

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

DENISE ELAYNE JONES and  
MARILYN A. MANZI, individually and  
on behalf of all others similarly situated,

Plaintiffs,

v.

CVS HEALTH CORPORATION, f/k/a  
CVS CAREMARK CORPORATION,  
SILVERSCRIPT INSURANCE  
COMPANY, LLC, CAREMARK L.L.C.,  
f/k/a CAREMARK INC., CVS  
PHARMACY, INC., and CVS  
CAREMARK PART D SERVICES,  
LLC,

Defendants.

Case No. 2:24-cv-01703

**AMENDED COMPLAINT - CLASS ACTION**

**DEMAND FOR JURY TRIAL**

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Plaintiffs Denise Elayne Jones (“Plaintiff Jones”) and Marilyn A. Manzi (“Plaintiff Manzi”) (collectively, “Plaintiffs”), bring this action individually and on behalf of all others similarly situated (as defined below, the “Classes”) and allege the following against Defendants CVS Health Corporation (“CVS Health”), SilverScript Insurance Company, LLC (“SilverScript”), Caremark L.L.C., CVS Caremark Part D Services, LLC (together, “CVS Caremark”), and CVS Pharmacy, Inc. (“CVS Pharmacy”) (collectively herein “Defendants” or “the CVS Defendants”). These allegations are based on information known to Plaintiffs, investigations of counsel, publicly available materials, and knowledge, information, and belief.

## **I. INTRODUCTION**

1. For years, the CVS Defendants, along with five of the largest manufacturers of brand drug products (the “Manufacturer Co-Conspirators”),<sup>1</sup> have implemented a fraudulent scheme to prevent Plaintiffs and other Medicare Part D beneficiaries covered by SilverScript plans from accessing cheaper generic equivalent versions of the prescription drugs Invega, Asacol HD, Renvela packets, Renvela tablets, Harvoni, Eplclusa, Ventolin HFA, Canasa Rectal Suppository, and Advair Diskus (together, the “Affected Drugs”). This scheme has resulted in these beneficiaries only having access to the costlier brand name versions of the Affected Drugs. As a result of their fraudulent scheme, the CVS Defendants and their co-conspirators have ensured astonishing profits for themselves at the expense of elderly patients suffering from the life-altering illnesses that the Affected Drugs and their generic equivalents treat.

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<sup>1</sup> The Manufacturer Co-Conspirators are Janssen Pharmaceuticals, Inc. (“Janssen”), the manufacturer of Invega; Allergan plc (now owned by AbbVie Inc.) (“Allergan”), the manufacturer of Asacol HD and Canasa Rectal Suppository; Sanofi-Aventis U.S. LLC (“Sanofi”), the manufacturer of Renvela packets and Renvela tablets; Gilead Sciences, Inc. (“Gilead”), the manufacturer of Harvoni and Eplclusa; and GlaxoSmithKline (“GSK”), the manufacturer of Ventolin HFA and Advair Diskus.

2. In order to provide health insurance to the elderly and disabled, Congress enacted Medicare Part D. To provide benefits to Medicare Part D enrollees, Medicare enters into contracts with private companies known as Part D sponsors. SilverScript, which is owned by CVS Health, is one such sponsor. Plaintiffs and members of the Classes are beneficiaries under SilverScript's Medicare Part D Prescription Drug Plan.

3. The CVS Defendants conspired with the Manufacturer Co-Conspirators to block SilverScript beneficiaries, including Plaintiffs and members of the Classes, from accessing less-expensive FDA-approved generic versions of the Affected Drugs. The scheme (hereinafter the "No Generic Scheme" or "NG Scheme") worked as follows. The CVS Defendants received lucrative rebates from the Manufacturer Co-Conspirators in exchange for preventing SilverScript beneficiaries from accessing FDA-approved generics of the Affected Drugs—by including only the brand drugs on the SilverScript formulary and inhibiting members of the Classes from seeking formulary exceptions and other means of receiving less costly generic versions of the Affected Drugs. The Manufacturer Co-Conspirators benefited by garnering greater sales revenue when SilverScript beneficiaries were prevented from accessing competing generic versions of the Affected Drugs and instead were dispensed brand versions of the Affected Drugs. Plaintiffs and members of the Classes, on the other hand, were harmed by this elicited scheme. They paid higher out-of-pocket costs for the brand name Affected Drugs, in lieu of receiving less costly generic versions of the Affected Drugs.

4. The CVS Defendants employed several methods to prevent Plaintiffs and members of the Classes from accessing generic equivalents of the Affected Drugs and to force Plaintiffs to continue to pay for the branded Affected Drugs.

5. First, as part of the No Generic Scheme, CVS Caremark, SilverScript's pharmacy benefit manager ("PBM"), negotiated with the Manufacturer Co-Conspirators to receive substantial rebates in exchange for agreeing to list the brand versions of the Affected Drugs, and exclude the less costly generic versions of those drugs, on the drug formularies for SilverScript. A drug formulary is a list of drugs covered by a health insurance plan. Typically, if a drug is not on formulary, then it is not covered by the plan, meaning the beneficiary must pay for most, if not all, of the cost of the drug themselves.

6. Because of this exclusive formulary arrangement, whenever a SilverScript beneficiary, like Plaintiffs and members of the Classes, attempted to fill a prescription for one of the Affected Drugs, the pharmacy, including CVS Pharmacies (as defined below), would fill the prescription with the brand instead of the generic. Accordingly, by not placing the generic equivalents of the Affected Drugs on SilverScript's formulary, SilverScript beneficiaries were left in a situation where only the brand versions of the Affected Drugs—and not their less-expensive generic equivalents—were covered by their health insurance plan.

7. Second, as part of the No Generic Scheme, CVS Pharmacy made deals with distributors and suppliers to ensure that the generic equivalents of the Affected Drugs were either not stocked at CVS Pharmacies or purposely kept in low supply. This was a remarkably brazen and far-reaching arrangement. It blocked access to generic drugs for not just SilverScript beneficiaries, but to any patients who attempted to fill their prescriptions at a CVS Pharmacy.

8. Third, SilverScript and CVS Pharmacies trained their customer care representatives and pharmacists to provide intentionally misleading and incomplete information to SilverScript beneficiaries about (i) the availability of less-costly generic drugs, and (ii) the cost differential between brand name and generic medications, even claiming at times that the brand name Affected

Drugs would be cheaper for Plaintiffs and members of the Classes than the generic equivalents of those drugs.

9. Normally, the existence of various entities in the chain of drug coverage and distribution would prevent this type of collusive behavior because arm's length competitive interactions between prescription drug plans ("PDPs"), PBMs, and pharmacies would serve as a system of checks and balances to ensure that consumers receive the least-expensive, clinically effective FDA-approved medication possible. As the U.S. Department of Health and Human Services ("HHS") Office of Health Policy has explained, "[t]he United States relies on the interactions of private entities—drug manufacturers, health plans and pharmaceutical benefit managers (PBMs)—to achieve value by negotiating prices, operating formularies and implementing other benefit management strategies."<sup>2</sup>

10. Instead, because the CVS Defendants—which include the PDP (SilverScript), the PBM (CVS Caremark), and the CVS Pharmacy chain—are all part of the same corporate family under CVS Health, they were able to ensure that the No Generic Scheme was implemented at every stage of the drug coverage and distribution line.

11. Notably, the CVS Defendants engaged in this No Generic Scheme for the Affected Drugs despite the fact that they knew that (i) the laws of 17 states and territories<sup>3</sup> require the automatic substitution of FDA-approved generic equivalents for brand name drugs and (ii)

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<sup>2</sup> Ass't Sec'y for Planning & Evaluation, *Medicare Part D: Competition and Generic Drug Prices*, HHS, (Jan. 19, 2021), [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files/198346/medicare-part-d-generic-comp.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/198346/medicare-part-d-generic-comp.pdf).

<sup>3</sup> The following states have statutes requiring the automatic substitution of generic prescription drugs for their brand name counterparts: Florida, Hawaii, Kentucky, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Pennsylvania, Puerto Rico, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin (collectively referred to herein as the "Automatic Substitution States").

Medicare regulations require Part D plan sponsors to ensure pharmacies inform beneficiaries of cost differentials between brand and generic drugs. By agreeing to and implementing the No Generic Scheme, the CVS Defendants knowingly violated their obligations under federal and state law to provide SilverScript beneficiaries with access to the generic equivalents of the Affected Drugs, and information regarding the price differentials between these generics and their brand counterparts.

12. Since at least November 2015 and continuing through today, Defendants have engaged in the fraudulent conduct described herein, including the No Generic Scheme.

13. Because the full details of the NG Scheme between the CVS Defendants and the Manufacturer Co-Conspirators are secretive, only full discovery will reveal the specific terms of their agreements. But what is clear now is that the CVS Defendants restricted SilverScript beneficiaries' access to generic versions of the Affected Drugs by not including those generic versions on the SilverScript formularies, by understocking those generic versions in CVS Pharmacies, and by providing misleading and incomplete information and making material omissions to members of the Classes. All of this was done in exchange for lucrative payments from the Manufacturer Co-Conspirators.

14. At its core, the No Generic Scheme and the conspiracy to engage in the NG Scheme has involved a concerted effort among the CVS Defendants and the Manufacturer Co-Conspirators to knowingly prevent SilverScript beneficiaries from accessing generic versions of the Affected Drugs, instead forcing those beneficiaries to purchase brand versions of the Affected Drugs to enrich Defendants at the expense of elderly and disabled SilverScript beneficiaries, including Plaintiffs and members of the Classes.



15. Plaintiffs and members of the Classes assert claims against the CVS Defendants for violation of the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §§ 1962(c) and (d), fraud, unjust enrichment, and violation of state consumer protection laws.

16. As a direct result of Defendants’ wrongful conduct, Plaintiffs and members of the Classes have been harmed and have suffered actual damages, including overpaying for the Affected Drugs when less-expensive generic equivalents of those drugs were available.

## **II. JURISDICTION AND VENUE**

17. This Court has original diversity jurisdiction, pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2) (“CAFA”), because Plaintiffs and many members of the Class are citizens of states different from Defendants’ home states and the aggregated amount in controversy in this action exceeds \$5,000,000, exclusive of interests and costs, and there are more than 100 members of the proposed Class.

18. Jurisdiction is also proper in this Court pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1964(c), because this action arises under the federal laws of the United States. Specifically, Plaintiffs assert claims under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1962, *et seq.*

19. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367.

20. This Court has personal jurisdiction over Plaintiffs because Plaintiffs submit to the Court’s jurisdiction. This Court has personal jurisdiction over Caremark LLC and CVS Pharmacy, Inc. because they consented to jurisdiction by registering to do business in Pennsylvania. Caremark LLC and CVS Pharmacy, Inc. (i) have been registered to do business in Pennsylvania since 2007 and 1997, respectively; (ii) established Commercial Registered Office Providers in Pennsylvania to receive service of process; and (iii) regularly update their information on file with the

Pennsylvania Secretary of State. This Court has supplemental personal jurisdiction over the remaining Defendants (CVS Health Corporation, SilverScript Insurance Company, LLC, and CVS Caremark Part D Services, LLC) pursuant to 28 U.S.C. § 1367. Moreover, at all relevant times, Defendants transacted substantial business in this District. CVS Health's operations within this District include numerous retail stores, along with offices in Blue Bell, Pennsylvania, and SilverScript has a substantial presence in this District, including over 90,000 SilverScript beneficiaries in Pennsylvania (many of whom reside in this District).

21. This Court also has personal jurisdiction over Defendants under 18 U.S.C. § 1965 because they are found, have agents and/or transact business in this District, and the Court has supplemental or pendant jurisdiction over Defendants for Plaintiffs' state law claims. Alternatively, 18 U.S.C. § 1965(b) provides that as long as one defendant is subject to service in a particular district, additional parties residing in other districts may be brought before the forum court, in the Court's discretion, to the extent that "the ends of justice require."

22. Venue is proper in this District under 28 U.S.C. § 1391 because Caremark LLC and CVS Pharmacy, Inc. consented to jurisdiction in Pennsylvania and because a substantial part of the events or omissions giving rise to the claims in this action have occurred in this District. Defendants devised and implemented their fraudulent No Generic Scheme in this District and dispensed the Affected Drugs to a substantial number of SilverScript beneficiaries in this District. Venue is also appropriate under 18 U.S.C. 1965(a).

### **III. PARTIES**

23. Plaintiff Denise Elayne Jones resides in Maryland. Plaintiff Jones has been a SilverScript beneficiary and has been prescribed Advair Diskus since at least 2016. Since at least 2016, Plaintiff Jones has regularly filled prescriptions for Advair Diskus at CVS Pharmacies in Maryland, an automatic substitution state. On these occasions, CVS Pharmacy fills Plaintiff

Jones's prescription with the brand version of Advair Diskus, manufactured by GSK. Plaintiff Jones has never been offered the generic version of Advair Diskus at any point when filling her prescriptions through her SilverScript plan at CVS retail pharmacies. On several occasions, Plaintiff Jones asked to purchase the generic form of Advair Diskus from a CVS retail pharmacy, but Defendants repeatedly told her that the generic form of the drug is not available for SilverScript members nor is it offered by CVS Pharmacy. For example, during the summer of 2023, a CVS Caremark representative told Plaintiff Jones by telephone that the generic version of Advair Diskus was not available for SilverScript members nor was it offered by CVS. From at least 2016 until 2024, when Plaintiff Jones received a 30-day supply of Advair Diskus, she paid a \$20.00 copay, and when she received a 90-day supply of Advair Diskus, she paid a \$40.00 copay. Plaintiff Jones would have paid less had the generic equivalent of Advair Diskus been included on her SilverScript formulary and dispensed to her by CVS Pharmacy. For example, under Plaintiff Jones's SilverScript plan, in 2023, Plaintiff Jones would have paid \$5 for a 30-day supply of generic Advair Diskus if the generic had been covered.

24. Plaintiff Marilyn A. Manzi resides in Florida, an automatic substitution state, and has been a SilverScript beneficiary for approximately ten years. Since at least 2018, Plaintiff Manzi has regularly filled prescriptions at CVS Pharmacies in Florida, including prescriptions for Renvela tablets. On these occasions, CVS Pharmacies have filled Plaintiff Manzi's prescription with the brand version of Renvela tablets, manufactured by Sanofi. For example, when Plaintiff Manzi receives a 180-count bottle of Renvela tablets, she pays a \$47.00 copay. Plaintiff Manzi would have paid less had the generic equivalent of Renvela tablets been included on her SilverScript formulary and dispensed to her by CVS Pharmacy. Plaintiff Manzi has never been

offered the generic version of Renvela tablets at any point when filling her prescriptions through her SilverScript plan at CVS retail pharmacies.

25. Defendant CVS Health Corporation, formerly known as CVS Caremark Corporation, is incorporated under the laws of the state of Delaware, and headquartered at One CVS Drive, Woonsocket, Rhode Island 02895. CVS Health provides prescription and healthcare services throughout the United States.

26. Defendant SilverScript Insurance Company is a Tennessee corporation with its principal place of business located at 300 Montvue Rd., Knoxville, Tennessee. SilverScript is a subsidiary of CVS Health. SilverScript is a private insurance company that offers Medicare Part D prescription drug plans nationwide.

27. CVS Health operates one of the largest PBMs in the United States, which includes subsidiaries Defendant Caremark L.L.C., formerly known as Caremark Inc., and Defendant CVS Caremark Part D Services, LLC (collectively, as defined above, “CVS Caremark”). CVS Caremark is headquartered in Woonsocket, Rhode Island. CVS Caremark provides PBM services, including formulary development and establishing and maintaining pharmacy networks, for prescription drug plans, including SilverScript. Caremark LLC has been registered to do business in Pennsylvania since 2007.

28. Defendant CVS Pharmacy, Inc., a subsidiary of CVS Health, is a Rhode Island corporation with a principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. operates over 9,900 retail pharmacies located throughout the U.S. and Longs Drugs, Inc. These entities, along with CVS Caremark Mail Service Pharmacy and CVS Specialty Pharmacy, are collectively referred to herein as the “CVS Pharmacies.” CVS Pharmacy, Inc. has been registered to do business in Pennsylvania since 1997.

29. CVS Health operates SilverScript (the PDP serving Plaintiffs and members of the Classes), CVS Caremark (SilverScript's PBM), and fills prescriptions for SilverScript beneficiaries through CVS Pharmacies.

#### IV. FACTS

##### A. Entities Involved in Drug Pricing

30. A network of entities, including pharmaceutical companies, wholesalers, PBMs, pharmacies, health benefit providers (or third-party payors), and patient-consumers, are involved in selling and paying for prescription drugs.

31. *Pharmaceutical Companies.* The Manufacturer Co-Conspirators here are pharmaceutical companies (also known as drug companies or drug manufacturers), who own the rights to manufacture and market prescription drugs, including the Affected Drugs. Pharmaceutical companies typically own or contract with facilities that manufacture drugs. Pharmaceutical companies also set the list prices of their drugs, including the Affected Drugs. These list prices are used to calculate the prices and co-payments consumers and third-party payors make at the point of sale (here, the CVS Pharmacies).

