Kenneth D. Capesius (SBN 347555)*
kcapesius@baronbudd.com
W. Scott Simmer (admitted *pro hac vice*)
ssimmer@baronbudd.com
Noah M. Rich (admitted *pro hac vice*)
nrich@baronbudd.com
BARON & BUDD, P.C.
600 New Hampshire Ave. NW, 10th Floor
Washington, DC 20037
Telephone: 202.333.4562
Facsimile: 214.523.6600

Roland Tellis (SBN 186269)
rtellis@baronbudd.com
Mark Pifko (SBN 228412)
mpifko@baronbudd.com
BARON & BUDD, P.C.
15910 Ventura Blvd., Suite 1600
Encino, CA 91436
Telephone: 818.839.2333
Facsimile: 214.520.1181

William H. von Oehsen (admitted *pro hac vice*)
William.vonOehsen@PowersLaw.com
Ronald S. Connelly (admitted *pro hac vice*)
Ron.Connelly@PowersLaw.com
POWERS PYLES SUTTER & VERVILLE PC
1501 M Street NW, 7th Floor
Washington, DC 20005
Telephone: 202.872.6765
Facsimile: 202.785.1756

*admitted only in California

Attorneys for Relator

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA *ex rel.* ADVENTIST HEALTH SYSTEM/ WEST and on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, WASHINGTON, the COMMONWEALTHS of MASSACHUSETTS, PUERTO RICO, and VIRGINIA, and the DISTRICT OF COLUMBIA,	**CASE NO.: 2:21-cv-4249** **FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT & STATE-LAW COUNTERPARTS** **JURY TRIAL DEMANDED**

Plaintiffs/Relator,

v.

ABBVIE INC.; ALLERGAN SALES, LLC; ALLERGAN USA, INC.; ASTRAZENECA LP; ASTRAZENECA PHARMACEUTICALS LP; NOVARTIS PHARMACEUTICALS CORPORATION; NOVARTIS AG; SANDOZ, INC.; SANOFI-AVENTIS U.S. LLC; SANOFI US SERVICES INC.; SANOFI S.A.; and GENZYME CORPORATION,

Defendants.

FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT AND STATE-LAW COUNTERPARTS

TABLE OF CONTENTS

I. INTRODUCTION

1. The Medicaid Drug Rebate Program ("MDRP") requires drug manufacturers to provide rebates to state Medicaid programs on their Medicaid drug purchases. In exchange for the rebates, state Medicaid programs generally must cover all of a participating manufacturer's drugs when prescribed for a medically accepted indication.

2. Section 340B of the Public Health Service Act, enacted in 1992, expanded elements of this price protection beyond the Medicaid program. Under Section 340B – commonly referred to as the "340B Program" – manufacturers participating in Medicaid must offer discounted drugs to hospitals and other health care facilities known as "Covered Entities." All of these Covered Entities provide essential healthcare services and significant amounts of uncompensated care to underserved and vulnerable populations, regardless of ability to pay. The 340B Program is a vital and indispensable tool to offset the costs of uncompensated or under-compensated care.

3. The 340B statute establishes a clear, straightforward statutory formula to determine the maximum allowable price of a drug, referred to as the "Ceiling Price." In addition to applying up-front, across-the-board discounts on all covered outpatient drugs, this formula penalizes manufacturers for increasing the prices of drugs faster than inflation—referred to as the "inflationary penalty."

4. The inflationary penalty can be substantial; if a manufacturer increases the price of a drug much faster than inflation, the discounts required by the 340B statute can eclipse the cost of the drug, resulting in a negative price.

5. The government responded to complaints from manufacturers regarding this situation by directing manufacturers to charge a price of $0.01 if and when the manufacturers' prices increases resulted in negative prices. This outcome—where the statutory Ceiling Price calculation results in a price of $0.01—often is referred to colloquially as "penny pricing."

6. This direction from the government to charge $0.01 for any drug which had a negative Ceiling Price dates back to the start of the program in the early 1990's. This informal policy was in place for nearly 20 years without interruption or change.

7. In 2010, Congress passed an amendment in 2010 that eliminated negative prices as a matter of law.

8. Although negative prices were prevented by the 2010 statute, zero prices were not. ("[B]ased on the provision in section 1927(c)(2)(D) of the Social Security Act that limits the unit rebate amount to 100% of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result in a negative 340B price, ***but could result in a zero 340B price***.") (emphasis added). Health Resources and Services Administration ("HRSA"), *Clarification of Penny Pricing Policy, Policy Release No. 2011-2* at 1 (Nov. 21, 2011).

9. Given that the 2010 statute did not state whether, in the case of a negative price, manufacturers should charge $0.00 or $0.01, the government formally adopted a written guidance in 2011 which expressly directed manufacturers to charge $0.01 if the statutory formula resulted in a negative Ceiling Price. HRSA, *Clarification of Penny Pricing Policy, Policy Release No. 2011-2* (Nov. 21, 2011). ("[W]hen the URA equals the AMP in the calculation of the 340B ceiling price . . . , the manufacturer should charge $0.01 per unit of measure for zero priced drugs.").

10. To be clear, the Ceiling Price formula results in a price of $0.01 per unit only if the manufacturer of the drug chooses to impose staggering price increases that far outpace the rate of inflation over a course of many years. Any manufacturer can easily avoid hitting a Ceiling Price of $0.01 by raising prices gradually and not in great disproportion to inflation. Put differently, a manufacturer who increases prices so rapidly and steeply that the Ceiling Price hits $0.01 has done so intentionally for economic gain in non-340B drug sales. Such a result is entirely avoidable.

11. Defendants—some of the largest drug manufacturers in the world—have unilaterally elected this path and have drastically increased the prices for many of their drugs far in excess of the rate of inflation for many years. Given the magnitude of these price increases, the correct Ceiling Price calculation for these drugs was $0.01. However, instead of following the very simple statutory formula, Defendants knowingly disregarded the formula.

12. In short, Defendants wanted it both ways: enjoying the benefit of price increases through the generation of additional revenue from non-340B customers while avoiding the requirement to provide 340B pricing to Covered Entities. To accomplish this, Defendants simply pretended that the statutory Ceiling Price formula did not exist.

13. Through their misconduct, Defendants have illegally overcharged 340B Covered Entities and caused those entities to unwittingly submit false claims to the Medicare and Medicaid Programs. Relator brings this action to recover the hundreds of millions of dollars of damages that Defendants' misconduct has caused to government-funded healthcare programs.

II. JURISDICTION & VENUE

14. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Court has original jurisdiction over the state law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under state laws for the recovery of funds paid as the result of false claims and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730 and 28 U.S.C. § 1367.

15. This Court has personal jurisdiction over Defendants because, among other things, they transact business in this District and engaged in wrongdoing in this District.

16. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) and (c). Defendants transact business within this District and acts

proscribed by 31 U.S.C. § 3729 occurred in this District.

17. The causes of action alleged herein are timely brought because, among other things, of efforts by Defendants to conceal from the United States and the Whistleblower States their wrongdoing in connection with the allegations made herein.

III. PERFECTION OF FILING & STANDING

18. The original Complaint was properly filed in camera and under seal, as required by the False Claims Act ("FCA") and the State *Qui Tam* statutes.

19. Prior to the filing of the original Complaint, Relator properly served a copy of the Complaint and a written disclosure of substantially all material evidence and information upon the United States and the *Qui Tam* States.

20. There has been no "public disclosure," as that term is used in the FCA or the State *Qui Tam* statutes, of the allegations forming the core elements of the Counts against Defendants.

21. In the event there is found to be any such public disclosure, Relator is an "original source," as that term is used in the FCA and the State *Qui Tam* statutes, of the allegations or transactions forming the core elements of the cause(s) of action against Defendants.

