because “[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary’s [of HHS] view, such a payment would not qualify as ‘a discount or other reduction in price.’” 82 F.R. 2340, at 2340 n.1. *See also id.* at 2343 (“To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption.”).

generic form of Adrenaclick from various formularies. In the Sanofi-Mylan antitrust case, Mylan admitted that: (a) Mylan paid some PBMs rebates specifically for formulary exclusivity (*i.e.* with EpiPen being the only EAI on the formulary), and/or formulary advantage (*i.e.*, better tier placement and terms) versus other EAI products such as Auvi-Q; and (b) in exchange for the increased rebates and fees, Mylan did, in fact, receive either complete formulary exclusivity (*i.e.* with EpiPen being the only EAI on the formulary), and/or formulary advantage (*i.e.*, better tier placement and terms) versus other EAI products. For example, from 2013-2015, seven PBMs made up 86% of the commercial market (CVS Caremark, Express Scripts, OptumRx, Aetna, MedImpact, Prime, and Cigna). Four of these (Express Scripts, OptumRx, Aetna, and MedImpact) excluded or restricted Auvi-Q and (the authorized generic (“AG”) version of) Adrenaclick in 2014.⁷² Three major ones (CVS, Prime, and Cigna) gave Auvi-Q formulary coverage, but behind EpiPen.⁷³ Mylan did not obtain its formulary advantages through lawful price discounting, but rather through illegal bribes and kickbacks.

117. Because, as alleged above, over 85% of EAI sales were covered by private/commercial health-plans and insurers during the 2013 to 2015 period, formulary coverage was crucial for a product to enter and compete vigorously in the EAI drug device market. The devices are almost exclusively distributed to individual patients and caregivers rather than through

⁷² OptumRx and Express Scripts excluded Auvi-Q from their respective formularies starting in July 2013 and July 2014, respectively. Medimpact and Aetna imposed on Auvi-Q “step-edits” which significantly restrict a products usage, in July 2013 and January 2014, respectively. Prior to those exclusions/restrictions, Auvi-Q was listed on the formularies at Tier 3, while EpiPen had preferential coverage at Tier 2.

⁷³ For example, while both EpiPen and Auvi-Q were covered on the CVS Caremark formulary from July 2013 to July 2014, EpiPen was covered on Tier 2 and Auvi-Q was covered on Tier 3. Similarly, Prime Therapeutics placed EpiPen as the exclusive EAI device on Tier 2 on its national formulary in 2014, with Auvi-Q on Tier 3. From January 2013 through late 2015, Cigna covered EpiPen as the preferred brand on Tier 2 of its main national formularies, and Auvi-Q as the non-preferred brand on Tier 3.

hospitals or other health care providers. Further, because they are necessary, life-saving devices, patients generally will not tolerate a lengthy appeals process to get coverage if their prescribed EAI drug device is not readily available — they will simply choose the device that is covered with no hassle. Thus, market access is based almost entirely on contracts with third-party payors, effectively meaning PBMs.

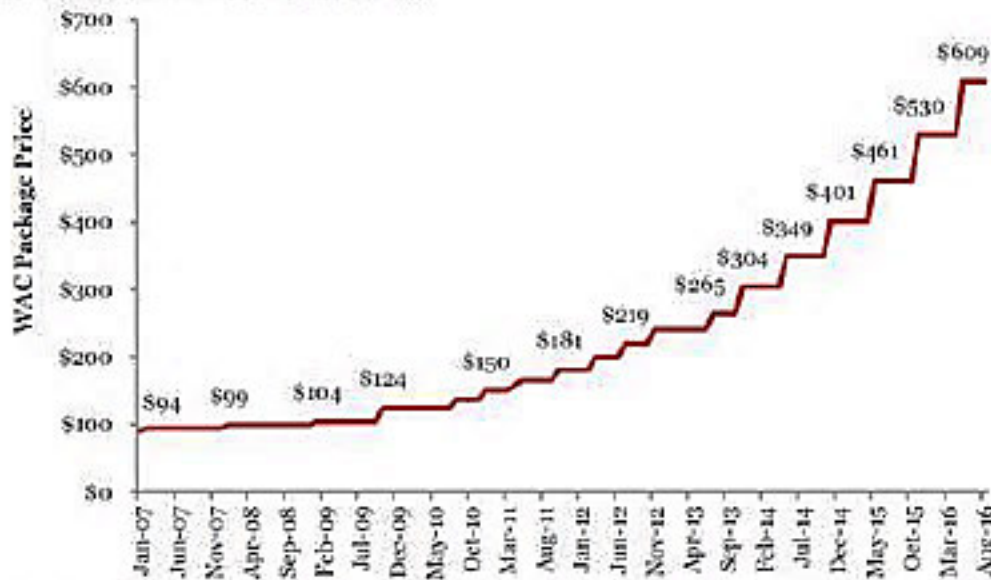
D. After Using Bribes And Kickbacks To Eliminate Defendant PBMs' Incentives To Curb Mylan's Pricing Power, Mylan Aggressively Raised EpiPen Prices

118. The purpose and effect of Mylan's scheme were to (a) eliminate the Defendant PBMs' motivation to penalize Mylan for significant price increases; and (b) eliminate/impede the price-restraining effect of competition from rival EAI products by eliminating the threat that the Defendant PBMs would shift business to competing products. Having paid bribes and kickbacks to the Defendant PBMs and other PBMs for formulary placement for its EpiPen products, and being freed from the threat of formulary exclusion, Mylan no longer faced the threat that the Defendant PBMs would penalize it by shifting sales to competing EAI products if Mylan raised its prices too high. Thus, Mylan no longer faced the price-disciplining effects from competing EAI products, and it had carte blanche to raise EpiPen list prices. Mylan aggressively increased EpiPen prices far beyond what it would have (and could have) done absent the scheme, in order to: (a) shift the cost of its bribes and kickbacks to direct purchasers, such as Plaintiffs (and Class members), and (b) earn increased profits by raising its prices beyond simply the amount of the bribes. The illicit, supra-competitive profits were split between Mylan and the PBMs through the bribes and kickbacks. In light of the fact that PBMs would historically penalize manufacturers who raised their prices too much: (a) it would have been economically irrational for Mylan to take the aggressive price increases it did unless it recognized that the PBMs had been coopted by the payments, and (b) the fact that Mylan did take such aggressive price increases reflects its

understanding that the PBMs had, in fact, been coopted because they kept a significant amount of the payments for themselves. Moreover, the fact that the PBMs did not make efforts to restrict Mylan’s ability to aggressively raise prices, and/or penalize Mylan after the fact, reflects that the PBMs were in fact coopted by Mylan’s payments which they significantly kept for themselves.

119. In November 2013, Mylan increased EpiPen prices by 15%, and then made five more successive increases, each by 15%, in or about May 2014, November 2014, May 2015, November 2015 and May 2016. In approximately 4 years (from 2012 to August 2016), EpiPen’s WAC price (per two-pack) almost tripled — going from \$219 to \$609.

Exhibit 1. EpiPen WAC Package Price



Source: Medi-Span, Clinical Drug Information, LLC and Wells Fargo Securities, LLC

Despite these huge price increases, Mylan’s market share has remained stable at extraordinarily high levels, and its unit sales grew from 7.3 million EpiPens sold in 2012 to 8.3 million sold in 2015.

120. There were three effects from these price increases. First, the price hikes increased the dollar value of the bribes to the Defendant PBMs. As alleged above, the bribes were set as a percentage of EpiPen volume purchases based on EpiPen list prices. As EpiPen’s list prices

increased, so did the dollar-value of the bribes to the Defendant PBMs. For example: (a) if Mylan sold 1000 units of EpiPens in July 2013 at a list price of \$219, then the total sales would be \$219,000, and the 30% bribe or kickback to PBMs would equal about \$65,000; and (b) if Mylan sold 1000 units of EpiPens in August 2016 at a list price of \$609, then the total sales would be \$609,000, and the 30% kickback to PBMs would equal about \$183,000.

121. Second, the price increases enabled Mylan to recoup the cost of the bribes by shifting the costs of the bribes to EpiPen direct purchasers (such as Plaintiffs), who are the first purchaser to pay the list price for drugs. On September 21, 2016, former Mylan CEO Bresch testified before Congress about EpiPen's high list prices. According to Bresch, \$334 of the \$609 list price for an EpiPen 2-Pak can be attributed to payments to PBMs (along with legitimate service fees to other types of entities).⁷⁴ As one commentator observed, "Bresch asserted [that] Mylan had little choice but to jack up the EpiPen list price to accommodate the middlemen's demands for rebates and fees."⁷⁵ The result is that Mylan has passed the cost of these bribes onto its direct purchasers (such as Plaintiffs), who have been forced to fund and finance Defendants' bribery scheme.

122. While the illegal bribes and kickbacks to the Defendant PBMs account for a significant portion of the list price increases, the price increases also deliver increased revenues

⁷⁴ Reviewing the Rising Price of EpiPens, Hearing before the United States House of Representatives Committee on Oversight and Government Reform (Sept. 21, 2016) (testimony of Heather Bresch, Chief Executive Officer, Mylan Inc.), available at <https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/pdf/CHRG-114hhrg24914.pdf>; CBS News, *Mylan CEO on EpiPen drug price controversy: "I get the outrage"* (Jan. 27, 2017), available at <http://www.cbsnews.com/newsepipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out.pdf>.

