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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI'I

STATE OF HAWAI'I ex rel. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff, vs. CAREMARKPCS HEALTH, L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX, INC., Defendants.	CIVIL NO. 1:23-cv-00464-LEK-RT **DEFENDANTS EXPRESS SCRIPTS, INC. & OPTUMRX, INC.'S MOTION TO SEAL PORTIONS OF UNREDACTED FIRST AMENDED COMPLAINT**; MEMORANDUM IN SUPPORT OF MOTION; DECLARATION OF HAROLD CARTER; DECLARATION OF JAMES MILLAR; EXHIBIT A; CERTIFICATE OF SERVICE Judge: Leslie E. Kobayashi No Trial Date Set

DEFENDANTS EXPRESS SCRIPTS, INC. & OPTUMRX, INC.'S MOTION TO SEAL PORTIONS OF UNREDACTED FIRST AMENDED COMPLAINT

Defendants EXPRESS SCRIPTS, INC. ("Express Scripts") and OPTUMRX, INC. (OptumRx) (collectively, "**Defendants**"),[1] through their respective counsel,

[1] Counsel for CaremarkPCS Health, L.L.C. ("**CVS Caremark**") has advised that CVS Caremark does not object to the relief requested by this motion, nor will it seek further sealing of the existing complaint beyond that which is sought by this motion. Counsel for CVS Caremark has also advised that CVS Caremark agrees with the premise that rebate information, as reflected in rebate agreements and other contracts, typically is non-public, highly confidential, and competitively sensitive business information, and that CVS Caremark reserves the right to seek sealing of future filings in the event they contain such information specific to CVS Caremark.

move to seal portions of paragraphs 101, 119 and 120 of the First Amended Complaint pursuant to LR 5.2 of the Local Rules of Practice for the United States District Court for the District of Hawai‘i. Plaintiff State of Hawai‘i previously filed a Motion for Leave to File Unredacted First Amended Complaint Under Seal, ECF No. 121, which the Court denied on the grounds that the State had "not even attempted to show a compelling reason to maintain portions of the Amended Complaint under seal." ECF No. 126. The Court's order stated that it would submit the unredacted First Amended Complaint to the Clerk's Office for filing as a publicly available document on July 29, 2024. Defendants respectfully request that the Court defer submission of the unredacted First Amended Complaint to the Clerk's office pending decision on the instant Motion.

This Motion is supported by the attached memorandum, the declarations of Express Scripts and OptumRx, the attached exhibit, and all other pleadings and papers on file in this action.

Here, the State's prior motion for leave to seal sought to seal redactions including the three redactions at issue in this Motion. Accordingly, Defendants did not confer with the State given that the State's motion reflected agreement on seeking redactions. Defendants conferred with counsel for CVS Caremark, as required by Local Rule 7.8, prior to filing the Motion.

DATED: Honolulu, Hawai‘i, July 26, 2024.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

STATE OF HAWAI‘I ex rel. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff, vs. CAREMARKPCS HEALTH, L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX, INC., Defendants.	CIVIL NO. 1:23-cv-00464-LEK-RT **MEMORANDUM IN SUPPORT OF MOTION** Judge: Leslie E. Kobayashi

MEMORANDUM IN SUPPORT OF MOTION

I. BACKGROUND

In late 2021, the State of Hawai‘i issued subpoenas to Defendants OptumRx, Inc., CaremarkPCS Health, L.L.C., and Express Scripts, Inc. As part of a good-faith effort to comply with the State's subpoenas while also protecting their highly confidential trade secrets and competitively sensitive business information, each Defendant requested that the State enter a confidentiality agreement. The purpose of these agreements is to protect Defendants' most sensitive materials from public disclosure, including, as is pertinent here, Defendants' competitively sensitive business information. The State agreed to and executed confidentiality agreements on May 18, 2022 (with OptumRx), June 8, 2022 (with CVS Caremark) and December 19, 2022 (with Express Scripts). On the condition that such information would be protected from public disclosure, Defendants produced confidential and highly confidential documents and data responsive to the State's requests.

Although not required, the State elected to include certain of Defendants' confidential and highly confidential information in its First Amended Complaint—including the precise rebate percentages Defendants negotiated for certain drugs.

In accordance with the parties' confidentiality agreements and Defendants' consistent designations, the State redacted information derived from Defendants' confidential materials in paragraphs 18–19, 76–80, 85, 90, 93, 99, 101, 111–112, 115–120, 123, 129, 131, and 133 of the First Amended Complaint.

Of these paragraphs, Express Scripts and OptumRx now seek a narrow order sealing or redacting portions of three paragraphs of the First Amended Complaint. Specifically, Defendants move to seal or redact portions of paragraphs 101, 119 and 120 of the First Amended Complaint, as reflected in Exhibit A, an annotated version of the unredacted First Amended Complaint submitted to the Court under seal. Defendants agree that paragraphs 18–19, 76–80, 85, 90, 93, 99, 111–112, 115–118, 123, 129, 131, and 133 may be unsealed, as reflected in Exhibit A (a redacted version of the State's First Amended Complaint filed concurrently, herewith). Paragraphs 101, 119, and 120 contain confidential, competitively sensitive financial information reflecting the terms of Defendants' contracts with their clients and with pharmaceutical manufacturers. *See* Declaration of Harold Carter (hereinafter, "ESI Decl."), ¶ 5; Declaration of James Millar (hereinafter, "OptumRx Decl."), ¶ 10. Defendants' proposed redactions are necessary to protect this information and are consistent with the need to balance the public's access to judicial records with Defendants' right to protect specific categories of confidential material from widespread disclosure. ESI Decl. ¶¶ 5–7; OptumRx Decl. ¶¶ 6, 9.

II. ARGUMENT

While there is a strong presumption in favor of the public's right to access judicial records, the public's "right of access . . . is not absolute and can be overridden given sufficiently compelling reasons for doing so." *See Foltz v. State*

Farm Mut. Auto. Ins. Co., 331 F.3d 1122, 1135 (9th Cir. 2003); *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 598 (1978) ("[T]he right to inspect and copy judicial records is not absolute.").[2] There are compelling reasons to support protecting Defendants' commercially sensitive business information from public disclosure. *See Ctr. for Auto Safety v. Chrysler Grp., LLC*, 809 F.3d 1092, 1097 (9th Cir. 2016).

Among the compelling reasons that justify sealing a judicial record is the improper use of court files to "release trade secrets"[3] (*Kamakana v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1179 (9th Cir. 2006)) or "sources of business information that might harm a litigant's competitive standing" (*Ctr. for Auto Safety*, 809 F.3d at 1097). Courts "routinely permit the sealing of records containing business information which competitors could potentially misuse if disclosed." *McCurley v. Royal Seas Cruises, Inc.*, 2018 WL 3629945, at *1 (S.D. Cal. July 31, 2018); *Res Exhibit Servs., LLC v. LNW Gaming, Inc.*, 2023 WL 4826506, at *1 (D. Nev. June 21, 2023) (granting motion to seal because the "material contain[ed] proprietary

[2] A party only needs to show "good cause" for filing under seal materials related to motions that are only "tangentially related to the merits of the case," like discovery motions. *Ctr. for Auto Safety v. Chrysler Grp., LLC*, 809 F.3d 1092, 1101 (9th Cir. 2016).

[3] For purposes of a motion to seal, a trade secret is "any formula, pattern, device or compilation, of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." *Apple Inc. v. Samsung Elecs. Co.*, 727 F.3d 1214, 1221-22 (Fed. Cir. 2013) (applying Ninth Circuit law regarding "sealing documents [] when the release of the documents will cause competitive harm to a business," and outlining the definition of "trade secret.").

business information and contents of contractual agreements between the parties"). And the Ninth Circuit has recognized that confidential business information contained in a party's commercial contracts is sufficient to meet the compelling reasons standard. *See, e.g.*, *In re Elec. Arts, Inc.*, 298 F. App'x 568, 569 (9th Cir. 2008) (threatened disclosure of "pricing terms, royalty rates and guaranteed minimum payment terms" in licensing agreement satisfied the "compelling reasons" standard necessary to seal records). That is precisely the confidential information Defendants seek to seal here.

Specifically, Defendants move to seal excerpts from paragraphs 101, 119, and 120 of the First Amended Complaint containing confidential, competitively sensitive financial information reflecting the terms of Defendants' contracts with their clients and pharmaceutical manufacturers. ESI Decl. ¶ 4; OptumRx Decl. ¶ 10; *see also In re Elec. Arts, Inc.*, 298 F. App'x at 569 (concluding contract terms "plainly f[ell] within the definition of 'trade secrets'" and warranted protection from disclosure). Public disclosure of this information would not only violate the confidentiality provisions contained within the pertinent agreements but would also jeopardize Defendants' competitive positions. ESI Decl. ¶¶ 5–7; OptumRx Decl. ¶¶ 6–8.

Defendants negotiate with numerous pharmaceutical manufacturers for discounts and rebates. ESI Decl. ¶¶ 5–7; OptumRx Decl. ¶ 4. Allowing the highly

sensitive pricing and rebate terms that the State includes in paragraphs 101, 119, and 120 of the First Amended Complaint to become public would give other pharmacy benefit managers (**PBMs**) and payors that compete with the Defendants—including both Defendants as well as non-defendant PBMs—a significant and unfair competitive advantage in future rebate negotiations. ESI Decl. ¶ 6; OptumRx Decl. ¶ 7; *see also FTC v. Exxon Corp.*, 636 F.2d 1336, 1349–50 (D.C. Cir. 1980) ("It cannot be disputed that the most critical of all protective measures is that which prevents the disclosure of competitively sensitive information of [one competitor] to [another]. Should such information be disclosed, all other protective measures would be virtually meaningless. If [one competitor] is able to secure competitively sensitive information of the [other], either intentionally or inadvertently, the ability of the [other party] to compete effectively . . . would be seriously impaired.").[4] The disclosure of rebate percentages Defendants negotiate, even if historical, would also unfairly disadvantage Defendants with respect to pharmaceutical manufacturers, who could use the terms of Defendants' contracts to leverage rebate concessions or other services. OptumRx Decl. ¶ 8. For example, if a drug manufacturer learned the rebate Express Scripts previously agreed to, other drug manufacturers could use

[4] Indeed, because the Defendants compete with each other, all parties agree that it is appropriate in this case to designate certain materials as HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" in discovery. *See* ECF No. 115-1 at §§ 2.7, 7.4; ECF No. 11 at §§ 2.7, 7.4.

that information to bid for a lower rebate in a future bid. ESI Decl. ¶ 6. For this reason, Defendants' confidentiality agreements with the State contain explicit confidentiality provisions that safeguard the proprietary information they contain. ESI Decl. ¶ 3; OptumRx Decl. ¶ 9.

Courts—including the Ninth Circuit—have recognized that it is proper for district courts to seal this type of information. *See e.g.*, *Foltz*, 331 F.3d at 1137; *Finisar Corp. v. Nistica, Inc.*, 2015 WL 3988132, at *5 (N.D. Cal. June 30, 2015) ("Courts regularly find that litigants may file under seal contracts with third parties that contain proprietary business information."); *China Falcon Flying Ltd. v. Dassault Falcon Jet Corp.*, 2017 WL 3718108, at *3 (D.N.J. Aug. 29, 2017) (recognizing that there is an undeniable and "legitimate private interest in keeping confidential business agreements and sensitive pricing information confidential."). Narrow, targeted redactions of the First Amended Complaint, as proposed by Defendants, will properly safeguard this proprietary information.

III. CONCLUSION

For these reasons, Express Scripts and OptumRx respectfully request that the Court seal the proposed excerpts from paragraphs 101, 119, and 120 of the First Amended Complaint.

DATED: Honolulu, Hawai'i, July 26, 2024.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

STATE OF HAWAI‘I, EX REL. ANNE E. LOPEZ, ATTORNEY GENERAL Plaintiff, v. CAREMARK HEALTH, L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX, INC., Defendants.	CASE NO. 1:23-cv-00464-LEK-RT **DECLARATION OF HAROLD CARTER**

DECLARATION OF HAROLD CARTER

I, Harold Carter, declare as follows:

1. I am Senior Vice President, Pharma Trade Relations at Express Scripts, Inc ("Express Scripts"). I have personal knowledge of the facts stated in this declaration.

2. I understand that Plaintiff State of Hawai'i, ex rel. Anne E. Lopez, (the "State") has sought to file under seal an unredacted copy of its First Amended Complaint in this action. *See* ECF No. 121.