22. Consistent with the meaning of "original source" under the FCA and the State *Qui Tam* statutes, Relator has knowledge that is independent of any publicly disclosed information that materially adds to any alleged public disclosure, and has voluntarily provided that information to the United States and the States before filing this action.

23. In particular, Relator has independent knowledge that materially adds to any alleged public disclosure in the form of (1) the fraudulently inflated Ceiling Prices paid by Covered Entities across the country for Defendants' drugs, and (2) the fraudulently inflated claims that the government has paid to Covered Entities for 340B drugs.

24. By analyzing its own proprietary, non-public purchase data, Relator has been able to determine the Ceiling Prices Defendants charged every Covered Entity across the country for each drug and time period at issue in the Complaint. Relator was able to do this because all drug manufacturers, including Defendants, calculate a single Ceiling Price for each individual drug—*i.e.*, there is a single Ceiling Price regardless of which Covered Entity is making a purchase.

IV. PARTIES

A. Relator

25. Adventist Health System/West ("Relator" or "Adventist Health") has its principal place of business in Roseville, California. Adventist Health operates throughout California, as well as in portions of Hawaii, Oregon, and Washington. It is a California nonprofit religious corporation operating a healthcare system comprising 26 hospitals, with more than 3,700 beds. Adventist Health has some 37,000 associates, including employees, medical staff physicians, and allied health professionals and volunteers. Adventist Health operates numerous clinics and outpatient facilities, 14 home care agencies, and 3 joint-venture retirement centers.

26. Since its beginning more than a century ago as a ministry of the Seventh-day Adventist Church, Adventist Health has taken a progressive approach to providing health care. Its commitment to serving its communities dates back to 1866, when the first Seventh-day Adventist health care facility opened in Battle Creek, Michigan. Their dedicated pioneers promoted the "radical" concepts of proper nutrition, exercise, and sanitation in a facility devoted not just to the healing arts, but also to the prevention of disease.

27. By the early twentieth century, Seventh-day Adventists on the West Coast had established a number of sanitariums and hospitals. Their early vision to treat the whole person—mind, body, and spirit—continues to provide the foundation for Adventist Health's mission. Today, the healthcare system sponsored by the Seventh-day Adventist Church circles the globe. Its West Coast system is part of an

international network with more than 220 hospitals, as well as numerous clinics and nursing homes worldwide.

28. Adventist Health has direct knowledge of the conduct alleged in this Complaint, and, with the assistance of 340B experts and pharmaco-economists, conducted an independent investigation to uncover false claims submitted to the United States and the Whistleblower States.

29. Using its internal, non-public purchase data between Covered Entities and Defendants, Relator has been able to identify dozens of drugs that should have been subject to a $0.01 Ceiling Price, but which were sold to Covered Entities at a significantly higher price. The pricing data used throughout this Complaint was compiled, organized, and analyzed by Relator and has not been subject to previous public disclosure.

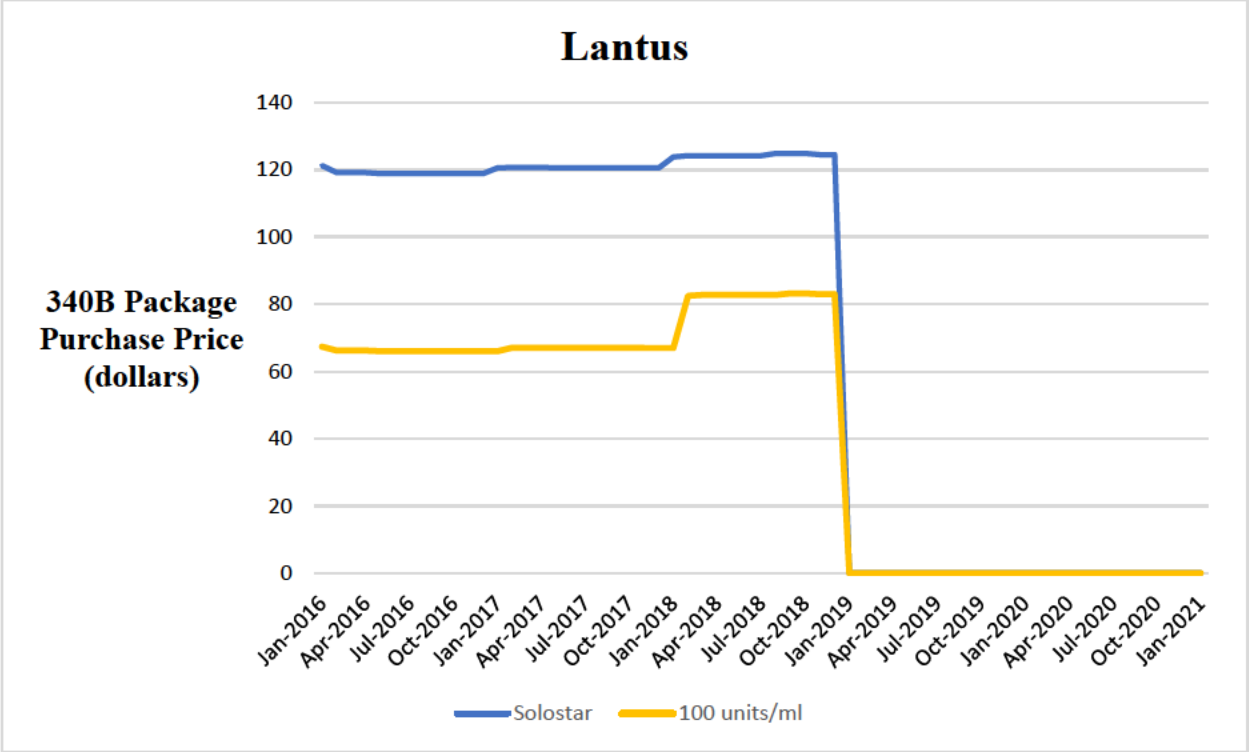
30. On January 1, 2019, a new regulation went into effect that imposed civil monetary penalties for violations of the 340B pricing formula. Importantly, the 2019 regulation did not change (nor could it change) the statutory definitions and requirements relating to Ceiling Prices. Instead, the regulation provided monetary penalties for violating these statutory requirements, and it codified HRSA's 2011 formal written guidance regarding "Penny Pricing."

31. Following the enactment of this 2019 financial penalty regulation, Relator observed a phenomenon. Specifically, Relator studied its proprietary pricing data and noted that for the drugs at issue in this case, shortly after January 2019 the prices charged by Defendants dropped precipitously to $0.01 per unit. Put differently, Relator's data revealed a sudden shift from non-penny pricing to penny pricing for these drugs.

32. For example, Relator had been purchasing the drug Lantus from Sanofi for many years prior to 2019, and the prices Relator paid ranged from $71.19 (Q1 2016) to $88.92 (Q4 2018) per package of Lantus 100 units/ml, and $128.00 (Q1 2016) to $133.38 (Q4 2018) per package of Lantus Solostar 100 units/ml. However,

once the 2019 regulation went into effect—that is, once the new civil monetary penalty was applicable—Sanofi finally began to follow the statutory Ceiling Price formula, which led Sanofi to sell Lantus to Relator for $0.10 per unit for Lantus 100 units/ml and $0.15 per unit for Lantus Solostar 100 units/ml, an 88,920% drop in price.

33. Sanofi's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Lantus 100 units/ml and Lantus Solostar 100 units/ml:



34. This drastic price change was uniform among several of Sanofi's drugs, and it cannot reasonably be explained by any benign factors, such as a sudden, drastic increase in prices across Sanofi's drug line that coincidentally caused the Ceiling Prices to fall to $0.01 per unit at once, because Relator's proprietary pricing data shows that no such pricing activity took place. Rather, the only reasonable explanation for Sanofi's conduct is that, prior to 2019, it had ignored the statutory formula and charged prices well in excess of its drugs' true Ceiling Prices.