⁷⁵ Michael Hiltzik, *How 'price-cutting' middlemen are making crucial drugs vastly more expensive*, L.A. Times (June 9, 2017), available at <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>.

and profits to Mylan. Thus, having used the bribes and kickbacks to eliminate the Defendant PBMs' gate-keeping efforts, Mylan used the list price increases as a way of splitting the increased profits between itself and the Defendant PBMs.

123. The fact that Mylan profited from the bribes and kickbacks to the Defendant PBMs is evident from a September 2016 U.S. EpiPen Profitability Analysis that was submitted to Congress and attached to a September 26, 2016 Mylan Form 8-K filing. That U.S. EpiPen profitability analysis showed that after taking into account the cost of the additional payments to the PBMs: (a) Mylan's Operating Profit per EpiPen grew 25% from 2012 to 2013, 57% from 2012-2014, and 97% from 2012-2016, and (b) Mylan's Net Product Profitability grew 43% from 2012 to 2013, 90.4% from 2012-2014, and 148% from 2012-2016. And so, the extreme EpiPen price increases from 2013 forward not only covered the costs of the illegal PBM payments, but also enabled Mylan's EpiPen profits to soar.

124. If the purpose and effect of Mylan's payments to the PBMs were to provide real "discounts" that reduced the ultimate prices that insurers, health-plans, and consumers paid for EpiPens, then EpiPen's "net" prices and net profitability (*i.e.*, the prices and profitability after the rebates) would decline (or at least stay flat) over time. For example, if in 2012 Mylan were charging a net price (after discounts or rebates) of \$85 per EpiPen, and the entry of Auvi-Q or the Adrenaclick AG forced Mylan to pay increased rebates or "discounts" to price compete for sales, then EpiPen net prices and per-unit profits would drop. But over the four-year period after Mylan started increasing its payments to PBMs, EpiPen's Operating Profit per EpiPen rose 97% and the Net Product Profitability per EpiPen rose 148%, even after considering the costs of the payments to PBMs.

125. Thus, the bribes and kickbacks to the PBMs did not reduce the EpiPen's "net price"

to health plans at all, but rather raised it, by giving Mylan free rein to raise prices to extreme levels. For example, during much of the period from 2013-2016, the Adrenaclick AG's list price was lower than EpiPen's, yet from July 2013 to August 2016, EpiPen's WAC price almost tripled — going from \$219 to \$609. Mylan continually increased both its list and net prices without any apparent concern that it would be punished by the Defendant PBMs who would use their formulary control to shift sales to Auvi-Q or the Adrenaclick AG. The fear that Defendant PBMs would use their formulary muscle to shift sales to rival products should have limited Mylan's pricing discretion, regardless of EpiPen's marketing efforts or brand-name recognition. Indeed, Mylan has asserted that it felt the need to price compete in response to Auvi-Q's 2013 entry, yet over the four years after Mylan started increasing its payments to PBMs, EpiPen's Operating Profit per EpiPen surged 97%, and the Net Product Profitability per EpiPen leaped 148%, even after deducting the cost of the payments to PBMs. This reflects the fact that Mylan's bribes and kickbacks eliminated the price-disciplining fears that are one of the key benefits from competition, and which had been the promise of the PBMs to the clients on whose behalf they were allegedly working.

126. Because EpiPen's brand prices have not fallen since 2016, the price increases caused by the bribes remain embedded in Mylan's brand EpiPen prices. Furthermore, because the price of the authorized generic EpiPen product that Mylan introduced in December 2016 was benchmarked to the price of its branded EpiPen product, the price of Mylan's authorized generic product has been (and continues to be) inflated by the price increases enabled by Mylan's illegal payments to the PBMs.

127. Absent the illegal bribes and kickbacks (and the Defendant PBMs' derogation of their fidelity and/or fiduciary duties to their clients): (a) Mylan would not have been able to

increase EpiPen list prices to the extent it did, and (b) Plaintiffs and the other direct purchaser class members would have paid lower list prices for the branded EpiPen products they purchased. Furthermore, Mylan's bribes and kickbacks caused not only the artificial list price inflation for Mylan's branded EpiPen products, but also for Mylan's "authorized generic" EpiPen products, the list price of which is and was set as a percentage of Mylan's supracompetitive brand list prices.

V. FRAUDULENT CONCEALMENT AND TOLLING

A. Lack Of Transparency In PBM Contracts With Drug Companies Conceals The Details Of Mylan's Bribery And Kickback Conduct

128. As alleged above, for many years the PBMs have widely proclaimed to clients (and the market as a whole) that: (a) PBMs use their negotiating power to reduce costs, and (b) the PBMs are acting in the best interests of their clients. However, because many insurers/health plans (and other PBM clients) have limited (or no) information about the Defendant PBMs' contract terms with the drug manufacturers,⁷⁶ Defendant PBMs are free to negotiate the payment of money by drug makers that falls outside the contract between the PBM and the insurer/health plan (and other PBM clients). As a result, Defendant PBMs secretly collect — and retain — large amounts of drug company payments simply by labeling those drug company payments differently than payments which the Defendant PBMs partly pass through to the insurers/plans (and other PBM clients). On information and belief, these payments transcend any particular plan, because they are based on total sales of a drug across the Defendant PBMs' pool of plan clients. In short, contractual agreements often leave insurers/health plans (and other PBM clients) with little idea what the PBM is actually being paid by drug manufacturers, and whether it is all being passed

⁷⁶ *It's Time To Determine How Much Your PBM Is Depriving Your Plan Of Rebates: File An "Accounting" Procedure*, Nat'l Prescription Coverage Coalition, <https://nationalprescriptioncoveragecoalition.com/its-time-to-determine-how-much-your-pbm-is-depriving-your-plan-of-rebates-file-an-accounting-procedure/>.

through to the insurer/health plan (and other PBM clients). Many payments from drug companies to PBMs are shrouded in secrecy and difficult to track.

129. In recent years, industry experts have confirmed this problem. For example, Linda Cahn of Pharmacy Benefit Consultants, a well-known PBM consultant to health plans, noted that PBMs routinely play a “Rebate Re-Labeling Game” in their client contracts. 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.⁷⁷ The Burchfield Group, a PBM auditing company based in Saint Paul, Minnesota, has echoed this concern.⁷⁸

130. Likewise, the American Health Policy Institute has found that PBMs have responded to health plan demands that PBMs pass back 100% of drug company rebate payments by relabeling manufacturer payments as “fees” which the PBMs do not share with clients:

[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 of the rebates have been carved-off and paid to the PBM as a purchase order discounts or admin fee, etc.⁷⁹

⁷⁷ Linda Cahn, “Don’t Get Trapped By PBM’s Rebate Labeling Games” Managed Care (Jan. 1, 2009), available at <https://www.managedcaremag.com/archives/2009/1/don-t-get-trapped-pbms-rebate-labeling-games>.

⁷⁸ 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>.

⁷⁹ 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.

131. HHS has remarked that PBMs hide from insurers/health plans the flow of money from drug manufacturers. In the February 2019 Federal Register notice for its proposed rule change, HHS wrote:

3. THE REBATE SYSTEM IS NOT TRANSPARENT

In some or many instances, plan sponsors under Medicare Part D and Medicaid MCOs have limited information about the percentage of rebates passed on to them and the percentage retained by their PBMs. The terms of rebate agreements manufacturers negotiate with PBMs may be treated as highly proprietary and, in many instances, may be unavailable to the plans. For example, in a 2011 evaluation, OIG learned that some Part D plan sponsors had limited information about rebate contracts and rebated amounts negotiated by their PBMs.⁸⁰

Likewise, Congressman Earl Carter stated in a September 21, 2016 Congressional hearing that “Nobody knows how much of this is going to the pharmacy benefits manager, because there is no transparency.”⁸¹

132. Similarly, the American Benefits Council has explained that PBMs conceal from insurers/health plans the amount of moneys flowing to the PBMs from drug manufacturers:

The current rebate structure used in the marketplace is complex and opaque for many employers, making it hard for these employers as well as plan participants and beneficiaries to understand the true prices of drugs and the true value of how the rebate is calculated. While some PBMs may disclose the nature and extent of specific drug rebates, this practice varies by PBM and does not appear to be the norm across the industry.

* * *

Even more important to employers than excluding rebates from the discount safe harbor is the need for increased transparency by the PBM regarding the extent of

⁸⁰ Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefits Manager Service Fees, A Proposed Rule by the Health and Human Services Department, 84 Fed. Reg. 2340 (Feb. 6, 2019), available at <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

⁸¹ Reviewing The Rising Price Of EpiPens, Hearing Before The Committee On Oversight And Government Reform House Of Representatives One Hundred Fourteenth Congress Second Session September 21, 2016, at 65-66.

discount pricing, including but not limited to, volume-based rebates that the PBM is receiving so that plans can bargain in good faith with the PBM over the PBM's retention of these amounts. This has been a desire for some in the employer community with respect to ERISA-covered plans for years. While retirement plan service providers are generally subject to upfront disclosure of the revenue they will earn with respect to a given plan pursuant to ERISA Section 408(b)(2), as well as back-end reporting to the plan on an annual basis regarding actual revenue earned, these rules do not apply to PBMs currently. Many employers believe increased transparency with respect to PBM rebates will help enable plan sponsors to work to recoup or otherwise retain some of these rebates for the benefit of plan participants and beneficiaries.