32. *Wholesalers.* After production, the Manufacturer Co-Conspirators sell their drugs to FDA-registered drug wholesalers for further distribution. Wholesalers, in turn, sell pharmaceutical products to a variety of providers, including retail pharmacies, like the CVS Pharmacies, outlets, hospitals, and clinics.

33. *Retail Pharmacies.* Retail pharmacies (pharmacies with physical locations) generally purchase drugs from wholesalers, and then sell these drugs to consumers, like Plaintiffs. At the time that a consumer fills a prescription at a retail pharmacy, the retail pharmacy determines whether or not that consumer holds health insurance with prescription drug coverage and then charges the consumer a price depending on multiple factors, including the consumer's insurance

status, whether the drug is included on the consumer's insurance formulary, and, if applicable, the position of the drug on that formulary. For drugs that are listed on a formulary, consumers with insurance are usually only responsible for paying a portion of the drug's cost (in the form of coinsurance, copayment, and/or deductible payment), with the health plan picking up the remainder of the bill.

34. ***Third-Party Payors.*** Third-party payors ("TPPs") include institutional insurers, self-insured employers, and health and welfare plans. TPPs submit payments to healthcare providers on behalf of insured individuals for services rendered to those individuals. TPPs also typically pay for a portion of their beneficiaries' prescription drugs costs—here, by submitting payments to the CVS Pharmacies on behalf of their members.

35. ***Pharmacy Benefit Managers and Mail-Order Pharmacies.*** PBMs arrange financial and contractual agreements between pharmaceutical companies, pharmacies, and TPPs. In this role, PBMs perform a variety of services on behalf of their TPP clients, including negotiating rebates with pharmaceutical companies, creating drug formularies, managing billing for prescription drugs, setting the prices in coordination with manufacturers that payors will pay for prescription drugs, constructing retail pharmacy networks for TPPs, and providing mail-order pharmacy services. Defendant CVS Caremark is a PBM and operates CVS Caremark Mail Service Pharmacy.

36. PBMs make a profit in a few primary ways. First, their TPP clients pay them service fees for processing prescriptions and operating mail-order pharmacies. Second, PBMs take a cut of the drug price discounts (i.e., rebates) they negotiate with drug companies (here, the Manufacturer Co-Conspirators), a portion of which may be shared with TPPs. The manufacturers' "rebate" arrangements are meant to create an incentive for PBMs to negotiate lower real drug

prices for consumers and TPPs. Third, PBMs receive administrative fees from drug manufacturers (like the Manufacturer Co-Conspirators), which are typically a percentage of the drug's price. Consequently, PBMs make higher profits (through rebates and administrative fees) when more costly drugs are dispensed.

37. As noted, PBMs also run their own mail-order pharmacies, allowing consumers to purchase their prescription drugs directly from the PBMs, who have taken those drugs into their own possession, and have those drugs shipped to them. SilverScript beneficiaries who purchase their prescriptions through CVS Caremark Mail Service Pharmacy and CVS Specialty Pharmacy, utilize mail order services and purchase directly from the PBM, CVS Caremark.

**B. The Drug Payment & Distribution Structure**

38. Generally speaking, prescription drugs are distributed from pharmaceutical company to wholesaler, wholesaler to retail or mail order pharmacy, and retail or mail order pharmacy to patient. The downstream charges are from pharmaceutical company to wholesaler, wholesaler to pharmacy (retail or mail order), and pharmacy to TPP (in the form of reimbursement and dispensing fees) and consumers (in the form of coinsurance, copayment, or deductible payment). Put another way, the wholesaler purchases from the manufacturer, the pharmacy purchases from the wholesaler, and the consumer or TPP purchases from the pharmacy. The upstream charges are from PBMs directly back to the pharmaceutical companies. These upstream charges are price discounts the Manufacturer Co-Conspirators offer PBMs in the form of "rebates" typically occurring well after the point-of-sale transactions.

39. When a consumer who holds health insurance with prescription drug coverage purchases a prescription drug, the consumer pays her portion of the cost (whether that be a co-pay, a co-insurance payment, or deductible payment), and her insurer or health plan pays the other

portion. The pharmacy reimbursement is set by a formula negotiated between the pharmacy and the health plan (or the health plan's PBM, on behalf of the health plan).

40. The Manufacturer Co-Conspirators' list prices are the basis from which PBMs and pharmaceutical companies negotiate rebates. As previously explained, the formularies that PBMs create for their TPP clients influence patients' drug purchasing behavior significantly, including whether a brand or generic version of a drug is dispensed. The Manufacturer Co-Conspirators offer PBMs rebates—discounts off list prices—to influence the PBMs' formulary decisions in a manner that affords the drugs that they manufacture favorable treatment.

41. The NG Scheme affords the Manufacturer Co-Conspirators the ability to pay the CVS Defendants secret, but significant, payments in exchange for inclusion of brand name drugs and exclusion of competing generics from the SilverScript formularies. This mutually beneficial scheme benefits all of the co-conspirators. It allows the Manufacturer Co-Conspirators to garner continued and greater sales revenues than would otherwise be possible. And the CVS Defendants profit from the NG Scheme by securing a piece for themselves of the overall cost of the more expensive brand medication through fees and rebates.

42. As a 2022 report by the Community Oncology Alliance explains, "PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates":

Among the different sources of revenue, the most prolific by far is in the form of rebates from pharmaceutical manufacturers that PBMs extract in exchange for placing the manufacturer's drug(s) on a plan sponsor's formulary or encouraging utilization of the manufacturer's drug(s) . . . [T]he growing number and scale of rebates is the primary fuel of today's high drug prices. The truth is that PBMs have a vested interest in having drug prices remain high, and extracting rebates off these high prices. ***PBM formularies tend to favor drugs that offer higher rebates over similar drugs with lower net costs and lower rebates.*** For the majority of prescription drug transactions, only the PBMs are privy to the amount that any other entity in the supply chain is paying or receiving for drugs, granting Defendants the



opportunity to extract billions of dollars from this payment and supply chain without detection.<sup>4</sup>

43. In theory, PBMs have the most leverage to negotiate rebates when drugs are FDA-approved as therapeutically equivalent and bioequivalent, i.e., when there are generic versions of a drug. This provides an incentive to create price parity between the brand and generic.

44. The typical arms-length structure between participants in the pharmaceutical distribution chain would have normally provided a competitive check and balance against the corrupt behaviors in the NG Scheme. For example, pharmacies would ordinarily be incentivized to dispense generic drugs, rather than brand name drugs, because the profit margin to the pharmacy is typically higher for generics due to increased competition (and because they have legal obligations to do so).<sup>5</sup> Likewise, because the cost to the pharmacy customers is lower for generics, customer satisfaction is higher. But under the NG Scheme, even though some components of the business, like the CVS Pharmacies, may lose money (by not stocking generic drugs) or face potential compliance scrutiny, the vast profits reaped by CVS Health through CVS Caremark's rebate deals outweighed those concerns.

**C. The Regulatory Structure for Approval Encourages Generic Drug Competition and Substitution of Generic Drugs**

45. At its core, the NG Scheme deprived Class members of the right to obtain less-expensive generic medications. In the United States, under the federal Food, Drug and Cosmetic Act ("FDCA"),<sup>6</sup> manufacturers that create a new drug must obtain approval from the Food and

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<sup>4</sup> Letter from Kashyap Patel, MD, President, and Ted Okron, Executive Director, Cmty. Oncology Alliance to Lina M. Khan, Chairman, FTC, COA Formal Comments to FTC on Harm of Pharmacy Benefit Managed Integration (May 25, 2022), <https://communityoncology.org/research-publications/comment-letters/coa-formal-comments-to-ftc-on-harm-of-pharmacy-benefit-manager-integration/>.

<sup>5</sup> See *Pharmacy Profits from Authorized Generics*, Drug Channels (Sept. 22, 2011), <https://www.drugchannels.net/2011/09/pharmacy-profits-from-authorized.html>.

<sup>6</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

Drug Administration (“FDA”) to sell the product by filing a New Drug Application (“NDA”).<sup>7</sup> If the FDA approves the NDA, the pharmaceutical manufacturer typically receives a period of “exclusivity” during which it has the sole right to market the drug to the exclusion of FDA-approved generic competitors. Manufacturers can charge higher prices for brand name drugs.

46. The FDCA’s Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.<sup>8</sup> A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturers’ original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, i.e., absorbed at the same rate and to the same extent as the brand. Generally, the basis for ANDA approval is whether the manufacturer can “prove the active ingredient is the same as the brand name drug that is being copied.”<sup>9</sup> Drug products that the FDA considers therapeutically equivalent to the reference drug product are assigned an “A” code. This includes products for which “there are no known or suspected bioequivalence problems” (AA, AN, AO, AP, or AT, depending on how the drug is administered) and drug products for which “actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence” (AB).<sup>10</sup>

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<sup>7</sup> 21 U.S.C. §§ 301-92.

<sup>8</sup> See Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

<sup>9</sup> *The Generic Drug Approval Process*, FDA (updated Mar. 17, 2022), <https://www.fda.gov/drugs/news-events-human-drugs/generic-drug-approval-process>.

<sup>10</sup> *Orange Book Preface*, FDA, (Jan. 25, 2024), <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>.

47. The Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another.

48. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

49. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, revenues for brand and prescription drugs totaled \$21.6 billion; by 2013, total prescription drug revenues had climbed to more than \$392.2 billion, with generics accounting for 86% of prescriptions.<sup>11</sup> Generics are dispensed about 95% of the time when a generic form is available.<sup>12</sup>

**D. AB-Rated Generics Quickly and Dramatically Drive Down Prices**

50. Generic versions of brand drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the brand and its A-rated generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic versions, or between multiple generic versions, is price.

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<sup>11</sup> See *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* at 30, 51, IMS Institute for Healthcare Informatics (Apr. 2014).

<sup>12</sup> *Id.* at 51.

51. When generic entry occurs, the brand manufacturer loses market share; the generic manufacturer gains the lost market share, but with reduced prices (which continue to decline as competition increases). When multiple generics enter the market, that competition drives prices down to near the marginal cost of production.

52. According to a recent FDA study,<sup>13</sup> “[f]irst-generics often yield substantial costs savings. Generic drugs approved in 2018 yield annual savings of \$17.8 billion, with \$4.0 billion from first-generic approvals. Savings from 2019 approvals amounted to \$24.8 billion, with \$9.4 billion coming from first-generic approvals. Savings from 2020 approvals are estimated at \$10.7 billion, with first-generic approvals contributing \$1.8 billion. Over all three years, first-generic approvals account for 29% of the total savings.” The FDA also highlighted the price reductions associated with generic drug approvals, reporting that “it observe[d] many instances where, within a year of the first-generic approval, prices fall by more than 75% compared to the brand price.”

53. Experience and economic research show that the first generic manufacturer entrant to market prices the product below the price of the brand counterpart.<sup>14</sup> Every state requires or permits that a prescription written for the brand be filled with an A-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand due to regulatory requirements and price competition.

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<sup>13</sup> Ryan Conrad PhD, *et al.*, *Estimated Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020* (Aug. 2022), <https://www.fda.Gov/media/161540/download#:text=Estimates%20of%20the%20total%2012,estimated%20%2410.7%20billion%20in%20savings>.

<sup>14</sup> *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* at ii-iii, vi, 34, FTC, (Aug. 2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

54. As additional generic competitors enter the market, the manufacturers typically compete through price, driving prices down toward marginal manufacturing costs.<sup>15</sup> In a recent study, the Federal Trade Commission (“FTC”) found that on average, within a year of generic entry, generics captured 90% of corresponding brand sales and (with multiple generics on the market) prices dropped 85%.<sup>16</sup>

55. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. As a result of this price competition and competing for market share among drug manufacturers, there is an ongoing reduction in the average price paid for a drug.

56. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies.

57. Generic drugs may also be sold under the authority of the brand drug company’s approved NDA. Under those circumstances, the drug is referred to as the “authorized generic” (“AG”) and is simply the brand name drug sold using a generic label. An AG is often sold for less than the brand name.

58. Importantly, a brand manufacturer does not need to seek additional FDA approval to market an authorized generic. Thus, nothing prevents a brand manufacturer from selling an AG at any time, including during the generic first-filer’s 180-day exclusivity period. In fact, it is typical

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<sup>15</sup> See, e.g., Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 Int’l J. Indus. Org. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 New. Eng. J. Med. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & Econ. 311 (2000).

<sup>16</sup> See *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* at 8, FTC, (Jan. 2010), <chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

for a manufacturer to begin selling the AG before the first-filer generic enters the market in order to establish supply contracts before its incoming generic competitors can enter the market.

**E. Pharmacies Typically Substitute Generics for Brand Name Drugs**

59. The process of a patient receiving a prescription drug begins with a prescriber writing a prescription. Generally, the prescriber does not indicate whether the pharmacy should dispense the brand name or generic drug.

60. That being said, every state allows pharmacists to substitute less costly generic drugs for brand name drugs in certain circumstances and the Automatic Substitution States require it.

61. When a prescriber has not indicated whether the brand name or generic drug should be dispensed, the pharmacy is permitted to, and typically will, dispense the option that is less expensive for the beneficiary.

62. As part of their minimum pharmacy standards, the Automatic Substitution States *require* that generic drugs must be substituted for brand name drugs for all payors, including Medicare Part D, when the generic version of the brand name drug is less costly for the beneficiary. These Automatic Substitution States' laws mandating generic substitution constitute the minimum standards for pharmacy practice with which Medicare Part D requires compliance. The Automatic Substitution States and laws include:

	<b>State</b>	<b>Citation</b>
1.	Florida	Fla. Stat. § 465.025
2.	Hawaii	Haw. Rev. Stat. § 328-92
3.	Kentucky	Ky. Rev. Stat. Ann. § 217.822
4.	Maine	Me. Rev. Stat. tit. 32, § 13781
5.	Maryland	Md. Code Ann., Health-Gen. § 15-118(a)
6.	Massachusetts	Mass. Gen. Laws ch. 112, § 12D
7.	Minnesota	Minn. Stat. § 151.21(3)

	State	Citation
8.	Nevada	Nev. Rev. Stat. § 639.2583
9.	New Jersey	N.J. Stat. Ann. §24:6E-7
10.	New York	N.Y. Educ. Law §6816-a
11.	Pennsylvania	35 Pa. Cons. Stat. § 960.3
12.	Puerto Rico	P.R. Laws Ann. tit. 20, § 410b
13.	Rhode Island	5 R.I. Gen. Laws § 5-19.1-19
14.	Tennessee	Tenn. Code Ann. § 53-10-205
15.	Vermont	Vt. Stat. Ann. tit. 18, § 4605(a)
16.	West Virginia	W.Va. Code § 30-5-12b
17.	Wisconsin	Wis. Stat. § 450.13

63. For example, Pennsylvania’s mandatory generic substitution law states in relevant part: “Whenever a pharmacist receives a prescription for a brand name drug, the pharmacist *shall* substitute a less expensive generically equivalent drug unless requested otherwise by the purchaser or indicated otherwise by the prescriber.” 35 Pa. Stat. and Cons. Stat. Ann. § 960.3.

64. Additionally, Pennsylvania’s law also states: “Every pharmacy shall post in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign which shall read: ‘Pennsylvania law permits pharmacists to substitute a less expensive generically equivalent drug or interchangeable biological product for a brand name drug unless you or your physician direct otherwise.’” *Id.* at § 960.4. And further: “Each pharmacy shall have available to the public a price listing of brand name and generic equivalent drug products and interchangeable biological products available at the pharmacy for selection by the purchaser.” *Id.*

65. Likewise, Florida’s mandatory generic substitution law states in relevant part: “A pharmacist who receives a prescription for a brand name drug *shall*, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product,” with limited

exceptions where a prescriber indicates that the brand drug is medically necessary. Fla. Stat. § 465.025(2).

66. Similarly, Maryland’s mandatory generic substitute law states in relevant part: “a pharmacist . . . shall inform a retail consumer to the best of the pharmacist’s . . . knowledge of the availability of a generically equivalent drug, . . . and shall inform a retail consumer of the approximate cost difference of the lowest–cost alternative as compared to the originally prescribed drug.” Md. Code Ann. Health Occ. Code § 12-504(b)(1). It further mandates: “Unless the prescriber directs otherwise on the form or on an attached signed certification of need, the generic form of the drug . . . *shall* be used to fill the prescription.” Md. Code Ann., Health-Gen. § 15-118(a)(1).

67. As a result, the failure to substitute generic drugs for more costly brand name drugs is a violation of the state laws mandating generic substitution.

68. Further, as discussed below, Medicare Part D laws mandate that the sponsor must ensure that the pharmacies it interacts with will comply with minimum standards for pharmacies as established by the States. In other words, Medicare Part D sponsors—including SilverScript—are responsible for the acts of themselves and the pharmacies they interact with.