35. Each of the Defendants named herein has engaged in similar conduct.

36. Stated differently, prior to 2019, each Defendant illegally ignored the statutory Ceiling Pricing formula that has been in effect since the 340B Program was enacted in 1992, causing hundreds of millions of dollars in government losses. In 2019, when financial penalties for such violations became effective, each Defendant began following the previously existing statutory requirements. To date, none of the Defendants has made whole the government programs they defrauded.

B. Defendants

1. AbbVie

37. Defendant AbbVie, Inc. is a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, IL 60064.

38. Defendant Allergan Sales, LLC is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, NJ 07940.

39. Defendant Allergan USA, Inc. is a Delaware corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

40. AbbVie is the corporate successor to Allergan Sales, LLC, Allergan USA, Inc., and Forest Laboratories, having completed its purchase of Allergan on May 8, 2020.

41. All of the aforementioned companies are collectively referred to herein as "AbbVie."

42. The drugs manufactured and sold by AbbVie and paid for by 340B Covered Entities, as well as federal and state programs for which it failed to charge correct Ceiling Prices, include: ACULAR LS 0.4% OPHTH SOL, DEPAKOTE ER 250 MG TABLET, DEPAKOTE ER 500 MG TABLET, FETZIMA 20-40 MG TITRATION PACK, FETZIMA ER 120 MG CAPSULE, FETZIMA ER 20 MG CAPSULE, FETZIMA ER 40 MG CAPSULE, FETZIMA ER 80 MG CAPSULE, LATISSE 0.03% EYELASH SOLUTION, LEXAPRO 10 MG TABLET, LEXAPRO 20 MG TABLET, LEXAPRO 5 MG TABLET, LINZESS 145 MCG

CAPSULE, LINZESS 290 MCG CAPSULE, NAMENDA 10 MG TABLET, NAMENDA 5-10 MG TITRATION PACK, NAMENDA XR 14 MG CAPSULE, NAMENDA XR 21 MG CAPSULE, NAMENDA XR 28 MG CAPSULE, NAMENDA XR 7 MG CAPSULE, NAMENDA XR TITRATION PACK, NAMZARIC 14 MG-10 MG CAPSULE, NAMZARIC 21 MG-10 MG CAPSULE, NAMZARIC 28 MG-10 MG CAPSULE, NAMZARIC 7 MG-10 MG CAPSULE, NAMZARIC TITRATION PACK, POLYTRIM EYE DROPS, SAVELLA 100 MG TABLET, SAVELLA 25 MG TABLET, SAVELLA 50 MG TABLET, SAVELLA TITRATION PACK, TRICOR 145 MG TABLET, TRILIPIX DR 135 MG CAPSULE, and ZENPEP DR 15,000 UNIT CAPSULE.

2. AstraZeneca

43. Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under and by virtue of the laws of the State of Delaware, and having its headquarters located at 1800 Concord Pike, Wilmington, Delaware 19850.

44. Defendant AstraZeneca LP is a limited partnership organized and existing under and by virtue of the laws of the State of Delaware, and having its principal place of business at 1800 Concord Pike, Wilmington, Delaware, 19850.

45. AstraZeneca Pharmaceuticals LP and AstraZeneca LP are collectively referred to herein as "AstraZeneca."

46. The drugs manufactured and sold by AstraZeneca and paid for by 340B Covered Entities and federal and state programs for which it failed to charge correct Ceiling Prices include: BYETTA 10 MCG DOSE PEN INJ, BYETTA 5 MCG DOSE PEN INJ, BYDUREON 2 MG VIAL, CRESTOR 10 MG TABLET, CRESTOR 20 MG TABLET, CRESTOR 40 MG TABLET, CRESTOR 5 MG TABLET, FARXIGA 10 MG TABLET, FARXIGA 5 MG TABLET, KOMBIGLYZE XR 2.5-1,000 MG TAB, KOMBIGLYZE XR 5-1,000 MG TAB, KOMBIGLYZE XR 5-500 MG TABLET, NEXIUM DR 10 MG PACKET, NEXIUM DR 20 MG CAPSULE, NEXIUM DR 20 MG PACKET, NEXIUM DR

40 MG CAPSULE, NEXIUM DR 40 MG PACKET, ONGLYZA 2.5 MG TABLET, ONGLYZA 5 MG TABLET, PULMICORT 180 MCG FLEXHALER, PULMICORT 90 MCG FLEXHALER, SYMBICORT 160-4.5 MCG INHALER, SYMBICORT 80-4.5 MCG INHALER, SYMLINPEN 120 PEN INJECTOR, SYMLINPEN 60 PEN INJECTOR, XIGDUO XR 10 MG-1,000 MG TAB, XIGDUO XR 10 MG-500 MG TABLET, XIGDUO XR 5 MG-1,000 MG TABLET, and XIGDUO XR 5 MG-500 MG TABLET.

3. Novartis

47. Defendant Novartis Pharmaceuticals Corporation is a Delaware corporation with its principal place of business in East Hanover, New Jersey. Defendant Novartis Pharmaceuticals Corporation is a subsidiary of Defendant Novartis AG.

48. Defendant Novartis AG is a Swiss corporation with its principal place of business at Lichtstrasse 35, CH-4002 Basel, Switzerland.

49. Defendant Sandoz Inc. is a corporation organized and existing under and by virtue of the laws of the State of New Jersey, and having its principal place of business at 506 Carnegie Drive, Suite 400, Princeton, New Jersey 08540. Sandoz is a subsidiary of Novartis AG, a global pharmaceutical company based in Basel, Switzerland.

50. Defendants Novartis Pharmaceuticals Corporation, Novartis AG, and Sandoz Inc. are collectively referred to herein as "Novartis."

51. The drugs manufactured and sold by Novartis and paid for by 340B Covered Entities and federal and state programs for which it failed to charge correct Ceiling Prices include: DIOVAN 320 MG TABLET, DIOVAN 40 MG TABLET, DIOVAN 80 MG TABLET, DIOVAN HCT 160-25 MG TABLET, DIOVAN HCT 80-12.5 MG TABLET, EXELON 13.3 MG/24HR PATCH, EXELON 4.6 MG/24HR PATCH, EXELON 9.5 MG/24HR PATCH, EXFORGE 10-160 MG TABLET, FOCALIN XR 10 MG CAPSULE, FOCALIN XR 15 MG CAPSULE,

FOCALIN XR 20 MG CAPSULE, FOCALIN XR 25 MG CAPSULE, FOCALIN XR 30 MG CAPSULE, FOCALIN XR 35 MG CAPSULE, FOCALIN XR 40 MG CAPSULE, FOCALIN XR 5 MG CAPSULE, GLEEVEC 100 MG TABLET, GLEEVEC 400 MG TABLET, LESCOL XL 80 MG TABLET, LOTREL 5-10 MG CAPSULE, LOTREL 5-20 MG CAPSULE, OMNITROPE 5 MG/1.5 ML CRTG, OMNITROPE 10 MG/1.5 ML CRTG, RITALIN LA 10 MG CAPSULE, RITALIN LA 20 MG CAPSULE, TEGRETOL XR 200 MG TABLET, TEGRETOL XR 400 MG TABLET, TRILEPTAL 150 MG TABLET, TRILEPTAL 300 MG TABLET, TRILEPTAL 600 MG TABLET.

4. Sanofi

52. Defendant Sanofi-Aventis U.S. LLC is a Delaware corporation with its principal place of business at 55 Corporate Drive, Bridgewater, NJ 08807.

53. Defendant Sanofi US Services Inc. is a Delaware corporation with its principal place of business at 55 Corporate Drive, Bridgewater, NJ 08807.