* * *

Under the current structure, many employers may not be aware of the extent of a rebate on a given drug. Even if the employer is aware of the rebate, the rebates are typically based on volume and, therefore, rebates may be provided/paid to the PBM by the manufacturer long after the drug has been sold (and the plan has been initially charged). Moreover, not all employers may have the ability to audit or account for rebates adequately.

* * *

As agents of the health plans with which they contract, the Council believes this PBM transparency requirement is important to ensure that the PBMs' arrangements with pharmaceutical manufacturers are aligned with the services the PBMs provide to the health plans.⁸²

133. 63% of employers surveyed by the National Pharmaceutical Council expressed the view that PBMs lacked transparency in how they make money.⁸³

134. PBM statements that they use their negotiating power to reduce the health plans' costs and are acting in the best interests of their clients have not only actively concealed information but also furthered and maintained the scheme in which Mylan paid Defendant PBMs undisclosed bribes and kickbacks to act contrary to the interests of their clients and their patient

⁸² Letter from American Benefits Counsel to Aaron Zajic, Office of Inspector General, Department of Health and Human Services (April 8, 2019) at 3, 4-5, 6, 9, available at <https://www.americanbenefitscouncil.org/pub/?id=17e8a540-d131-080d-5144-1d4f42e64742>.

⁸³ National Pharmaceutical Council. Toward better value: employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it. October 2017. <http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf>.

members through: (a) large rebates and fees which did not flow to their clients, and (b) huge list price increases as a vehicle to pay Defendant PBMs.

135. The Defendant PBMs and Mylan have falsely and affirmatively mischaracterized the payments, repeatedly referring to them as “discounts” that benefit health plans and their patient members, when such is not the case for the reasons alleged herein. Moreover, even if an insurer/health plan (or other PBM client) were aware of the PBMs’ tactics regarding retained rebates and fees, the insurer/health plan (or PBM client) would not be able to determine the total dollar or percentage amounts of drug company payments that the PBM retains. Indeed, PBMs refuse to disclose such information to any plan client.⁸⁴

136. From time to time, plans seek an audit in order to ascertain whether their PBM is passing through the appropriate amount of drug company payments. During these audits, PBMs ensure that their clients remain in the dark, unable to learn the true cost of any specific drug, including EpiPens. For example, PBMs 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 Defendant PBMs’ contracts with Mylan). The auditor is only allowed to share the aggregate “rebate” amount the auditor ultimately concludes is

⁸⁴ Stephan Barlas, *Employers and Drugstores Press for PBM Transparency, A Labor Department Advisory Committee Has Recommended Changes*, Pharmacy and Therapeutics (Mar. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/>; *Understanding Your PBM Contract*, Pharmacy Benefit Consultants, available at <http://pharmacybenefitconsultants.com/offering/analyze-your-pbm-contract/>; David Contorno, *Lawsuit Sheds Light on PBM Fees*, Insurance Thought Leadership at *1-2 (Sept. 1, 2017), available at <http://insurancethoughtleadership.com/lawsuit-sheds-light-on-pbm-fees/pdf/>.

owed to the plan client.⁸⁵

137. PBMs are so secretive about their collection and distribution of drug company payments that, during an audit, PBMs, including Defendant PBMs, 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) 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 restrictions.⁸⁶ Audits are more like spot checks — with little chance of being fulsome or independent of restrictions imposed by PBMs.

B. Discovery Rule Tolling

138. Plaintiffs and the proposed Class had no way of knowing about Mylan's scheme and deception with respect to EpiPen's list pricing and no way of knowing about Mylan's bribing of Defendant PBMs. Plaintiffs and the proposed Class have little if any interaction with PBMs, including Defendant PBMs.

139. Mylan and Defendant PBMs refuse to disclose the real reasons behind Mylan's

⁸⁵ Cahn, Linda, *Eliminate All PBM Contract Loopholes*, benefits magazine, Vol. 50, Oct. 2013 at 40-46; *Testimony of Susan Hayes, Hearing on PBM Compensation and Fee Disclosure*, U.S. Dep't of Labor (Aug. 20, 2014), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/about-us/erisa-advisory-council/2014-pbm-compensation-and-fee-disclosure-hayes-08-20.pdf>; *PBM Compensation and Fee Disclosure*, Report to Thomas E. Perez, U.S. Secretary of Labor, U.S. Dep't of Labor (Nov. 2014), available at <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-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), available at https://aishealth.com/sites/all/files/file_downloads/c4p04f_012814.pdf.

⁸⁶ *Id.*

increased list prices for EpiPens, and have not until recently disclosed Mylan's scheme to bribe Defendant PBMs by way of increased EpiPen list prices.

140. Specifically, prior to late September of 2016, Plaintiffs and members of the proposed Class could not have discovered, through the exercise of reasonable diligence, that Mylan was concealing the conduct complained of herein and that the reason for its list price increases to EpiPens was to bribe Defendant PBMs for favorable formulary placement.

141. Prior to late September of 2016, Plaintiffs and the other Class members did not discover, and did not know of facts that would have caused a reasonable person to suspect, that Mylan was engaged in a bribery scheme using increased EpiPen list prices, nor would a reasonable and diligent investigation have disclosed the true facts.

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

C. Fraudulent Concealment Tolling

143. All applicable statutes of limitation have also been tolled by Mylan and the Defendant PBMs' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the period relevant to this action.

VI. CLASS ACTION ALLEGATIONS

144. Plaintiffs brings this action on behalf of themselves and all others similarly situated under Federal Rule of Civil Procedure 23(a) and 23(b)(3), as representative of a class defined as follows:

All persons or entities in the United States and its territories that directly purchased EpiPen, EpiPen Jr., EpiPen 2-Pak,⁸⁷ and/or EpiPen Jr. 2-Pak from Mylan, or any

⁸⁷ An EpiPen 2-Pak is a package containing two EpiPen devices. As of August 2011, Mylan stopped shipping single EpiPens and made EpiPens available only in 2-Paks. Mylan Press Release, "Dey Pharma to Offer EpiPen 2-Pak and EpiPen Jr 2-Pak Exclusively," 8/24/2011.

authorized generic version thereof from January 1, 2013 forward (the “Class”). Excluded from the class are the defendants and all federal governmental entities.

145. The Class period is tolled to the earliest date of Mylan’s initiation of the scheme described herein, wherein Mylan artificially inflated the list prices of its EpiPen products to increase payments to PBMs in exchange for favorable formulary status. The Class period runs through the date on which Mylan’s artificial inflation of EpiPen prices ceases.

146. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Plaintiffs believe that the Class is over 40 in number and widely dispersed throughout the United States. Moreover, given the costs of complex litigation, it would be uneconomic for many Plaintiffs to bring individual claims and join them together. The Class is readily identifiable from information and records in the possession of Mylan.

147. Plaintiffs’ claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of Defendants. As a result of Defendants’ misconduct, Plaintiffs, like all direct purchasers, paid artificially inflated prices for EpiPens and will continue to do so in the future.

148. 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.

149. Plaintiffs have retained counsel experienced in the prosecution of class action litigation, who have particular experience with class action litigation involving pharmaceutical products.

150. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect

to the Class as a whole appropriate. Such generally-applicable conduct is inherent in Defendants' wrongful conduct.

151. Questions of law and fact common to the Class include, but are not limited to:

- a. Whether Mylan engaged in a pattern and practice of paying illegal kickbacks and bribes, disguised as "rebates" and other sums, to the Defendant PBMs and to other PBMs, that were intended to, and did, induce the Defendant PBMs to give EpiPens favorable placement on the Defendant PBMs' formularies;
- b. Whether Mylan and each of the Defendant PBMs engaged in a fraudulent and/or deceptive scheme or course of conduct — through the respective Mylan-PBM EpiPen Pricing Enterprises — by improperly inflating WAC prices of EpiPens that Plaintiffs and Class members purchased;
- c. Whether Mylan had monopoly power;
- d. Whether Mylan artificially inflated WAC prices of EpiPens;
- e. Whether Mylan and the Defendant PBMs conspired for the purpose of carrying out the bribery and kickback schemes;
- f. Whether Mylan formed one-on-one enterprises with each of the Defendant PBMs for the purpose of carrying out the bribery and kickback schemes;
- g. Whether Mylan engaged in unlawful activity by paying kickbacks and bribes, and engaged in mail and/or wire fraud, in furtherance of the schemes;
- h. Whether the Defendant PBMs engaged in unlawful activity by soliciting and/or accepting kickbacks and bribes, and engaged in mail and/or wire fraud, in furtherance of the schemes;
- i. Whether the scheme caused Plaintiffs and Class members to pay inflated prices for EpiPens;
- j. Whether Defendants engaged in a pattern of deceptive and/or fraudulent activity intended to conceal their conduct;
- k. Whether Defendants violated RICO;
- l. Whether Mylan's conduct violated § 2 of the Sherman Act;

- m. Whether Defendants' conduct affected interstate commerce;
- n. Whether Defendants are liable to Plaintiffs and Class members for damages, measured as overcharges, from their misconduct; and
- o. The amount of overcharge damages Plaintiffs and the Class are owed as a result of Defendants' unlawful conduct.