**F. The Centers for Medicare and Medicaid Services Require Part D Plan Sponsors to Inform Beneficiaries of the Cost Differential for Lower-Price Generic Alternatives**

69. Under Federal law, beneficiaries are entitled to receive information about costs of drugs, request that their plan cover specific drugs, and appeal coverage determinations. To this end, the statutes specifically provide that beneficiaries have the right to:

- a. “Get information in a way [they] understand from Medicare, health care providers, and, under certain circumstances, contractors. Get easy to understand information about Medicare like [w]hat’s covered[;] [w]hat



Medicare pays for covered items and services[;] [h]ow much [they] have to pay[;] [and h]ow to file a complaint or an appeal;”<sup>17</sup>

- b. “Ask for an appeal to resolve differences with [their] plan. [They] have the right to ask [their] plan to provide or pay for an item or service [they] think should be covered, provided, or continued. If [their] plan denies [their] request, [they] have the right to appeal that decision;”<sup>18</sup> and
- c. “Get a coverage decision or coverage information from [their] plan before getting services. Before [they] get an item or service, [they] can call [their] plan to find out if it will be covered. [Their] plan must tell [them] if [they] ask.”<sup>19</sup>

70. Medicare requires each Part D plan sponsor to employ a “cost-effective drug utilization management program” with “incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs.”<sup>20</sup>

71. Part D plans are responsible for ensuring that pharmacies that dispense drugs covered by Part D advise beneficiaries of price differentials between the price of the prescribed drug and the price of the lowest-priced generic available at the pharmacy.<sup>21</sup>

72. The Medicare regulations lay out the disclosure requirements regarding lower-priced generic drugs: “[A] Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being

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<sup>17</sup>*Medicare Rights & Protections*, CMS (May 2023), <https://www.medicare.gov/Pubs/pdf/11534-medicare-rights-and-protections.pdf>.

<sup>18</sup> *Id.* at 11.

<sup>19</sup> *Id.* at 12.

<sup>20</sup> 42 U.S.C.A. § 1395w-104(c)(1)(A).

<sup>21</sup> Medicare Modernization Act § 1860D-4 (k)(1); 42 U.S.C. § 1395w-104(k)(1).

purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.”<sup>22</sup>

73. This requirement is not limited to instances where the beneficiary affirmatively requested the information. The Centers for Medicare and Medicaid Services (“CMS”) has stated that pharmacies must disclose the price of equivalent generic drugs whether the beneficiary asks or not.

74. For example, CMS has explained:

Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. We cannot limit this requirement to circumstances in which an enrollee specifically asks for the information. Furthermore, we believe such disclosure will provide enrollees—many of whom may not know that less expensive generic equivalents are available—with valuable information that will save money for beneficiaries, Part D plans, and Medicare.<sup>23</sup>

75. Additionally, CMS has suggested that this requirement applies even when a prescriber had designated a prescription “Do Not Substitute”:

Part D plans must require network pharmacies, except for those which we have specifically exempted from the requirement, to disclose information about price differentials. *We cannot limit this requirement to circumstances in which a prescriber has written a prescription for a brand name drug and has not specifically stated that the pharmacy must not substitute the brand name drug for a generic drug.* We believe such disclosure will provide enrollees many of whom may not know that less expensive generic equivalents are available with valuable information that will save money for beneficiaries, Part D plans, and Medicare.<sup>24</sup>

76. Part D plan sponsors are also obligated to ensure that each pharmacy in their pharmacy networks comply with the generic price disclosure requirement:

Under section 1860D-4(k) of the Act, Part D Plans must provide that each pharmacy in their networks complies with the requirement to disclose to beneficiaries information about less expensive, therapeutically equivalent, and bioequivalent covered Part D drugs. Specifically, Part D Plans must provide information about the differential between the price of the covered Part D drug to

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<sup>22</sup> 42 CFR § 423.132.

<sup>23</sup> Medicare Program; Medicare Prescription Drug Benefit, 42 C.F.R. § 423.132 (2005) (emphasis added).

<sup>24</sup> *Id.* (emphasis added).

the enrollee (factoring in any applicable cost sharing) and the price of the lowest priced therapeutically equivalent and bioequivalent drug available at that pharmacy.<sup>25</sup>

77. Indeed, on May 17, 2018, CMS Administrator Seema Verma reiterated that plan sponsors “must require their network pharmacies to disclose any differential between the price of a Part D drug and the price of the lowest cost therapeutically-equivalent generic version of that Part D drug.”<sup>26</sup>

78. A fundamental part of compliance with CMS’s Medicare Part D requirements is acting ethically and honestly. CMS states that, “[a]s part of the Medicare Program, [a Part D Plan] must conduct [itself] in an ethical and legal manner. It’s about doing the right thing!” To do so, a Part D Plan must, “[a]ct fairly and honestly, [a]dhere to high ethical standards in all [it does], [c]omply with all applicable laws, regulations, and CMS requirements, [and r]eport suspected violations.”<sup>27</sup>

79. CVS Health’s own Code of Conduct (the “Code”) also makes clear that choosing not to follow a Medicare Program policy “could be interpreted by the government as fraud or payment abuse.”<sup>28</sup> Likewise, CVS Health recognizes that the Code is the “underlying framework for [its] Medicare Compliance Program. . . .”<sup>29</sup>

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<sup>25</sup> *Id.*

<sup>26</sup> Memorandum from Seema Verma, Administrator, CMS to All Part D Plan Sponsors, Unacceptable Pharmacy Gag Clauses (May 17, 2018), <https://downloads.cms.gov/files/2018-05-17.pdf>.

<sup>27</sup> *Medicare Parts C and D General Compliance Training Web-Based Training Course*, CMS (Jan. 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedCandDGenCompdownload.pdf>.

<sup>28</sup> *Code of Conduct* at 25, CVS Health Corp. (updated Jan. 2, 2024), <https://www.cvshealth.com/content/dam/enterprise/cvs-enterprise/pdfs/cvs-health-code-of-conduct.pdf>.

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

80. The United States Government acts in reliance of Medicare Part D sponsors' statements, including with respect to the availability, safety and efficacy, superiority, and medical necessity and appropriateness of drugs, to the public, to patients, to health care providers, in paying claims for these drugs and in allowing sponsors to continue to offer prescription drug coverage through the Medicare Part D program.

**G. Medicare Part D and SilverScript Plans**

81. Medicare is a federal health insurance program for the elderly and disabled administered by HHS through CMS.

82. Medicare Part D programs are “a voluntary outpatient prescription drug benefit for people with Medicare provided through private plans that contract with the federal government.”<sup>30</sup>

83. Each Part D plan has a list of covered drugs, called its formulary. If a drug is not on the formulary, a Part D beneficiary will have to pay out of pocket for that drug or request an exception which is a long and daunting process that may result in denial or higher costs.<sup>31</sup>

84. Part D beneficiaries receive prescription drug coverage under a phased plan design put forth by CMS. The phases fall into the following categories:

- a. **Deductible**: An annual deductible means beneficiaries have to pay full price for their medicines until they've met that threshold (for example, up to \$545 for 2024);<sup>32</sup>
- b. **Initial Coverage Limit**: After meeting the deductible amount, the

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<sup>30</sup> *An Overview of the Medicare Part D Prescription Drug Benefit*, KFF (Oct. 17, 2023), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

<sup>31</sup> *Part D Basics*, Medicare Interactive, <https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-coverage/part-d-basics> (last visited Apr. 23, 2024).

<sup>32</sup> Dena Bunis, *What You Need to Know About Part D Prescription Drug Plans*, AARP (Mar. 18, 2022), <https://www.aarp.org/health/medicare-insurance/info-2018/part-d-prescription-drugs.html>.

beneficiary receives prescription drug benefits up to an annual cap (\$5,030 for 2024);<sup>33</sup>

- c. **Coverage Gap (the “Donut Hole”)**: Many Medicare beneficiaries with high drug bills are subject to a coverage gap. Beneficiaries will pay 25% of brand name and generic prescription drug costs within this gap until their total out-of-pocket costs reach the threshold for Catastrophic Coverage (\$8,000 in 2024);<sup>34</sup>
- d. **Catastrophic Coverage**: After meeting the Catastrophic Coverage threshold, until 2024, beneficiaries paid 5% of prescription costs.

85. SilverScript is one of the largest Medicare Part D plan sponsors by enrollment. In 2019, it had nearly 6 million enrollees.<sup>35</sup> By way of example, in the same year, SilverScript offered three plans: SilverScript Choice, SilverScript Plus, and SilverScript Allure. SilverScript has since replaced its Allure plan with a SmartSaver option.<sup>36</sup>

86. SilverScript’s plans follow the same basic structure. Generally, there are no deductibles (\$0) in the Deductible stage. In the Initial Coverage stage of the Medicare Part D benefit (and, for Plus Plans, in the Coverage Gap Stage), SilverScript structures its beneficiary cost-sharing obligations based on five tiers.<sup>37</sup> Generally speaking, beneficiaries “will often pay less for a drug on Tier 1 than [they] would on Tier 4.”<sup>38</sup>

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<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> CVS Health Corp., Annual Report (Form 10-K) (Feb. 16, 2021).

<sup>36</sup> *Prescription drug plans offer real options*, Aetna Medicare Solutions, <https://www.aetnamedicare.com/en/compare-plans-enroll/part-d-prescription-drug-plans.html> (last visited Apr. 23, 2024).

<sup>37</sup> *2023 Summary of Benefits*, Aetna (2023), [https://www.aetnamedicare.com/documents/individual/2023/summaryofbenefits/Y0001\\_S5601\\_SB\\_2023\\_M.pdf](https://www.aetnamedicare.com/documents/individual/2023/summaryofbenefits/Y0001_S5601_SB_2023_M.pdf).

<sup>38</sup> Christina Joseph, *Unpacking Medicare: What do I need to know about prescription drug coverage?*, Aetna Medicare Solutions, <https://www.aetnamedicare.com/en/understanding-medicare/medicare-prescription-drug-plans-need-to-know.html> (last visited Apr. 23, 2024).

87. The five tiers of the SilverScript formularies are: Preferred Generic (Tier 1); Generic (Tier 2); Preferred Brand (Tier 3); Non-Preferred Drug (Tier 4); and Specialty Tier (Tier 5). The effect of this structure is that generic drugs (which are typically covered at Tiers 1 and 2) almost always cost less than branded drugs.

88. By way of example, in 2019, the cost-sharing obligations for beneficiaries with SilverScript Choice plans was as follows:

INITIAL COVERAGE	SilverScript Choice is a \$0 deductible plan, meaning your initial coverage stage begins the day your plan takes effect.						
	YOUR COPAYS (\$) AND COINSURANCE (%)						
	Preferred Pharmacy <sup>3</sup>		Standard Pharmacy		CVS Caremark Mail Service Pharmacy <sup>7</sup>		
drug tiers	30-day	90-day	30-day	90-day	90-day	90-day	
Tier 1	\$3-\$9	\$9-\$27	\$7-\$10	\$21-\$30	\$0	\$21-\$30	
Tier 2	\$10-\$19	\$30-\$57	\$19 or \$20	\$57 or \$60	\$25-\$47.50	\$57 or \$60	
Tier 3	\$34-\$46	\$102-\$138	\$46 or \$47	\$138 or \$141	\$85-\$115	\$138 or \$141	
Tier 4	34%-49%	34%-49%	49% or 50%	49% or 50%	34%-49%	49% or 50%	
Tier 5	33%	N/A	33%	N/A	N/A	N/A	

  

COVERAGE GAP (DONUT HOLE)	You leave initial coverage and enter the Medicare coverage gap when you reach \$3,820 in total yearly drug costs (not including monthly premiums).
<b>Generic drugs</b>	You pay 37% of the cost
<b>Brand drugs</b>	You pay 25% of the cost

  

CATASTROPHIC COVERAGE (AFTER DONUT HOLE)	You enter catastrophic coverage when you spend \$5,100 out of pocket (not including monthly premiums).
<b>Generic drugs</b>	You pay the greater of 5% coinsurance or \$3.40 copay
<b>All other drugs</b>	You pay the greater of 5% coinsurance or \$8.50 copay

89. By way of example, in 2019, the cost-sharing obligations for beneficiaries with SilverScript Plus plans was as follows:

**INITIAL COVERAGE**

SilverScript Plus is a \$0 deductible plan, meaning your initial coverage stage begins the day your plan takes effect.

drug tiers	YOUR COPAYS (\$) AND COINSURANCE (%)					
	Preferred Pharmacy		Standard Pharmacy		CVS Caremark Mail Service Pharmacy <sup>7</sup>	
	30-day	90-day	30-day	90-day	Preferred	Standard
Tier 1	\$1	\$3	\$10	\$30	\$0	\$30
Tier 2	\$5 or \$10	\$15 or \$30	\$20	\$60	\$0	\$60
Tier 3	\$31, \$33, \$35, or \$42	\$93, \$99, \$105, or \$126	\$47	\$141	\$77.50, \$82.50, \$87.50, or \$105	\$141
Tier 4	40%	40%	50%	50%	40%	50%
Tier 5	33%	N/A	33%	N/A	N/A	N/A

**COVERAGE GAP (DONUT HOLE)**

You leave initial coverage and enter the Medicare coverage gap when you reach \$3,820 in total yearly drug costs (not including monthly premiums).

	30-day	90-day	30-day	90-day	90-day	90-day
Tier 1	\$1	\$3	\$10	\$30	\$0	\$30
Tier 2	\$5 or \$10	\$15 or \$30	\$20	\$60	\$0	\$60
Tiers 3, 4 and 5	<b>Generic drugs</b> You pay 37% of the cost <b>Brand drugs</b> You pay 25% of the cost					

**CATASTROPHIC COVERAGE (AFTER DONUT HOLE)**

You enter catastrophic coverage when you spend \$5,100 out of pocket (not including monthly premiums).

<b>Generic drugs</b>	You pay the greater of 5% coinsurance or \$3.40 copay
<b>All other drugs</b>	You pay the greater of 5% coinsurance or \$8.50 copay

90. By way of example, in 2019, the cost-sharing obligations for beneficiaries with SilverScript Allure plans was as follows:

### INITIAL COVERAGE

SilverScript Allure is a \$0 deductible plan, meaning your initial coverage stage begins the day your plan takes effect.

drug tiers	YOUR COPAYS (\$) AND COINSURANCE (%)					
	Preferred Pharmacy		Standard Pharmacy		CVS Caremark Mail Service Pharmacy <sup>7</sup>	
	30-day	90-day	30-day	90-day	Preferred 90-day	Standard 90-day
Tier 1	\$1	\$3	\$10	\$30	\$0	\$30
Tier 2	\$5	\$15	\$20	\$60	\$12.50	\$60
Tier 3	20%	20%	25%	25%	20%	25%
Tier 4	40%	40%	50%	50%	40%	50%
Tier 5	33%	N/A	33%	N/A	N/A	N/A

### COVERAGE GAP (DONUT HOLE)

You leave initial coverage and enter the Medicare coverage gap when you reach \$3,820 in total yearly drug costs (not including monthly premiums).

**Generic drugs** You pay 37% of the cost

**Brand drugs** You pay 25% of the cost

### CATASTROPHIC COVERAGE (AFTER DONUT HOLE)

You enter catastrophic coverage when you spend \$5,100 out of pocket (not including monthly premiums).

**Generic drugs** You pay the greater of 5% coinsurance or \$3.40 copay

**All other drugs** You pay the greater of 5% coinsurance or \$8.50 copay

91. In sum, Medicare Part D beneficiaries are obligated to pay monthly premiums, annual deductibles, copayments or coinsurance, and catastrophic coverage coinsurance to participate in a Medicare Part D program.<sup>39</sup>

<sup>39</sup> *Medicare Prescription Drug Plan (Part D)*, N.C. Dep't of Insurance, <https://www.ncdoi.gov/consumers/medicare-and-seniors-health-insurance-information-program-shiip/medicare-prescription-drug-plan-part-d#Tab-MyCosts-390> (last visited Apr. 23, 2024).



92. Under the SilverScript Choice, Plus, and Allure plans, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage, if the generics had not been excluded from formulary coverage. Because the generic versions of the Affected Drugs were significantly less expensive than the brand versions of the Affected Drugs at all relevant times, SilverScript beneficiaries would have paid less for generic versions of the Affected Drugs than they paid for brand versions of the Affected Drugs if the generics had been included on the formulary.

93. Additionally, the higher costs SilverScript beneficiaries incurred when they paid for brand versions of the Affected Drugs rather than less-costly generic versions of those same drugs drive beneficiaries into the Coverage Gap and Catastrophic Coverage phases of the Medicare Part D benefit—where beneficiary out-of-pocket costs are higher—more quickly than they would have reached these stages if the CVS Defendants had not restricted their access to generics.

**H. Defendants Colluded and Conspired with the Manufacturer Co-Conspirators to Execute the Fraudulent NG Scheme**

94. CVS Health coordinated the efforts of its subsidiaries CVS Caremark, SilverScript, and CVS Pharmacy, as well as the Manufacturer Co-Conspirators, to execute a fraudulent scheme to deny SilverScript beneficiaries' access to less expensive generic alternatives to brand name drugs, in contravention of federal and state laws, in order for the CVS Defendants to collect substantial rebates from the Manufacturer Co-Conspirators. As a result of the NG Scheme, SilverScript beneficiaries paid increased out-of-pocket costs to obtain the Affected Drugs instead of cheaper generic equivalents.