3. The State has included in the unredacted copy of the First Amended Complaint certain information that I understand it received from Express Scripts in response to the State's investigative subpoena issued pursuant to Haw. Rev. Stat. Section 480-18. I also understand that Express Scripts entered into a confidentiality agreement with the State to protect from public disclosure documents and/or information designated "Confidential" by Express Scripts.

4. The unredacted copy of the First Amended Complaint contains information that Express Scripts designated as confidential regarding the precise rebate percentages Express Scripts negotiated from certain drug manufacturers. Those confidential rebate percentages are included in paragraphs 101 and 119 of the First Amended Complaint.

5. The rebates Express Scripts negotiates from drug manufacturers are commercially sensitive information. Maintaining the confidentiality of rebate

negotiations preserves the competitive process by which drug manufacturers negotiate rebates for insulin products and other mediations.

6. The disclosure of the rebate percentages Express Scripts negotiated with respect to one drug, even if historical, could be used by other manufacturers and/or pharmacy benefit managers to gain a competitive advantage in current and future negotiations. For example, if a drug manufacturer learned the rebate Express Scripts previously agreed to, other drug manufacturers could use that information to bid for a lower rebate in a future bid.

7. For these reasons, the disclosure of the precise amounts Express Scripts negotiated in rebates increases the risk of commercial harm to Express Scripts by hampering its ability to negotiate rebates from drug manufacturers.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: July 25, 2024

DocuSigned by:
Harold Carter
CB807CD0BD004B0...

Harold Carter, PharmD

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAI'I

STATE OF HAWAI'I ex rel. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff, vs. CAREMARKPCS HEALTH, L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX, INC., Defendants.	CIVIL NO. 1:23-cv-00464-LEK-RT Judge: Leslie E. Kobayashi **DECLARATION OF JAMES MILLAR**

I, **JAMES MILLAR**, declare as follows:

1. I am over 18 years of age, am of sound mind and body, and am otherwise competent to testify. I have personal knowledge of the facts set forth in this Declaration. If called as a witness, I could and would testify to them.

2. I am employed by OptumRx, Inc. (OptumRx) as Senior Vice President for Industry Relations. In that role, among other things, I lead the team charged with formulary management strategy and interactions with pharmaceutical manufacturers with respect to pricing and discounts, rebates, rebate operations, and rebate reporting.

3. OptumRx provides pharmacy care services to customers across the United States. Its clients include, but are not limited to, insurers, third party administrators, corporate health plans, managed care organizations, unions, and other benefit plans.

4. OptumRx negotiates with pharmaceutical manufacturers for discounts and rebates to help its clients achieve the lowest net costs.

5. OptumRx competes with other pharmacy benefit managers (PBMs) and payors to attract the business of potential clients and to retain the business of its current clients.

6. Because the PBM industry is highly competitive, the specific terms of OptumRx's agreements with its clients and with pharmaceutical manufacturers are kept confidential, even within the company.

7. Widespread disclosure of the terms of OptumRx's client contracts and rebate agreements would give other PBMs and payors that compete with OptumRx a significant and unfair competitive advantage in future rebate negotiations.

8. The disclosure of rebate percentages OptumRx negotiates, even if historical, would also unfairly disadvantage OptumRx with respect to pharmaceutical manufacturers who could use the terms of OptumRx's contracts to leverage rebate concessions or other services.

9. As such, OptumRx takes significant measures to safeguard this competitively sensitive information, by limiting its distribution, marking it confidential, and seeking to protect it pursuant to protective orders and sealed filings whenever it must be submitted to a court.

10. The rebate rates set forth in Paragraph 120 of the State of Hawaii's First Amended Complaint are competitively sensitive and subject to confidentiality provisions contained within OptumRx's agreements with Novo Nordisk Pharmaceutical.

11. Requiring OptumRx to reveal this confidential, competitively sensitive, and proprietary information would have adverse consequences to OptumRx's business and that of its clients.

I declare under penalty of perjury under the laws of the United States that the facts in this declaration are true and correct.

James G Millar (Jul 26, 2024 10:17 EDT)

James Millar
OptumRx, Inc.
Senior Vice President, Industry Relations

EXHIBIT A

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IN THE CIRCUIT COURT OF THE FIRST CIRCUIT

STATE OF HAWAI‘I

STATE OF HAWAI‘I, EX REL. ANNE E. LOPEZ, ATTORNEY GENERAL, Plaintiff, vs. CAREMARKPCS HEALTH, L.L.C.; EXPRESS SCRIPTS, INC.; and OPTUMRX, INC., Defendants.	CIVIL NO. 1CCV-23-0001281 (Other Civil Action) FIRST AMENDED COMPLAINT JUDGE: The Honorable John M. Tonaki No trial date has been set.

FIRST AMENDED COMPLAINT

State of Hawai‘i ex rel. Anne E. Lopez, Attorney General (“State”) brings this action against CaremarkPCS Health L.L.C. (“CVS Caremark”), Express Scripts, Inc. (“Express Scripts”), and OptumRx, Inc. (“OptumRx”) (collectively, “Defendants”) pursuant to HRS § 480-1, *et seq*., and in support thereof alleges as follows:

INTRODUCTION

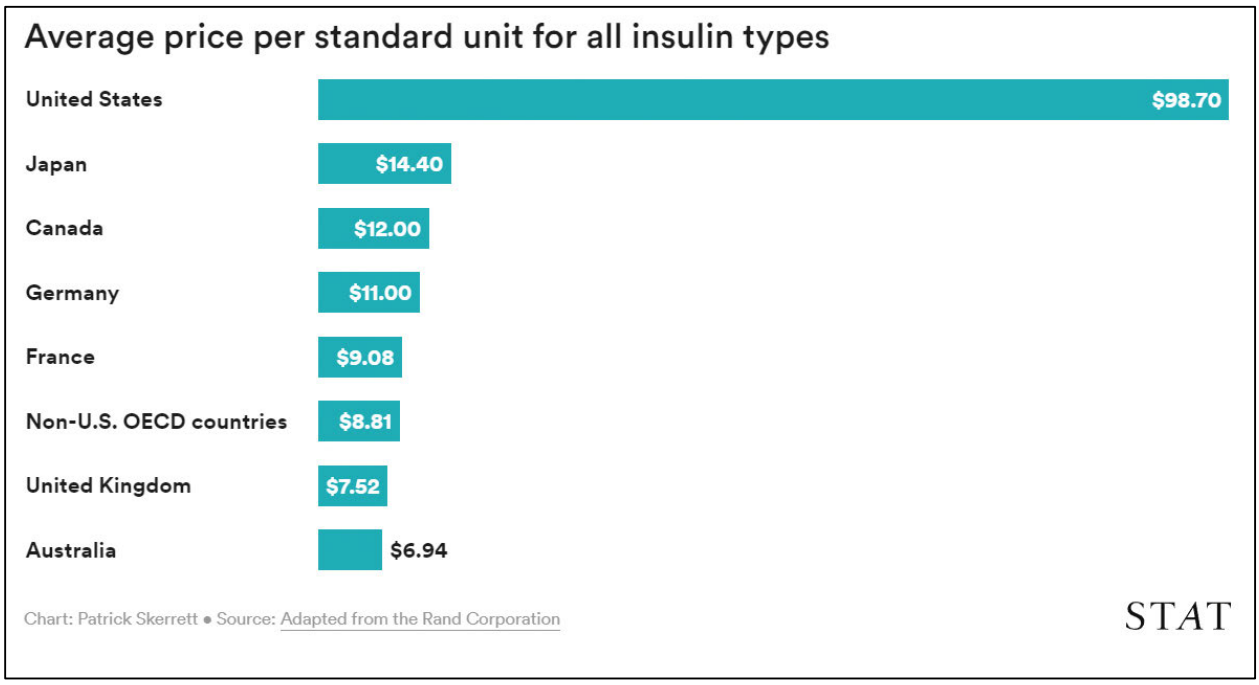
1. Prescription drug pricing in the United States is complex and opaque—allowing pharmacy benefit managers (“PBMs”) to siphon increasing amounts of money from the pharmaceutical supply chain while significantly increasing prices for consumers, employers, and other health care payers.

2. In the past couple of decades, prescription drug prices in the United States have skyrocketed, making life-saving medications—including insulin, which many Hawai‘i residents need to survive—unaffordable for many consumers. For example, one insulin product (Humalog) was priced at $21 in 1999 and rose to $332 in 2019—an increase of more than 1000%.

3. Prescription drug costs in the United States are considerably higher than prescription drug costs in comparable countries (*e.g.*, Australia, Canada, France, Germany, United Kingdom). For example, Humalog, which sells for over $300 in the United States, is only $30.23 in Canada.

4. The average price per standard unit for all insulin types is significantly higher than in other countries (as shown in Figure 1 below).[1]

Figure 1: Average Price Per Standard Unit For All Insulin Types



[1] Danielle Ofri, *Even with lawsuits and copay caps, will insulin ever be affordable?*, STAT News (Jan. 20, 2023), https://www.statnews.com/2023/01/20/will-insulin-ever-be-affordable/.

5. PBMs, which operate mostly in the United States, play a major role in the prescription drug supply chain. They are administrators hired by third-party payers (*e.g.*, government entities, insurers, employers) for the benefit of consumers to design and administer prescription drug programs, including creating drug formularies—a list of prescription drugs covered by health plans tiered according to consumers' cost-share obligations (*e.g.*, tier 1 drugs require a $5 co-payment, tier 2 drugs require a $10 co-payment).

6. While purporting to work for third-party payers, PBMs have instead engineered a business model which distorts the market to their benefit, rather than serving the best interest of their client, the payer, or the end consumer, the patient.

7. PBMs deceptively represent that they work to reduce prescription drug costs. Yet, over time, PBMs have developed a business model that does the opposite, and in doing so, evolved business practices designed to maximize their own profits while essentially forcing manufacturers to raise prices for brand-name prescription drugs.

8. PBMs have created a business model where prescription drug manufacturers must pay rebates and other fees to PBMs to ensure their drugs will receive preferential placement on PBMs' drug formularies allowing access to the products for patients.

9. While consumers are told the price of a medication at the point of sale, and are charged a copayment or co-insurance based on this price, the price that they are quoted is based on the list price of the medication before rebates and other price adjustments.

10. Consumers are not informed that the price they are quoted at the point of sale is not the actual price paid for the medication by the PBM or their health plan.

11. Rebates are discounts for prescription drugs paid by manufacturers on an aggregate basis across all prescriptions serviced by a PBM after prescriptions are dispensed. These rebates are paid to PBMs and are not provided to individual consumers at the point of sale.

12. Manufacturers typically offer rebates only for brand-name drugs, not generics.

13. Rebates are important to the business models created by PBMs because PBMs typically retain a percentage of these rebates, so the greater the rebate, the greater the revenue retained by the PBM.

14. The Defendants collectively manage 80% of prescription drug benefits for more than 220 million Americans. As such, placement on their formularies is a significant bargaining chip when negotiating drug rebates.

15. Around 2014, PBMs began increasingly exerting their leverage against prescription drug manufacturers to demand higher rebates and fees. One tactic PBMs use is to exclude one or more drugs used to treat the same condition from a PBM formulary to intensify competition among manufacturers.

16. Rebates drive manufacturers' pricing decisions for their products. As rebates increased, prescription drug manufacturers, in turn, began increasing the wholesale acquisition cost ("WAC") (known as the "list price" or "sticker price") for their brand-name drugs to maintain their revenue from the product sales. For example, if a drug manufacturer sold a drug for $100 and a PBM wanted a $20 rebate, that drug manufacturer might give the PBM a $20 rebate and increase the WAC to $120 to achieve their revenue target of $100.

17. Not surprisingly, since 2014, there has been a fundamental shift in payments from prescription drug manufacturers to PBMs. Manufacturer payments to PBMs and other intermediaries have risen by over 16% per annum and now constitute 40% or more of brand-name

prescription drug costs.[2] In 2013, the manufacturer Sanofi offered rebates for insulin products between 2% and 4% for preferred placement on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56% for preferred formulary placement.[3]

18. During the State's investigation, CVS Caremark and OptumRx only produced data relating to insulin products and Express Scripts produced data relating to insulin products and one non-insulin product (Humira, AbbVie's blockbuster rheumatoid arthritis drug). Using insulin as a case study, the internal data for CVS Caremark—the PBM with the largest market share in Hawai'i—from 2016 to 2019 (the only years for which CVS Caremark produced insulin data) shows how rebates have increased, rather than reduced, insulin prices. From 2016 to 2018, the average WAC price per prescription rose over 38% from $326 to $451 while the average rebate for insulin products increased from 31% of the WAC price to 57% of the WAC price. During the same time, the average out-of-pocket cost for consumers with coinsurance (meaning they pay a percentage of the WAC price rather than a flat copayment) increased over 83% from $52.11 to $95.45 per prescription. In contrast, in 2019—the year Congress asked several PBMs, including CVS Caremark, to testify regarding skyrocketing drug prices—CVS Caremark's data shows a modest decrease in the rebate rate which corresponds to a modest decrease in the average WAC price per insulin prescription and out-of-pocket costs for consumers with coinsurance.