152. A class action under Rule 23(b)(3) is superior to other available methods for the fair and efficient adjudication of this controversy. Such treatment will permit a large number of similarly-situated persons or entities 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 direct purchasers a method for obtaining overcharge damages on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action. Absent a class action, most members of the Class likely would find the cost of litigating their claims to be prohibitive and will have no effective remedy at law. The class treatment of common questions of law and fact is also superior to multiple individual actions or piecemeal litigation in that it conserves the resources of the courts and the litigants and promotes consistency and efficiency of adjudication.

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

VII. CLAIMS FOR RELIEF

COUNT ONE

VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATION ACT ("RICO"), 18 U.S.C. § 1962(c) (Against All Defendants)

154. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege and

incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint.

155. 18 U.S.C. § 1962(c) makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.”

156. Defendants Mylan, CVS Caremark, Express Scripts and OptumRx are each “persons,” as that term is defined in 18 U.S.C. § 1961(3).

157. This count alleges violations of Section 1962(c) against defendants Mylan, CVS Caremark, Express Scripts and OptumRx, as culpable persons under RICO.

158. Under 18 U.S.C. § 1961(4), a RICO “enterprise” may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s purpose.

159. As alleged and described herein, Mylan formed respective association-in-fact enterprises with each of CVS Caremark, Express Scripts and OptumRx, and Defendants, respectively, have conducted and/or participated in the conduct in the affairs of the respective RICO enterprises through a pattern of racketeering activity in violation of § 1962(c) for the purposes of carrying out their schemes, which caused Plaintiffs and the Class to pay inflated prices for EpiPens.

160. Plaintiffs and the members of the Class are “persons” as defined in 18 U.S.C. §§ 1961(3) and 1964(c), have been financially injured as a result of Defendants’ unlawful conduct in the form of overcharges paid for EpiPens, and assert this count for relief pursuant to 18 U.S.C. § 1964(c).

A. THE MYLAN-PBM EPIPEN PRICING RICO ENTERPRISES

161. The RICO enterprises are the following associations-in-fact consisting of (a) Mylan, including its directors, employees, and agents, and (b) one of the three Defendant PBMs, CVS Caremark, Express Scripts, or OptumRx (including its respective directors, employees and agents), which administer insurance and prescription drug coverage of EpiPens: (1) the Mylan-CVS Caremark association-in-fact enterprise; (2) the Mylan-Express Scripts association-in-fact enterprise; and (3) the Mylan-OptumRx association-in-fact enterprise. These association-in-fact enterprises are collectively referred to herein as the “Mylan-PBM EpiPen Pricing Enterprises.”

162. Each of the Mylan-PBM EpiPen Pricing Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, promoting and recommending for purchase, and administering prescriptions for EpiPens, and deriving secret profits from these activities. These profits are greater than either Mylan or the PBMs could obtain absent their fraudulent concealment of the substantial “rebates” and other fees from Mylan to the PBMs.

163. As part of and to accomplish the common purpose of the respective Mylan-PBM EpiPen Pricing Enterprises, Mylan systematically paid bribes and kickbacks — falsely labeled as rebates, administrative fees and/or other monies — to the Defendant PBMs in exchange for exclusive and/or favorable formulary placement. Mylan did so willfully, knowing that the sales of EpiPens were based on inflated list prices. The Mylan-PBM EpiPen Pricing Enterprises then reported Mylan’s list price increases to the general public, and to the respective PBM’s clients, including insurers and health plans (and participants and beneficiaries), while simultaneously concealing that the true reason for the price increases was to fund bribes and kickbacks to the Defendant PBMs in exchange for formulary placement, and also to increase the dollar value of those bribes and kickbacks to increase profits to both Mylan and the Defendant PBMs.

164. As outlined herein, the bribes and kickbacks paid by Mylan to the Defendant PBMs, which the Defendant PBMs solicited and accepted, violated the federal anti-kickback statute and various state anti-kickback statutes, as well as a number of state bribery statutes. The bribes and kickbacks paid by Mylan caused the Defendant PBMs to breach their duties of fidelity, and fiduciary duties, to their clients, including insurers and health plans (and plan participants and beneficiaries), and likewise deprived the clients, including insurers and health plans that retained the Defendant PBMs to develop, manage and administer formularies and prescription drug programs and negotiate prices with Mylan of the honest services of the Defendant PBMs, in that the PBMs: (a) favored Mylan's higher-priced EpiPen products over lower-priced EAI products; and/or (b) encouraged rather than discouraged EpiPen price increases, both of which were contrary to the economic interests of PBM clients (such as insurers/health plans) and their plan participants and beneficiaries.

165. Mylan's list price increases were fraudulent in that they were artificially inflated to fund the bribes and kickbacks, which the Mylan-PBM EpiPen Pricing Enterprises concealed. The Mylan-PBM EpiPen Pricing Enterprises also concealed the economic purpose of these list price increases to Mylan and the Defendant PBMs: the increases ultimately result in higher profits for Mylan, enabling it to purchase formulary access without requiring significant price reductions; and they result in higher profits for the Defendant PBMs, which earn rebates, fees and other compensation based on Mylan's list prices increases and sale volume. In addition, Mylan, as described above, realized significant increases in net profit through its substantial list prices increases, notwithstanding the increased payments (bribes and kickbacks) to Defendant PBMs necessary to secure and maintain formulary placement of EpiPens, and resulting from EpiPen sales.

166. Each Mylan-PBM EpiPen Pricing Enterprise also shares a common purpose of perpetuating the use of inflated EpiPen list prices. Mylan requires the inflated EpiPen list prices in part to fund the bribes and kickbacks to the Defendant PBMs in exchange for favorable formulary positions. The Defendant PBMs share this common purpose because the inflated EpiPen list prices increase the value of the rebates, administrative fees, and other monies they can keep, and thus increase their profits. Formulary placement determines which drugs are covered and prescribed for purchase. Given that rebates and other fees to the Defendant PBMs are determined and paid based in part on sales, the Defendant PBMs provided formulary placement to EpiPen to ensure prescriptions and sales of EpiPens, maximizing their financial gains. As a result, each of the Defendant PBMs have, in concert with Mylan through the respective Mylan-PBM EpiPen Pricing Enterprises, engaged in the hidden profit-making schemes, the Defendant PBMs garnering rebates and other fees and compensation from Mylan that the Defendant PBMs, to a significant extent, keep, and do not share with or provide to their clients, including insurers and health plans (or plan participants and beneficiaries). Mylan, meanwhile, unlawfully and fraudulently obtained sales, market share, and profits from EpiPens.

167. Each of the Mylan-PBM EpiPen Pricing Enterprises has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Mylan and each Defendant PBM that is an associate in the respective enterprise. As to each of the Mylan-PBM EpiPen Pricing Enterprises, there is a common communication network by which Mylan and each PBM share information on a regular basis, including information regarding EpiPen prices. As to each of the Mylan-PBM EpiPen Pricing Enterprises, Mylan and each Defendant PBM functioned as a continuing unit. At all relevant times, each of the Mylan-PBM EpiPen Pricing Enterprises was operated for criminal and fraudulent purposes, namely, carrying

out the bribery and kickback scheme and its concealment.

168. At all relevant times, the Mylan-PBM EpiPen Pricing Enterprises had an existence separate and distinct from that of its members. Mylan, CVS Caremark, Express Scripts and OptumRx are distinct corporate entities. Further, each member of the respective RICO Enterprises has an existence separate and apart from the pattern of racketeering activities of the RICO Enterprise. Each Defendant carries on distinct businesses and operations. However, as alleged and described herein, each member of each Mylan-PBM EpiPen Pricing Enterprise was essential to the operation of the schemes conducted through the Mylan-PBM EpiPen Pricing Enterprises.

169. The Defendant PBMs, at all relevant times, have been knowing and willing participants in the conduct of the respective Mylan-PBM EpiPen Pricing Enterprises, and have reaped large profits from that conduct. The Defendant PBMs used their position to strike rebate deals with Mylan to receive bribes and kickbacks for EpiPens and profit from Mylan's inflated list prices. The Defendant PBMs have represented to their respective clients, including insurers and health plans (and plan participants and beneficiaries) and the public that the rebates lower drug costs when, in fact, as the Defendant PBMs are well aware, the inflated list prices required to fund the bribes and kickbacks to them in exchange for favorable formulary placement increased drug costs, including list prices and downstream reimbursement and cost-sharing obligations of health plans and their participants and beneficiaries. In addition, as part of and to further the respective schemes, the Defendant PBMs misrepresent and/or conceal from insurer/health plan clients, plan participants and beneficiaries and the public the existence, amount and purpose of the rebates, administrative fees and/or other monies the Defendant PBMs are paid by Mylan as well as the effect of the rebates, administrative fees and/or other monies on EpiPen list prices, and also publish, distribute and disseminate materials and information concerning EpiPen list prices, net

prices and the purpose of “rebates” and so-called “discounts” to conceal the Mylan-PBM EpiPen Pricing Enterprises’ schemes.

170. But for the Mylan-PBM EpiPen Pricing Enterprises’ common purpose of inflating Mylan’s list prices to fund the bribes and kickbacks, the Defendant PBMs would have had the incentive to disclose the fraudulent inflation of Mylan’s list prices, and would have used their control over the management and administration of their health plan clients’ formularies to penalize Mylan’s undue price increases. By concealing this information, the Defendant PBMs and Mylan perpetuated the conduct of the Mylan-PBM EpiPen Pricing Enterprises.