95. In its Code, CVS Health emphasizes its commitment to “Doing the right thing,” including that, in undertaking all of its “contractual promises,” while it strives to outperform its

competition, it will “do so honestly, openly, fairly and with integrity.”<sup>40</sup> The Code further commits CVS Health to “deal fairly with [its] customers, members, providers, clients, suppliers, regulators, shareholders and others around the world with whom we do business.”<sup>41</sup> The Code also states CVS Health’s refusal to participate in any conduct “intended to mislead, manipulate or take unfair advantage of anyone.”<sup>42</sup>

96. The conduct of CVS Health and its subsidiaries cheated SilverScript beneficiaries (and taxpayers) by blocking access to less costly generic versions of the Affected Drugs in exchange for rebates from the Manufacturer Co-Conspirators.

97. Despite its commitments under the Code, CVS Health and its subsidiaries sold off SilverScript Part D formulary access to the Manufacturer Co-Conspirators who were intent on obstructing competition for their blockbuster drugs.

98. CVS Health utilized its control of SilverScript, CVS Caremark, and the CVS Pharmacies to ensure that it would be able to omit and block SilverScript beneficiaries from receiving accurate information about and access to less expensive medications.

99. The complicity among CVS Health’s Part D Plan Sponsor (SilverScript), its pharmacy benefit manager (CVS Caremark), and pharmacies (CVS Pharmacies) has allowed the Manufacturer Co-Conspirators the ability to block beneficiary access to less costly generic drugs.

100. Because CVS Health owned (and therefore controlled) the SilverScript PDP, CVS Caremark PBM, and the CVS Pharmacies, any potential competitive discord between its goal of dispensing more expensive brand name versions of the Affected Drugs over less costly generics and what federal and state laws required would simply be ignored. Because of what they cynically

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<sup>40</sup>*Code of Conduct*, *supra* note 28.

<sup>41</sup> *Id.* at 24.

<sup>42</sup> *Id.*

termed internally as the “enterprise-wide” benefit to the parent CVS Health, they would simply flout any obligation to provide truthful, non-deceptive information to beneficiaries, to include the generic drugs on SilverScript formularies and/or to dispense the less costly generics.

101. In or around 2014, CVS Health began implementing a strategy that preferred brand name drugs when only a single generic alternative existed. According to internal documents, CVS Health was purportedly interested in pursuing this policy because it believed that when only a brand name drug and single generic were on the market, the generic price was usually roughly the same, or even higher, than the brand drug:

**Single-Source Generics Aren't Always the Most Cost-Effective Choice**

<ul style="list-style-type: none"> <li>• In most cases, generics cost less than branded prescription drugs</li> <li>• Members and clients generally save when plan designs encourage generic use</li> <li>• However, single source generics challenge this model</li> </ul>	<p><b>SINGLE-SOURCE GENERICS: A NEW CHALLENGE</b></p> <ul style="list-style-type: none"> <li>• SSGs are new-to-market generics produced by a single manufacturer</li> <li>• Historically, pricing for SSGs has been approximately the same or higher than branded drugs because of exclusivity</li> </ul>
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**The launch of a single source generics presents challenges for both clients and members**

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CVSHealth. 4

102. By 2015, CVS Health was pocketing much of the savings generated by preferring brand name drugs, rather than passing the full benefit to beneficiaries.

103. As *Drug Channels* recently highlighted, the purpose of requiring the brand name be dispensed over the less expensive generic equivalent is so that plan sponsors can collect lucrative rebates and administrative fees from drug manufacturers and distributors. Commenters have also noted another potential incentive: “Here’s the twist: Plans can use the additional rebates

earned from the high-list price products to reduce monthly premiums and grab more Part D market share. The weird math of Part D bidding and its benefit structure encourage this gaming.”<sup>43</sup>

104. Confidential witnesses and senior executives employed by CVS explained how the scheme unfolded. According to a confidential witness who was employed as a CVS Staff Pharmacist in Pennsylvania, an Automatic Substitution State, for approximately two years beginning in or around 2020 (“CW 1”), CVS Pharmacies’ drug dispensation system is an electronic system established by CVS Caremark that routes all prescription requests electronically to and through CVS Caremark for determination and approval. CW 1 explains that on many occasions CW 1 attempted to fill prescriptions with generic equivalents. For certain drugs, including the Affected Drugs, the CVS Caremark system would not allow the pharmacist to dispense the generic.

105. Moreover, according to CW 1, CVS Pharmacies, would often have inadequate stock of certain generic medications at CVS retail pharmacy locations. At the same time, CW 1 explained that there was also an unusual overstocking of the brand name drug. Thus, without a supply of these generics, even if beneficiaries were somehow able to beat the CVS Caremark computer system, patients filling generic prescriptions at CVS Pharmacies would be denied access to the less-expensive generic versions of these drugs.

106. The practical effect of this scheme was that anyone filling a prescription at those pharmacies, even individuals without SilverScript plans, would be forced to pay for the more expensive brand versions of the Affected Drugs. Said another way, faced with no other option, and in need of medically necessary medication, Plaintiffs and members of the Classes would end up buying the brand name Affected Drugs.

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<sup>43</sup> See Adam Fein, *Why Part D Plans Prefer High List Price Drugs That Raise Costs for Seniors, Drug Channels* (May 6, 2020), <https://www.drugchannels.net/2020/05/why-part-d-plans-prefer-high-list-price.html>.

107. According to CW 1, several CVS staff pharmacists were concerned about the outright refusal by the CVS Caremark system to dispense less costly generics, and CW 1 was particularly frustrated when Medicare recipients were required to pay higher cost share amounts for brand name drugs when generic equivalents were available. CW 1 explained that CW 1 and other staff pharmacists spoke with CVS Health District Manager, Simon Mittelholzer, to inquire why the CVS Caremark system would not authorize generics for certain brand names. Mittelholzer explained that CVS had certain deals with the manufacturers and suppliers to dispense the brand versions of the Affected Drugs over their generic equivalents.

108. For example, Defendants' agreements with Gilead regarding Harvoni and Epclusa required SilverScript to deny any and all formulary exceptions and appeals for the less costly generic versions of Harvoni and Epclusa, and also required that CVS Pharmacies would no longer stock the generic versions of Harvoni and Epclusa on their shelves. This meant generic versions of Harvoni and Epclusa were unavailable to not just SilverScript beneficiaries, but also to other patients filling their prescriptions at CVS Pharmacies, regardless of their prescription drug plan.

109. Defendants' agreements with Gilead were very controversial within the Defendant companies. Even though its Executive Committee had approved the scheme, some members of CVS Health's senior management team complained to Alexandra Miller, a senior CVS executive, that the agreement was "highly unethical." For example, CVS Health Vice President of Medicare Operations, Emily Pefanis, aired concerns in multiple conversations with Amy Moyer-Carey, CVS Health Vice President Coverage Determinations. Even though Moyer-Carey was reportedly "sick over this," she was told by Mitch Betses (CVS Health Executive Vice President, Member Services), Todd Meek (President of SilverScript), and Patrick Jeswald (CVS Health Chief Compliance Officer, Medicare Part D) that they were to carry out the agreement with Gilead.

110. Similarly, on information and belief, the CVS Health Executive Committee decided on or around February 18, 2019 that, as part of its agreement with GSK, CVS Pharmacies would stop stocking the generic version of Ventolin HFA. These blocking measures were also highly controversial among the CVS Health leadership, with staff complaining that Defendants' arrangement with GSK could create serious access issues for patients needing the less costly generic version of the rescue inhaler Ventolin HFA. According to internal CVS documents, there were concerns that blocking the generic would result in "[h]igher cost share for clients and members if they fill brand Ventolin" which would drive "questions/issues from clients." Moreover, Defendants recognized that if the "impact occurs on a weekend, members will be forced to go to another pharmacy or will be without a rescue inhaler until Dr can be reached" to write a new prescription. On information and belief, Defendants' agreement with GSK also required CVS Pharmacies to stop stocking the generic version of Advair Diskus.

111. It was not just CVS Pharmacies that were omitting the truth about the availability and pricing of generics and denying their access altogether. CVS Health also carried out its illicit scheme through customer care representatives. These representatives are employed by SilverScript and respond to beneficiary phone calls inquiring about their prescription drug coverage. SilverScript provided customer care representatives with scripts to use when responding to beneficiary inquiries about their access to less expensive generic drugs. Customer care representatives were expected to master use of these scripts and were monitored to ensure that they were relying on the scripts in their interactions with consumers.

112. SilverScript used these scripts to mislead beneficiaries about the availability of less expensive generic alternatives to the drugs they had been prescribed. For example, customer care representatives would often:

113. State that there were “few” manufacturers marketing generic versions of the Affected Drugs, even when multiple generics were available, while omitting the price differential between the cost of the generic and the brand name<sup>44</sup>;

114. State that retaining brand name medications on the formulary “can help keep out-of-pocket costs low for SilverScript Beneficiaries” and that the cost of generics “will likely be similar,” while omitting the price differential between the cost of the generic and the brand name<sup>45</sup>;

115. State that the generic was on a higher formulary tier or that it was not covered, while omitting the price differential between the cost of the generic and the brand name<sup>46</sup>; and

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<sup>44</sup> *E.g.*, Exhibit A at CVS-000242 (“Generic prescription drugs are typically the lowest-cost option when compared to branded prescription drugs. SilverScript promotes the use of generic prescription drugs to help plan beneficiaries save money. During the initial launch phase for the generic, there will be few manufacturers marketing the generic and the cost of the generic is expected to be relatively high. To help keep out-of-pocket costs low, SilverScript is retaining brand RENVELA TABLETS on its formulary on Preferred Brand Tier (Tier 3). RENVELA TABLETS is eligible for a manufacturer discount in the coverage gap.”).

<sup>45</sup> *E.g.*, *id.* at CVS-000243 (“Retaining brand RENVELA TABLETS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. Beneficiaries have the option to request an exception if they wish to obtain sevelamer carbonate tablets. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”); *id.* at CVS-000245-46 (“In this case, the price of the generic version of RENVELA TABLETS will likely be similar to the price of the brand version for a minimum of six months, and perhaps longer. There are few manufacturers of the generic version of RENVELA TABLETS to drive the price [d]own. Until there are competitors and the price of the generic version goes down, your plan will continue to cover brand name RENVELA TABLETS at the Preferred Brand Tier (Tier 3) copay/coinsurance in [2018 and] 2019.”); *id.* at CVS-000246 (“When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called sevelamer carbonate tablets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”).

<sup>46</sup> *E.g.*, Exhibit B at CVS-000516-17 (“Retaining brand ADVAIR DISKUS on Preferred Brand Tier (Tier 3) can help keep out-of-pocket costs low for SilverScript beneficiaries. . . . Beneficiaries have the option to request an exception if they wish to obtain fluticasone-salmeterol aerosol powder breath activated. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level. Brand ADVAIR DISKUS is available at the Preferred Brand Tier (Tier 3) copay/coinsurance, so if the request for the generic is granted, the beneficiary would pay the amount associated with the plan’s exception

116. Attribute SilverScript’s lack of coverage for generic versions of the Affected Drugs to “market conditions” while omitting the existence of the true cause—Defendants’ NG Scheme.<sup>47</sup>

117. Additionally, customer care representatives would steer beneficiaries away from requesting a formulary exception from their provider by explaining that that even if the exception was approved, the generic was still on a higher formulary tier. This, however, omitted the fact that in most cases, despite being on a higher formulary tier, the generic version of the drug was still cheaper to the beneficiary. While the beneficiary would be responsible for paying a higher percentage of the generic’s cost as co-insurance, the actual dollar amount they would pay for the generic would be lower due to the significantly lower prices of the generic drug.

118. From the time the NG Scheme was implemented until 2018, SilverScript beneficiaries who requested formulary exceptions through the coverage determination process were largely approved. Thus, although SilverScript hid the existence of less expensive generics to beneficiaries, it did not block the beneficiaries from getting the non-formulary options if the exception process, which can be long and daunting, was implemented. However, in late 2018, SilverScript began issuing blanket denials of formulary exceptions for the Affected Drugs.

119. CW 2, who was employed by CVS Health as a Pharmacy Benefits Manager between approximately 2020 and 2023, explained how this scheme unfolded in practice. CW 2’s

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tier. This may be a different cost than the brand.”); *id.* at CVS-000215-16 (“When a generic version is first available, it is typically similar in price to the brand version. At this time the generic version, called ledipasvir/sofosbuvir 90MG-400 MG tablets, is not on the formulary. You do have the option to request a formulary exception. However, exception requests for non-formulary prescription drugs, if approved, are typically approved for coverage at the highest cost share level.”).

<sup>47</sup> *E.g.*, Exhibit C at CVS-000226 (“We anticipate that RENVELA ORAL PACKETS will remain on the formulary on the Preferred Brand Tier (Tier 3) in 2019 until the price of the generic form of RENVELA drops. We anticipate it will be a minimum of six months, however that is based on market conditions not within our control and could change.”).



duties involved speaking with insured individuals, including SilverScript beneficiaries, who had questions regarding their prescriptions. CW 2 stated that CVS Health “pushed” certain prescriptions, such as Ventolin and Advair Diskus, meaning it required the brand version to be prescribed over the generic versions. CW 2 confirmed that CVS Health would provide “scripts” to CW 2 and others that needed be read verbatim to customers to explain why they had to accept a particular medication CVS was pushing. CW 2 “felt like CVS was forcing people to take the more expensive medications.” CW 2 additionally stated many SilverScript beneficiaries “pretty much hit a dead end” trying to get certain prescriptions filled, and if a pharmacist tried to substitute a generic version of certain branded drugs, CVS Health would simply say “we’re not going to fill it.” CW 2 also stated that CVS Health had a proprietary computer program that listed each state’s prescription regulations, including automatic substitution requirements.

120. All of this illicit behavior was at the expense of beneficiaries, who were prevented from accessing lower cost generic drugs, and forced to shoulder greater and greater out of pocket costs for branded drugs. Indeed, the Medicare Part D SilverScript program presented the optimal opportunity for Defendants to get away with forcing expensive brand name drugs on unsuspecting patients because, in most cases, the beneficiary and U.S. Government ultimately foot the bill for the drug cost. Tellingly, Aetna, a CVS Health subsidiary who markets SilverScript, does not list the brand versions of the Affected Drugs on the formulary for any of its own insurance plans (i.e., non-Part D plans) because, of course, Aetna itself foots the bill in that scenario.

121. For example, according to the February 2019 GoodRx.com pricing for these drugs, the price differences between the brand name drugs and the identical authorized generics at CVS Pharmacies ranged from 233% to 467%:

Brand	Brand Cash Price	Authorized Generic Cash Price	Percentage Difference
Invega	\$1240.44	\$265.25	467%
Asacol HD	\$893.48	\$243.65	366%
Renvela Packets	\$1,686.98	\$466.85	361%
Renvela Tablets	\$540.35	\$146.45	368%
Harvoni	\$32,704.50	\$10,087.51	324%
Epclusa	\$25,874.46	\$6,727.50	385%
Ventolin HFA	\$67.79	\$28.99	233%
Advair Diskus	\$436.81	\$123.49	354%

122. SilverScript’s failure to disclose these significant price differentials for these AGs is particularly disconcerting because these AGs are the exact same drugs as the brand name versions.

123. Additionally, to this day, SilverScript’s formularies still retain a number of the drugs as part of the NG Scheme. Specifically, today all of SilverScript’s formularies include only brand—and not generic—versions of Epclusa.<sup>48</sup> Additionally, the SilverScript Choice formulary includes only brand—and not generic—versions of Renvela packets, Renvela tablets, and Ventolin HFA.<sup>49</sup> The SilverScript Plus formulary includes only brand—and not generic—versions of Renvela packets, Renvela tablets, and Harvoni.<sup>50</sup> The SilverScript SmartSaver formulary includes only brand—and not generic—Harvoni.<sup>51</sup> The fact that these drugs remain a part of the NG Scheme, even in instances where multiple generic equivalents are available, demonstrates that this

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<sup>48</sup> *SilverScript Choice (PDP) 2024 Formulary*, Aetna (updated Feb. 1, 2024), [https://img1.wsimg.com/blobby/go/b4173e73-a727-4193-b5f1-ab1aab591020/downloads/Smart\\_saver%20Formulary.pdf?ver=1699387203063](https://img1.wsimg.com/blobby/go/b4173e73-a727-4193-b5f1-ab1aab591020/downloads/Smart_saver%20Formulary.pdf?ver=1699387203063); *SilverScript Plus (PDP) 2024 Formulary*, Aetna (updated Mar. 6, 2024), [https://www.aetnamedicare.com/documents/individual/2024/formularies/FORM\\_2024\\_24022SS2GCz\\_EN.pdf](https://www.aetnamedicare.com/documents/individual/2024/formularies/FORM_2024_24022SS2GCz_EN.pdf); *SilverScript SmartSaver (PDP) 2024 Formulary*, Aetna (updated Mar. 1, 2024), [https://www.aetnamedicare.com/documents/individual/2024/formularies/FORM\\_2024\\_24023SS3NGz\\_EN.pdf](https://www.aetnamedicare.com/documents/individual/2024/formularies/FORM_2024_24023SS3NGz_EN.pdf).