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[2] Emery P. Weinstein and Kevin Schulman, *Exploring Payments in the U.S. Pharmaceutical Market 2011-2019: Update on Pharmacy Benefit Manager Impact*, 227 Am. Heart J. 107-110, (2020), https://doi.org/10.1016/j.ahj.2020.06.017.

[3] United States Senate Finance Committee, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*, at 82 (Jan. 14, 2021), https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. Herein referred to as "Senate Finance Committee Insulin Report").

19. The State expects that, based on publicly available national data, it will see even sharper increases in the WAC price once it is able to obtain pre-2016 data from CVS Caremark.

20. PBMs' manipulation of drug pricing benefits PBMs because they typically retain a portion of the rebate, but it harms consumers in several ways. First, many consumers' out-of-pocket payments are tied to WAC—meaning consumers' out-of-pocket payments increase when WAC increases. Second, PBMs' tactics increase the risk of non-medical switching—altering a patient's drug therapy for reasons other than a drug's efficacy, side effects, or clinical outcome. This happens when PBMs exclude drugs from their formularies to extract higher rebates for competing products. Further, it overlooks the fact that even though drugs may treat the same condition, some drugs produce better outcomes for certain patients. Third, the high list prices impact the entire market, not just patients served by a PBM. Patients without prescription drug insurance pay the high list prices that result from the PBM business model.

THE PARTIES

Plaintiff State of Hawai'i

21. Plaintiff, State of Hawai'i, by and through the Attorney General of Hawai'i, Anne E. Lopez, brings this action to protect the interest of the State of Hawai'i and its residents. The Attorney General brings this action pursuant to her statutory authority under HRS § 480-2 to enforce Hawai'i laws prohibiting unfair or deceptive acts or practices and unfair methods of competition in trade or commerce.

22. The State is not seeking relief relating to any federal program (*e.g.*, Medicaid, Medicare, TRICARE, FEHBA) or any contract related to a federal program. Moreover, the State's claims are not limited to insulin or other diabetes medications, but rather are based on the larger

unfair and deceptive scheme that violates HRS § 480-2 and increased prices and reduced access to brand-name prescription drugs for Hawai‘i consumers.

Defendant CaremarkPCS Health, L.L.C.

23. Defendant CaremarkPCS Health, L.L.C. ("CVS Caremark") is a Delaware limited liability company that maintains its principal place of business in Rhode Island and is registered to do business in Hawai‘i. At all times relevant to this complaint, CVS Caremark provided pharmacy benefit management services in Hawai‘i.

24. At all relevant times, CVS Caremark had agreements with pharmaceutical manufacturers related to payments for placement on CVS Caremark's standard formularies.

25. CVS Caremark has the largest PBM market share based on total prescription claims managed, representing approximately 33% of the national market.[4] CVS Caremark also has, by far, the largest PBM market share in the State of Hawai‘i.

Defendant Express Scripts, Inc.

26. Defendant Express Scripts, Inc. ("Express Scripts") is a Delaware corporation that maintains its principal place of business in Missouri and is registered to do business in Hawai‘i. At all times relevant to this complaint, Express Scripts provided pharmacy benefit management services in Hawai‘i.

27. At all relevant times, Express Scripts had agreements with pharmaceutical manufacturers related to payments for placement on Express Scripts standard formularies.

[4] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger*, Drug Channels (Apr. 5, 2022), https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html.

28. Prior to merging with Cigna in 2019, Express Scripts was the largest independent PBM in the United States. During the relevant period of this Complaint, Express Scripts controlled 26% of the PBM market in the United States.[5]

Defendant OptumRx, Inc.

29. Defendant OptumRx, Inc. ("OptumRx") is a California corporation that maintains its principal place of business in California and is registered to do business in Hawai'i. At all times relevant to this complaint, OptumRx provided pharmacy benefit management services in Hawai'i.

30. At all relevant times, OptumRx had agreements with the pharmaceutical manufacturers related to payments for placement on OptumRx's standard formularies.

31. During the relevant period of this Complaint, OptumRx controlled 21% of the PBM market in the United States.[6]

JURISDICTION AND VENUE

32. This Court has jurisdiction over this case pursuant to HRS § 480-2, which confers jurisdiction on this Court to award relief sought by the State, including injunctions and such other relief as may be appropriate. This Court is also the appropriate venue pursuant to HRS § 480-2 because the seat of government of the State of Hawai'i, the plaintiff in this action, is situated within the City and County of Honolulu, Hawai'i.

33. This Court has jurisdiction over the above-named Defendants pursuant to HRS § 634-35, which extends this Court's *in personam* jurisdiction over foreign defendants because Defendants were, at all material times herein, registered to do business in the State of Hawai'i and/or were doing business in the State of Hawai'i, and/or performed services, which are the

[5] *Id.*
[6] *Id.*

subject of this action, in the stream of commerce with the knowledge and intent that their services would impact both the State of Hawai‘i and its residents, and/or otherwise directed their activities toward the State of Hawai‘i and/or otherwise availed themselves of the benefits and protections of the laws of the State of Hawai‘i.

BACKGROUND

Drug Prices Have Skyrocketed Over the Last Couple of Decades

34. From 2014 to 2020, prescription drug prices increased by 33%, outpacing inflation and price increases for any other medical commodity or service.[7]

35. Rising drug costs have made life-saving medications unaffordable for many Americans—particularly seniors. For the average older American taking 4.7 brand-name prescription drugs per month, if drug prices had increased at the rate of general inflation, the annual cost of therapy in 2020 would have been $13,682 instead of the actual cost of $31,037.[8]

36. According to a 2019 study, medication insecurity—the inability to pay for prescribed medications—rose 4% from January 2019 to September 2019 (18.9% vs. 22.9%).[9] The study also showed a significant gender gap. In September 2019, medication insecurity affected 27.5% of women but only 18.1% of men.

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[7] Tori Marsh, *Prices for Prescription Drugs Rise Faster Than Prices for Any Other Medical Good or Service*, GoodRx Health (Sept. 17, 2020), https://www.goodrx.com/healthcare-access/drug-cost-and-savings/prescription-drugs-rise-faster-than-medical-goods-or-services; Stephen W. Schondelmeyer & Leigh Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2020*, AARP Public Policy Institute (June 2021), at 1, https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf.

[8] Schondelmeyer & Purvis, *supra* note 7.

[9] Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, Gallup (Nov. 12, 2019), https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx.

37. In 2020, it was estimated that high out-of-pocket costs for drugs would cause 1.1 million premature deaths of seniors in the Medicare program over the next decade, and lead to an additional $177.4 billion in avoidable Medicare medical costs.[10]

38. Insulin—a drug that millions with diabetes need to live—is a prime example of skyrocketing drug costs. At a century in use, insulin is one of the oldest biologic drugs in modern medicine. In 1999, Humalog (insulin) was affordably priced at $21. Twenty years later, the price had increased by more than 1000% to $332.[11] Due to unprecedented pressure on PBMs and insulin manufacturers, insulin costs are finally starting to decrease. For example, on April 3, 2019, Express Scripts announced the launch of its Patient Assurance Program, which Express Scripts claims will "ensure eligible people with diabetes in participating plans pay no more than $25 for a 30-day supply of insulin."[12] Unfortunately, PBMs have not provided this same type of broad relief for the high cost of drugs other than insulin. Further, PBMs have not provided restitution for the prior years' worth of overpayments and their promise to offer insulin at reduced prices is not indefinite.

39. The price increases in the United States—one of the few countries (if not the only country) that use PBMs—are not matched globally. In the Province of Ontario, Canada, Eli Lilly currently markets Humalog for $30.23.[13]

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[10] Xcenda, *Modeling the Population Outcomes of Cost-Related Nonadherence: Model Report*, (Sept. 21, 2020), https://global-uploads.webflow.com/5e5972d438ab930a0612707f/5fa9bf4419f4da03a7daf190_WHPC-Xcenda_NonAdherence%20Population%20Model_Report_22Oct2020r.pdf.

[11] S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95(1), Mayo Clinic Proc. (Jan. 1, 2020) at 22, https://doi.org/10.1016/j.mayocp.2019.11.013.

[12] Cigna, *Cigna and Express Scripts Introduce Patient Assurance Program to Cap Out of Pocket Costs at $25 per 30-Day Insulin Prescription* (Apr. 3, 2019), https://newsroom.cigna.com/cigna-and-express-scripts-introduce-patient-assurance-program-to-cap-out-of-pocket-costs-at-25-per-30-day-insulin-prescription.

[13] Ontario Drug Benefit Formulary/Comparative Drug Index, https://www.formulary.health.gov.on.ca/formulary/results.xhtml?q=Humalog&type=2 (last visited Jan. 30, 2022).

40. For a consumer with Type 1 diabetes with commercial insurance, the annual cost of insulin nearly doubled from approximately $3,200 in 2012 to $5,900 in 2016.[14]

41. Inflated insulin costs are particularly difficult for Hawai‘i. Approximately 11% of the population is diabetic, which is slightly above the national average, but approximately 41.5% of the adult population have prediabetes.[15] Some groups in Hawai‘i are disproportionally affected, with about 14.2% of Native Hawaiians, 17.7% of Pacific Islanders and 22.1% of Samoans diagnosed with diabetes.[16]

42. A study from New Haven, Connecticut reported that one in four people with diabetes at an urban medical center reported cost-related insulin underuse. Diabetics who reported financial challenges associated with insulin prices were more likely to have poor glycemic control (clinical management of their diabetes), which leads to negative health outcomes, such as blindness, amputations, and even death.[17]

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[14] Jean Fuglesten Biniek & William Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute (Jan. 21, 2019), https://healthcostinstitute.org/diabetes-and-insulin/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices.

[15] Diabetes Research Center, *Diabetes in Hawaii*, https://drc.jabsom.hawaii.edu/diabetes-in-hi/ (last visited Dec. 19, 2022).

[16] Kirstin Downy, *New Scrutiny on the High Price of a Life-Saving Drug for Diabetics*, Honolulu Civil Beat (Dec. 27, 2021), https://www.civilbeat.org/2021/12/new-scrutiny-on-the-high-price-of-a-life-saving-drug-for-diabetics/.

[17] Darby Herkert et al., *Cost-Related Insulin Underuse Among Patients With Diabetes*, 179(1) JAMA Intern Med. 112, 112-114 (Jan. 2019), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2717499; Mary Caffrey, *Gathering Evidence on Insulin Rationing: Answers and Future Questions*, AJMC (Sept. 26, 2019), https://www.ajmc.com/view/gathering-evidence-on-insulin-rationing-answers-and-future-questions.

43. Another study showed that 20% of Americans with diabetes have rationed their insulin because of financial reasons.[18] The issue has become so common that there are now algorithms for doctors to use when their patients can no longer afford their prescribed insulin.

PBMs Provide Services to Consumers

44. The Defendants provide services to consumers by administering prescription drug benefits. As CVS Caremark explains to consumers through its welcome kit: "We manage your prescription drug benefits just like your health insurance company manages your medical benefits."[19]

45. Defendants provide identification cards to consumers with their company logos to present to pharmacies for the purpose of determining consumers' prescription drug coverage.

46. All three Defendants have consumer-facing websites representing that they "serve" consumers and that consumers are their "members."[20]

47. Defendants further represent on their websites that giving consumers access to necessary prescription drugs at an affordable price is a top priority.[21]

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[18] Ofri, *supra* note 1.

[19] CVS Caremark, *Welcome Kit*, https://benefits.vmware.com/wp-content/uploads/2018/10/CVS-Caremark-Sample-Welcome-Kit_ID-Card.pdf (last visited Feb. 13, 2022).