171. The Defendant PBMs readily participated in the schemes so that they could continue to earn money from Mylan that was calculated based on EpiPen’s list price.

172. In order effectuate the schemes, Mylan and each Defendant PBM met on a regular basis to discuss EpiPen prices, formulary position, rebates, administrative fees, other monies to the Defendant PBM, what the PBM had to do for Mylan in order to obtain those monies, and coordination of all of the above.

173. Further, the common communication network between each Defendant PBM and Mylan effectuated the purpose of implementing the list price inflation and rebate schemes and the exchange of financial rewards for the PBM activities that benefitted — and continue to benefit — Mylan, as well as the Defendant PBMs.

174. At all relevant times, Mylan and each Defendant PBM knowingly, purposefully and willingly engaged and participated in the list price inflation and rebate scheme through each Mylan-PBM EpiPen Pricing Enterprise, and reaped substantial profits from that scheme.

175. The Mylan-PBM EpiPen Pricing Enterprises (Mylan- CVS Caremark, Mylan- Express Scripts, and Mylan-OptumRx) knowingly made material misrepresentations and/or

omissions to the Defendant PBMs' clients (and plan participants and beneficiaries) and to the general public in furtherance of the scheme regarding:

- a. The reasons for the list price increases of EpiPens;
- b. The existence, purpose and amount of the rebates and other monies paid to the Defendant PBMs;
- c. The effect of the rebates on EpiPen prices;
- d. The effect of the rebates and other monies from Mylan on the Defendant PBMs' development, management and administration of their client formularies;
- e. The extent to which Mylan negotiated rebates of EpiPens in good faith and for a proper purpose;
- f. Whether the rebates were intended to benefit Defendant PBMs' clients (including insurers/health plans), plan participants and beneficiaries and/or the general public;
- g. Whether the rebates lowered drug costs for Defendant PBMs' clients (including insurers/health plans) and plan participants and beneficiaries;
- h. Whether the "preferred" formulary status of EpiPens reflects the drugs' safety, efficacy, or cost-effectiveness, as determined by the Defendant PBMs' formulary committees;
- i. Whether the Defendant PBMs used their position regarding the development, management and administration of formularies for their own financial benefit and in contravention of the economic interests of their clients (and plan participants and beneficiaries); and
- j. Whether EpiPens would have been placed in "preferred" formulary positions absent the bribes.

176. Mylan alone could not have accomplished the purposes of the Mylan-PBM EpiPen Pricing Enterprises without the Defendant PBMs. For Mylan to profit from the scheme, the Defendant PBMs needed to convince clients, including insurers and health plans to select their formularies, on which EpiPens were given favorable treatment. And the Defendant PBMs did so through misrepresentations: they told clients, potential clients, and investors that they secured

lower prices. Instead, Mylan inflated list prices and funded the bribes and kickbacks in exchange for favorable placement on the Defendant PBMs' formularies, which resulted in increased drug costs. Without these misrepresentations, the common purpose of the Mylan-PBM EpiPen Pricing Enterprises could not have been achieved.

177. The foregoing evidences that Mylan and the Defendant PBMs were each willing participants in the Mylan-PBM EpiPen Pricing Enterprises, had a common, unlawful and fraudulent purpose and interest in the objective of the scheme by the respective enterprises, and functioned within a structure designed to effectuate the Enterprises' purposes, *i.e.*, to increase profits for both Mylan and the Defendant PBMs through list price increases, bribes and kickbacks to the PBMs, and continued formulary status without price reductions from Mylan, preserving and increasing Mylan's profits.

178. Further, the impacts of the Mylan-PBM EpiPen Pricing Enterprises are still in place as a result of the EpiPen's inflated list prices. As described herein, the bribes and kickbacks are an essential part of the Mylan-PBM EpiPen Pricing Enterprises, and are embedded in ongoing EpiPen prices, which likewise have inflated the price of Mylan's authorized generic EpiPen. This conduct, which has been in effect since in or about 2012, constitutes a threat of continued criminal activity.

**B. USE OF THE U.S. MAILS AND INTERSTATE WIRE FACILITIES/
INTERSTATE COMMERCE**

179. During the Class period, each of the Mylan-PBM EpiPen Pricing Enterprises engaged in and affected interstate commerce because it engaged and engages in the following activities across state boundaries: the sale, promotion and recommendation for purchase, and/or administration of prescriptions for EpiPens; the setting of the prices of EpiPens and price increase announcements in connection therewith; the negotiation of formulary placement, rebate, and other

contracts; the transmission and/or receipt of sales and marketing literature; and the transmission and receipt of invoices, statements, and payments related to the purchase, use, formulary placement and/or administration of EpiPens. During the Class period, the Mylan-PBM EpiPen Pricing Enterprises participated in the sale, promotion and recommendation for purchase, and administration of prescriptions for EpiPens throughout the United States.

180. During the Class period, the illegal conduct and wrongful practices by Mylan and each Defendant PBM as part of and in furtherance of the Mylan-PBM EpiPen Pricing Enterprises were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information and products and funds through the U.S. mails and interstate wire facilities.

181. The nature and pervasiveness of the Mylan-PBM EpiPen Pricing Enterprise schemes were concertedly orchestrated out of the Defendants' corporate headquarters, and necessarily required Mylan's headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the headquarters of each of the Defendant PBMs, and vice versa.

182. Most of the precise dates of the uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts as outlined herein) have been hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the bribery and kickback scheme alleged herein depended upon secrecy. The Mylan-PBM EpiPen Pricing Enterprises took deliberate steps to conceal the wrongdoing. Plaintiffs can nevertheless generally describe the occasions on which the RICO predicate acts of unlawful payment of bribes and kickbacks, mail fraud, and wire fraud occurred, and how those acts were in furtherance of the scheme.

183. Mylan's and the PBMs' use of the U.S. mails and interstate wire facilities to perpetrate the scheme of the respective Mylan-PBM EpiPen Pricing Enterprises involved thousands of communications throughout the Class period including, *inter alia*:

- a. Marketing materials about the list prices for EpiPens, which Mylan sent to the Defendant PBMs and others located across the country;
- b. Written and oral representations about EpiPen prices that Mylan made at least annually and, in many cases, several times during a single year;
- c. Thousands of written and oral communications discussing, negotiating, conditioning, and confirming the placement of Mylan's EpiPens on a particular Defendant PBM's formulary;
- d. Written and oral representations to conceal the true reasons for EpiPen list price increases and to conceal the scheme;
- e. Written communications, including checks, wires and/or other payment mechanisms, relating to rebates, bribes, kickbacks, or other financial inducements paid by Mylan to each of the Defendant PBMs to induce it to place Mylan's EpiPens on the Defendant PBMs' formularies in an exclusive or favorable position;
- f. Written and oral communications with U.S. government agencies and health plans and insurers that fraudulently misrepresented the reasons for list price increases, or that were intended to deter investigations into the true nature of the list price increases or to forestall changes to reimbursement based on something other than list prices;
- g. Written and oral communications with direct purchasers from Mylan concerning the list prices;
- h. Written and oral communications by the Defendant PBMs and/or Mylan with Defendant PBMs' clients and patients concerning list prices and/or the reasons for increases thereof;
- i. Transmission of list prices from Mylan to third parties;
- j. Receipts and payments of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities, constituting the wrongful proceeds of the scheme; and
- k. In addition to the RICO predicate acts, Mylan's and each of the Defendant PBMs'

corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their own various local headquarters or divisions, in furtherance of the scheme.

C. CONDUCT OF THE RICO ENTERPRISES' AFFAIRS

184. During the Class period, Mylan has exerted control over each Mylan-PBM EpiPen Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, Mylan has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly, as follows:

- a. Controlling the list prices for EpiPens, which determine the amount of rebates, administrative fees, and other monies each of the PBMs realize in compensation in exchange for formulary placement;
- b. Controlling EpiPen list prices and increases thereof that it publicly reports and purports to explain;
- c. Controlling the creation and distribution of marketing, sales, and other materials used to inform each of the Defendant PBMs of the profit potential of its EpiPens;
- d. Promoting the scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with the Defendant PBMs;
- e. Providing bribes and kickbacks, labeled as rebates, administrative fees and or other monies, to induce the Defendant PBMs to place Mylan's EpiPens in a favorable position on the formularies that were designed, implemented and/or administered by the Defendant PBMs;
- f. Publicly stating, falsely and misleadingly, through testimony, the press and through promotional and other materials, including through the U.S. mail and interstate wire facilities, that rebates lowered drug costs for Defendant PBMs' clients, and for plan participants and beneficiaries;
- g. Intending that the Defendant PBMs would (and did) distribute, through the U.S. mail and interstate wire facilities, promotional and other materials which falsely and misleadingly claimed that rebates lowered drug costs for insurers/health plan clients and their plan participants and beneficiaries; and
- h. Publishing and announcing list price increases and the reasons therefor but concealing that the increases were to fund the bribes and kickbacks to the Defendant

PBMs to secure exclusive and/or favorable formulary placement.