54. Defendant Genzyme Corporation is a Massachusetts corporation with its principal place of business at 500 Kendall Street, Cambridge, MA 02142.

55. Defendant Sanofi S.A., also known as Sanofi Consumer Healthcare, is a French multinational pharmaceutical company with its principal place of business in Paris, France. Defendant Sanofi S.A. was formed as Sanofi-Aventis in 2004 by the merger of Aventis and Sanofi-Synthélabo, which were each the product of several previous mergers.

56. At all relevant times, Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Genzyme Corporation have been wholly owned subsidiaries of Defendant Sanofi S.A., with the profits of each inuring to Defendant Sanofi S.A.'s benefit. All of these entities are collectively referred to herein as "Sanofi."

57. The drugs manufactured and sold by Sanofi and paid for by 340B Covered Entities and federal and state programs for which it failed to charge correct Ceiling Prices include: AMARYL 1 MG TABLET, AMARYL 2 MG TABLET,

AMBIEN 10 MG TABLET, AMBIEN 5 MG TABLET, AMBIEN CR 12.5 MG TABLET, AMBIEN CR 6.25 MG TABLET, APIDRA 100 UNITS/ML VIAL, APIDRA SOLOSTAR 100 UNITS/ML, ARAVA 10 MG TABLET, ARAVA 20 MG TABLET, AVALIDE 150-12.5 MG TABLET, AVALIDE 300-12.5 MG TABLET, AVAPRO 150 MG TABLET, AVAPRO 300 MG TABLET, AVAPRO 75 MG TABLET, DOXERCALCIFEROL 2.5 MCG CAP, LANTUS 100 UNIT/ML VIAL, LANTUS SOLOSTAR 100 UNIT/ML, RENAGEL 400 MG TABLET, RENAGEL 800 MG TABLET, RENVELA 0.8 GM POWDER PACKET, RENVELA 2.4 GM POWDER PACKET, RENVELA 800 MG TABLET, ZOLPIDEM TART ER 12.5 MG TAB, and ZOLPIDEM TART ER 6.25 MG TAB.

V. FEDERAL & STATE FALSE CLAIMS ACTS

58. The federal False Claims Act ("FCA") makes it unlawful for any person to defraud the Government and cause it to pay money it otherwise would not pay.

59. The FCA imposes liability on "any person who," among other things:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A),

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *id.* § 3729(a)(1)(B),

c. "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property," *id.* § 3729(a)(1)(D), or

d. "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government," *id.* § 3729(a)(1)(G).

60. Any person who violates the FCA "is liable to the United States for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person." *Id.* § 3729(a)(1). Adjusted for inflation, these penalties currently range from $13,508 to $27,018. *See* 28 C.F.R. § 85.5.

61. The FCA provides that "the terms 'knowing' and 'knowingly' (A) mean that a person, with respect to information—(i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1).

62. The FCA provides that "the term 'claim' (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—(i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded." *Id.* § 3729(b)(2).

63. The FCA provides that "the term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment." *Id.* § 3729(b)(3). For Medicare and Medicaid funds, "[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation . . . for purposes of [the FCA]." 42 U.S.C. § 1320a-7k(d)(3). An

overpayment must be reported and returned "[b]y the later of . . . 60 days after the date on which the overpayment was identified . . . or the date any corresponding cost report is due, if applicable." *Id.* § 1320a-7k(d)(2).

64. The FCA provides that "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

65. Additionally, many jurisdictions have passed False Claims Act laws, which generally closely track the FCA. These statutes include the California False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-304 *et seq.*; the Connecticut False Claims Act, Conn. Gen. Stat. tit. 4 Ch. 55e §§ 4-274 *et seq.*; the Delaware False Claims and Reporting Act, Del. Code tit. 6, §§ 1201 *et seq.*; the District of Columbia False Claims Act, D.C. Code §§ 2-308.13 *et seq.*; the Florida False Claims Act, Fla. Stat. tit. 6, §§ 68.081 *et seq.*; the Georgia False Medicaid Claims Act, Ga. Code §§ 49-4-168 *et seq.*; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*; the Illinois False Claims Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*; the Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7 *et seq.*; the Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*; the Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A *et seq.*; the Michigan Medicaid False Claims Act, Mich. Comp. Laws §§ 400.601 *et seq.*; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*; the Montana False Claims Act, Mont. Code §§ 17-8-401 *et seq.*; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 *et seq.*; the New Jersey False Claims Act, N.J. Stat. §§ 2A:32C-1 *et seq.*; the New York False Claims Act, N.Y. State Fin. Law Art. XIII §§ 187 *et seq.*; the North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq.*; the Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*; the Tennessee Medicaid False Claims Act, Tenn. Code §§

71-5-181 *et seq.*; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§ 36.001 *et seq.*; the Texas Medical Assistance Program, Damages, and Penalties Act, Tex. Hum. Res. Code. §§ 32.039 *et seq.*; the Vermont False Claims Act, Vt. Stat. tit. 32 §§ 631 *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 *et seq.*; the Washington State Medicaid False Claims Act, Wash. Rev. Code. §§ 74.66.005 *et seq.*; and the False Claims to Government of Puerto Rico Programs, Contracts, and Services Act, P.R. Laws tit. 32, §§ 2934 *et seq*. The aforementioned jurisdictions are referred to collectively herein as the "Whistleblower States" and the aforementioned statutes are referred to collectively herein as the "State *Qui Tam* Statutes" or "State FCAs." The State FCAs proscribe the same conduct described above.

66. The State FCAs apply, *inter alia*, to the state portion of Medicaid losses caused by false claims to the jointly federal-state funded Medicaid program and failure to report and return any overpayments therefrom. The State FCAs also apply to Covered Entities that are state-owned and/or funded in whole or in part by the state.

VI. LEGAL BACKGROUND

A. The MDRP and the 340B Program

67. The MDRP was enacted in 1990. The MDRP requires a drug manufacturer to enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services ("HHS") in exchange for state Medicaid coverage of most of the manufacturer's drugs. The Secretary has delegated authority to administer the Medicaid program, including the MDRP, to the Centers for Medicare and Medicaid Services ("CMS").

68. Under the MDRP, manufacturers agree to pay a rebate "of each dosage form and strength and package size of each covered outpatient drug dispensed . . . for which payment was made," 42 U.S.C. § 1396r-8(b)(1), (2), which includes an

adjustment to disincentivize manufacturers to increase the prices of their drugs faster than inflation.

69. The MDRP provides discounts to state Medicaid agencies for outpatient prescription drugs. It does not extend these discounts to other entities, including federally funded clinics and public hospitals, which, in the wake of the enactment of the MDRP, were experiencing substantial increases in their outpatient drug costs. H.R. Rep. No. 102-384(II), at 11 (1992).

70. In 1992, Congress expanded the scope of these discounted prices by enacting Section 340B of the Public Health Service Act, known as the 340B Program. Congress intended the program to lower drug costs for certain public and not-for-profit hospitals, community health centers, and other government-funded clinics that serve large numbers of low-income and underserved communities ("Covered Entities"). Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4967 (Nov. 4, 1992) (codified at 42 U.S.C. § 256b).

71. The 340B Program is designed to provide Covered Entities with substantial discounts on drug purchases. Congress intended for the 340B Program "to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II) (Sept. 22, 1992), 1992 WL 239241, at *10.

72. The 340B statute provides a clear, straightforward formula for calculating the maximum price a manufacturer may charge a Covered Entity for a covered outpatient drug. The formula results in what is called the "Ceiling Price." *See generally* 340B Glossary of Terms (2019) (defining common terms used in the 340B Program, including "340B ceiling price"), attached as Exhibit 1.