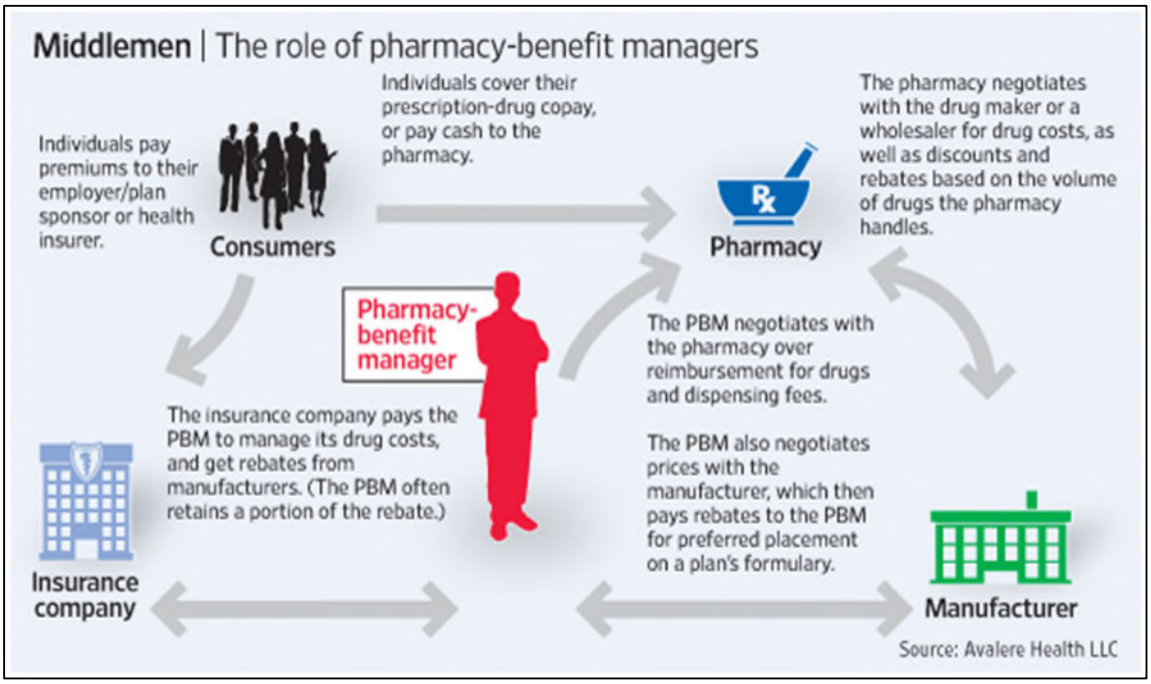
[20] CVS Caremark, https://www.caremark.com/welcome-center.html#tab_link_tabs_2 (last visited Feb. 13, 2022); CVS Caremark, https://www.caremark.com/about-us.html (last visited Feb. 15, 2022).
Express Scripts, Inc., https://www.express-scripts.com/corporate/about (last visited Feb. 13, 2022); Express Scripts, Inc., *Frequently Asked Questions*, https://www.express-scripts.com/frequently-asked-questions/about (last visited Feb. 13, 2022); Express Scripts, Inc., *Who We Help Overview*, https://www.express-scripts.com/corporate/who-we-help/members (last visited Feb. 13, 2022).
OptumRx Inc., optumrx.com (last visited Feb. 13, 2022); OptumRx Inc., *OptumRx Welcome Video*, https://optumrx.video.uhc.com/media/OptumRx+Welcome+Video/0_ug0m5mm2 (last visited Feb. 13, 2022).

[21] *Id*.

PBMs Are The Middleman In A Complex Drug Pricing System

48. PBMs act as intermediaries between their third-party payers, such as government entities, insurers, and employers, and other entities in the drug distribution chain, such as prescription drug manufacturers and pharmacies (as shown in Figure 2 below).[22] PBMs are involved in and benefit from almost every link in the chain.

Figure 2: The Role of Pharmacy Benefit Managers



49. Consumers pay premiums to their employers or insurance companies (third-party payers) for health insurance. Third-party payers then pay PBMs to administer prescription drug benefits for consumers. PBMs in turn negotiate and contract with pharmacies to determine the amount PBMs will pay pharmacies for prescription drugs (minus any cost-share amounts that consumers pay directly to pharmacies). Traditionally, PBMs mark up the price they pay to

[22] Dan Fleshler, *Opening Up the Black Box on PBMs (Pharmacy Benefit Managers)*, healthline (Sept. 21, 2018), https://www.healthline.com/diabetesmine/PBM-primer.

pharmacies when seeking reimbursement for those payments from third-party payers—creating another revenue stream for the PBM.

Consumer Costs Are Typically Linked to WAC

50. Consumers' out-of-pocket costs for drugs are determined by whether they have insurance and the terms of their coverage. Consumer payments range from high to low from 1) the cash price (either because consumers are uninsured or have a high-deductible plan), to 2) a cost-share payment based on a percentage of drug costs, to 3) what is typically the least expensive option, a flat copayment.

51. Consumers without insurance pay the "usual and customary" price (*i.e.*, the "cash price")—typically greater than WAC, which federal law defines as the manufacturer's list price to wholesalers and direct purchasers (not including rebates or other discounts). *See* 42 USC § 1395w-3a(c)(6)(B). For example, in 2022, the WAC for Lantus (Sanofi's top-selling insulin) was $283.56 per vial and the average retail usual and customary price for Lantus was $343 per vial.[23]

52. In addition, an increasing number of consumers have high-deductible plans, which require consumers to pay the cash price for drugs until they meet their deductible—averaging nearly $2,200 a year.[24]

[23] Sanofi-aventis U.S. LLC, Lantus Pricing Sheet, https://www.lantus.com/-/media/EMS/Conditions/Diabetes/Brands/lantus-final/Header/Lantus-Pricing.pdf (last visited Feb. 11, 2022); Benita Lee, *How Much Does Insulin Cost? Here's How 28 Brands and Generics Compare*, GoodRx Health (Jan. 26, 2022), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands.

[24] Gary Claxton et al., *Employer Health Benefits 2020 Annual Survey, Kaiser Family Foundation*, at 137 (Oct. 8, 2020), https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf.

53. About 30-50% of insured consumers pay a coinsurance amount, which is a percentage of WAC (not including rebates).[25]

54. Other insured consumers pay a flat copayment amount, such as $5 for generic drugs and $10 for preferred brand-name drugs. The copayment is not directly tied to WAC; however, the overall cost of drugs factors into a plan's decision when determining health insurance premiums and consumer copayment amounts.

PBMs Obtain Payments from Manufacturers Classified as Rebates, Administrative Fees, and Price Protections

55. In addition to relationships with third-party payers and pharmacies, PBMs negotiate and contract for various payments from prescription drug manufacturers. The bulk of these payments are for rebates, but also include data access fees, service fees, and other payments.

56. Prescription drug rebates are reductions from WAC redeemed from manufacturers after the transaction. Yet, unlike traditional point-of-sale rebates, manufacturers pay prescription drug rebates to PBMs, not to insured (or uninsured) consumers who paid WAC.

57. In a quid pro quo agreement, prescription drug manufacturers pay rebates and other fees to PBMs for the purpose of securing placement on the PBMs' drug formularies.

58. A drug formulary is a list of generic and brand name prescription drugs covered by health plans. Formularies are usually divided into three to five tiers that determine the cost-share amounts (*e.g.*, the co-payment or co-insurance) that consumers must pay toward the cost of a prescription. The lower tiers have lower cost-share amounts than the higher tiers. For example, a typical three-tier formulary may be designed as follows:

[25] Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices: Here's why prices keep going up, plus how to combat the sticker shock—and still protect your health*, Consumer Reports (Nov. 26, 2019), https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/.

- Tier 1 contains generic drugs with the lowest cost-share amount for consumers.
- Tier 2 contains preferred brand-name drugs with a cost-share amount that is higher than tier 1 but lower than tier 3.
- Tier 3 contains non-preferred brand-name drugs with the highest payment by consumers.

59. Generally, manufacturers of brand-name prescription drugs pay higher rebates for preferred formulary placement (*e.g.*, tier 2 status instead of tier 3 status). This is because, upon information and belief, consumers are more likely to fill prescriptions for drugs with lower cost-share amounts (and ask their physicians to prescribe products on lower formulary tiers).

60. The rebates PBMs negotiate are highly confidential and, for the most part, the exact terms of the agreements between PBMs and prescription drug manufacturers are unknown to others in the supply chain—creating a pricing black box.

61. Drug rebates are usually based on WAC. For example, a manufacturer may offer the PBM a rebate of 40% of WAC for a particular drug.

62. In addition to prescription drug rebates, manufacturers pay various fees to PBMs, including administrative fees and fees for price protection relating to brand-name drugs.

63. In another quid pro quo agreement, manufacturers pay PBMs administrative fees for administering rebates, which are separate from any administrative fees PBMs may charge third-party payers. Like rebates, administrative fees are tied to WAC and paid according to PBMs' confidential contracts with manufacturers. Administrative fees typically range from 3% to 5% of WAC.[26]

[26] Senate Finance Committee Insulin Report, *supra* note 3, at 82.

64. Price protection is another way that PBMs extract payments. PBMs present price protection as a means to reduce costs, but the Senate Finance Committee's investigation revealed price protection does very little to keep costs down. Price protection establishes a cap on the amount by which prescription drug manufacturers can increase WAC for a particular drug (ranging from 0% to 12%).[27] Any price increase by manufacturers above the established cap triggers additional rebate payments to PBMs known as "price protection." For example, if there is a 5% cap on WAC, and the manufacturer increases WAC by more than 5%, the manufacturer must pay additional rebates (*e.g.*, 50% of WAC instead of 45% of WAC), of which PBMs typically retain a portion. Price protection does not provide any discount to consumers at the point of sale.

65. Under a traditional PBM pricing model, PBMs retain a portion of the payments they receive from prescription drug manufacturers and return the remainder to third-party payers.

FACTUAL ALLEGATIONS

I. PBMs Deceptively Represent That They Lower Drug Prices

66. The Defendants have made numerous deceptive representations about their role in the market—mainly that PBMs serve to lower prices.

67. CVS Caremark represents it is "[w]orking to keep prescription drug costs down for members and clients."[28] CVS Caremark further claims it is "[i]mproving health through affordability" because "people are more likely to take their prescribed medications when they know they can afford them – and that can lead to better health outcomes."[29] CVS Caremark has also represented:

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[27] *Id*. at 84.
[28] CVS Health, *Prescription Drug Coverage*, https://www.cvshealth.com/services/prescription-drug-coverage/member-affordability.html (last visited October 3, 2023).
[29] *Id*.

- "MYTH: Rebates negotiated by PBMs are driving up the prices of prescription drugs for consumers and plan sponsorship. FACT: Pharmaceutical manufacturers set the list price for a given drug. PBMs then negotiate with manufacturers to secure the drug at a lower cost for their plan sponsors and their members."[30]

- "MYTH: PBMs increase cost-sharing burdens for beneficiaries. FACT: Plan designs are determined by clients – employers and health plans – who decide how they subsidize their members' coverage."[31]

- "MYTH: PBMs lower drug costs by restricting patient access to needed medication. FACT: PBMs help ensure that beneficiaries have access to the prescriptions they need to stay healthy, at a price they can afford."[32]

- "As a PBM and an Employer, We Know Rebates and Innovation Lower Drug Costs."[33]

- "Making sure you have access to affordable medication and convenient options for filling is our priority."[34]

68. Express Scripts claims it "work[s] with plan sponsors to provide a benefit that delivers the best clinical outcome and the lowest possible cost."[35] It also represents:

- "By delivering smarter solutions to patients and clients, PBMs provide better care and lower cost with every prescription, every time."[36]

- "Rebates do not raise drug prices, drug makers raise drug prices, and they alone can lower them. Consider the cost of Humalog® (insulin lispro): over the past seven years, the list price for this medication has increased dramatically, yet the net cost has remained relatively constant. Without PBMs, and specifically without Express Scripts, plan sponsors would have paid exponentially more for their prescription drugs."[37]

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[30] CVS Health, *Myths vs. Fact Pharmacy Benefit Management*, at 2 (Jan. 2021), https://www.cvshealth.com/sites/default/files/cvs-health-myth-vs-fact-pbm-2021-01.pdf.
[31] *Id*. at 3.
[32] *Id*. at 4.
[33] @CVSHealth, Twitter (Oct. 31, 2018, 11:11 AM), https://twitter.com/CVSHealth/status/1057651382155653121.
[34] CVS Caremark, caremark.com (last visited Jan. 25, 2022).
[35] Paul Reyes, *What's a Pharmacy Benefit Manager*, Express Scripts (Aug. 1, 2019), https://www.express-scripts.com/corporate/articles/whats-pharmacy-benefit-manager.
[36] *Id*.
[37] Express Scripts, Inc., *The Rebate Debate* (June 29, 2017), https://www.express-scripts.com/corporate/articles/rebate-debate.