185. Further, during the Class period, each Defendant PBM has exerted control over each Mylan-PBM EpiPen Pricing Enterprise with which it is associated and, in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, by, among other things as described herein:

- a. Soliciting and/or obtaining bribes and kickbacks (labeled as rebates, administrative fees, and/or other monies) in exchange for placing Mylan's EpiPens in a favorable (exclusive or preferred) position on the PBMs' formularies;
- b. Misrepresenting and/or concealing from their clients (including insurers and health plans), plan participants and beneficiaries and the public the existence, amount, and purpose of the rebates, administrative fees and/or other monies from Mylan;
- c. Misrepresenting and/or concealing from their clients (including insurers and health plans), plan participants and beneficiaries and the public the effect of the rebates, administrative fees, and/or other monies from Mylan on EpiPen list prices; and
- d. Publishing, distributing and disseminating materials and information concerning EpiPen list prices, net prices and/or the purpose of rebates (and administrative fees and/or other monies) falsely and misleadingly portrayed as lowering drug costs to perpetuate and conceal the scheme.

D. PATTERN OF RACKETEERING ACTIVITY

186. Mylan and each of the Defendant PBMs have conducted and participated in the affairs of their respective Mylan-PBM EpiPen Pricing Enterprise through a pattern of racketeering activity under 18 U.S.C. § 1961, and committed the following violations outlined below knowingly and with the intent to advance the scheme.

187. Defendants' pattern of racketeering has involved thousands, if not hundreds of thousands, of acts, and has occurred over a number of years.

188. All of Defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purposes. The payments of bribes and kickbacks, misrepresentations and omissions, and separate uses of the U.S. mail and/or interstate wires by

Defendants and each Mylan-PBM EpiPen Pricing Enterprise were substantially related, had similar intended purposes, involved similar participants and methods of execution, and had similar results effecting similar victims. The racketeering activity constitutes a threat of continuing criminal activity.

189. Defendants have committed the following predicate acts, all constituting racketeering activity under 18 U.S.C. § 1961.

1 Violation Of State Bribery Laws

190. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of New Jersey. Specifically, in violation of N.J.S.A. § 2C:21-10, Mylan conferred benefits on the Defendant PBMs, which the PBMs solicited and/or accepted, in excess of \$75,000 as consideration for knowingly violating (or agreeing to violate) their duties of fidelity to their various clients (and/or the participants and beneficiaries therein) through the rebate and administrative fee negotiations and formulary decisions and recommendations alleged above. Moreover, in violation of N.J.S.A. § 30:4D-17(c), Mylan paid bribes to the PBMs, which the PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of EpiPens, for which payment may be made (or whose cost is or may be reported) in whole or in part under New Jersey's P.L. 1968, c. 413.

191. Defendant PBMs owe a duty of fidelity to their clients (and/or the participants and beneficiaries thereof), because of (a) the contractual relationships between the Defendant PBMs and their clients and (b) the PBMs' position as agents, trustees, fiduciaries, employees, and/or contractors for their clients. Because of the degree of reliance, trust and confidence that their clients give to Defendant PBMs in negotiating rebates and designing and implementing formulary management, the Defendant PBMs have that duty of fidelity.

192. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Missouri. Specifically, in violation of V.A.M.S. §§ 191.905.2 and 191.905.3, Mylan knowingly paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to induce the PBMs to use their control or influence over formulary design to refer clients (and participants and beneficiaries) to Mylan for the furnishing or arranging for the furnishing of EpiPens.

193. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Minnesota. Specifically, in violation of M.S.A. § 609.86, Mylan has corruptly given consideration in amounts exceeding \$500 to the Defendant PBMs with the intent to purchase placement on the Defendant PBMs' formularies, which the PBMs solicited and/or accepted.

194. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Rhode Island. Specifically, in violation of R.I. Gen. L. §§ 11-7-3 and 11-7-4, Mylan has corruptly given valuable consideration to the Defendant PBMs, and each of them, as an inducement or reward for favorable formulary placement on the Defendant PBMs' formularies, which the PBMs solicited and/or accepted.

195. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Alabama. Specifically, in violation of Ala. Code. § 22-1-11, Mylan has paid bribes to the Defendant PBMs, which the PBMs solicited and/or accepted, to induce the Defendant PBMs to use their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients (and their participants and beneficiaries) purchase EpiPens, for which payment may be made in whole or in part by the

Alabama Medicaid Agency, or its agents.

196. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Connecticut. Specifically, in violation of Conn. Gen. Stat. §§ 53a-161c and 53a-161d, Mylan paid bribes to the Defendant PBMs, which the PBMs solicited and/or accepted, to influence the Defendant PBMs to use their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients (and their participants and beneficiaries) purchase EpiPens, for which a claim of benefits or reimbursement has been filed with a local, state or federal agency.

197. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Florida. Specifically, in violation Fla. Stat. § 409.920, Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients and their participants and beneficiaries purchase EpiPens, for which product payment may be made in whole or in part under the Florida Medicaid program.

198. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Illinois. Specifically, in violation of 305 ILCS §§ 5/8A-3(b) and 5/8A-3(c), Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients and their participants and beneficiaries purchase EpiPens for which payment may be made in whole or in part under Illinois's Public Aid Code.

199. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the

Defendant PBMs have committed bribery under the laws of the State of Michigan. Specifically, in violation of MCLS § 400.604, Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of EpiPens, for which payment may be made in whole or in part pursuant to a program established under Michigan's Act No. 280 of the Public Acts of 1939, as amended.

200. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Mississippi. Specifically, in violation of Miss. Code Ann. § 43-13-207, Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to obtain favorable formulary placement in connection with the furnishing of EpiPens, for which payment may be made in whole or in part pursuant to the Medicaid program.

201. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Utah. Specifically, in violation of Utah Code Ann. § 26-20-4, Mylan paid bribes to the Defendant PBMs in excess of \$1,500, which the Defendant PBMs solicited and/or accepted, to induce the purchase of EpiPens, for which payment may be made in whole or in part pursuant to a Utah medical benefit program.

202. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Virginia. Specifically, in violation of Va. Code Ann. §§ 32.1-315(A) and 32.1-315(B), Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients (and their participants and beneficiaries) purchase EpiPens, for which payment may be made in whole or in part under a Virginia medical assistance program.

203. Comprising racketeering activity under 18 U.S.C. § 1961(1)(A), Mylan and the Defendant PBMs have committed bribery under the laws of the State of Washington. Specifically, in violation of Rev. Code Wash. § 74.09.240, Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that Defendant PBMs' clients and their participants and beneficiaries purchase EpiPens, for which payment may be made in whole or in part under Washington public assistance or other applicable law.

2. Violation Of The Travel Act: Unlawful Activity Of Bribery Under State Law

204. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of New Jersey, as set forth above.

205. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Missouri, as set forth above. Moreover, and specifically in violation of V.A.M.S. §§ 570.150.1(1) and 570.150.1(3), Mylan paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, to influence the Defendant PBMs' placement of EpiPens on the Defendant PBMs' formularies.

206. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the

unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Minnesota, as set forth above.

207. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Rhode Island, as set forth above.

208. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Alabama, as set forth above.

209. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Arkansas. Specifically, in violation of A.C.A. §§ 20-77-902(6) and 20-77-902(7)(A), Mylan has knowingly paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to arrange for or recommend that clients and their participants and beneficiaries purchase EpiPens, for which payment may be made in whole or in part by the Arkansas Medicaid Program.

210. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in

interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Connecticut, as set forth above.

211. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Florida, as set forth above.

212. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Illinois, as set forth above.

213. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Indiana. Specifically, in violation of Burns Ind. Code Ann. § 12-17.6-6-12, Mylan knowingly and/or intentionally paid bribes to the Defendant PBMs, which the Defendant PBMs solicited and/or accepted, in return for the Defendant PBMs using their control or influence over formulary design to refer the clients and their participants and beneficiaries to EpiPens, for which payment may be made by the Indiana Children's Health Insurance Program.

214. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the

Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Michigan, as set forth above.

215. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Mississippi, as set forth above.

216. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Utah, as set forth above.

217. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Virginia, as set forth above.

218. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Mylan and the Defendant PBMs have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of Washington,

as set forth above.

3. Violation Of The Travel Act: Unlawful Bribery Under The Anti-Kickback Act

219. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1952(a), used mail and wire facilities in interstate commerce to intentionally promote, manage, establish, carry on, and facilitate the unlawful activity, as defined by 18 U.S.C. § 1952(b)(2), of bribery under the laws of the United States. Specifically, in violation of 42 U.S.C. §§ 1320a-7b(b)(1) and 1320a-7b(b)(2) (the “Anti-Kickback Act”), Mylan paid bribes to Defendant PBMs, which the Defendant PBMs solicited and/or accepted, with the intention of purchasing, and in fact purchasing, formulary placement for EpiPens for which payment may be made in whole or in part under a Federal health care program. No “safe harbor” applies, because “[r]ebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary’s [of HHS] view, such a payment would not qualify as ‘a discount or other reduction in price.’” 82 F.R. 2340, at 2340 n.1. *See also id.* at 2343 (“To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption.”).

220. The Anti-Kickback Act is a criminal prohibition against payments made purposefully to induce or reward the referral or generation of federal health care business. The Anti-Kickback Act criminalizes a drug manufacturer’s offer or payment of anything of value in return for a PBM’s placing that manufacturer’s drug in a favorable formulary position with respect to, in whole or part, a federal health care program. This includes a drug manufacturer’s offer or payment to a PBM respecting private, nonfederal business that implicitly or explicitly requires that the PBM place the manufacturer’s drug in a favorable position with respect to a federal health care

program. The Anti-Kickback Act extends not just to a drug manufacturer's payment, but also to the solicitation or acceptance of remuneration by PBMs.