73. The 340B Program is intended to provide Covered Entities with discounts "at least as great as those which Medicaid receives under the rebate program." H.R. Rep. No. 102-384(II) (Sept. 22, 1992), 1992 WL 239241, at *12. To that end, the Ceiling Price adopts the same formula used to calculate the drug

rebate amount under the MDRP: a discount equal to the difference between the drug's average manufacturer price ("AMP") from the previous quarter and its unit rebate amount ("URA").

74. Manufacturers are not required to participate in the MDRP or the 340B Program. However, if they wish to have their drugs covered and reimbursed by Medicaid and the Medicare Part B outpatient insurance program, they must also participate in the 340B Program. (Medicare is generally divided into Part A, which covers inpatient service, Part B, which covers outpatient services, Part C, which comprises healthcare plans from private companies that offer an alternative to traditional Medicare, and Part D, which covers prescription drugs.)

75. The Secretary of HHS has delegated authority to administer the 340B statute to the Health Resources & Services Administration ("HRSA"), which administers the 340B Program through its Office of Pharmacy Affairs ("OPA").

76. If manufacturers or other stakeholders have questions concerning the operation of the 340B Program, they may contact the OPA through various means, including phone calls, emails, or requesting a meeting with OPA representatives.

B. 340B Covered Entities

77. Since the 340B statute was implemented, Covered Entities have used the savings generated to provide critical safety-net healthcare services for their communities, including low-income and underserved populations within those communities—for example, by providing free or discounted drugs and other health and case management services, increasing service locations, developing patient education programs, and providing translation and transportation services to improve patients' access to high-quality care.

78. When the 340B statute was enacted, Covered Entities included federally funded health centers and clinics providing services such as family planning, AIDS intervention, and hemophilia treatment, as well as public and certain

not-for-profit hospitals serving a large proportion of low-income populations. Pub. L. No. 102-585, § 340B(a)(4)(A)-(L), 106 Stat. at 4967-68.

79. Recognizing the value of the 340B Program, Congress expanded the categories of eligible Covered Entities in 2010, as a part of the Patient Protection and Affordable Care Act. In addition to making other changes to the Program to improve drug companies' compliance and to protect Covered Entities from overcharges, Congress expanded the definition of Covered Entities to include certain critical access hospitals, children's hospitals, free-standing cancer hospitals, and sole community hospitals. Pub. L. No. 111-148, § 7101(a), 124 Stat 119, 821-22 (Mar. 23, 2010).

80. Currently, six types of hospitals and ten types of clinics that receive certain federal grants are eligible to participate in the 340B Program. A Covered Entity (such as Relator Adventist Health) may have multiple sites participating in the program as long as each site is an integral part of the Covered Entity, is registered with HRSA, and follows the program's rules.

81. Multiple sites of Relator Adventist Health are Covered Entities, including:

- Adventist Health Clear Lake, 15630 18th Ave., Clearlake, CA 95422;
- Adventist Health Tehachapi Valley, 1100 Magellan Dr., Tehachapi, CA 93561;
- Adventist Health Medocino Coast, 700 River Dr., Fort Bragg, CA 95437;
- Adventist Health Castle, 640 Ulukahiki St., Kailua, HI 96734;
- Adventist Health Glendale, 1509 Wilson Terr., Glendale, CA 91206;
- Adventist Health Hanford, 115 Mall Dr., Hanford, CA 93230;
- Adventist Health Selma, 1141 Rose Ave., Selma, CA 93662;
- Adventist Health Lodi Memorial, 975 S. Fairmont Ave., Lodi, CA 95240;
- Adventist Health Tillamook, 1000 3rd St., Tillamook, OR 97141;
- Adventist Health Portland, 10123 SE Market St., Portland, OR 97216;
- Adventist Health Reedley, 372 West Cypress Ave., Reedley, CA 93654;

- Adventist Health and Rideout, 726 4th St., Marysville, CA 95901;
- Adventist Health Bakersfield, 2615 Chester Ave., Bakersfield, CA 93301;
- Adventist Health Sonora, 1000 Greenley Rd., Sonora, CA 95370;
- Adventist Health St. Helena, 10 Woodland Rd., St. Helena, CA 94574;
- Adventist Health Ukiah Valley, 275 Hospital Dr., Ukiah, CA 95482;
- Adventist Health White Memorial, 1720 East Cesar E. Chavez Ave., Los Angeles, CA 90033; and
- Adventist Health Howard Memorial, 1 Marcela Dr., Willits, CA 95490.

C. Calculation of the 340B Ceiling Price

82. The 340B Program applies to "covered outpatient drugs," which are defined as prescription drugs and biological products other than vaccines approved by the Food and Drug Administration. 42 U.S.C. § 1396r-8(k)(2). Manufacturers are legally obligated by statute to provide accurate Ceiling Prices and to ensure that the 340B discount is passed on to the Covered Entity, regardless of whether the Covered Entity purchases drugs from a wholesaler or directly from the manufacturer.

83. In 1992, the 340B statute established a straightforward statutory formula for calculating the Ceiling Price, based on the drug rebate amount from the MDRP: a discount equal to the difference between the drug's average manufacturer price ("AMP") from the previous quarter and its unit rebate amount ("URA"). Put algebraically:

Ceiling Price = (AMP – URA) × drug package size

42 U.S.C. § 256b(a)(1).

84. This formula has not changed since 1992. The formula is functionally identical to the formula used in the MDRP. The only difference between the MDRP and the 340B Program is ***when*** the purchaser receives the discounted price. Under the MDRP, Medicaid initially purchases drugs at retail price, and manufacturers subsequently pay rebates to Medicaid to reach the discounted price. By contrast, the 340B statute uses the above formula to calculate the Ceiling Price and manufacturers

are required to provide the Ceiling Price to Covered Entities at the time the drug is initially purchased. *Id.*

85. Turning to the elements of the formula, AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers (for drugs distributed to retail community pharmacies) and retail community pharmacies (that purchase drugs directly from the manufacturer). 42 U.S.C. § 1396r-8(k)(1)(A).

86. The URA has two parts: the basic rebate and the additional rebate. The basic rebate is calculated by using the greater of the following two formulas: (1) subtracting the manufacturer's "best price" from the AMP; or (2) AMP multiplied by a specified percentage, which has been 23.1 percent for brand-name drugs since January 1, 2010. *Id.* § 1396r-8(c)(1)(A). All the drugs at issue in this Complaint are brand-name drugs subject to a 23.1-percent basic rebate.

87. The "best price" represents the best price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity, excluding prices charged to certain federal programs, 340B Covered Entities, Medicare Part D plans, and certain other purchasers. *Id.* § 1396r-8(c)(1)(C).

88. The additional rebate is the difference between the drug's current AMP and its initial AMP, adjusted for inflation. *See id.* § 1396r-8(c)(2).

89. Specifically, the additional rebate is the amount that the drug's AMP for a particular quarter exceeded the "base date AMP," which is a covered outpatient drug's AMP for the third quarter of 1990 if the drug was FDA-approved on or before October 1, 1990, or the AMP for the first full quarter of sales if the drug was FDA-approved after that date, either of which is adjusted by an inflation factor. 42 U.S.C. § 1396r-8(c)(2). The rate of inflation is measured by the consumer price index for all urban consumers ("CPI-U") since the drug's market date. This additional rebate, called the "inflationary penalty," is added to the URA. The inflationary penalty was originally limited to single-source (brand-name) drugs, but Congress extended the

penalty to generic drugs under the Bipartisan Budget Act of 2015. Pub. L. 114-74, § 602(a)(2), 129 Stat. 584, 596-97 (Nov. 2, 2015).