- "We . . . negotiate with drug manufacturers so no one pays more than they need to."[38]

- "FACT: Public disclosure of negotiated rebates will not lower prescription drug costs. #PBMs Express Scripts negotiates with drug manufacturers to increase competition and lower costs for patients."[39]

69. OptumRx claimed "Rebates are a longstanding tool used by PBMs to negotiate with drug manufacturers to achieve lower prescription drugs costs for clients."[40] It also represents:

- "PBMs develop pharmacy networks, negotiate with drug companies for the best medication prices, process pharmacy claims, and may operate a home delivery pharmacy."[41]

- "Learn how we make the consumer experience a top priority to create better outcomes, lower costs, and improve the overall healthcare system."[42]

- "Helping millions of people get medication safely, conveniently and at the best price."[43]

- "We strive to contain medication costs and our clinical programs are designed to provide better care and outcomes."[44]

70. These representations do not accurately represent the way Defendants impact drug pricing. As discussed below, PBMs significantly contribute to and benefit from the dysfunctional market dynamic they create that harms consumers.

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[38] Paul Reyes, *What's a Pharmacy Benefit Manager*, Express Scripts (Aug. 1, 2019), https://www.express-scripts.com/corporate/articles/whats-pharmacy-benefit-manager.
[39] @ExpressScripts, Twitter (Apr. 9, 2019, 3:10 PM), https://twitter.com/ExpressScripts/status/1115693403285741568.
[40] OptumRx, *Regulatory developments affecting pharmacy*, (Feb. 2022), https://www.optum.com/business/resources/library/regulatory-updates-q1-2022.html.
[41] Kevira Voegele, *Who is OptumRx?*, OptumRx (Sept. 4, 2018), https://optumrx.video.uhc.com/media/Who+is+OptumRxF/0_8lrxn39l.
[42] @OptumRx, Twitter (Sept. 8, 2020), https://twitter.com/OptumRx/status/1303226564751036416.
[43] Kevira Voegele, *What is a formulary?*, OptumRx (Aug. 8, 2019), https://optumrx.video.uhc.com/media/What+is+a+formularyF/1_tnrtatvy.
[44] *Id.*

71. PBMs' deceptive representations mask their impact on the market, making the black box of drug pricing even more difficult to understand and regulate.

II. PBMs Drive Up Drug Prices By Leveraging Formulary Decisions to Extract Increasingly Steeper Payments from Manufacturers

72. The PBM industry is heavily concentrated. The three largest PBMs are: (1) CVS Caremark (owned by CVS Health, which also owns CVS Pharmacy—the largest retail pharmacy chain in the United States); (2) Express Scripts (owned by Cigna); and (3) OptumRx (owned by UnitedHealth Group).

73. Collectively, the big three PBMs manage 80% of drug benefits for more than 220 million Americans—making preferred placement on their drug formularies a significant bargaining chip when negotiating payments from prescription drug manufacturers.[45]

74. PBMs began increasingly exerting their leverage in 2012 by excluding drugs from certain therapeutic classes from their formularies to intensify competition among manufacturers for rebates. The threat of exclusion fundamentally changed drug pricing. Rebates went from modest discounts to steep payments that manufacturers were all but forced to make because not paying PBMs could ruin a drug's chance of success. Over time, rebates have become a significant factor that manufacturers consider when setting drug prices.

A. PBMs Exclude Drugs From Their Formularies to Increase Rebates

75. CVS Caremark started excluding drugs from its formulary in 2012. Express Scripts and OptumRx began the practice in 2014 and 2016, respectively (*see* Figure 3 below showing the number of exclusions by PBM per year).[46]

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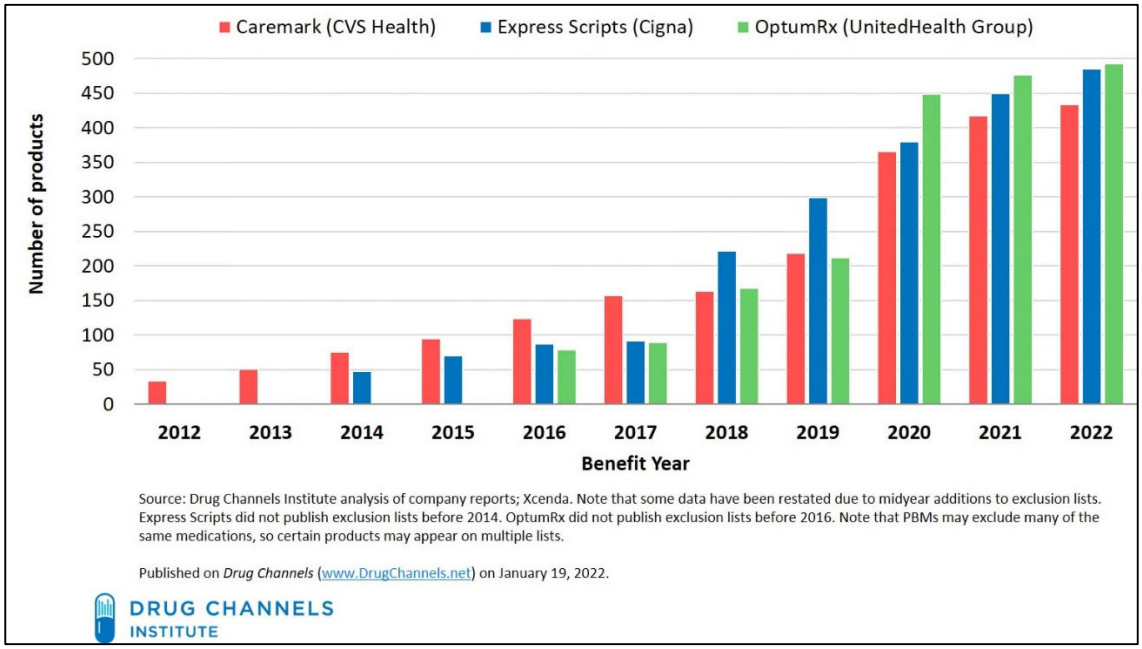
[45] Senate Finance Committee Insulin Report, *supra* note 3, at 68.

[46] Adam Fein, *Five Takeaways from the Big Three PBMs' 2022 Formulary Exclusions*, Drug Channels (Jan. 19, 2022), https://www.drugchannels.net/2022/01/five-takeaways-from-big-three-pbms-2022.html.

Figure 3: PBM Formulary Exclusions from 2012-2022



76. In 2011, CVS Caremark realized it needed a "shift in formulary strategy." Pre-2011, CVS Caremark's formulary covered nearly all drugs on the market. But CVS Caremark's new strategy—after it began losing rebates from increased utilization of generics—was to negotiate with manufacturers and require "higher rebates to stay on formulary" coupled with a "willingness to walk away."

77. This strategy resulted in, among things, "increased rebate rates for preferred/exclusive positions," "increased rebate rates to prevent exclusion," and "shift of utilization to rebated drugs." It also "[s]et a new precedent with pharma for drug inclusion and rebate levels" and "[d]emonstrated an increased level of control to the market."

78. These effects are reflected in a 2018 internal email where Express Scripts admits to "applying leverage with pharma to tightly manage drug lists" to "extract value from retailers, wholesalers, and pharma . . . while supporting our sales margin and growth." A presentation from the following year argues that by "increasing out-of-pocket copayment differentials" and "closing

competitive product categories or formularies" Express Scripts can generate additional rebates and improve formulary compliance.

79. Likewise, in a 2017 presentation, OptumRx admitted: "If we put drugs into exclusion we will have more leverage and we can earn more rebates." Another OptumRx internal document explains that "pharma pays rebates for protection of or growth of market share."

80. In some instances, PBMs even exclude generic drugs to protect the brand-name drug's market share. For example, in a 2017 presentation, OptumRx discussed that to get maximum rebates for Adderall XR, OptumRx had to ensure that Adderall XR had at least a certain percentage of the market. OptumRx achieved this by excluding the generic Adderall XR.

81. The number of medicines excluded from the big three PBMs' formularies increased 961% from 2014 (109 unique drugs exclusions) to 2022 (1,156 unique drug exclusions).[47] Drugs used to treat chronic conditions—including insulin, antidepressants, antipsychotics, and antiarrhythmics—are most frequently excluded by PBMs.

82. The payment increases PBMs gain from prescription drug manufacturers by threatening exclusion are substantial.

83. Since PBMs began excluding drugs from their formularies, rebates have skyrocketed. For example, in July 2013, the manufacturer Sanofi offered rebates for insulin products between 2% and 4% for preferred placement on CVS Caremark's formulary. By contrast, in 2018, Sanofi's rebates for insulin products were as high as 56% for preferred formulary placement.[48]

[47] Xcenda, *Skyrocketing growth in PBM formulary exclusions continues to raise concerns about patient access* at 2 (May 2022), https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[48] Senate Finance Committee Insulin Report, *supra* note 3, at 67.

84. The overall amount prescription drug manufacturers paid in rebates and other fees nationally doubled from 2013 ($83 billion) to 2018 ($166 billion).[49]

85. OptumRx was the last of the big three PBMs to start excluding drugs. In 2016—when OptumRx first began excluding drugs—it noted in an internal document that Express Scripts and CVS Caremark (OptumRx's main competitors) excluded the hepatitis C medication Zepatier even though the WAC price for Zepatier was 40% lower than the competing product, Harvoni. OptumRx stated that it "forfeited rebates and admin fees on Harvoni by placing Zepatier in a preferred status with Harvoni. This decision is saving our clients $22M annually in costs." OptumRx further opined that it is "extremely important to send the right message to Pharma when they do the right thing, i.e. by [Zepatier's manufacturer] trying to keep the cost curve down, we will place them in a preferred position on our formulary."

86. PBMs argue that exclusions reduce costs, but evidence suggests otherwise. A study from the Tufts Center for the Study of Drug Development found that cost-effectiveness does not appear to correlate with a drug's excluded or recommended status and rebates appear to play an important role in determining exclusion and recommendation decisions.[50] The Tufts study conducted a head-to-head comparison of excluded versus recommended drugs in the same therapeutic class. In 9 out of 18 instances, the more cost-effective drug was excluded from coverage.

87. The big three PBMs' treatment of biosimilars perfectly illustrates the perverse incentives in drug pricing. Biosimilars are biologic products (like insulin) that the FDA has

[49] Gill, *supra* note 25.
[50] Joshua P. Cohen et al., *Rising Drug Costs Drive the Growth of Pharmacy Benefit Managers Exclusion Lists: Are Exclusion Decisions Value-Based?*, 53 (Supp 1) Health Servs. Rsch., at 2767, 2764 (Aug. 2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6056588/pdf/HESR-53-2758.pdf.

approved to be therapeutic substitutes for an existing biologic product because the biosimilar and the existing biologic product are highly similar and have no clinically meaningful difference.[51]

88. Biosimilars directly compete with existing biologic products. In general, biosimilars are lower priced than the existing biologic product. One would expect that when PBMs are faced with fully interchangeable products that have no clinically meaningful difference, PBMs would choose the lowest-priced product. Many times, however, the opposite is true. As of April 2022, there were twenty-one biosimilars on the market in the United States. Fourteen of these twenty-one biosimilars have been excluded by at least one of the big three PBMs.[52]

89. For example, Viatris (a company formed by the merger between Mylan and Upjohn) launched two identical biosimilar insulins that are fully interchangeable with Sanofi's top-selling Lantus. One product is a brand-name biosimilar insulin called Semglee. The other product is a generic biosimilar insulin (Insulin Glargine). Semglee is offered at a WAC 5% below the WAC for Lantus. Insulin Glargine is offered at a WAC 65% lower than the WAC for Lantus. Semglee and Insulin Glargine are the exact same product—the only difference between the two products is price.[53]

90. In their 2022 formularies, none of the big three PBMs preferred the insulin product with the lowest WAC (Insulin Glargine). OptumRx preferred Lantus and excluded Semglee but failed to even mention Insulin Glargine—despite its acknowledgement in the 2016 internal document that "it is extremely important to send the right message to Pharma when they do the right thing . . . by . . . trying to keep the cost curve down[.]" Express Scripts preferred the higher-

[51] Xcenda, *supra* note 47 at 7.
[52] *Id*.
[53] Adam Fein, *Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira*, Drug Channels (Nov. 9, 2021), https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html.

priced biologic (Semglee) and excluded the lower-priced biologic (Insulin Glargine)—even though Semglee and Insulin Glargine are identical. CVS Caremark excluded Lantus and preferred Basaglar—a product that is not even a biosimilar to Lantus—without mentioning Semglee or Insulin Glargine.[54]

91. In some instances, PBMs prefer products that are more expensive ***and*** have seemingly inferior safety profiles. For example, in 2020, Express Scripts excluded AstraZeneca's Calquence (drug used to treat Chronic Lymphocytic Leukemia) in favor of the higher-priced Imbruvica (manufactured by AbbVie and Johnson & Johnson)—perhaps the first major PBM restriction of an oncology therapy. This is even more troubling considering that significantly fewer people who took Calquence suffered atrial fibrillation compared to Imbruvica in a head-to-head trial.[55]

92. Often, CVS Caremark's preferred or recommended products are excluded by Express Scripts, and vice versa—further suggesting exclusions are not evidence- or value-based.[56] The justification for formulary exclusions are not shared with patients, their physicians, or even the PBMs' clients.