<sup>49</sup> *SilverScript Choice (PDP) 2024 Formulary*, *supra* note 48.

<sup>50</sup> *SilverScript Plus (PDP) 2024 Formulary*, *supra* note 48.

<sup>51</sup> *SilverScript SmartSaver (PDP) 2024 Formulary*, *supra* note 48.

was merely a pretext used to enrich CVS Health and not a strategy to keep drug prices affordable for SilverScript beneficiaries.

**I. Defendants' Conduct Violated Federal Law in all States and Federal and State Law in the Automatic Substitution States**

124. As noted, Part D plan sponsors, including SilverScript, are required to provide accurate information regarding beneficiary cost-sharing obligations such as co-payments, co-insurance, and deductibles.<sup>52</sup> Part D plan sponsors, including SilverScript, are further required to provide information that allows “current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.”<sup>53</sup> Accurate information concerning SilverScript’s generic substitution policies is necessary for beneficiaries to “make informed decisions among the available choices for Part D coverage.”

125. SilverScript’s formularies do not disclose that in certain instances they would require beneficiaries to pay higher costs for brand name drugs when a cheaper generic equivalent was available. Instead, SilverScript’s formularies informed patients that SilverScript would from time to time substitute the lower-cost generic drug. Nor did SilverScript’s formularies disclose to beneficiaries that the NG Scheme would force certain beneficiaries into the Donut Hole and Catastrophic Coverage stages sooner.

126. In the Automatic Substitution States, CVS Pharmacies are required to dispense generic drugs for brand name drugs when the generic version of the drug is less costly for the beneficiary, even without any specific request by the beneficiary. In implementing the NG Scheme, the CVS Pharmacies repeatedly violated their obligations under the generic substitution laws of the Automatic Substitution States.

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<sup>52</sup> 42 U.S.C. § 423.128(b)(2)(iii).

<sup>53</sup> 42 U.S.C. § 423.48.

127. Defendants have routinely rejected thousands of beneficiary attempts to obtain access to less costly generic versions of the Affected Drugs. For example, attached hereto as Exhibit D is a representative sampling of 502 denials of Transition Fill requests beneficiaries made to SilverScript seeking generic Ventolin HFA during the just first week Ventolin HFA was added to the NG Scheme (from February 7, 2019 to February 13, 2019). Almost a third of these denials (165 total), were issued in instances where the prescriptions for these drugs would have been filled in Automatic Substitution States.<sup>54</sup>

128. Likewise, attached hereto as Exhibit E is a representative sampling of 148 denials of SilverScript claims for the authorized generic Harvoni and Epclusa prescriptions for just the month of January 2019, shortly after Harvoni and Epclusa were added to the NG Scheme. Again, almost a third of these denials (51 total), were issued in instances where the prescriptions for these drugs would have been filled in Automatic Substitution States.<sup>55</sup>

129. Each of these beneficiaries denied generic versions of Harvoni and Epclusa was sent a letter from SilverScript including a blanket denial of formulary exceptions implemented for Harvoni and Epclusa authorized generics. The letter also included new language denying a formulary exception unlike any language Defendants had ever used before, stating that the formulary exceptions for generic versions of Harvoni and Epclusa were denied based on their clinical equivalence—i.e., the fact that they are authorized generics to Harvoni and Epclusa.

130. Until 2018, even when the brand drug was included in its NG Scheme, SilverScript had universally allowed all formulary exceptions to dispense the less costly generic. For the first time, the rebate deal that Defendants had inked with Gilead required that SilverScript would deny

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<sup>54</sup> Exhibit D.

<sup>55</sup> Exhibit E.

all formulary exceptions for generic versions of Harvoni and Epclusa, including authorized generics.

131. Notwithstanding the agreement to deny any formulary exception for these drugs, SilverScript's denial letter tells beneficiaries that they had the right to ask for an appeal of the denial of the formulary exception. What the letter from SilverScript omitted was that the result of any appeal was already predetermined because the Defendants had already agreed with Gilead that SilverScript would deny all appeals.

132. Similarly, Exhibit F is a representative sampling of 73 denials of SilverScript claims for generic Advair Diskus prescriptions for just one day, February 27, 2019, (the day Defendants initiated the NG Scheme for this drug).<sup>56</sup> Each rejected beneficiary was sent SilverScript's letter denying formulary exceptions implemented for the Advair Diskus generic. These letters failed to inform the recipients that the non-formulary generic Wixela, sold by Mylan, was 70% less costly than GSK's brand version of the drug.

133. Mirroring the letter denying formulary exceptions requests for Harvoni and Epclusa, the formulary exception letter SilverScript sent to beneficiaries rejecting their requests for the less costly generic version of Advair Diskus tells them that they had the right to ask for an appeal of the denial of the formulary exception, but fails to tell them that the result of any appeal was already doomed to fail because Defendants had already agreed with GSK that SilverScript would summarily deny all appeals.

134. Claim records further demonstrate that SilverScript has failed to require the CVS Pharmacies and non-CVS owned network pharmacies to substitute versions of the Affected Drugs, including in the Automatic Substitution States. For example:

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<sup>56</sup> Exhibit F.

135. A 2019 record for a paid Asacol HD claim indicates that brand Asacol HD was dispensed at a total plan cost allowed of \$190.01, with a beneficiary copayment of \$96.25, instead of the less costly generic.<sup>57</sup> This prescription was dispensed at a pharmacy located in Maryland, violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution.

136. A 2019 record for a paid Renvela tablets claim indicates that despite the prescription not being marked “Dispense as Written” (which would have indicated the prescriber’s request that the patient specifically receive the brand version of Renvela tablets), brand Renvela tablets were dispensed at a total plan cost allowed of \$4,290.08, with a beneficiary copayment of \$291.09, instead of the less costly generic.<sup>58</sup> This prescription was dispensed at a pharmacy located in Pennsylvania, violating the obligation to dispense the less costly generic in a State requiring mandatory generic substitution.

137. Defendants knew that the NG Scheme raised serious ethical and legal concerns. For example, after entering into the agreements with Gilead to block generic substitution of Harvoni and Epclusa, CVS Health instructed Alexandra Miller, a senior CVS executive, during a December 17, 2018 meeting to monitor beneficiary grievances for Harvoni and Epclusa outside the formal grievance tracking system typically used to track instances of formulary disruption and member dissatisfaction about drug coverage. She was to watch for any “member disruption” or complaints related to lack of generic access, and notify management of any such issues. This allowed Defendants to avoid creating a paper trail documenting concerns about member disruption and illustrating trends that may signal compliance risks for front-line employees.

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<sup>57</sup> Exhibit G.

<sup>58</sup> Exhibit H.

138. Moreover, numerous executives within CVS Health senior management complained to the CVS Health Executive Committee that the NG scheme was unethical and violated the Code. In addition, these executives expressed concern that CVS Health pharmacists in charge of Medicare Part D coverage determinations would call the CVS Health “Ethics Line” over fears that they could lose their licenses because they were being asked to deceive beneficiaries. In at least one instance, Alexandra Miller, a senior executive, was informed by her supervisor that senior management on the Executive Committee, as well as the Chief of Compliance for CVS Health, Medicare, Patrick Jeswald, had already decided that the upside benefit to the “enterprise” was much greater than the risk that its wrongdoing would be detected by the Government.

139. In sum, instead of “Doing the right thing” in accordance with its Code, CVS Health and its subsidiaries conspired to effectuate a systematic scheme of dishonest and unethical behavior to mislead and deceive Medicare Part D beneficiaries and prevent them from accessing lower-cost generic versions of the Affected Drugs in order to collect rebates from the Manufacturer Co-Conspirators.

## **J. The Affected Drugs**

### **1. Invega**

140. Paliperidone is an atypical antipsychotic approved for the treatment of schizophrenia and schizoaffective disorder. Janssen, a wholly-owned subsidiary of Johnson & Johnson, manufactures paliperidone under the brand name Invega. Invega is available as 1.5 mg, 3 mg, 6 mg, and 9 mg extended-release tablets.

141. Invega was first approved by the FDA in 2006.

142. The FDA granted the first approval for a generic version of Invega to Actavis on August 3, 2015. In response to impending new generic entrants, Patriot Pharmaceuticals, LLC, a

wholly-owned subsidiary of Janssen, announced on September 24, 2015 that it would begin selling an authorized generic version of Invega. This authorized generic was manufactured by Janssen and was identical to brand Invega.

143. Allergan launched the first non-brand generic version of Invega, relying on Actavis's ANDA, on September 25, 2015. On September 28, 2015, Mylan announced the launch of its own generic version of Invega. Several additional generic versions of Invega subsequently became available, including versions sold by Sun, Inventia, Amneal, CSPC Ouyi, and Lupin.

144. On information and belief, on November 6, 2015, the CVS Defendants entered into an agreement with Janssen, whereby they would add Invega to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

145. The generic versions of Invega would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

146. Second, because the generic versions of Invega were significantly less expensive than the brand versions of Invega at all relevant times, SilverScript beneficiaries would have paid less for generic versions of Invega than they paid for brand versions if the generics had not been excluded from formulary coverage as part of the NG Scheme.

147. For example, by February 2019, the GoodRx price of the generic paliperidone tablet was \$265.25 compared to the price of the brand Invega of \$1,240.44, making the generic a much lower cost option both for out-of-pocket costs, including co-pays, and for SilverScript beneficiaries



in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

## **2. Asacol HD**

148. Mesalamine was an aminosalicylate approved for the treatment of moderately active ulcerative colitis in adults. Allergan manufactured mesalamine delayed-release tablets under the brand name Asacol HD.

149. Asacol HD was first approved by the FDA in 2008.

150. Zydus launched an authorized generic version of Asacol HD in August 2016.

151. On information and belief, on September 23, 2016, the CVS Defendants entered into an agreement with Allergan, whereby they would add Asacol HD to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

152. The authorized generic version of Asacol HD would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower copayments), if the generics had not been excluded from formulary coverage.

153. Second, because the authorized generic version of Asacol HD was significantly less expensive than the brand version of Asacol HD at all relevant times, SilverScript beneficiaries would have paid less for generic versions of Asacol HD than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

154. For example, by February 2019, the GoodRx price of the generic mesalamine delayed-release tablets was \$240.96 compared to the price of the brand Asacol HD of \$885.91, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap

and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

### **3. Renvela Packets**

155. Sevelamer carbonate is a phosphate binding drug used to treat hyperphosphatemia in patients with chronic kidney disease. Sanofi manufactures sevelamer carbonate under the brand name Renvela. Renvela is available in powder form (in packets) as well as in tablet form.

156. Renvela packets were first approved by the FDA in 2009.

157. Aurobindo launched the first non-brand generic version of Renvela packets immediately upon announcing, in June 2017, that its generic had received FDA approval, with at least four additional non-brand generics launched, including versions sold by Dr. Reddy's, BionPharma, Hangzhou AnPrime, Impax, and Strides. Additionally, Winthrop—a division of Sanofi—began marketing an authorized generic version of Renvela packets in January 2018.

158. On information and belief, effective August 1, 2017, the CVS Defendants entered into an agreement with Sanofi, whereby they would add Renvela packets to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

159. The generic versions of Renvela packets would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

160. Second, because the generic versions of Renvela packets were significantly less expensive than the brand version of Renvela packets at all relevant times, SilverScript beneficiaries

would have paid less for generic versions of Renvela packets than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

161. For example, by February 2019, the GoodRx price of the generic was \$403.98 compared to the brand Renvela packets price of \$1,589.42, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

#### **4. Renvela Tablets**

162. Renvela tablets were first approved by the FDA in 2007.

163. Impax launched an authorized generic version of Renvela tablets on April 16, 2014.

164. The FDA approved the first non-brand generic version of Renvela tablets, manufactured by Aurobindo, on July 17, 2017. Several additional generic versions of Renvela tablets subsequently became available, including versions sold by Dr. Reddy's, Invagen, Amneal, Twi, Anxin, Zydus, and Micro Labs.

165. On information and belief, effective August 22, 2017, the CVS Defendants entered into an agreement with Sanofi, whereby they would add Renvela tablets to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

166. The generic versions of Renvela tablets would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand version of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

167. Second, because the generic versions of Renvela tablets were significantly less expensive than the brand version of Renvela tablets at all relevant times, SilverScript beneficiaries

would have paid less for generic versions of Renvela tablets than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

168. For example, by February 2019, the GoodRx price of the generic was \$135.65 compared to the brand Renvela tablets price of \$540.35, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

## **5. Harvoni**

169. Ledipasvir/SofosBuvir is a fixed-dose combination of ledipasvir, a hepatitis C virus ("HCV") NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor approved for the treatment of chronic hepatitis C virus in certain adults. Gilead manufactures Ledipasvir/SofosBuvir under the brand name Harvoni.

170. Harvoni was first approved by the FDA in 2014.

171. On January 1, 2019 Asegua Therapeutics, a wholly-owned subsidiary of Gilead, launched an authorized generic version of Harvoni. Brand Harvoni costs approximately \$32,127 per treatment and the authorized generic versions costs approximately \$12,265.

172. On information and belief, effective January 1, 2019 (the same day Asegua's AG launched), the CVS Defendants entered into an agreement with Gilead, whereby they would add Harvoni to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

173. The generic versions of Harvoni would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generic had not been excluded from formulary coverage.

174. Second, because the authorized generic of Harvoni was significantly less expensive than the brand versions of Harvoni at all relevant times, SilverScript beneficiaries would have paid less for generic version of Harvoni than they paid for brand version if the authorized generic had not been excluded from formulary coverage as part of the NG Scheme.

175. For example, by February 2019, the GoodRx price of the generic ledipasvir/sofosbuvir 90 MG-400 MG tablets was \$12,117.14 compared to the brand Harvoni price of \$32,127.27, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

## **6. Eplusa**

176. Sofosbuvir/Velpatasvir is a fixed-dose combination of sofosbuvir, approved for the treatment of hepatitis C in certain adults. Gilead manufactures Sofosbuvir/Velpatasvir under the brand name Eplusa.

177. Eplusa was first approved by the FDA in 2016.

178. In November 2018, Asegua Therapeutics, a wholly-owned subsidiary of Gilead, launched an authorized generic version of Eplusa.

179. On information and belief, effective November 27, 2018, the CVS Defendants entered into an agreement with Gilead, whereby they would add Eplusa to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

180. The authorized generic version of Eplusa would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial

Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

181. Second, because the authorized generic versions of Epclusa was significantly less expensive than the brand version of Epclusa at all relevant times, SilverScript beneficiaries would have paid less for the authorized generic version of Epclusa than they paid for brand version if the authorized generic had not been excluded from formulary coverage as part of the NG Scheme.

182. For example, by February 2019, the GoodRx price of the generic was \$8,083.79 compared to the brand Epclusa price of \$25,184.05, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

## **7. Ventolin HFA**

183. Albuterol sulfate inhalation aerosol is a short acting beta agonist, and also known as a “rescue inhaler,” approved for the treatment or prevention of bronchospasm in patients aged 4 years and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients aged 4 years and older.

184. Bronchospasms cause difficulty breathing due to the tightening and narrowing of the airways in the lungs. Access to affordable albuterol inhalers is critical to asthma patients, because serious consequences of asthma attacks, including death, can be avoided with proper treatment and care, such as the use of rescue inhalers. GSK manufactures albuterol sulfate inhalation aerosol under the brand name Ventolin HFA.

185. Ventolin was first approved by the FDA in 1981. At the time it was approved, Ventolin used chlorofluorocarbons (“CFCs”) as a propellant. The FDA banned CFCs as a propellant in 2008 because of their ozone-depleting properties. GSK thereafter switched to the propellant hydrofluoroalkane (“HFA”). The FDA 2008 change all but eliminated generic

competition for albuterol inhalers like Ventolin HFA, substantially increasing out-of-pocket costs for the drug and leading to huge profits for GSK.<sup>59</sup>

186. On January 15, 2019, GSK announced that Prasco would begin selling an authorized generic version of its Ventolin HFA that was manufactured by GSK. The only difference would be that there would be a different name on the label. Prasco's authorized generic for Ventolin HFA was priced at a wholesale acquisition cost ("WAC") of \$36.00, representing approximately a 35% reduction in WAC cost compared to Ventolin HFA.

187. On information and belief, on or about February 7, 2019, the CVS Defendants entered into an agreement with GSK, whereby they would add Ventolin HFA to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

188. The generic versions of Ventolin HFA would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

189. Second, because the generic versions of Ventolin HFA were significantly less expensive than the brand version of Ventolin HFA at all relevant times, SilverScript beneficiaries would have paid less for generic versions of Ventolin HFA than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

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<sup>59</sup> See Anupam Jena, Oliver Ho, Dana Goldman, *The Impact of the US Food and Drug Administration Chlorofluorocarbon Ban on Out-of-pocket Costs and Use of Albuterol Inhalers Among Individuals With Asthma* at 1171-1179, 175 JAMA Intern Med. (July 2015), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2293081>.