90. The total inflation rate from 2010 to 2020 was 18.3%, or an annual inflation rate of 1.7%. The following table shows the CPI-U for the last decade:

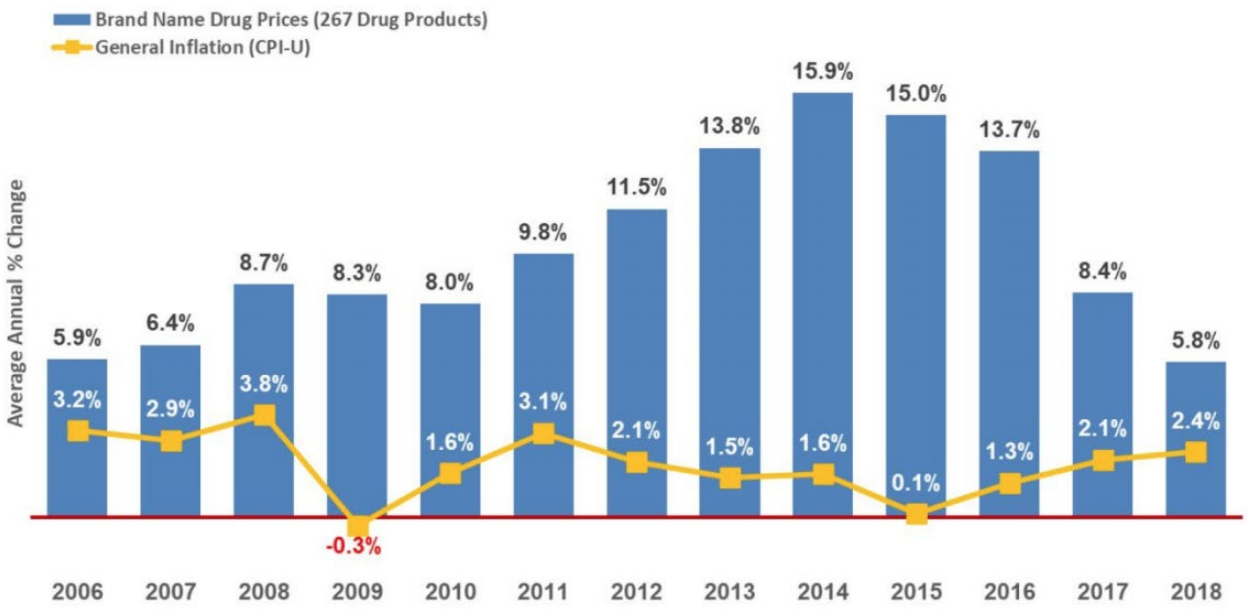
CONSUMER PRICE INDEX FOR ALL URBAN CONSUMERS (CPI-U)
(not seasonally adjusted)

ALL ITEMS (1982-84=100)	U.S. City Average											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Consumer Price Index												
2013	230.280	232.166	232.773	232.531	232.945	233.504	233.596	233.877	234.149	233.546	233.069	233.049
2014	233.916	234.781	236.293	237.072	237.900	238.343	238.250	237.852	238.031	237.433	236.151	234.812
2015	233.707	234.722	236.119	236.599	237.805	238.638	238.654	238.316	237.945	237.838	237.336	236.525
2016	236.916	237.111	238.132	239.261	240.229	241.018	240.628	240.849	241.428	241.729	241.353	241.432
2017	242.839	243.603	243.801	244.524	244.733	244.955	244.786	245.519	246.819	246.663	246.669	246.524
2018	247.867	248.991	249.554	250.546	251.588	251.989	252.006	252.146	252.439	252.885	252.038	251.233
2019	251.712	252.776	254.202	255.548	256.092	256.143	256.571	256.558	256.759	257.346	257.208	256.974
2020	257.971	258.678	258.115	256.389	256.394	257.797	259.101	259.918	260.280	260.388	260.229	260.474
2021	261.582	263.014	264.877	267.054	269.195	271.696	273.003	273.567	274.310	276.589	277.948	278.802
2022	281.148	283.716	287.504	289.109	292.296	296.311	296.276	296.171	296.808	298.012	297.711	296.797
2023	299.170	300.840	301.836	303.363	304.127	305.109	305.691	307.026				
Percent change from 12 months ago												
2013	1.6	2.0	1.5	1.1	1.4	1.8	2.0	1.5	1.2	1.0	1.2	1.5
2014	1.6	1.1	1.5	2.0	2.1	2.1	2.0	1.7	1.7	1.7	1.3	0.8
2015	-0.1	0.0	-0.1	-0.2	0.0	0.1	0.2	0.2	0.0	0.2	0.5	0.7
2016	1.4	1.0	0.9	1.1	1.0	1.0	0.8	1.1	1.5	1.6	1.7	2.1
2017	2.5	2.7	2.4	2.2	1.9	1.6	1.7	1.9	2.2	2.0	2.2	2.1
2018	2.1	2.2	2.4	2.5	2.8	2.9	2.9	2.7	2.3	2.5	2.2	1.9
2019	1.6	1.5	1.9	2.0	1.8	1.6	1.8	1.7	1.7	1.8	2.1	2.3
2020	2.5	2.3	1.5	0.3	0.1	0.6	1.0	1.3	1.4	1.2	1.2	1.4
2021	1.4	1.7	2.6	4.2	5.0	5.4	5.4	5.3	5.4	6.2	6.8	7.0
2022	7.5	7.9	8.5	8.3	8.6	9.1	8.5	8.3	8.2	7.7	7.1	6.5
2023	6.4	6.0	5.0	4.9	4.0	3.0	3.2	3.7				

U.S. Bureau of Labor Statistics, *Consumer Price Index Historical Tables for U.S. City Average*, https://www.bls.gov/regions/mid-atlantic/data/consumerpriceindex historical_us_table.htm (last visited Oct. 9, 2023).

91. Prices for many prescription drug prices have significantly outpaced inflation. By way of illustration, AARP's Rx Price Watch Report provides pricing trend data for prescriptions widely used by Americans. The September 2018 report found that the "annual percent change in retail prices for brand name prescription drugs has consistently increased substantially faster than general inflation" at a rate

of "8.4% compared with 2.1%." Stephen W. Schondelmeyer & Leigh Purvis, *AARP Rx Price Watch Report - Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update* 5 (Sept. 2018), www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf. The following chart from AARP's 2018 report demonstrates this stark difference:



92. Because the 340B statute as originally enacted did not expressly state whether a manufacturer should charge $0.00 or $0.01 for a drug which had a negative Ceiling Price, HRSA has directed manufacturers – since the start of the 340B program in 1992 – to use a price of $0.01. This direction has remained constant for over three decades.

93. As noted above, in 2010, Congress capped the URA at 100% of the AMP, preventing negative prices. Pub. L. 111-148, § 2501(e), 124 Stat. at 309.

94. Although negative prices were prevented by the 2010 statute, zero prices were not. ("[B]ased on the provision in section 1927(c)(2)(D) of the Social Security Act that limits the unit rebate amount to 100% of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result

in a negative 340B price, ***but could result in a zero 340B price***.") (emphasis added). Health Resources and Services Administration ("HRSA"), *Clarification of Penny Pricing Policy, Policy Release No. 2011-2* at 1 (Nov. 21, 2011).

95. Given that the 2010 statute did not state whether, in the case of a negative price, manufacturers should charge $0.00 or $0.01, the government formally adopted a written guidance in 2011 which expressly directed manufacturers to charge $0.01 if the statutory formula resulted in a negative Ceiling Price. HRSA, *Clarification of Penny Pricing Policy, Policy Release No. 2011-2* (Nov. 21, 2011). ("[W]hen the URA equals the AMP in the calculation of the 340B ceiling price . . . , the manufacturer should charge $0.01 per unit of measure for zero priced drugs.").