93. In a 2014 email, Express Scripts hid the CPC's and P&T committee notes for 39 of the 48 drugs it excluded from its formulary from its client's consultant, Aon. It justified its decision to the client by stating that the information was "confidential and proprietary." However,

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[54] Fein, *supra* note 46.
[55] Arlene Weintraub, *Express Scripts axes Novartis' psoriasis drug in favor of Lilly's as discounting takes over: analyst*, Fierce Pharma (Aug. 20, 2020), https://www.fiercepharma.com/pharma/express-scripts-axes-novartis-psoriasis-drug-favor-lilly-s-as-discounting-takes-over-analyst; John C. Byrd, et al., *First results of a head-to-head trial of acalabrutinib versus ibrutinib in previously treated chronic lymphocytic leukemia*, 39(15) J. Clin. Oncol. 7500 (May 28, 2021), https://ascopubs.org/doi/abs/10.1200/JCO.2021.39.15_suppl.7500.
[56] Cohen, *supra* note 50.

internally, Express Scripts acknowledged that providing the information would expose the company to "quite a bit of risk." In another email discussing the formulary positions of Invokana versus Jardiance, Express Scripts admits that "we need to be careful how we respond" because if it is "fully transparent, we could los[e] leverage with the brand name pharmaceutical manufacturers."

94. The only explanation for these actions is that the higher WAC prices are associated with higher rebates and/or other payments to the PBMs.

B. PBMs' Rebate Tactics Lead to WAC Inflation

95. Manufacturers compensate for rising rebates by increasing WAC to maintain profit margins. Over time, the gap between WAC and the net price (the price the manufacturer receives for selling the drug) has become significant.

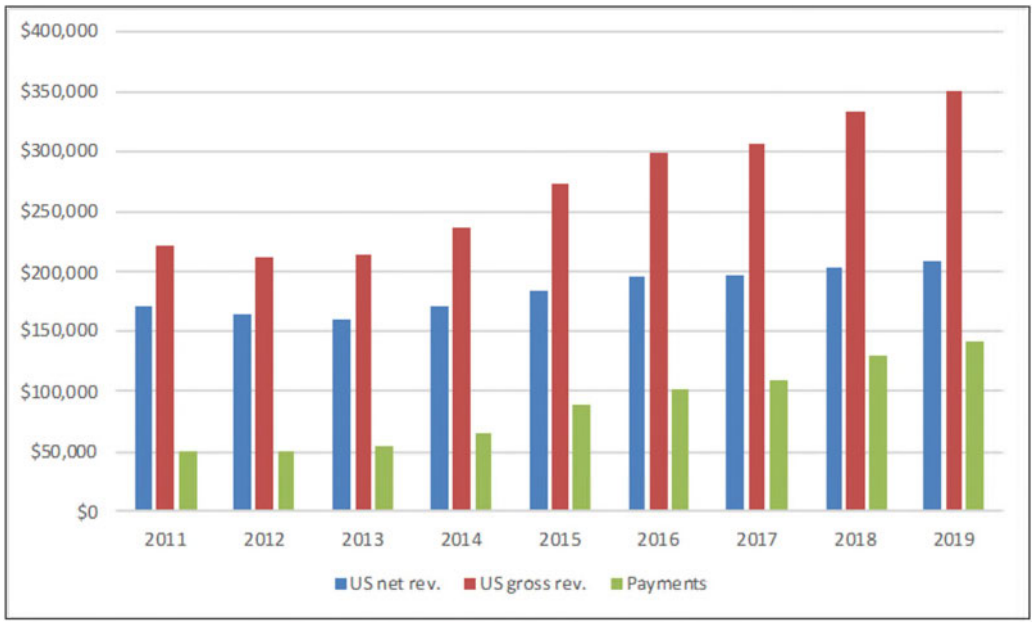
96. From 2011 to 2019, payments from prescription drug manufacturers (mostly rebates to PBMs) nearly tripled.[57] In 2011, a sample of 13 manufacturers paid 29.2% of their net revenue ($50.1 billion) to PBMs and other intermediaries to generate $171.8 billion in net sales. By 2019, the same manufacturers paid more than twice that amount: 67.4% of net revenue ($141.4 billion) to generate $209.9 billion in net sales.

97. In January of 2021, the Senate Finance Committee released a report detailing a bipartisan investigation into the skyrocketing price of insulin. One of the report's key findings is that WAC prices for insulin rose sharply between 2013 and 2019 in step with an exponential increase in rebates for these products.[58]

[57] Gill, *supra* note 25.
[58] Senate Finance Committee Insulin Report, *supra* note 3 at 7.

98. Around 2014—when PBMs' exclusion tactics created a rise in rebates—WAC and payments from manufacturers began growing disproportionately higher than manufacturers' net revenue (as shown in Figure 4 below).

Figure 4: Prescription Drug Manufacturer Revenue & Payments from 2011-2019

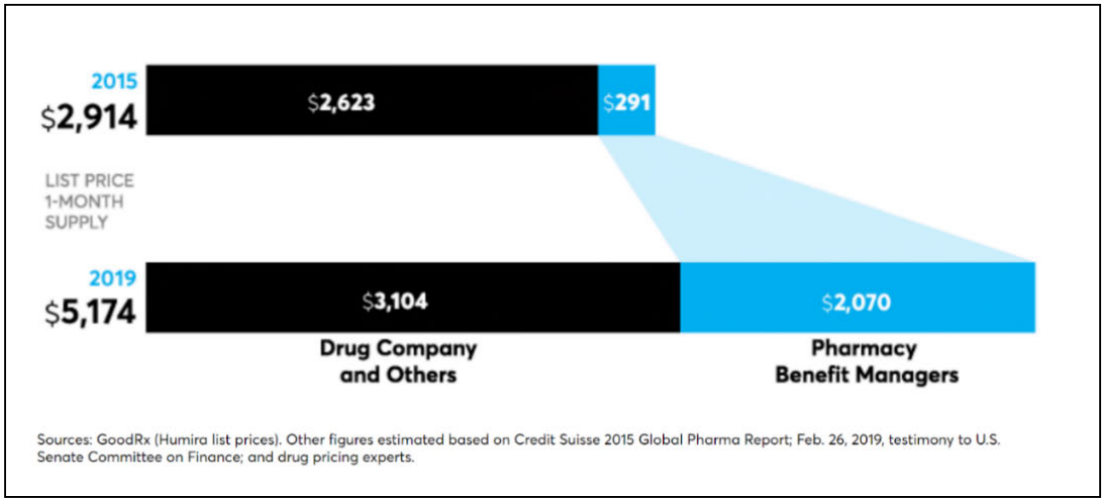


99. In a 2015 internal presentation, CVS Caremark observed that price inflation was higher for preferred drugs (*i.e.*, drugs that CVS Caremark awarded preferred formulary placement) than it was for non-preferred drugs.

100. Humira, AbbVie's blockbuster rheumatoid arthritis drug, is a good example of WAC inflation (as shown in Figure 5 below). Humira's WAC increased 78% from 2015 to 2019.[59] Yet, most of the WAC increase is attributable to rebates—which grew over 600% during this period. In sharp contrast, the net price AbbVie received for Humira only grew about 18% (from $2,623 to $3,104 in 2019).

[59] Gill, *supra* note 25.

Figure 5: Humira Price Increase from 2015-2019



101. Express Scripts provided data for the Humira pen 40mg/0.8ml. From 2015 to 2018, the WAC price rose 53% from $3,382.56 to $5,184.25 while the rebate went from [redacted] to [redacted].

102. A 2020 study found that for prescription drugs sold from 2016 to 2018, on average, a $1 increase in rebates was associated with a $1.17 increase in WAC.[60]

103. PBMs claim that prescription drug manufacturers—not PBMs—are responsible for inflating WAC. This is misleading. Manufacturers set WAC for their drugs; however, PBMs indirectly control list prices by negotiating drug rebates so high that manufacturers must raise WAC to protect their revenue and profit margins.

104. In January of 2022, in an argument before the Tenth Circuit, Sanofi claimed that PBMs were responsible for the exorbitant cost of Mylan's EpiPen. Sanofi explained that Mylan raised the price of EpiPen in order to allow the manufacturer to cut deals with PBMs and other purchasers in exchange for their agreement to give EpiPen preferential treatment or to not cover

[60] Neeraj Sood et al, *The Association Between Drug Rebates and List Prices*, USC Schaeffer Center (Feb. 11, 2020), https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/.

Sanofi's competing product, Auvi-Q. Sanofi also disclosed that it paid Express Scripts $36 million in rebates on an unrelated product in exchange for Express Scripts agreeing to cover Auvi-Q.[61]

105. In another example of PBMs driving list price inflation, Eli Lilly decided to offer its brand-name insulin product (Humulin) as an authorized generic—a highly unusual move for a drug that is still under patent—because PBMs do not impose rebates on generic drugs.[62] Eli Lilly sold Humulin (a brand-name product) for $184 with a net revenue of $83.44. In sharp contrast, Eli Lilly sold its authorized generic insulin for $92.50—half the price of its brand-name insulin. Because Eli Lilly's authorized generic has no rebates, there is nothing incentivizing Eli Lilly to inflate the list price. To the contrary, Eli Lilly was able to reduce the price of its product by 50% and make slightly more profit.

III. PBMs Profit from Inflated WAC and High Rebates

106. PBMs are incentivized to drive up WAC. Typically, PBMs retain a portion of the manufacturer payments they negotiate. Thus, the larger the spread between manufacturer payments and WAC, the greater the potential for PBMs to profit.

107. CVS Health (CVS Caremark's parent company) admitted that CVS Caremark profits from the inflated list price/high rebate dynamic in 2019 when CVS Health reported that CVS Health missed its projected earnings, because CVS Caremark "was experiencing a squeeze related to . . . rebates" and "seeing slower growth than it . . . expected in the list prices of branded drugs."[63]

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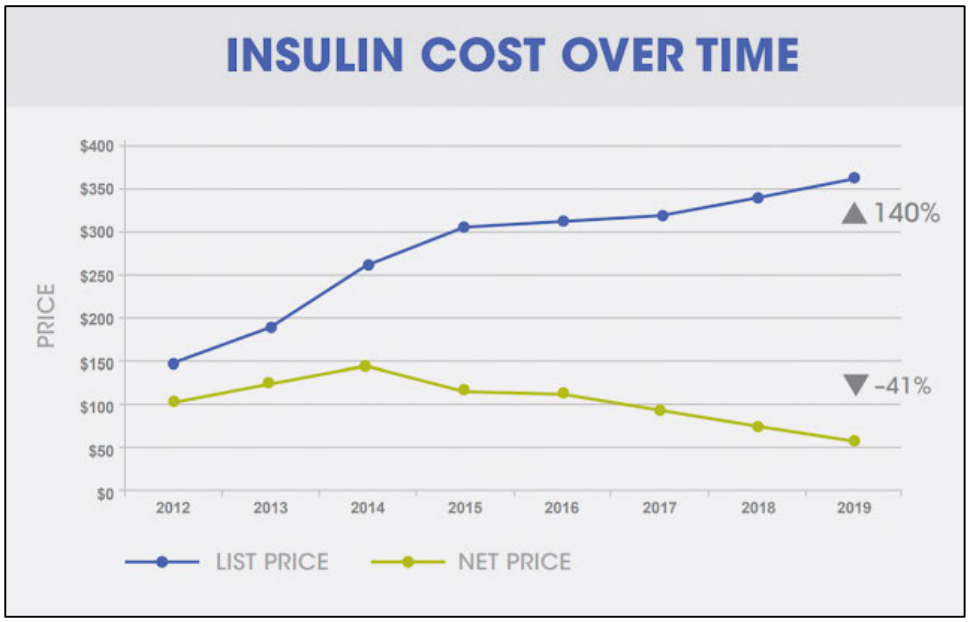
[61] Matthew Perlman, *Sanofi Tells 6th Cir. It Paid $36M To Access ApiPen Market*, Law360 (Jan. 19, 2022), https://www.law360.com/competition/articles/1456660/sanofi-tells-10th-circ-it-paid-36m-to-access-epipen-market.