221. The OIG and the Secretary of HHS have long warned that “[l]ump sum payments for inclusion in a formulary or for exclusive or restricted formulary status are problematic and should be carefully scrutinized.” 68 FR 23731, at 23736 (2003).

222. The OIG and the Secretary of HHS have also stated that PBMs are not, and have never been, “buyers” within the meaning of the Anti-Kickback Act’s “safe harbor” for “discounts.” 82 F.R. 2340, 2343 n.36 (2019) (“the payments manufacturers retrospectively make to PBMs under rebate agreements would not constitute discounts or other reductions in price to the extent such payments are retained by the PBM and not passed through to any buyer”).

223. The OIG and the Secretary of HHS have also stated, “Rebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price. In the Secretary’s view, such a payment would not qualify as ‘a discount or other reduction in price.’” 82 F.R. 2340, at 2340 n.1. *See also id.* at 2343 (“To the extent those rebates are paid to or through PBMs to buy formulary position, such payments would not be protected by the discount statutory exemption.”).

4. Mail And Wire Fraud: Deprivation Of Honest Services

224. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1341, utilized the interstate mails, and have, in violation of 18 U.S.C. § 1343, utilized wires in interstate commerce, in furtherance of a scheme or artifice to defraud to deprive patients covered under plans of drug insurance, and the Defendant PBMs’ clients themselves, of the right of honest services, namely by paying Defendant PBMs bribes and kickbacks, solicited and/or accepted by the Defendant PBMs, which, unknown to such covered patients and clients, were paid with the specific intent that they serve as payment for formulary

position in such plans of drug insurance even though materially falsely and misleadingly labeled “rebates,” “administrative fees,” and the like, and achieved through increases in EpiPen’s list price that were falsely and misleadingly described, and which foreseeably caused Defendant PBMs, in purposeful contravention of their fiduciary duty to covered patients and clients, to change Mylan’s EpiPen position on the formulary, and intentionally caused such covered patients, clients and others to pay more for EpiPens, all in violation of 18 U.S.C. § 1346.

225. Mylan paid bribes and kickbacks to Defendant PBMs in return for the Defendant PBMs violating their fiduciary duties by using their control and/or influence over formulary decisions to favor higher-priced EpiPen instead of lower-priced EAIs, even though that was contrary to the interests of the clients who retained the Defendant PBMs.

226. The federal and state anti-kickback statutes discussed above make it illegal for Defendant PBMs to receive rebates, administrative fees, or other moneys in exchange for formulary placement if such payments are not passed along as purchase discounts and disclosed to the federal government. These statutes impose upon the Defendant PBMs a duty of honest services when negotiating rebates, which requires (at a minimum) that Defendant PBMs disclose that they are receiving kickbacks in exchange for recommending and promoting higher-priced drugs over lower-priced drugs indicated for the same uses.

227. As alleged above, for many years the PBMs have widely proclaimed to their clients (and the market as a whole) that: (a) PBMs use their negotiating power to reduce their clients’ drug costs, and (b) the PBMs are acting in the best interests of their clients. For example, according to Optum RX:

pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working *to reduce costs for their customers and the only ones able to effectively negotiate with drug companies*. OptumRx manages pharmacy benefits *on behalf of customers*, including self-insured employer groups, fully insured health

plans, union funds, Medicare, Medicaid, and federal and state government employee plans.⁸⁸

228. In addition, plan sponsors and plan administrators have reposed trust and confidence in PBMs with regard to the services the PBMs provide to their clients, and the PBMs have accepted that responsibility on behalf of health plans, plan sponsors, and other PBM clients as described herein. Indeed, in 2003, Express Scripts enacted its “client pledge” (applicable to employers and health plans, among others) to “always align its interests” with its clients and members.

229. Based on the degree of discretionary control that the Defendant PBMs have over the negotiation of rebates, Defendant PBMs act as either agents and/or trustees, and/or fiduciaries, in the negotiation of rebates regarding their clients’ drug purchases. As agents and/or trustees, and/or fiduciaries, in the negotiation of rebates regarding their clients’ drug purchases, the Defendant PBMs have duties of fidelity and honesty, and/or fiduciary duties, to not misuse their negotiating powers in a manner that is contrary to, and harmful to, their clients’ interests. It is contrary to these duties for a PBM to use its negotiating power to receive rebates, administrative fees, and other monies by inducing manufacturers to increase list prices of EpiPen, which price increases are detrimental to the Defendant PBMs’ clients.

230. Furthermore, in making decisions regarding the design, implementation, and administration of their clients’ formularies (including the addition and deletion of drugs on the clients’ formularies and changes in drugs’ position on their clients’ formularies) in accordance with their clients’ plan design, the Defendant PBMs act as agents for their clients. In cases that

⁸⁸ April 10, 2019 Written Testimony, Sumit Dutta, M.D., Chief Medical Officer, OptumRx, Before the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, at 2 (emphasis added).

the Defendant PBMs have discretionary control over the design, structure and modification of their clients' formularies, the Defendant PBMs act as trustees. As agents and/or trustees regarding the design, implementation, modification and administration of their clients' formularies, the Defendant PBMs have fiduciary duties of fidelity and honest services.

231. Each Defendant PBM's discretionary control and authority over its own compensation, including control over the inputs to that compensation, which, depending upon the PBM's characterization of those inputs (e.g., "fees" or "rebates") will impact a client's contractual rights to portions of that compensation payable by the PBM make the PBMs a functional fiduciary under trust law principles. This fiduciary control and authority arise by virtue of the PBM's contractual authority to negotiate the size of the payments it receives, and to assign at its own discretion the various labels and classifications to those payments. The label Defendant PBMs apply to a particular payment, or portion thereof, determines the amount retained by the PBM for its own account as opposed to the amount, if any, remitted to the PBMs' clients, as applicable. Even if, in some instances, Defendant PBMs pass 100% of certain "rebates" through to their clients, Defendant PBMs have applied different labels to certain payments (or portions thereof) to conceal and retain a significant portion of the payments they receive from drug manufacturers (including Mylan), which are hidden from or undisclosed to the PBM's clients. For example, by self-classifying the amount of the payments they receive from drug manufacturers as "fees" instead of "rebates," and by retaining the entirety of the former classification for themselves, Defendant PBMs effectively set their own compensation for services.

5. Mail Fraud

232. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1341, used the U.S. mails in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or

promises. Specifically, as outlined above, Mylan's EpiPens have been promoted through the mails, thereby announcing to PBM clients and to patients Mylan's list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup Mylan's bribes and kickbacks to Defendant PBMs to secure formulary placement. Moreover, as alleged above, for many years the PBMs have widely proclaimed to clients (and the market as a whole) that: (a) PBMs use their negotiating power to reduce drug costs, and (b) the PBMs are acting in the best interests of their clients. Defendants have falsely and misleadingly described the bribes and kickbacks to the Defendant PBMs (in the form of rebates, administrative fees and/or other monies) as "discounts"— which have been publicly represented as lowering drug costs — when, in fact, the bribes and kickbacks are for formulary placement, which enabled Mylan to sell EpiPen at inflated prices.

233. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails in furtherance of their schemes.

6. Wire Fraud

234. Comprising racketeering activity under 18 U.S.C. § 1961(1)(B), Defendants have, in violation of 18 U.S.C. § 1343, transmitted or caused communications to be transmitted by means of wire, radio, or television in interstate commerce, in conducting a scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. Specifically, as outlined above, Mylan's EpiPens have been promoted through electronic means, thereby announcing to PBM clients and to patients Mylan's list price increases, but omitting the material fact that the reason for the increased list prices was to fund, increase, and/or recoup Mylan's bribes and kickbacks to Defendant PBMs to secure formulary placement. Moreover, as alleged above, for many years the PBMs have widely proclaimed to clients (and the market as a whole) that: (a) PBMs use their negotiating power to reduce the drugs costs, and (b)

the PBMs are acting in the best interests of their clients. Defendants have falsely and misleadingly described the bribes and kickbacks to the Defendant PBMs (in the form of rebates, administrative fees and/or other monies) as “discounts” — which have been publicly represented as lowering drug costs — when, in fact, the bribes and kickbacks are for formulary placement, which enabled Mylan to sell EpiPen at inflated prices.

235. Defendants’ pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of interstate wires in furtherance of their schemes.

F. HARM CAUSED BY THE SCHEME

236. Defendants’ violations of federal and state law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and members of the Class to be injured in their business or property by overpaying for EpiPens. Plaintiffs and the Class directly purchase EpiPens from Mylan, and thus were directly and immediately harmed by the schemes of the respective Mylan-PBM Pricing Enterprises. Mylan and each of the Defendant PBMs intended and foresaw that Plaintiffs and members of the Class would, by paying list prices for EpiPen, pay substantial overcharges due to Defendants’ patterns of racketeering activity.

237. During the Class period, Mylan paid bribes and kickbacks to the Defendant PBMs in exchange for preferred formulary placement in order to maintain and/or increase sales and profits.