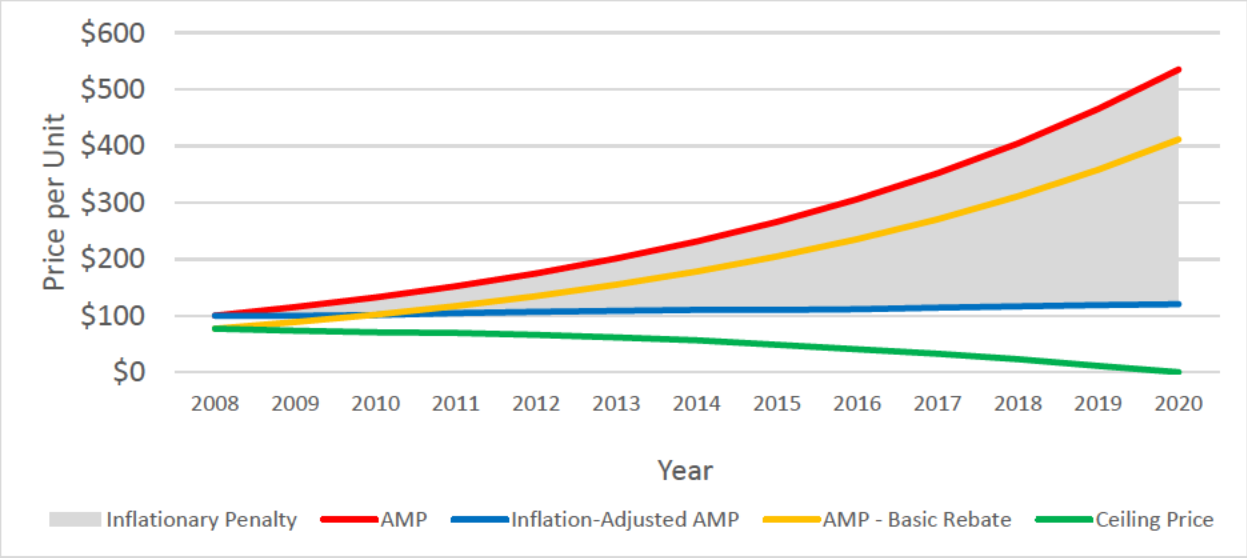
96. HHS further stated that any other formula would "nullify the [inflationary] pricing penalty" and would clearly be inconsistent with the 340B statute. *Id.*

97. In 2017, HHS again expressly stated that the statute did not permit prices above a penny per unit when the AMP minus URA equals zero, as such a result "would decrease the effect of the inflationary component of the statutory formula established by Congress." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1215 (Jan. 5, 2017).

98. As noted above, the Ceiling Price of a drug becomes $0.01 only in extreme circumstances that are entirely under a manufacturer's control. Specifically, a manufacturer must increase the price of a drug to 433 percent of its inflation-adjusted AMP before the Ceiling Price formula leads to so-called penny pricing.

99. For example, the following graph depicts the impact of the inflationary penalty on a fictional drug introduced in 2008 whose price increases at a rate of fifteen percent annually, compared to the much lower annual rate of inflation. The basic rebate is expressed as a fraction of the current AMP, but the additional rebate anchors the price to the AMP at launch, adjusted for inflation. Therefore, as

illustrated below, once the inflationary penalty begins to apply in 2009, it reduces the 340B Ceiling Price. By 2020, the AMP has increased from $100 per unit to more than $500 per unit, but the inflation-adjusted AMP is only $120.21 per unit, resulting in a large inflationary penalty where the URA equals the AMP:



100. Defendants, all of whom are participants in the MDRP and 340B Program, have increased the prices of their drugs so quickly that the URA equals the AMP. However, even modestly decreasing the extreme rate of price increases would have permitted the Defendants to avoid such a scenario.

101. Most manufacturers have complied with the 340B Ceiling Price formula. The Defendants in this case have not, and instead have used their own profitable, but illegal alternative methods for calculating Ceiling Prices.

102. Defendants, keen to realize both: (1) the profits resulting from steep price increases in the non-340B market, ***and*** (2) the benefits of participating in the 340B Program, but disgruntled with Congress's decision to impose price controls when they have intentionally increased the prices of their drugs faster than the rate of inflation, have implemented—without any basis in law or fact—"alternative" methodologies for calculating the Ceiling Price, such as using so-called "prior quarter pricing," wholesale acquisition cost ("WAC"), or Federal Ceiling Price ("FCP"). These and any other alternative formulas are not grounded in the text of

the statute, the legislative history, the canons of statutory construction, reason, or common sense.

103. In sum, the 340B statute unambiguously requires a price of $0.00 or $0.01 when the URA equals the AMP. The government has repeatedly and unambiguously stated for over three decades that when AMP = URA, the price per unit should be $0.01. That policy was formally published in an official HRSA 340B Pricing Program Notice in 2011. Nonetheless, as detailed below, Defendant's ignored the straightforward statutory formula, and in so doing, knowingly violated the 340B Program requirements for calculating the Ceiling Price and caused false claims to be submitted to the government.

D. Manufacturer Agreements

104. Each pharmaceutical manufacturer participating in the 340B Program, including Defendants, must sign a Pharmaceutical Pricing Agreement ("PPA") with HHS that limits the prices they may charge Covered Entities for 340B Program drugs to a price at or below the Ceiling Price. *Id.* § 256b(a)(1); *see Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities*, 58 FR 27289-02, 1993 WL 145178 (May 7, 1993) (terms of PPA). PPAs are effective for one year and are automatically renewed for successive one-year terms unless the pharmaceutical manufacturer gives written notice of its intent not to renew.

105. These PPAs contain independent, explicit requirements to offer a drug to a Covered Entity at $0.01 per unit when the URA equals the AMP.

106. Under their PPAs, Defendants have contractually agreed to provide covered outpatient drugs to 340B Covered Entities at or below the Ceiling Price. Specifically, each PPA states that "the Manufacturer agrees," for brand-name drugs, "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug . . . , reduced by the rebate percentage"—that is, the URA. *See* HRSA, *General Instructions for Completing the*

340B Drug Pricing Program Pharmaceutical Pricing Agreement, https://www.hrsa.gov/sites/default/files/opa/manufacturer-ppa-addendum.pdf (last visited Nov. 3, 2023).

107. Defendants have also been required to, and did, sign a PPA Addendum under which they agreed to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." *See id.*

108. These contractual requirements unambiguously required Defendants to comply with the statutory Ceiling Price formula, with no exceptions.

VII. THE FRAUDULENT SCHEME

109. For years, Defendants have knowingly charged materially false, unlawfully inflated prices for their drugs. Defendants' fraudulent scheme has caused the federal and state governments to wrongly pay hundreds of millions of dollars.

A. Scope of Liability

110. Defendants have violated the FCA and the State FCAs in three basic ways.

111. *First*, Defendants have overcharged Medicaid for 340B Program drugs used to treat Medicaid fee-for-service ("FFS") patients. Covered Entities that dispense 340B drugs to Medicaid FFS patients are required to bill Medicaid at the actual acquisition cost of their drugs. So, if a Covered Entity acquires a drug at an inflated price, that inflated price is passed directly through to Medicaid.

112. *Second*, Defendants have overcharged Medicare by reporting inflated Ceiling Prices to critical access hospitals ("CAHs"). In these circumstances, CAHs bill Medicare at 101 percent of their drug costs, meaning Defendants' overcharges to CAHs are passed directly through to Medicare.

113. *Third*, Defendants have overcharged government-funded 340B Covered Entities, such as prisons and county-owned hospitals. In these circumstances, the government is harmed because it directly pays fraudulently

inflated prices (as opposed to paying inflated charges via a "pass through" model, as in Medicaid FFS and CAHs).