[62] Weinstein and Schulman, *supra* note 2, at 108.

[63] Sharon Terlep and Joseph Walker, *Generic-Drug Trends Squeeze Walgreens Profit*, Wall St. J. (Apr. 2, 2019), https://www.wsj.com/articles/walgreens-cuts-earnings-guidance-after-a-challenging-second-quarter-11554204891.

108. Prescription drug manufacturers, on the other hand, do not seem to be retaining the benefit of (or at least not most of the benefit of) WAC increases. For example, as shown in Figure 6 below, Sanofi disclosed that WAC for its insulins grew 140% from 2012 to 2019, while net prices (*i.e.*, the revenue Sanofi received) declined by 41%.[64]

Figure 6: Sanofi Insulin Prices from 2012-2019



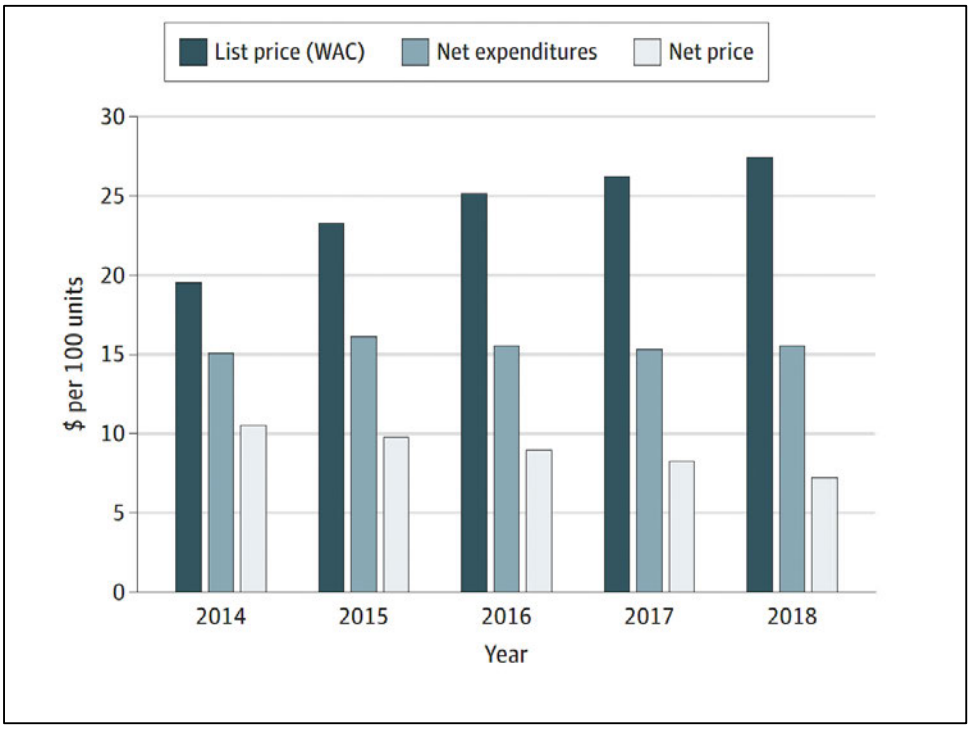
109. A recent study from the University of Southern California's Schaeffer Center confirmed this dynamic. It found (as shown in Figure 7 below) that from 2014-2018, WAC prices for insulin have risen, while net prices have dropped.[65] Further, it discovered that intermediaries, such as PBMs, drug wholesalers, and pharmacies, received an ever-growing share of the difference

[64] Adam Fein, *Drug Channels News Roundup, March 2020: Sanofi's Gross-to-Net Bubble, Drug Pricing Findings, Amazon Replaces Express Scripts, and Drug Channels Video*, Drug Channels (Mar. 31, 2020), https://www.drugchannels.net/2020/03/drug-channels-news-roundup-march-2020.html.

[65] Karen Van Nuys, *Estimation of the Share of Net Expenditures on Insulin Captured by US Manufacturers, Wholesalers, Pharmacy Benefit Managers, Pharmacies, and Health Plans from 2014 to 2018*, 2(11) JAMA Health Forum (Nov. 5, 2021), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2785932.

between WAC and net revenue. The PBMs' share of insulin expenditures increased by 154.6% from $5.64 out of every $100 in 2014 to $14.36 in 2018.

Figure 7: Mean List Price, Net Price, and Net Expenditures for Select Insulin Products (2014-2018)



110. Internal documents from Novo Nordisk (another large insulin manufacturer) show that in 2018 the company considered, but ultimately decided against, lowering WAC for its insulin products by 50%.[66] The company's pricing committee warned that reducing WAC posed significant financial risk to the company—even though the manufacturer's net price would remain the same. One of Novo Nordisk's primary concerns was facing retributive action from other entities in the pharmaceutical supply chain that derive payments based on WAC (like PBMs). Novo Nordisk specifically identified as downsides "formulary removal" and "CVS, Express Scripts, & Optum push to be kept whole." In other words, Novo Nordisk worried that if it set the

[66] Senate Finance Committee Insulin Report, *supra* note 3 at 61-63 and Appendix 3 p. 206-212.

WAC for its insulin products at their true costs (Novo Nordisk's net price) instead of an inflated price with a 50% rebate, Novo Nordisk risked being removed from the big three PBMs' formularies or having to pay the big three PBMs their cut of the now eliminated 50% rebate.

111. In a 2014 internal email, CVS Caremark remarked that a "substantial price increase" would generate additional revenue for CVS Caremark: "We've run this through our price protection forecast model and have determined the impact to 1Q15 is substantial. On the commercial book we expect this price increase to generate ~ $24.5mm in gross rebates and at a 25% retention would mean ~$6mm net. On the Med D book we expect ~$8mm in gross rebates and at a 14% retention would mean ~$1mm net."

112. Similarly, in a 2016 email, Express Scripts stated that it had "very large" rebates, as high as 50%, for insulins and that they continue to negotiate deeper rebates with each contracting cycle. They continued to state that insulins are "a high cost driver for the vast majority of our book." Two years later, Express Scripts discussed removing Novo Nordisk's Basal insulins from its Commercial Formulary to "capture Lantus' exclusive rate," which would "force Novo to split Tresiba and Levemir if they wanted to save one." In addition, it would force Sanofi to offer a "much deeper rate" if it wanted to capture the newly vacated market share.

IV. PBMs' Manipulation of Drug Pricing Harms Consumers and the State

113. PBMs' tactics to manipulate drug pricing harm consumers. The most obvious harm is increased prices. Inflating WAC increases consumers' costs because most consumers' out-of-pocket costs are tied to WAC.

114. For example, when AbbVie raised WAC for Humira from $2,914 in 2015 to $5,174 in 2019, consumers with coinsurance (who typically pay around 30% of WAC) saw their out-of-pocket costs for a one-month supply balloon from $874 in 2015 to $1,552 in 2019.[67]

115. In the context of insulin, the State found through its review of CVS Caremark's insulin data for Hawai'i that from 2016 to 2018, the average WAC price per prescription rose over 38% from $326 to $451 while the average rebate for insulin products increased from 31% of the WAC price to 57% of the WAC price. During the same time, the average out-of-pocket cost for consumers with coinsurance (meaning they pay a percentage of the WAC price rather than a flat copayment) increased over 83% from $52.11 to $95.45 per prescription.

116. In contrast, 2019—the year Congress asked several PBMs, including CVS Caremark, to testify regarding skyrocketing drug prices—CVS Caremark's Hawai'i data shows a modest decrease in the rebate rate which corresponds with a modest decrease in the average WAC price per insulin prescription and out-of-pocket costs for consumers with coinsurance.

117. Even more surprising, the increase in the WAC price and consumers' out-of-pocket costs are not shown in the net payments to manufacturers. For example, as discussed above, from 2016 to 2018, the average WAC price per prescription in Hawai'i rose over 38% from $326 to $451; however, the average net cost per prescriptions (*i.e.*, the average price the manufacturers received for each prescription) barely changed. The average net cost per prescription from 2016-2018 was $164.67, $141.37, and $166.94, respectively.

118. These disparities become even more stark when the insulin data is disaggregated. From 2014 to 2019, the price of the Lantus Solostar pen increased 40% from $303.12 and

[67] Gill, *supra* note 25.

$425.25.[68] The rebate for Lantus Solostar increased over 240% from 18% in 2016 to 62% in 2019. Yet, out-of-pocket costs for consumers with coinsurance during the same time climbed sharply from $45.22 per prescription to $87.03 per prescription (an increase of over 90%).

119. The Hawai‘i data for Express Scripts and OptumRx followed the same trend. For example, Express Scripts' Hawai‘i data shows the price of Levemir FlexTouch (an insulin product) increased over 50% from $303.12 in 2014 to $462.21 in 2020.[69] Likewise from 2016 to 2020, the rebate rose from [redacted] to [redacted] (an increase of nearly [redacted]). The average out-of-pocket cost per prescription for Levemir FlexTouch, however, increased from $1.94 in 2015 to $10.62 in 2020 (down from $24.25 in 2018 and $18.13 in 2019).

120. OptumRx's Hawai‘i insulin data shows a similar spike in the price of the Novolog FlexPen. From 2013 to 2021, the price of the Novolog FlexPen increased 72% from $324.75 to $558.90.[70] Interestingly, there were no price increases for Novolog FlexPen from 2019 to 2021—a time during which PBMs and insulin manufactures faced intense scrutiny over the cost of insulin. From 2016 to 2021, the rebate for the Novolog Flex Pen went from [redacted] to [redacted]. Despite the substantial rebate increase, consumers' average out-of-pocket costs per prescription grew by over 30% from $25.83 to $34.16. OptumRx did not provide the State a breakdown between out-of-pocket costs for consumers with coinsurance versus flat copayments; however, it is very likely that cost increases were borne disproportionately by consumers with coinsurance as opposed to flat copayments.

[68] Although CVS Caremark only produced data from 2016 to 2019, the State obtained additional pricing data from the Senate Finance Committee Insulin report.
[69] Although Express Scripts only produced data from 2016 to 2020, the State obtained additional pricing data from the Senate Finance Committee Insulin report.
[70] Although OptumRx only produced data from 2016 to 2021, the State obtained additional pricing data from the Senate Finance Committee Insulin report.

121. At an April 2019 Congressional hearing on the rising cost of insulin, Novo Nordisk's President acknowledged that the "perverse incentive" in drug pricing harms consumers:

> [T]here is this perverse incentive and misaligned incentives and this encouragement to keep list prices high, and we've been participating in that system because the higher the list price, the higher the rebate. . . . There's a significant demand for rebates. . . . [W]e're spending almost $18 billion a year in rebates, discounts, and fees, and we have people with insurance with diabetes that don't get the benefit of that.[71]

122. At that same hearing, an executive from Sanofi stated: "I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient."[72]

123. Upon information and belief, CVS Caremark also caused the State to pay a greater percentage of the increased drug costs. For example, CVS Caremark services Hawaii's Employer-Union Health Benefits Trust Fund ("EUTF"), which provides prescription drug benefits, as well as other health benefits, to eligible State of Hawai'i, City and County of Honolulu, County of Hawai'i, County of Maui and County of Kauai employees and retirees. The State's review of CVS Caremark's data shows that from 2016 to 2019, the prescription drug plan sponsored by EUTF consistently received lower rebates for insulin products than non-State health plans (*see* Figure 8 below summarizing CVS Caremark's data). During this time, the State kept cost-share payments in its EUTF program relatively flat—and as a result, upon information and belief, the State paid a higher portion of the increased drug costs than other payers. This is a significant burden to the State which, for example, paid claims for over 150,000 insulin products from 2016-2019.