190. For example, by February 2019, the GoodRx price of the generic was \$52.13 compared to the brand Ventolin HFA price of \$63.29, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

#### **8. Canasa Rectal Suppository**

191. Mesalamine rectal suppository is approved for the treatment of inflammatory disease, including ulcerative colitis and Crohn's disease. Allergan manufactures mesalamine rectal suppositories under the brand name Canasa.

192. Canasa was first approved by the FDA in 2001.

193. On December 7, 2018, Greenstone, LLC began selling an authorized generic version of Canasa that was manufactured by Allergan.

194. The FDA approved the first generic version of Canasa, manufactured by Mylan, on November 24, 2015. Mylan launched the first non-brand generic version of Canasa on December 17, 2018. Several additional generic versions of Canasa subsequently became available, including versions sold by Pharm Sourcing, Sandoz, Amring, Annora, Zydus, and Actavis.

195. On information and belief, on February 22, 2019, the CVS Defendants entered into an agreement with Allergan, whereby they would add Canasa to the NG Scheme and include in on SilverScript formularies instead of generics, in exchange for rebates.

196. The generic versions of Canasa would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.



197. Second, because the generic versions of Canasa were significantly less expensive than the brand versions of Canasa at all relevant times, SilverScript beneficiaries would have paid less for generic versions of Canasa than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

198. For example, February 2019, the GoodRx price of the generic was \$332.75 compared to the brand Canasa price of \$1,213.43, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

### **9. Advair Diskus**

199. Fluticasone-salmeterol inhalation powder is used to control and prevent symptoms (wheezing and shortness of breath) caused by asthma or ongoing lung disease (chronic obstructive pulmonary disease-COPD, which includes chronic bronchitis and emphysema). It contains two medications: fluticasone and salmeterol. GSK manufactures fluticasone-salmeterol inhalation powder under the brand name Advair Diskus.

200. Asthma impacts more than 20 million adults and 6 million children in the United States. Since it was launched in 2001, Advair Diskus has surpassed \$100 billion in sales for GSK. Though the medication's patent had expired in 2010, GSK protected its blockbuster drug by obtaining patents on the Diskus delivery system.<sup>60</sup>

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<sup>60</sup> See Ben Hirschler, *In fight for GSK's Advair, generic firms step carefully on price*, Reuters (June 3, 2016), <https://www.reuters.com/article/us-gsk-advair/in-fight-for-gsks-advair-generic-firms-step-carefully-on-price-idUSKCN0YP1E0>.

201. On January 30, 2019, the FDA approved Mylan's first generic version of Advair Diskus under the brand name Wixela.<sup>61</sup> Mylan launched its generic on February 12, 2019.<sup>62</sup>

202. At the time, Mylan's competing generic was priced on GoodRx at \$135.74 compared to \$421.27 for the brand, 70% less than Advair Diskus and 67% less than GSK's authorized generic product.<sup>63</sup>

203. On February 8, 2019, GSK announced that Prasco had launched an authorized generic version of its Advair Diskus. As part of the launch, Prasco stressed the identical nature of the authorized generic product:

The Prasco authorized generic, fluticasone propionate and salmeterol Inhalation Powder will provide patients with the same quality and experience as the brand product. A unique and exciting part of this launch is that the DISKUS inhaler itself will also be identical. . . . We are grateful to expand our relationship with a leader in the industry like GSK.<sup>64</sup>

204. On information and belief, effective February 27, 2019, the CVS Defendants entered into an agreement with GSK, whereby they would add Advair Diskus to the NG Scheme and include it on SilverScript formularies instead of generics, in exchange for rebates.

205. At least two additional non-brand generic versions of Advair Diskus subsequently launched, sold by Teva and Hikma, September 2020 and December 2020, respectively.

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<sup>61</sup> See Press Release, *FDA approves first generic Advair Diskus*, FDA (Jan. 30, 2019), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-advair-diskus>.

<sup>62</sup> Press Release, *Mylan Launches Wixela™ Inhub™ (fluticasone propionate and salmeterol inhalation powder, USP), the First Generic of ADVAIR DISKUS® (fluticasone propionate and salmeterol inhalation powder), at a List Price 70% Less than the Brand*, Mylan (Feb. 12, 2019), <https://investor.mylan.com/news-releases/news-release-details/mylan-launches-wixelatm-inhubtm-fluticasone-propionate-and>.

<sup>63</sup> See Kristen Coppock, *Generic Version of Advair Diskus Launched at Discounted List Price*, Pharmacy Times (Feb. 13, 2019), <https://www.pharmacytimes.com/view/generic-version-of-advair-diskus-launched-at-discounted-list-price>.

<sup>64</sup> Press Release, Prasco Laboratories (Feb. 8, 2019), [https://prasco.com/news/2019/prasco-launches-the-authorized-generic-of-advair-diskus-\(fluticasone-propionate-and-salmeterol-inhalation-powder\).html](https://prasco.com/news/2019/prasco-launches-the-authorized-generic-of-advair-diskus-(fluticasone-propionate-and-salmeterol-inhalation-powder).html).

206. The generic versions of Advair Diskus would have resulted in lower out-of-pocket costs to SilverScript beneficiaries during the relevant period. First, because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

207. Second, because the generic versions of Advair Diskus were significantly less expensive than the brand version of Advair Diskus at all relevant times, SilverScript beneficiaries would have paid less for generic versions of Advair Diskus than they paid for brand version if the generics had not been excluded from formulary coverage as part of the NG Scheme.

208. For example, by February 2019, the GoodRx price of Mylan's generic version of Advair Diskus was \$135.74 compared to the price of the brand Advair Diskus of \$421.27, making the generic a much lower cost option for SilverScript beneficiaries in the Coverage Gap and Catastrophic Coverage tiers, where the beneficiaries' contribution is based on the overall cost of the drug.

## **V. PLAINTIFFS' AND THE CLASSES' DAMAGES**

209. To date, Plaintiffs have paid more than \$400.00 in out-of-pocket costs for Affected Drugs during the Class Periods.

210. On information and belief, Defendants' NG Scheme caused Plaintiffs and members of the Classes to overpay millions of dollars for brand name Affected Drugs and dissuaded them from seeking formulary exceptions and other means of receiving less costly generic versions of the Affected Drug.

211. Plaintiffs and members of the Classes are entitled to damages in the amount of the difference between the out-of-pocket costs they paid for the Affected Drugs and the price they would have paid for generic versions of those drugs.

212. Because generic drugs are generally placed on a lower tier than the brand versions of the same drugs, SilverScript beneficiaries would generally pay less for generic drugs than their brand counterparts in the Initial Coverage stage (in the form of lower co-payments), if the generics had not been excluded from formulary coverage.

213. Moreover, because the generic versions of the Affected Drugs were significantly less expensive than the brand versions at all relevant times, SilverScript beneficiaries would have paid less for generic versions even in the Coverage Gap and Catastrophic Coverage Stages.

214. Plaintiffs and members of the Classes are also entitled to statutory, treble, and punitive damages, among others.

215. Defendants concealed and misrepresented the NG Scheme until the Second Amended Complaint in *U.S. ex rel. Ellsworth Assocs., LLP v. CVS Health Corp.*, No. 2:19-cv-02553-JMY (E.D. Pa.) was unsealed on May 6, 2022. Order, ECF No. 21. Without further disclosure of information within Defendants' possession, Plaintiffs are unable to determine the full scope of the damages to themselves and the Class caused by Defendants' misconduct.

## **VI. TOLLING**

### **A. Continuing Violations Doctrine**

216. The conduct of Defendants central to Plaintiffs' claims has not ceased; the pricing scheme remains in effect. And all of the relevant conduct of Defendants is part of a continuing unlawful practice. Accordingly, under the continuing violations doctrine, this action is timely because the last act evidencing the continuing practice falls within the applicable limitation periods.

**B. Discovery Rule Tolling**

217. As a result of the acts and omissions of Defendants, Plaintiffs could not have discovered, through the exercise of reasonable due diligence, the existence of the NG Scheme until at least May 2022, when the Second Amended Complaint was unsealed in *U.S. ex rel. Ellsworth Assocs., LLP v. CVS Health Corp.*, No. 2:19-cv-02553-JMY (E.D. Pa.). Plaintiffs could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Thus, the applicable limitations periods did not begin to accrue until Plaintiffs discovered, or through the exercise of reasonable diligence should have discovered, Defendants' wrongful acts and omissions.

**C. Fraudulent Concealment Tolling**

218. All applicable statutes of limitation have also been tolled by Defendants' knowing and active fraudulent concealment and denial of the facts alleged herein throughout the period relevant to this action. Specifically, Defendants concealed and misrepresented the existence of cheaper generic drugs and/or the NG Scheme. At all times, Defendants were under a continuous duty to disclose the existence of cheaper generic drugs and/or the existence of the NG Scheme.

**D. Estoppel**

219. Defendants were under a continuous duty to disclose to Plaintiffs and members of the Classes the existence of cheaper generic drugs and/or the NG Scheme.

220. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action.

**VII. CLASS ACTION ALLEGATIONS**

221. Plaintiffs bring this action as a class action under Federal Rules of Civil Procedure 23(a), 23(b)(2), and 23(b)(3) on behalf of themselves and on behalf of all others similarly situated, defined as follows (the "Classes"):

**The Nationwide Class:** All individuals who were SilverScript beneficiaries and paid for the brand versions of the Affected Drugs during the following periods (the “Class Periods”):

Drug	Class Period
Invega	From November 6, 2015 until the Class is certified
Asacol HD	From September 23, 2016 until May 13, 2022
Renvela Packets	From August 1, 2017 until the Class is certified
Renvela Tablets	From August 22, 2017 until the Class is certified
Harvoni	From January 1, 2019 until the Class is certified
Epclusa	From November 27, 2018 until the Class is certified
Ventolin HFA	From February 7, 2019 until the Class is certified
Canasa Rectal Suppository	From February 22, 2019 until the Class is certified
Advair Diskus	From February 8, 2019 until the Class is certified

**The Direct Purchaser Sub-Class:** All individuals who were SilverScript beneficiaries and purchased brand versions of the Affected Drugs from CVS Pharmacy, CVS Caremark Mail Service Pharmacy, Inc., CVS Specialty Pharmacy, Inc, and/or Longs Drugs, Inc. during the Class Periods.

**The Maryland Sub-Class:** All individuals who were SilverScript beneficiaries and paid for the brand versions of the Affected Drugs during Class Periods in the State of Maryland.

**The Florida Sub-Class:** All individuals who were SilverScript beneficiaries and paid for the brand versions of the Affected Drugs during Class Periods in the State of Florida.

222. Excluded from the Class are Defendants and any entity in which they have a controlling interest and their legal representatives, officers, directors, assignees, successors, and their officers, directors, management, employees, subsidiaries, and affiliates.<sup>65</sup>

223. Members of the Classes are so numerous and widely geographically dispersed throughout the United States and its territories that joinder is impracticable. Plaintiffs believe that there are thousands of members of the Classes, in an amount to be determined in discovery and at trial. Further, the identities of Class members will be readily ascertainable through business records kept in regular order.

224. Plaintiffs' claims are typical of the claims of members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct by Defendants.

225. Plaintiffs will fairly and adequately protect and represent the interests of the Classes.

226. Plaintiffs' interests are coincident with, and not antagonistic to, the Classes'.

227. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving the pharmaceutical industry.

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

- a. Whether Defendants orchestrated and engaged in the NG Scheme;
- b. Whether Defendants caused Class members to incur damages, including overpayment and out-of-pocket costs, in connection with prescriptions of the Affected Drugs through the NG Scheme;
- c. Whether Defendants violated federal and state law regarding full and accurate disclosure of pricing differentials between brand name and generic

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<sup>65</sup> Plaintiffs reserve the right to revise the definition of the Classes, and reserve the right to establish additional sub-classes where appropriate.

- drugs;
- d. Whether Defendants violated state laws in the Automatic Substitution States by failing to substitute the Affected Drugs with generic equivalents;
  - e. Whether Defendants conspired with the Manufacturer Co-Conspirators for the purpose of carrying out the NG Scheme;
  - f. Whether Defendants conducted, or participated in the conduct of, the Janssen NG Scheme Enterprise, Allergan NG Scheme Enterprise, Sanofi NG Scheme Enterprise, Gilead NG Scheme Enterprise, and/or GSK NG Scheme Enterprise;
  - g. Whether Defendants engaged in mail or wire fraud in furtherance of the Janssen NG Scheme Enterprise, Allergan NG Scheme Enterprise, Sanofi NG Scheme Enterprise, Gilead NG Scheme Enterprise, and/or GSK NG Scheme Enterprise;
  - h. Whether Defendants engaged in a pattern and practice that caused Plaintiffs and Class members to incur damages in connection with the purchase of the Affected Drugs;
  - i. Whether Defendants engaged in deceptive and/or fraudulent conduct;
  - j. Whether Defendants' deceptive and/or fraudulent activity was intended to defraud or harm Plaintiffs and Class members;
  - k. Whether Defendants violated the Racketeer Influenced and Corrupt Organizations Act;
  - l. Whether Defendants violated state consumer protection acts;
  - m. Whether Defendants owed a duty to Plaintiffs and Class members, and whether Defendants breached that duty; and
  - n. Whether Defendants were unjustly enriched.

229. Questions of law and fact common to members of the Classes predominate over questions, if any, that may affect only individual members of the Classes, because Defendants have acted on grounds generally applicable to the Classes. Such generally applicable conduct is inherent in Defendants' wrongful conduct.



230. Class action treatment is a superior method for the fair and efficient adjudication of this controversy. Among other things, class treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in the management of this class action.

231. The Classes may also be certified under Federal Rule of Civil Procedure 23(b)(2) because Defendants have acted on grounds generally applicable to the Classes, thereby making it appropriate to award declaratory and injunctive relief with respect to the Classes.

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

## **VIII. CLAIMS FOR RELIEF**

### **FIRST CLAIM FOR RELIEF VIOLATION OF CIVIL RICO, 18 U.S.C. § 1962(c) (On behalf of the Direct Purchaser Sub-Class)**

233. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.

234. Plaintiffs bring this claim on behalf of themselves and the Direct Purchaser Sub-Class and allege violations of Section 1962(c) of RICO. 18 U.S.C. § 1962(c).

#### **A. Defendants are Culpable “Persons” Under RICO**

235. Plaintiffs, Direct-Purchaser Sub-Class members, and each Defendant are all “persons,” as that term is defined in 18 U.S.C. § 1961(3).

**B. The NG Scheme Enterprises**

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

237. For purposes of this claim, the RICO “enterprises” are associations-in-fact consisting of (a) CVS Health, who directed the NG Scheme; (b) CVS Caremark, who received rebates from the Manufacturer Co-Conspirators in exchange for excluding generic versions of the Affected Drugs from SilverScript formularies; (c) SilverScript, who denied Plaintiffs and Direct-Purchaser Sub-Class members formulary coverage of generic versions of the Affected Drugs and misrepresented and omitted the availability and cost of generic versions of the Affected Drugs; (d) CVS Pharmacies, who failed to inform Plaintiffs and Direct-Purchaser Sub-Class members about the availability of generic versions of the Affected Drugs, failed to automatically dispense generic versions of the Affected Drugs where required to do so by generic substitution laws in Automatic Substitution states, and agreed not to stock generic versions of the Affected Drugs; and (e) *one* of the Manufacturer Co-Conspirators, who paid rebates and administrative fees to the CVS Defendants to ensure preferred formulary treatment of the Affected Drugs that they manufacture. Each NG Scheme Enterprise is a separate bilateral enterprise with Defendants. These association-in-fact enterprises are collectively referred to herein as the “NG Scheme Enterprises.”

238. Each of the NG Scheme Enterprises is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common and/or shared purposes of selling, purchasing, and dispensing the Affected Drugs to Plaintiffs and Direct-Purchaser Sub-Class members and concealing the availability of less costly generic versions of these drugs to generate higher profits.

239. To accomplish this common purpose, Defendants restricted Plaintiffs' and Direct-Purchaser Sub-Class members' ability to access generic versions of the Affected Drugs by not including those drugs on the SilverScript formularies, by understocking and/or failing to stock those generics at CVS Pharmacies, and by providing misleading information omitting the actual price and availability of these drugs to members of the Direct Purchaser Sub-Class. They did so willfully, and with knowledge that Direct-Purchaser Sub-Class members would rely on their misrepresentations, concealment, and/or omissions.

240. It is this scheme that is fraudulent. The NG Scheme Enterprises restricted access to generic versions of the Affected Drugs by Direct-Purchaser Sub-Class members and concealed the fact that the CVS Defendants were receiving rebate payments and administrative fees from the Manufacturer Co-Conspirators in exchange for the inclusion of the Affected Drugs in the NG Scheme.