238. Though the Defendant PBMs could have used their control over the development, management, and administration of the formularies and prescription drug programs that their client insurers/health plans relied upon to drive down the prices for EpiPens by forcing Mylan to lower its list prices, the Defendant PBMs instead leveraged their respective positions to solicit and obtain Mylan’s bribes and kickbacks for their own financial benefit and contrary to the economic interests of their clients and plan participants and beneficiaries.

239. Rather than lower prices to gain market share via formulary inclusion, Mylan instead engaged in schemes with the Defendant PBMs through the Mylan-PBM EpiPen Pricing Enterprises to corrupt the supply chain by artificially inflating list prices in exchange for preferred formulary placement, shifting the cost of the bribes and kickbacks to direct purchasers of EpiPens and sharing the financial benefits with the Defendant PBMs.

240. Plaintiffs and the Class are the only purchasers of EpiPen directly from Mylan, and were directly harmed by Mylan's schemes with the Defendant PBMs through the respective Mylan-PBM Pricing Enterprises.

241. Absent the payment of bribes and kickbacks, and their achievement through EpiPen list price increases, Mylan would have been forced to compete for preferred formulary placement through lower prices, as they would in a legitimate market. As the gatekeepers in the supply chain, the Defendant PBMs could and would have used formulary placement (or exclusion) to penalize manufacturers who raised prices as Mylan did here, rather than perversely rewarding manufacturers who raised prices and inducing them to do so with favorable formulary placement.

242. But for the payment of bribes and kickbacks to secure favorable formulary placement, and their achievement through EpiPen list price increases, EpiPens would have had a lower list price, and Plaintiffs would have paid less for EpiPens. Plaintiffs and Class members have overpaid hundreds of millions of dollars for EpiPens purchased directly from Mylan based on inflated list prices.

243. Defendants' racketeering activity directly and proximately caused Plaintiffs' injuries because Plaintiffs and the Class members were and are the initial and only direct purchasers of the EpiPens from Mylan. Further, given that Plaintiffs and the Class members were and are the most direct and immediate victim of the unlawful and fraudulent schemes, Plaintiffs

and the Class members are best situated to vindicate the law and seek recovery for the economic harm caused by Defendants based on the substantial overcharges for EpiPen, which only Plaintiffs and the Class members paid.

244. By virtue of these violations of 18 U.S.C. § 1962(c), pursuant to 18 U.S.C. § 1964(c), Defendants are, respectively, jointly and severally liable to Plaintiffs and members of the Class for three times the damages that Plaintiffs and Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT TWO

VIOLATIONS OF RICO, 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c) (Against All Defendants)

245. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

246. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

247. Mylan and each of the Defendant PBMs have violated § 1962(d) by agreeing and conspiring to violate 18 U.S.C. § 1962(c). The object of the respective conspiracies has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the respective § 1962(c) Mylan-PBM EpiPen Pricing Enterprises described previously through patterns of racketeering activity.

248. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting patterns of racketeering activity, in furtherance of the conspiracy. Defendants intended to engage in the schemes resulting in Plaintiffs and the Class members paying substantial overcharges for EpiPens. Defendants knew that their predicate

acts were part of patterns of racketeering activity and agreed to the commission of those acts to further the schemes outlined herein.

249. The nature of the Defendants' acts, material misrepresentations and omissions in furtherance of the conspiracy, as set forth in detail above, gives rise to an inference that they not only agreed to the objective of 18 U.S.C. § 1962(d) violations of RICO by conspiring to violate 18 U.S.C. § 1962(c), but that they were aware that their ongoing unlawful and fraudulent acts have been and are part of overall patterns of racketeering activity.

250. Defendants have engaged (and continue to engage) in the commission of overt acts in furtherance of the Mylan-PBM EpiPen Pricing Enterprise schemes, including the following unlawful racketeering predicate acts (as outlined in detail above):

- a. Multiple instances of unlawful bribery and kickbacks in violation of 18 U.S.C. § 1952 and various federal and state laws comprising racketeering activity under 18 U.S.C. § 1961;
- b. Multiple instances of honest services fraud/deprivation under 18 U.S.C. § 1346;
- c. Multiple instances of mail fraud in violations of 18 U.S.C. § 1341; and
- d. Multiple instances of wire fraud in violations of 18 U.S.C. § 1343.

251. Defendants' violations of the above federal and state laws and the effects thereof outlined in detail above are continuing and will continue. As a direct and proximate result of these violations, Plaintiffs and members of the Class have been injured in their business and property; Plaintiffs and Class members have made hundreds of millions of dollars in overpayments for EpiPens purchased directly from Mylan that they would not have paid but for the Defendants' conspiracies to violate 18 U.S.C. § 1962(c).

252. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are, respectively, liable to Plaintiffs and the Class for three times the damages Plaintiffs and the Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT THREE

**VIOLATIONS OF SHERMAN ACT, 15 U.S.C. § 2
MONOPOLIZATION
(Against Mylan Only)**

253. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

254. Mylan's willful maintenance of its ability to charge supra-competitive, monopoly prices through a course of anticompetitive conduct, including payment of bribes and kickbacks to Defendant PBMs to gain favorable formulary placement for its EpiPens and exclude competitor's products, constitutes unlawful maintenance of monopoly power in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

255. As a result of this unlawful maintenance of monopoly power, Plaintiffs and members of the Class paid artificially inflated prices for their EpiPen requirements. But for Mylan's illegal conduct, competitors would have either: (a) marketed lower priced competitive EAIs more successfully than they actually did, and/or (b) forced Mylan to lower its prices or limit its price increases.

256. The goal, purpose, and effect of Mylan's conduct were to maintain and extend its monopoly power with respect to EpiPens, including maintaining (and/or increasing) its ability to charge supra-competitive prices. Mylan's illegal conduct was designed to prevent, delay, and/or minimize the success of competing EAIs, and to enable Mylan to continue charging supra-competitive prices for EpiPens without a substantial loss of sales.

257. If manufacturers of competitive EAIs had been able to fairly compete with Mylan's

EpiPens absent the anticompetitive conduct, Plaintiffs and members of the Class would have substituted lower-priced EAIs for some or all of their EpiPen requirements in far greater quantities, and/or would have received lower prices on some or all of their remaining EpiPen purchases. Furthermore, absent the bribes and kickbacks, Defendant PBMs would have used their formulary control to force Mylan to lower its EpiPen prices and/or limit the extent of its EpiPen price increases.

258. During the relevant period, Plaintiffs and members of the proposed Class purchased substantial amounts of EpiPens directly from Mylan. As a result of Mylan's illegal conduct, alleged herein, Plaintiffs and the members of the proposed Class were compelled to pay, and did pay, artificially inflated prices for their EpiPen requirements. Plaintiffs and all other proposed Class members paid prices for EpiPens that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, including because class members were deprived of the opportunity to purchase lower-priced competitive EAIs instead of expensive EpiPens.

259. At all material times, EpiPens sold by Mylan were shipped across state lines and sold to customers located outside their state of manufacture.

260. During the relevant time period, in connection with the purchase and sale of EpiPens, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

261. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. Mylan's activities were within the flow of, and have substantially affected, interstate commerce.

262. At all relevant times, Mylan had market power with respect to EpiPens because they had the power to maintain the price of EpiPens at supracompetitive levels without losing sales so as to make the supracompetitive price unprofitable.

263. Direct proof exists that Mylan had monopoly power over the price of EpiPens. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by Mylan and Mylan's ability to profitably maintain EpiPens' price well above competitive levels.

264. The existence of other EAIs has not significantly constrained Mylan's pricing of EpiPens. On information and belief, Mylan has never lowered the price of EpiPens in response to the pricing of other branded or generic drugs or EAIs.

265. Mylan needed to control only the sales of EpiPens, and no other products, in order to maintain the price of EpiPens profitably at supracompetitive prices.

266. To the extent a relevant product market must be defined, the relevant product market at issue in this case is EAIs.

267. A small but significant, non-transitory price increase above the competitive level for EpiPens did not and would not cause a significant loss of sales to other EAIs sufficient to make such a price increase unprofitable.

268. At all relevant times, Mylan had, and exercised, the power to exclude and restrict competition to EpiPens.

269. At all relevant times, Mylan enjoyed high barriers to entry with respect to competition to EpiPens due to high costs of entry and expansion.

270. The relevant geographic market is the United States and its territories, possessions and commonwealth of Puerto Rico.

271. From at least 2011 through 2017, Mylan's enjoyed 80% to 98% of the EAI market

in the United States, implying monopoly power.

272. But for the anticompetitive conduct alleged above, competitive EAI, including Auvi-Q, would have gained greater market entry into the EAI market.

273. Mylan's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting EpiPens from competition.

274. But for Mylan's anticompetitive conduct, Plaintiffs and members of the proposed Class would have paid less for EpiPens by substituting purchases of less-expensive EAI for their purchases of more-expensive EpiPens, and/or purchasing EpiPens at lower prices sooner.

275. Thus, Mylan's unlawful conduct deprived Plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

DEMAND FOR JUDGMENT

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), 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;

B. Enter joint and several judgments against Mylan, CVS Caremark, Express Scripts, and OptumRx and in favor of the Plaintiffs and the Class;

C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial, pursuant to 18 U.S.C. § 1964(c) and 15 U.S.C. § 15(a);

D. Award the Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

E. Award such further and additional relief as the case may require and the

Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, Plaintiffs, on behalf of themselves and the proposed class, demand a trial by jury on all issues so triable.

Dated: August 14, 2020

Respectfully submitted,

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