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[71] *Priced Out Of A Lifesaving Drug: Getting Answers On The Rising Cost Of Insulin Before the Subcomm. On Oversight and Investigations*, 116th Cong. 86, 88 (2020) (Statement of Doug Langa, President of Novo Nordisk), https://www.congress.gov/event/116th-congress/house-event/LC65499/text?s=1&r=1.

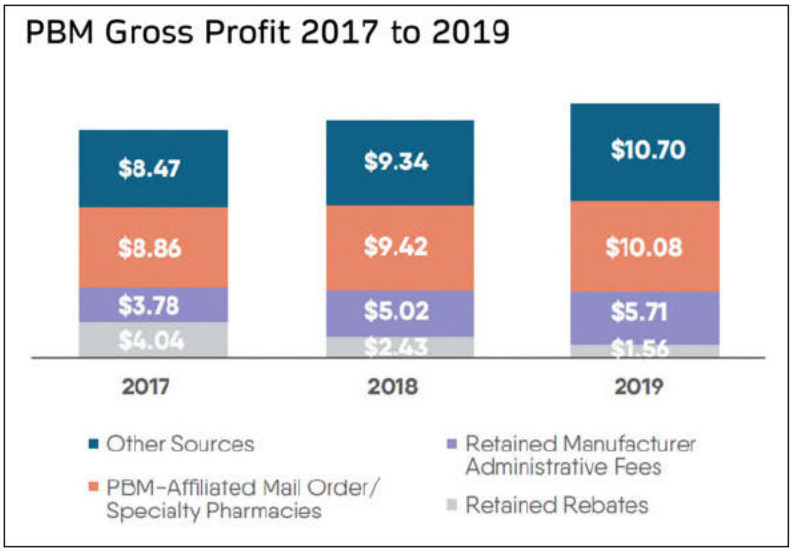
[72] *Id*. at 112 (Statement of Kathleen Tregoning, Executive Vice President for External Affairs of Sanofi).

Figure 8: Rebates for Non-State Programs vs. Rebates for EUTF

Year	Rebate for Non-State Programs (% of the WAC Price)	Rebate for EUTF (% of the WAC Price)
2016	33%	27%
2017	57%	50%
2018	63%	55%
2019	60%	33%

124. Moreover, it appears that PBMs may be reclassifying rebates as other fees in order to retain a higher percentage of these payments. From 2017 to 2019, PBMs' gross profits have increased from $25B to $28B even as retained rebates have decreased, as a result of increasing administrative and data fees (as shown in Figure 9 below).[73]

Figure 9: PBMs' Gross Profits from 2017 to 2019



125. Upon information and belief, Defendants may be conducting these activities through the use of group purchasing organizations ("GPOs")—some of which are offshore

[73] Seth Joseph, *How To Get Away With Corporate Murder: Unbundling And Disrupting Pharmacy Benefit Managers (Part 1)*, Forbes (Nov. 13, 2022), https://www.forbes.com/sites/sethjoseph/2022/11/13/how-to-get-away-with-corporate-murder-unbundling-and-disrupting-pharmacy-benefit-managers-part-1/?sh=1bcfd0647bc0.

corporations—to categorize and recategorize income streams, which allows Defendants to, at arm's length, determine how they will define "rebates" and, by extension, their obligation to pass through "rebates."[74]

126. Beyond pricing, drug exclusions cause harm by forcing non-medical switching (altering a consumer's drug therapy for reasons other than a drug's efficacy, side effects, or clinical outcome). In other words, the choice of drugs available to consumers becomes driven not by which drug is safest or most effective for consumers, but on financial side-deals governing whether and at what cost-share a drug is placed on a PBM's formulary.

127. In 2008, CVS Caremark entered into a $38.5 million settlement agreement with 28 State Attorneys General (not including Hawai'i) to resolve allegations that the PBM engaged in deceptive business practice by encouraging doctors to switch consumers to different brand-name drugs by saying the consumers or their health plans would save money without disclosing that the drug switching would benefit CVS Caremark.[75]

128. In the intervening years, the basic business practices have not changed, but have only become more profitable to PBMs, still at consumers' expense. Historically, PBM exclusions have focused on medicines with generic equivalents or classes where multiple products have been shown to achieve similar clinical outcomes. Now, PBMs often exclude medicines for conditions, such as oncology, HIV, and autoimmune disorders, for which variation in patient response to treatment has been well-documented.[76]

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[74] *Id.*
[75] Illinois Attorney General, *Madigan, 28 Attorneys General Reach Settlement with Caremark for Drug Switching Practices* (Feb. 14, 2008), https://www.illinoisattorneygeneral.gov/pressroom/2008_02/20080214.html.
[76] Xcenda, *supra* note 47, at 1.

129. PBMs have claimed that formulary exclusions only affect a small percentage of consumers. However, each of the big three PBMs manages prescription drug coverage for tens of millions of consumers, including hundreds of thousands of Hawai‘i residents. For example, in a 2018 presentation related to Medicare formulary exclusions, Express Scripts admitted that changes to its Basal and Long-Acting Insulin categories would impact nearly 99% of Medicare members. The same presentation also shows that exclusion decisions based on the lowest WAC on its standard formulary would impact 1 in 6 beneficiaries. Upon information and belief, non-Medicare beneficiaries are likely equally impacted by drug exclusions.

130. This means that hundreds of thousands of individuals may be forced to switch from their current medication to their PBM's preferred alternative each year. Further, because medications to treat chronic diseases are among the most frequently targeted by formulary exclusions, vulnerable patients with chronic illnesses are disproportionately affected.[77]

131. For these patients, who often have treatment regimens involving multiple medications that need to work together, having access to their choice of medications can be critical. Frequent changes can be particularly problematic, as changes in one medication can trigger the need for other changes and disrupt treatment.[78] A 2013 complaint to Express Scripts reflects this problem as one member affected by Express Scripts' decision to exclude Novolog noted in an email with the company's representatives that "many type-1 diabetics experience a change in blood sugars when transitioning from Humalog to Novolog and vice versa."

132. Similarly, PBMs have been increasingly excluding drugs approved under the FDA's expedited pathways for novel medicines that meet specific criteria and address unmet

[77] Xcenda, *supra* note 47, at 11.
[78] *Id.*

medical needs in the treatment of serious and even life-threatening conditions (*e.g.*, Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval, and Priority Review). In 2016, the big three PBMs each excluded one or two products approved through an expedited pathway. In 2022, the big three PBMs each excluded between fourteen to thirty-four products approved through an expedited pathway.

133. In a 2014 internal presentation, CVS Caremark noted that if it covered all drugs with a Breakthrough Therapy designation, it was essentially assigning its formulary decisions to the FDA, which "results in loss of leverage with pharma."

134. Moreover, because each PBM excludes different medications, and different health plans contract with different PBMs, consumers who change jobs and/or health plans may find their current medications are not covered.

CLAIMS FOR RELIEF

COUNT ONE

Violations of HRS § 480-2
Deceptive Acts and Practices

135. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

136. HRS § 480-2 prohibits deceptive acts or practices in any trade or commerce.

137. At all times relevant to this Complaint, the Defendants engaged in deceptive acts or practices in trade or commerce in violation of HRS § 480-2 by:

a. Misrepresenting that the Defendants function to lower the cost of prescription drugs;

b. Misrepresenting that rebates and other payments from manufacturers lower the cost of prescription drugs;

c. Misrepresenting that rebates and other payments from manufacturers do not inflate the WAC price for brand-name prescription drugs;

d. Misrepresenting that formulary decisions are evidence and/or value based;

e. Failing to disclose that the cost share payments insured consumers pay for brand-name prescription drugs are tied to inflated WAC prices rather than the prices that Defendants and/or third-party payers actually pay for prescription drugs;

f. Failing to disclose that the Defendants financially benefit from inflated WAC prices, which allow them to negotiate substantial rebates and other payments from manufacturers for brand-name prescription drugs;

g. Failing to disclose that the Defendants financially benefit from preferring and/or excluding certain prescription drugs in their formularies; and

h. Failing to disclose that formulary exclusions are not based on the best clinical interests of the patient.

138. Upon information and belief, the State believes Defendants' conduct is ongoing.

139. The Defendants' misrepresentations and omissions were material and likely to mislead consumers and third-party payers.

140. The Defendants' deceptive practices constitute multiple violations of HRS § 480-2.

COUNT TWO

Violations of HRS § 480-2
Unfair Acts and Practices

141. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

142. HRS § 480-2 prohibits unfair acts or practices in any trade or commerce.

143. At all times relevant to this Complaint, the Defendants engaged in unfair acts or practices in trade or commerce in violation of HRS § 480-2 by engaging in a scheme to inflate the WAC price for prescription drugs to allow the Defendants to extract higher fees.

144. Defendants' unfair acts and practices offend established public policy in Hawai'i and are immoral, unethical, oppressive, and unscrupulous and substantially injurious to consumers.

145. Upon information and belief, the State believes Defendants' conduct is ongoing.

COUNT THREE

Violations of HRS § 480-2
Unfair Methods of Competition

146. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

147. HRS § 480-2 prohibits unfair methods of competition in any trade or commerce.

148. Defendants' business practices described herein, including practices that inflate the WAC price for brand-name prescription drugs to allow the Defendants to extract higher fees, constitute unfair methods of competition.

149. Defendants' practices harm competition because they inflate the price for prescription drugs beyond their fair market value and restrict consumers' access to life-saving drugs. In addition, Defendants' practices disadvantage manufacturers unwilling to pay exorbitant rebates and other payments—even if those manufacturers make a superior or more cost-effective prescription drug. Defendants' practices also disadvantage PBMs that are not engaging in similar practices by making them less competitive in the PBM market and lessening their abilities to lower drug costs for their clients and, ultimately, consumers.

150. The State is not seeking relief relating to any federal program (*e.g.*, Medicaid, Medicare, TRICARE, FEHBA) or any contract related to a federal program. Moreover, the State's

claims are not limited to insulin or other diabetes medications, but rather are based on the larger unfair and deceptive scheme that violates HRS § 480-2 and increased prices and reduced access to brand-name prescription drugs for Hawai‘i consumers.

151. Upon information and belief, the State believes Defendants' conduct is ongoing.

COUNT FOUR

Violations of HRS § 480-2
State Damages

152. The State re-alleges and incorporates herein by reference each of the allegations contained in the preceding paragraphs.

153. HRS § 480-14 states: "Whenever the State or any of its political subdivisions or governmental agencies is injured, directly or indirectly, in its business or property by reason of anything forbidden or declared unlawful by this chapter, it may sue to recover threefold the actual damages sustained by it, whether directly or indirectly."

154. As described above, Defendants' unfair and deceptive scheme to inflate the WAC price for brand-name prescription drugs allowed the Defendants to extract higher fees. Upon information and belief, this scheme ultimately resulted in artificially inflated prices across the market for brand-name prescription drugs because the WAC price remains constant regardless of who is purchasing the drugs.

155. Defendants' unlawful conduct thus damaged the State by increasing the price the State paid for brand-name prescription drugs.

PRAYER FOR RELIEF

The State of Hawai‘i prays for entry of judgment against Defendants individually, and jointly and severally, for all the relief requested herein and to which the State may otherwise be entitled, including, without limitation:

A. The Court enter an order and judgment against Defendants and in favor of the State for each violation alleged in this Complaint;

B. Declare that Defendants' acts and practices alleged herein are unfair and deceptive practices in violation of HRS § 480-2; and that Defendants' conduct breached and violated the statutory and common law causes of action alleged herein;

C. Enjoin Defendants from engaging in unfair and deceptive practices in violation of HRS § 480-2;

D. Require Defendants to pay all consumer restitution that may be owed to consumers in Hawai'i affected by Defendants' unlawful acts and practices, under the authority of HRS § 661-10;

E. Require Defendants to disgorge ill-gotten gains;

F. Require Defendants to pay threefold the actual damages incurred by the State as a result of Defendants' unfair and deceptive scheme resulting in increased prescription drug prices pursuant to HRS § 480-14;

G. Given the repeated and ongoing violations of the law, punish violations of HRS § 480-2 by an Order requiring Defendants to pay maximum civil penalties under HRS § 480-3.1 for each and every violation of section 480-2, and additional civil penalties for each violation committed against an elder under HRS § 480-13.5;

H. Assess and award a judgment in favor of the State and against Defendants for attorneys' fees and costs and pre- and post-judgment interest; and

I. Award any and all other relief this Court deems appropriate.

DATED: Honolulu, Hawai‘i, November 6, 2023.

/s/ *Ciara W.K. Kahahane*
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