241. Each NG Scheme Enterprise also shares a common purpose of boosting sales of brand versions of the Affected Drugs notwithstanding the availability of generic versions of the Affected Drugs that are less costly for health care payors, including the government and the Direct Purchaser Sub-Class. With respect to the Manufacturer Co-Conspirators, these corporations would not be able to sustain the same level of sales of the Affected Drugs without the favorable formulary positions for those drugs on SilverScript formularies facilitated by the NG Scheme and the misrepresentations and omissions Defendants made to Direct-Purchaser Sub-Class members regarding the price and availability of less costly generic versions of the Affected Drugs. Defendants share this common purpose because, without the favorable formulary positions granted to the Affected Drugs on SilverScript formularies, they would not receive lucrative payments from the Manufacturer Co-Conspirators. As a result, Defendants have, with the knowing and willful

participation and assistance of the Manufacturer Co-Conspirators, engaged in hidden schemes wherein they collect payments from the Manufacturer Co-Conspirators in exchange for restricting Direct-Purchaser Sub-Class members' access to less costly generic versions of the Affected Drugs.

242. Each of the NG Scheme Enterprises has a systemic linkage because they involve contractual relationships, financial ties, and continuing coordination of activities between each Manufacturer Co-conspirator, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. As to each of the NG Scheme Enterprises, there is a common communication network by which each Manufacturer Co-conspirator and the CVS Defendants share information on a regular basis, including price and rebate information. Each of the NG Scheme Enterprises functioned as a continuing unit. At all relevant times, each of the NG Scheme Enterprises was operated by the CVS Defendants for criminal purposes, namely, carrying out the NG Scheme.

243. At all relevant times, Defendants have been aware of the NG Scheme Enterprises' conduct, have been knowing and willing participants in that conduct, and have reaped profits from that conduct. Defendants struck rebate deals with the Manufacturer Co-Conspirators to provide favorable formulary status to the Affected Drugs and profit from increased sales of brand versions of the Affected Drugs. Defendants have known that the NG Scheme does not decrease Direct-Purchaser Sub-Class members' out-of-pocket costs but omitted and failed to disclose this to Plaintiffs and members of the Direct-Purchaser Sub-Class. But for the NG Scheme Enterprises' common purpose of boosting sales of brand versions of the Affected Drugs notwithstanding the availability of generic versions of the Affected Drugs that are less costly for health care payors, the Defendants would have had the incentive to disclose the availability of less costly generic versions of the Affected Drugs to Direct-Purchaser Sub-Class members and to provide automatic substitution of prescriptions with generic versions of the Affected Drugs where applicable. By

failing to disclose this information and make these substitutions, Defendants perpetuated the conduct of the NG Scheme Enterprises.

244. Further, Defendants took instructions and commands from the Manufacturer Co-Conspirators regarding exclusion of generic versions of the Affected Drugs from the SilverScript formularies, so that they could earn rebates for placement of products on their formularies from the Manufacturer Co-Conspirators.

245. In order to garner these rebates from the Manufacturer Co-Conspirators, the CVS Defendants and Manufacturer Co-Conspirators meet on a regular basis to discuss placement of the Affected Drugs on SilverScript's formularies.

246. There is a common communication network between each Defendant and each Manufacturer Co-conspirator for the purpose of implementing the NG Scheme and for the exchange of financial rewards for Defendants' activities that benefit the Manufacturer Co-Conspirators.

247. At all relevant times, each one of the Defendants was aware of the NG Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme.

248. For purposes of this count, the NG Scheme Enterprises are further identified as follows:

**1. The Janssen NG Scheme Enterprise**

249. The Janssen NG Scheme Enterprise is a separate association-in-fact consisting of each of Janssen, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. The Janssen NG Scheme Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanging kickbacks or "rebates" for preferred formulary positions for Invega on SilverScript's formulary, and an agreement that Defendants would not fill prescriptions for Invega with generic

versions of Invega. The Janssen NG Scheme Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Janssen and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy, with a common communication network by which Janssen and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy share information on a regular basis. At all relevant times, the Janssen NG Scheme Enterprise was operated and conducted by Defendants and Janssen for criminal purposes, namely, carrying out the NG Scheme.

## **2. The Allergan NG Scheme Enterprise**

250. The Allergan NG Scheme Enterprise is a separate association-in-fact consisting of each of Allergan, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. The Allergan NG Scheme Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or “rebates” for preferred formulary positions for Asacol HD and Canasa Rectal Suppository, on SilverScript’s formulary, and an agreement that Defendants would not fill prescriptions for Asacol HD and Canasa Rectal Suppository with generic versions of Asacol HD and Canasa Rectal Suppository. The Allergan NG Scheme Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Allergan and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy, with a common communication network by which Allergan and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy share information on a regular basis. At all relevant times, the Allergan NG Scheme Enterprise was operated and conducted by Defendants and Allergan for criminal purposes, namely, carrying out the NG Scheme.

### **3. The Sanofi NG Scheme Enterprise**

251. The Sanofi NG Scheme Enterprise is a separate association-in-fact consisting of each of Sanofi, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. The Sanofi NG Scheme Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or “rebates” for preferred formulary positions for Renvela packets and Renvela tablets on SilverScript’s formulary, and an agreement that Defendants would not fill prescriptions for Renvela packets and Renvela with generic versions of Renvela packets and Renvela tablets. The Sanofi NG Scheme Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Sanofi and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy, with a common communication network by which Sanofi and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy share information on a regular basis. At all relevant times, the Sanofi NG Scheme Enterprise was operated and conducted by Defendants and Sanofi for criminal purposes, namely, carrying out the NG Scheme.

### **4. The Gilead NG Scheme Enterprise**

252. The Gilead NG Scheme Enterprise is a separate association-in-fact consisting of each of Gilead, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. The Gilead NG Scheme Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or “rebates” for preferred formulary positions for Harvoni and Epclusa on SilverScript’s formulary, an agreement that Defendants would not fill prescriptions for Harvoni and Epclusa with generic versions of Harvoni and Epclusa, and agreements that CVS Pharmacies would not stock generic versions of Harvoni and Epclusa. The Gilead NG Scheme Enterprise has

a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between Gilead and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy, with a common communication network by which Gilead and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy share information on a regular basis. At all relevant times, the Gilead NG Scheme Enterprise was operated and conducted by Defendants and Gilead for criminal purposes, namely, carrying out the NG Scheme.

#### **5. The GSK NG Scheme Enterprise**

253. The GSK NG Scheme Enterprise is a separate association-in-fact consisting of each of GSK, CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy. The GSK NG Scheme Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals that are and have been associated for the common or shared purposes of exchanges kickbacks or “rebates” for preferred formulary positions for Ventolin HFA and Advair Diskus on SilverScript’s formularies, and agreements that Defendants would not fill prescriptions for Ventolin HFA and Advair Diskus with generic versions of Ventolin HFA and Advair Diskus, and agreements that CVS Pharmacies would not stock generic versions of Ventolin HFA and Advair Diskus. The GSK NG Scheme Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between GSK and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy, with a common communication network by which GSK and CVS Health, CVS Caremark, SilverScript, and CVS Pharmacy share information on a regular basis. At all relevant times, the GSK NG Scheme Enterprise was operated and conducted by Defendants and GSK for criminal purposes, namely, carrying out the NG Scheme.

254. The NG Scheme Enterprises (the Janssen NG Scheme Enterprise, Allergan NG Scheme Enterprise, Sanofi NG Scheme Enterprise, Gilead NG Scheme Enterprise, and GSK NG



Scheme Enterprise) knowingly made material misrepresentations and omissions to Direct-Purchaser Sub-Class members in furtherance of the fraudulent scheme regarding:

- a. The availability of generic versions of the Affected Drugs;
- b. The relative out-of-pocket costs Direct-Purchaser Sub-Class members would pay for the generic versions of the Affected Drugs;
- c. Whether the generic versions of the Affected Drugs would have been cheaper than the brand;
- d. Whether the exclusion of generic versions of the Affected Drugs from SilverScript's formularies harmed Direct-Purchaser Sub-Class members by forcing them to pay more; and
- e. The extent to which the NG Scheme forced Plaintiffs and Direct-Purchaser Sub-Class members to incur additional expenses for their Affected Drug prescriptions.

255. The Manufacturer Co-Conspirators alone could not have accomplished the purposes of the NG Scheme Enterprises without the assistance of Defendants. For the Manufacturer Co-Conspirators to profit from the scheme, Defendants needed to exclude generic versions of the Affected Drugs from the SilverScript formularies, omit material information, and prevent Direct-Purchaser Sub-Class members from accessing generic versions of the Affected Drugs. Without this conduct, the NG Scheme Enterprises could not have achieved their common purpose.

256. The impacts of the NG Scheme Enterprises are still in place for many of the Affected Drugs, i.e., generic versions remain excluded from SilverScript coverage.

257. The foregoing evidences that the Defendants were willing participants in the NG Scheme Enterprises, had a common fraudulent purpose and interest in the objective of the scheme, and functioned within a structure designed to effectuate the Enterprises' purposes, i.e., to increase profits for both the Manufacturer Co-Conspirators and the Defendants through kickbacks to the

Defendants and continued exclusion of Direct-Purchaser Sub-Class members' access to generic versions of the Affected Drugs.

**C. The NG Scheme Enterprises' Use of the U.S. Mails and Interstate Wire Facilities**

258. Each of the NG Scheme Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale, purchase, and/or administration of the Affected Drugs; the creation of SilverScript's formularies governing Direct-Purchaser Sub-Class members' access to prescription drugs; the transmission to patients of individual prescriptions for the Affected Drugs; the receipt of rebate payments from the Manufacturer Co-Conspirators; training SilverScript representatives to mislead SilverScript beneficiaries about access to and cost of generics for the Affected Drugs over the phone; and/or the transmission and/or receipt of invoices, statements, and payments related to the use or administration of the Affected Drugs. During the Class Periods, the NG Scheme Enterprises participated in the administration of the Affected Drugs to tens of thousands of individuals located throughout the United States.

259. During the Class Periods, Defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents, information, products, and funds through the U.S. mails and interstate wire facilities.

260. The nature and pervasiveness of Defendants' NG Scheme, which was orchestrated out of the corporate headquarters of Defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities between Manufacturer Co-Conspirators and Defendants.

261. Most of the precise dates of Defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to these Defendants' books and records. Indeed, an essential part of the successful operation of the NG Scheme alleged herein depended upon secrecy, and as alleged above. Defendants took deliberate steps to conceal their wrongdoing. However, Plaintiffs can generally describe the occasions on which RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the NG Scheme.

262. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the NG scheme involved thousands of communications throughout the Class Periods including, *inter alia*:

- a. Marketing materials about the SilverScript's Medicare Part D Plans, which SilverScript sent to SilverScript beneficiaries and prospective SilverScript beneficiaries throughout the country;
- b. Formularies, which SilverScript sent to SilverScript beneficiaries throughout the country;
- c. Written and oral communications discussing, negotiating, and confirming the placement of a Manufacturer Co-Conspirator's Affected Drugs on SilverScript formularies and/or the exclusion of generic versions of the Affected Drugs;
- d. Written and oral communications between SilverScript customer care representatives and Direct-Purchaser Sub-Class members regarding the cost and availability of generic versions of the Affected Drugs;
- e. Written communications, including checks, relating to rebates, kickbacks, fees or other financial inducements paid to the Defendants to persuade them to restrict Direct-Purchaser Sub-Class members' access to generic versions of the Affected Drugs; and
- f. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities—i.e., the wrongful proceeds of Defendants' NG Scheme.

263. In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the NG Scheme.

**D. Conduct of the RICO Enterprises' Affairs**

264. During the Class Periods, each of the Defendants has exerted control over the NG Scheme Enterprises, in violation of Section 1962(c) of RICO, each of the Defendants have conducted or participated in the conduct of the affairs of those association-in-fact RICO enterprises, directly or indirectly, and such participation was carried out in the following ways:

- a. CVS Health has coordinated and directed the activity of the Defendants, including conceiving of the NG Scheme and coordinating the efforts of CVS Caremark, SilverScript, and CVS Pharmacy in implementing the NG Scheme;
- b. CVS Caremark has negotiated with the Manufacturer Co-Conspirators to obtain rebates in exchange for agreements to exclude generic versions of the Affected Drugs from SilverScript's formularies;
- c. SilverScript has controlled the creation and distribution of formularies, sales, and other materials as well as made oral representations to deceive Direct-Purchaser Sub-Class members regarding the availability of less costly generic versions of the Affected Drugs and has rejected requests for formulary exceptions that would allow Direct-Purchaser Sub-Class members to receive generic versions of the Affected Drugs;
- d. CVS Pharmacy has omitted and failed to inform Direct-Purchaser Sub-Class members of the availability of less costly generic versions of the Affected Drugs, has failed to automatically substitute generic versions of the Affected Drugs as directed by the generic substitution laws in effect in the Automatic Substitution States, and has understocked generic versions of the Affected Drugs; and
- e. Each of the Defendants has relied upon its employees and agents to promote the NG Scheme through the U.S. mails, through interstate wire facilities,

and through direct contacts with beneficiaries, the Manufacturer Co-Conspirators, and the other Defendants.

265. Each of the NG Scheme Enterprises identified above had a hierarchical decision-making structure headed by CVS Health.

266. In violation of Section 1962(c) of RICO, each of the Defendants has conducted and/or participated in the affairs of each of the NG Scheme Enterprises as described above.

**E. Defendants' Pattern of Racketeering Activity**

267. Each of the Defendants has conducted and participated in the affairs of the NG Scheme Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their pricing schemes. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which Defendants intended to defraud Plaintiffs, Direct-Purchaser Sub-Class members, and other intended victims of the pricing scheme.

268. Each Defendant's fraudulent and unlawful scheme consisted, in part, of deliberately restricting Direct-Purchaser Sub-Class members' access to generic versions of the Affected Drugs in exchange for payments from the Manufacturer Co-Conspirators.

269. The NG Scheme was calculated and crafted such that Plaintiffs and Direct-Purchaser Sub-Class members would pay higher out-of-pocket costs for brand versions of the Affected Drugs despite the availability of less costly generic versions of those drugs, boosting the revenues of the Manufacturer Co-Conspirators and allowing Defendants to benefit from kickback

payments received from the Manufacturer Co-Conspirators. In designing and implementing the NG Scheme, Defendants were cognizant, at all times, of the fact that Plaintiffs and Direct-Purchaser Sub-Class members, and the government (who covered a portion of the cost of the Affected Drugs) were not part of the enterprise and relied upon the integrity of Defendants in providing information about the cost and availability of generics.

270. By intentionally omitting generic versions of the Affected Drugs from the SilverScript formularies and understocking those generic versions, each of the Defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

271. Defendants' racketeering activities amounted to a common course of conduct, with similar patterns and purposes, intended to deceive Plaintiffs and Direct-Purchaser Sub-Class members. Each separate use of the U.S. mails and/or interstate wire facilities employed by each of the Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiffs and Direct-Purchaser Sub-Class members. Each of the Defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the NG Scheme Enterprises.

**F. Defendants' Motive**

272. Defendants' motive in creating and operating the NG Scheme and conducting the affairs described herein was to fraudulently obtain sales, profits, fees, and rebates from the Affected Drugs.

273. The NG Scheme was designed to, and did, bolster sales of the Affected Drugs even when less costly generic versions of these drugs were available. In exchange for favorable placement of the Affected Drugs on the SilverScript formularies and misrepresentation and

omission of the availability and cost of generic versions of the Affected Drugs, Defendants received kickbacks in the form of rebates and/or fees from the Manufacturer Co-Conspirators.

**G. Damages Caused by Defendants' No Generic Scheme**

274. Defendants' violations of federal law and their pattern of racketeering activity have directly and proximately caused Plaintiffs and Direct-Purchaser Sub-Class members to be injured in their business or property. Plaintiffs and Direct-Purchaser Sub-Class members have overpaid millions of dollars for their prescription drugs when their access to generic versions of the Affected Drugs was limited by the NG Scheme. Each Defendant intended and foresaw that Plaintiffs and Direct-Purchaser Sub-Class members would make such payments in reliance on their scheme and misrepresentations and omissions regarding the availability and cost of generic versions of the Affected Drugs.

275. Plaintiffs and Direct-Purchaser Sub-Class members have incurred higher out-of-pocket costs for their prescription drugs when their prescriptions were filled with brand versions of the Affected Drugs rather than lower-cost generic versions of these drugs. Plaintiffs' and Direct-Purchaser Sub-Class members' damages are *inter alia*, overpayment and/or the difference between their out-of-pocket costs for dispenses of brand versions of the Affected Drugs and the out-of-pocket costs they would have incurred if they had been dispensed generics versions of those drugs.

276. Prescription drug pricing is obscure. The lack of transparency obfuscates the relative costs to Plaintiffs and Direct-Purchaser Sub-Class members of the brand and generic versions of the Affected Drugs, leaving Plaintiffs and Direct-Purchaser Sub-Class members unable to ascertain whether the prices at which they receive the Affected Drugs are fair and competitive.

277. This lack of transparency and omission of material information regarding the availability and cost of generic versions of the Affected Drugs has misled Plaintiffs and Direct-Purchaser Sub-Class members and has forced them to pay more for the Affected Drugs, and

dissuaded them from seeking formulary exceptions and other means of receiving less costly generic versions of the Affected Drugs.

278. Defendants have told beneficiaries, like Plaintiffs, that they are benefitting from SilverScript's formulary design and the exclusion of generic versions of the Affected Drugs. Defendants also failed to disclose the existence of lower-cost generic alternatives to the Affected Drugs. If Defendants had disclosed the relative out-of-pocket costs of brand and generic versions of the Affected Drugs, Plaintiffs and Direct-Purchaser Sub-Class members would seek out the generic versions of the Affected Drugs.

279. Plaintiffs' injuries, and those of the Direct-Purchaser Sub-Class members, were proximately caused by Defendants' racketeering activity. But for Defendants' efforts to restrict access to generic versions of the Affected Drugs, Plaintiffs and Direct-Purchaser Sub-Class members would have received generic versions of the Affected Drugs and would have incurred lower out-of-pocket costs.

280. Defendants' racketeering activity directly and proximately caused Plaintiffs' injuries.

281. By virtue of these violations of 18 U.S.C. § 1962(c), under the provisions of Section 1964(c) of RICO, Defendants are jointly and severally liable to Plaintiffs and Direct-Purchaser Sub-Class members for three times the damages that Plaintiffs and Direct-Purchaser Sub-Class members have sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

**SECOND CLAIM FOR RELIEF**  
**CONSPIRACY TO VIOLATE CIVIL RICO, 18 U.S.C. § 1962(d)**  
**(On behalf of the Direct Purchaser Sub-Class)**

282. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.



283. Plaintiffs bring this claim on behalf of themselves and the Direct Purchaser Sub-Class.

284. 18 U.S.C. § 1962(d) provides that it “shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section.”

285. Defendants have violated 18 U.S.C. § 1962(d) by conspiring with the Manufacturer Co-Conspirators to violate 18 U.S.C. § 1962(c). The object of their conspiracy has been to conduct, or participate directly or indirectly in the conduct of, the affairs of the Enterprise through a pattern of racketeering activity.

286. As set forth in detail above, Defendants have engaged in numerous overt and predicate unlawful and fraudulent acts, constituting patterns of racketeering activity, in furtherance of the conspiracy. Specifically, Defendants made false or misleading statements and material omissions to Direct-Purchaser Sub-Class members regarding the cost of generic versions of the Affected Drugs; made false or misleading statements and material omissions to Direct-Purchaser Sub-Class members regarding availability of generic versions of the Affected Drugs; and received unlawful kickbacks (rebates) from the Manufacturer Co-Conspirators in exchange for the NG Scheme, including excluding generic versions of the Affected Drugs from SilverScript’s formularies. Disclosure of the truth about the cost and availability of generic versions of the Affected Drugs would be material to a reasonable consumer. Defendants intended to engage in the scheme resulting in Plaintiffs and Direct-Purchaser Sub-Class members paying increased out-of-pocket costs for prescriptions of the Affected Drugs.

287. From the outset, Defendants knew, but did not disclose, that generic versions of the Affected Drugs were available and would result in lower out-of-pocket costs to Direct-Purchaser Sub-Class members. Yet they misrepresented, concealed, and omitted the availability of generic

versions of the Affected Drugs and the cost differential from Direct-Purchaser Sub-Class members in order to collect lucrative payments from the Manufacturer Co-Conspirators in the form of rebates. Defendants knowingly and deliberately omitted this material information and misled consumers regarding availability and cost of generic versions of the Affected Drugs.

288. The nature of the above-described Defendants' and co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

289. Defendants have and continue to engage in the commission of overt acts in furtherance of the NG Enterprise Schemes, including the following racketeering predicate acts (as outlined in detail above):

- a. Multiple instances of mail fraud in violation of 18 U.S.C. § 1341; and
- b. Multiple instances of wire fraud in violation of 18 U.S.C. § 1343.

290. Defendants' violations of the above federal and state laws and the effects thereof detailed above are continuing and will continue. Plaintiffs and Direct-Purchaser Sub-Class members have been injured in their property by reason of these violations: Plaintiffs and Direct-Purchaser Sub-Class members have incurred millions of dollars in out-of-pocket costs for the branded Affected Drugs that they would not have incurred but for Defendants' conspiracy to violate 18 U.S.C. § 1962(c).

291. Defendants' racketeering activity directly and proximately injured Plaintiffs and Direct-Purchaser Sub-Class members: Plaintiffs and Direct-Purchaser Sub-Class members substantially overpaid for their prescribed drugs than they would have paid if Defendants had

accurately represented and not omitted material information regarding the costs and availability of generics, had included generic versions on the Affected Drugs on SilverScript formularies, and had dispensed and processed claims for generic versions of the Affected Drugs.

292. By virtue of these violations of 18 U.S.C. § 1962(d), Defendants are jointly and severally liable to Plaintiffs and Direct-Purchaser Sub-Class members for three times the damages Plaintiffs and Direct-Purchaser Sub-Class members have sustained, plus the cost of this suit, including reasonable attorneys' fees.

**THIRD CLAIM FOR RELIEF**

**FRAUD**

**(On behalf of the Nationwide Class or, alternatively, the Maryland and Florida Sub-Classes)**

293. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.

294. Plaintiffs bring this claim on behalf of themselves and the Nationwide Class or, alternatively, the Maryland and Florida Sub-Classes.

295. Defendants' fraudulent scheme specifically targeted SilverScript beneficiaries such as Plaintiffs.

296. As alleged above, Defendants, *inter alia*, knowingly misrepresented, concealed, suppressed, and/or omitted material information regarding: (a) Defendants' rebate agreements for the Affected Drugs, (b) the cost savings to beneficiaries if generic versions of the Affected Drugs had been included on SilverScript's formularies or made available through formulary exceptions; (c) that generic equivalents of the Affected Drugs would be routinely, inadequately stocked at CVS Pharmacies forcing Plaintiffs and Class members to purchase brand versions of the Affected Drugs; (d) whether generic drugs were covered and available; and (e) the cost differential between

the brand versions of the Affected Drugs and their generic equivalents as Defendants were required to disclose under federal and state law.

297. Defendants made these misrepresentations and/or omissions knowingly, or at least with reckless disregard of their falsity, given that Defendants knew generic versions of the Affected Drugs were available and knew the price differential between brand versions of the Affected Drugs and their generic equivalents.

298. Plaintiffs were unaware of Defendants' illegal scheme until May 2022, when the Second Amended Complaint was unsealed in *U.S. ex rel. Ellsworth Assocs., LLP v. CVS Health Corp.*, No. 2:19-cv-02553-JMY (E.D. Pa.). Order (May 6, 2022), ECF No. 21.

299. At all times material hereto, Defendants were under an affirmative, ongoing duty and obligation to disclose the price differential between the brand versions of the Affected Drugs and their generic equivalents to Plaintiffs and Class members per federal Medicare and state generic substitution laws. Additionally, Defendants had an affirmative, ongoing duty and obligation to dispense the cheaper generic equivalent according to federal Medicare and state generic substitution laws

300. The facts misrepresented, concealed, and/or omitted by Defendants were material to Plaintiffs' and Class members' decision to pay out-of-pocket costs associated with prescriptions for the Affected Drugs. If Plaintiffs had known those facts, they would have refused to pay out-of-pocket costs in connection with brand versions the Affected Drugs or would have paid less. They would have requested that their pharmacy dispense the less-costly generic versions of the Affected Drugs.

301. Defendants knew that Plaintiffs and Class members lacked knowledge of the true cost and availability of generic versions of the Affected Drugs and that, as a result, Plaintiffs and

Class members paid out-of-pocket costs for the Affected Drugs they otherwise would not have paid. Defendants intended to induce Plaintiffs and Class members to rely on their misrepresentations and/or omissions.

302. Plaintiffs had no reason to suspect that Defendants misrepresented, concealed, and/or omitted the true out-of-pocket costs and availability of generic versions of the Affected Drugs. Plaintiffs reasonably believed that Defendants were accurately relating the relative costs of the Affected Drugs and generic versions of the Affected Drugs. Plaintiffs and Class members actually, and reasonably and justifiably relied on Defendants' misrepresentations, concealment, and/or omissions in that Plaintiffs and Class members would not have purchased brand versions of the Affected Drugs but for Defendants' misrepresentations, concealment, and/or omissions. Plaintiffs' and Class members' reliance on CVS's misrepresentations, concealment, and/or omissions was, thus, to their detriment.

303. As a proximate result of Defendants' conduct, Plaintiffs and Class members have been damaged because they overpaid and/or paid out-of-pocket costs for the Affected Drugs that they would not have paid absent Defendants' fraud, and suffered millions of dollars in damages, the amount of which is to be determined at trial.

304. Plaintiffs and Class members are entitled to compensatory and punitive damages, in amounts to be determined at trial.

**FOURTH CLAIM FOR RELIEF**  
**UNJUST ENRICHMENT UNDER THE LAWS OF ALL FIFTY STATES AND THE**  
**DISTRICT OF COLUMBIA**  
**(On behalf of the Nationwide Class under the laws of all fifty states and the District of**  
**Columbia or, alternatively, the Maryland and**  
**Florida Sub-Classes under the laws of Maryland and Florida)**

305. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.

306. Plaintiffs bring this claim under the laws of all fifty states and the District of Columbia, on behalf of themselves and the Nationwide Class or, alternatively, the Maryland and Florida Sub-Classes under the laws of Maryland and Florida. The law of unjust enrichment is materially the same in all fifty states and the District of Columbia.

307. Defendants benefitted when, by means of Defendants' wrongful conduct alleged herein, Defendants knowingly caused Plaintiffs and Class members to make payments for the Affected Drugs.

308. Defendants have voluntarily and knowingly accepted and retained wrongful benefits in the form of, *inter alia*, payments from Plaintiffs and Class members, profits and/or rebates. In so doing, Defendants acted with conscious disregard for the rights of Plaintiffs and Class members.

309. As a result of Defendants' wrongful conduct alleged herein, Defendants have been unjustly enriched at the expense of, and to the detriment of, Plaintiffs and Class members.

310. Defendants' unjust enrichment is traceable to, and resulted directly and proximately from, the conduct alleged herein.

311. It is inequitable and unjust for Defendants to retain the benefits they received, without justification, from Plaintiffs and Class members in an unfair and unconscionable manner. Defendants' retention of such benefits under circumstances making it inequitable to do so constitutes unjust enrichment.

312. Plaintiffs and Class members did not confer these benefits officiously or gratuitously, and it would be inequitable and unjust for Defendants to retain these wrongfully obtained benefits.

313. Defendants are therefore liable to Plaintiffs and Class members, under the law of the District of Columbia and the laws of all fifty states.

314. As a result of Defendants' unjust enrichment, Plaintiffs seek restitution in the amount of the value of the benefit conferred on Defendants and/or disgorgement of any profits and/or benefit retained by Defendants, pre-and post-judgment interest, attorneys' fees and costs, and any other relief the Court deems just and appropriate.

**FIFTH CLAIM FOR RELIEF**  
**VIOLATIONS OF STATE CONSUMER PROTECTION ACTS**  
**(On behalf of the Nationwide Class or, alternatively, the Maryland and Florida Sub-Classes)**

315. Plaintiffs incorporate by reference all of the allegations above as though fully set forth herein.

316. This claim is brought by Plaintiffs on behalf of the Nationwide Class for violations of state consumer protection acts including:

- a. the Alabama Deceptive Trade Practices Act, Ala. Code § 8-19-1, *et seq.*;
- b. the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, *et seq.*;
- c. the Arizona Consumer Fraud Act, Ariz. Rev. Stat. Ann. § 44-1521, *et seq.*;
- d. the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. § 4-88-101, *et seq.*;
- e. the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* and § 17500, *et seq.*;
- f. the California Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.*;
- g. the Colorado Consumer Protection Act, Colo. Rev. Stat. § 6-1-101, *et seq.*;
- h. the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110, *et seq.*;
- i. the Delaware Consumer Fraud Act, Del. Code Ann. tit. 6, § 2513, *et seq.*;
- j. the District of Columbia Consumer Protection Procedures Act, D.C. Code § 28-3901, *et seq.*;
- k. the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.*;

- l. the Georgia Uniform Deceptive Trade Practices Act, Ga. Code. Ann. § 10-1-370, *et seq.*
- m. the Hawaii Deceptive Trade Practices Act, Haw. Rev. Stat. § 480-1, *et seq.*;
- n. the Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.*<sup>66</sup>;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1, *et seq.*;
- p. the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-2, *et seq.*;
- q. the Iowa Private Right of Action for Consumer Frauds Act, Iowa Code § 714H.1, *et seq.*;
- r. the Kansas Consumer Protection Act, Kan. Stat. Ann. § 50-623, *et seq.*;
- s. the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, *et seq.*;
- t. the Louisiana Unfair Trade Practices and Consumer Protection Law, La. Stat. Ann. § 51:1401, *et seq.*;
- u. the Maine Unfair Trade Practices Act, Me. Stat. tit. 5, § 207, *et seq.*;
- v. the Maryland Consumer Protection Act, Md. Code Ann., Com. Law § 13-101, *et seq.*;
- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, Mass. Gen. Laws ch. 93A, § 11, *et seq.*;
- x. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, *et seq.*;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F, *et seq.*;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*;
- aa. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.010, *et seq.*;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act, Mont. Code Ann. § 30-14-101, *et seq.*;
- cc. the Nebraska Consumer Protection Act, Neb. Rev. Stat. § 59-1601, *et seq.*;
- dd. the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 41.600, *et seq.*;

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<sup>66</sup> Plaintiffs acknowledge that the Court dismissed the Idaho Consumer Protection Act claim pursuant to its October 31, 2024 Orders. ECF Nos. 42, 43. The claim is reasserted here for appellate preservation purposes only.



- ee. the New Hampshire Regulation of Business Practices for Consumer Protection, N.H. Rev. Stat. Ann. § 358-A:1, *et seq.*;
- ff. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8-1, *et seq.*;
- gg. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq.*;
- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, *et seq.*;
- ii. the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1.1, *et seq.*;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15, *et seq.*;
- kk. the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, *et seq.*
- ll. the Oklahoma Consumer Protection Act, 15 Okla. Stat. Ann. § 751, *et seq.*;
- mm. the Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605, *et seq.*;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protect Law, 73 Pa. Cons. Stat. § 201-1, *et seq.*;
- oo. the Rhode Island Unfair Trade Practice and Consumer Protection Act, 6 R.I. Gen. Laws § 6-13.1-2, *et seq.*;
- pp. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. § 39-5-10, *et seq.*;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection Act, S.D. Codified Laws § 37-24-1, *et seq.*;
- rr. the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, *et seq.*;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code Ann. § 17.41, *et seq.*;
- tt. the Utah Consumer Sales Practices Act, Utah Code Ann. § 13-11-1, *et seq.*;
- uu. the Vermont Consumer Fraud Act, Vt. Code Ann. tit. 9, § 2451, *et seq.*;
- vv. the Virginia Consumer Protection Act of 1977, Va. Code Ann. § 59.1-199, *et seq.*;
- ww. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, *et seq.*;
- xx. the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-6-101, *et seq.*;
- yy. the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, *et seq.*; and
- zz. the Wyoming Consumer Protection Act, Wyo. Stat. Ann. § 40-12-101, *et seq.*

317. Alternatively, this claim is brought on behalf the Maryland and Florida Sub-Classes for violations of the Maryland Consumer Protection Act, Md. Code Ann., Com. Law § 13-101, *et seq.* and the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq.*, respectively.

318. Plaintiffs have complied with the applicable notice requirements of the state statutes.

319. The acts, practices, misrepresentations, concealment, and/or omissions by Defendants described above, and Defendants' conduct restricting access to and omitting material information regarding the price and availability of generic versions of the Affected Drugs occurred in the course of conduct involving trade or commerce, and constitute unfair and/or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

320. Defendants' acts and practices created a likelihood of confusion or of misunderstanding and misled, deceived, or damaged Plaintiffs and Class members in connection with the sale of, and payments for, the Affected Drugs. Defendants' conduct also constituted the use or employment of deception, fraud, false pretense, false promise, misrepresentation, or knowingly concealing, suppressing, or omitting a material fact with intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of goods, whether or not a person has in fact been misled, deceived or damaged in violation of each of the above-enumerated statutes.

321. Plaintiffs and Class members purchased the Affected Drugs primarily for personal, family, or household purposes. The Affected Drugs were paid for, in whole or in part, by Plaintiffs and Class members.

322. Plaintiffs, on behalf of themselves and the Class members, seek injunctive relief, monetary damages, treble damages and such other and further relief as set forth in each of the above enumerated statutes.

#### **IX. DEMAND FOR JUDGMENT**

WHEREFORE, Plaintiffs, on their own behalf and on behalf of the proposed Classes, pray for judgment against Defendants and that this Court:

- a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Classes, and appoint Plaintiffs as the named representatives of the Classes and Plaintiffs' counsel as Class Counsel for the Classes;
- b. Award Plaintiffs and the Classes compensatory, statutory, treble, and punitive damages in an amount to be determined at trial, plus pre- and post-judgment interest in accordance with law;
- c. Award restitution and/or disgorgement of the benefit unlawfully retained by Defendants;
- d. Award Plaintiffs and the Classes their costs of suit, including reasonable attorneys' fees as provided by law;
- e. Award appropriate equitable and injunctive relief; and
- f. Award such other and further relief as the Court deems just and proper.

#### **X. JURY DEMAND**

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

Dated: November 14, 2024

/s/ Joseph H. Meltzer

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