1. Medicaid Fee-For-Service Programs

a. Drugs Dispensed by Retail Pharmacies Post-April 1, 2017

114. In a fee-for-service system, state Medicaid programs contract with and pay health care providers for services that they provide to Medicaid beneficiaries. By regulations effective beginning on April 1, 2017, state Medicaid FFS programs have been required to reimburse Covered Entities for drugs dispensed from their retail pharmacies at a price which does not exceed the actual acquisition cost ("AAC") incurred by the Covered Entity for the drug (plus a nominal dispensing fee). *Medicaid Program; Covered Outpatient Drugs*, 81 Fed. Reg. 5170, 5342, 5355 (Feb. 1, 2016). The AAC is defined by regulation as a state Medicaid agency's determination of the pharmacy providers' actual prices paid to acquire the drugs (plus a nominal dispensing fee). 42 C.F.R. § 447.502.

115. As a practical matter, this means that for claims accruing on or after April 1, 2017, Medicaid reimbursement for retail 340B drugs prescribed to Medicaid FFS beneficiaries cannot exceed the 340B Ceiling Price (plus a nominal dispensing fee).

116. The impact of Defendants' fraud is easily illustrated using a simple example. Assume that the price of a drug was raised quickly and steeply enough to cause the correct Ceiling Price under the statutory formula to be $0.01, but the manufacturer instead charged the Covered Entity $15 dollars for the drug, and the Covered Entity subsequently dispensed the drug to a Medicaid FFS patient. This sequence would cause the Covered Entity to submit a bill to Medicaid—and cause Medicaid to pay—$15 plus a nominal dispensing fee. The resulting fraudulent overcharge is the difference between what Medicaid should have been charged ($0.01) and what it was charged ($15.00)—*i.e.*, $14.99.

117. Put differently, when manufacturers fraudulently charge inflated Ceiling Prices to Covered Entities, the Covered Entities directly pass those inflated prices through to Medicaid when submitting claims for reimbursement, causing Medicaid to pay more than it should have, in exact proportion to the amount the manufacturer has inflated the Ceiling Price.

b. State-Specific AAC Regulations Predating April 1, 2017

118. Prior to April 1, 2017, there was no CMS regulation prohibiting a Covered Entity from billing a state Medicaid agency—and a state Medicaid agency from paying—above actual acquisition cost for drugs provided to Medicaid FFS patients.

119. However, many states, cognizant of the savings to state Medicaid programs, have enacted state-specific regulations prior to the 2017 CMS regulation cited above which capped Medicaid FFS reimbursement rates at the 340B Ceiling Price. These states include:

- California, effective Nov. 8, 2016, following litigation. Cal. Welf. & Inst. Code § 14105.46; *Aids Healthcare Found. V. Douglas*, 666 F. App'x 601, 604 (9th Cir. 2016).
- Illinois, effective June 14, 2012. 305 Ill. Comp. Stat. § 5/5-5.12(b), (l).
- New York, effective July 23, 2015. N.Y. State Dep't of Health, *NYS Medicaid Fee-for-Service NCPDP D.0 Billing Changes for 340B Drug Claims*, https://www.health.ny.gov/health_care/34medicaid/program/update/2015/2015-07.htm#dd0 (last visited Apr. 30, 2021).
- North Dakota, effective October 16, 2016. CMS, *N.D. State Plan Amendment ND-16-0011* (Feb. 14, 2017), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/ND/ND-16-0011.pdf.
- Texas, effective June 1, 2016. *Tex. State Plan Amendment TX-15-005* (Feb. 6, 2017), https://www.medicaid.gov/sites/default/files/State-

resource-center/Medicaid-State-Plan-Amendments/Downloads/TX/TX-15-005.pdf.

120. Importantly, in all of these states except Texas, the AAC reimbursement restriction applies not only to retail drugs, but also to non-retail drugs such as infusion products, drugs used in hospital outpatient departments, and physician-administered drugs.

121. Thus, any inflated Ceiling Prices which have been paid by Covered Entities post-dating the enactment of these state regulations led directly to the submission of false or fraudulent claims under the State FCAs of these states.

c. "Carved In" vs. "Carved Out"

122. Both 340B discounts and Medicaid rebates are calculated using the same formula. However, the formulas operate at different points in the drug purchase process: 340B discounts are provided at the time a drug is purchased and take the form of a lower purchase price, whereas Medicaid rebates are made after a drug has been purchased and the state Medicaid office (or its designee) provides the manufacturer with proof that it has dispensed rebate-eligible drugs.

123. When a Covered Entity treats a Medicaid FFS beneficiary, a dilemma arises. The 340B Covered Entity might treat the patient with drugs purchased at the Ceiling Price, and then bill Medicaid for the cost of the drugs. But if the state Medicaid agency then seeks a rebate from the manufacturer, the manufacturer will have provided two discounts on the same drug: one in the form of a discounted 340B Ceiling Price to the Covered Entity and the other in the form of a post-purchase rebate to the state.

124. Therefore, when treating a Medicaid FFS beneficiary, ***either*** a Covered Entity may use 340B pricing ***or*** the government may avail itself of the Medicaid rebate. *See* 42 U.S.C. § 256b(a)(5)(A)(i). This provision is commonly known as the "duplicate discount prohibition."

125. When a Covered Entity uses 340B pricing for a drug dispensed to a Medicaid FFS beneficiary, it is said to "carve in" the purchase. When a Covered Entity uses ordinary, non-340B pricing for a drug dispensed to a Medicaid FFS beneficiary, it is said to "carve out" the purchase. For example, consider the following scenario: John Doe is a Medicaid FFS beneficiary. A Covered Entity dispenses a drug to Mr. Doe. The 340B Ceiling Price of the drug is $1, and the Covered Entity's usual and customary charge for the drug is $5. When the Covered Entity submits a bill to Medicaid for the treatment of Mr. Doe, it may carve in the purchase and bill Medicaid for $1 (with no rebate to Medicaid), or carve out the purchase and bill Medicaid for $5, after which Medicaid is entitled to rebate from the manufacturer under the MDRP.

126. Across the country, approximately 60% of Covered Entities sites "carve in" 340B drugs for Medicaid FFS patients. Indeed, two states (California and Illinois), carving in is required by law – *i.e.*, these states require Covered Entities carve in 340B prices for all Medicaid FFS claims. Cal. Welf. & Inst. Code § 14105.45(b), (d); 305 Ill. Comp. Stat. 5/5-5.12(b). Attached as Exhibits 2 and 3 are lists of current Covered Entities in California (Exhibit 2) and Illinois (Exhibit 3) which are incorporated herein by reference.

2. Critical Access Hospitals ("CAH") Billing to Medicare

127. CAHs bill Medicare based on actual drug costs. CAHs receive Medicare reimbursement at 101% of cost for outpatient Part B services. 42 U.S.C. § 1395m(g)(1); *see also* CMS, *Critical Access Hospital* 3 (July 2019), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CritAccessHospfctsht.pdf.

128. Because CAHs bill Medicare at a direct proportion of their drug costs, if a manufacturer illegally inflates its Ceiling Prices, those inflated prices directly cause an increase in what Medicare pays, thus resulting in false or fraudulent claims to Medicare.

3. Government-Funded 340B Covered Entities

129. Many 340B Covered Entities are owned by state or local government and/or funded in whole or in part by state or local funds. For example, virtually all state, county, and city health departments participate in the 340B Program, as do many prisons. Because these Covered Entities use state and/or local funds for the purchase of 340B Program drugs that were subject to an overcharge by Defendants, those overcharges have resulted in false or fraudulent claims under the State FCAs in the same manner as alleged above as to the federal FCA. Attached as Exhibit 4 is a list of representative government-funded Covered Entities in all fifty states which is incorporated herein by reference.

B. Allegations Specific to Each Defendant

130. The below examples of Defendants' specific unlawful conduct are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant.

131. To the extent that Defendants' unlawful conduct is not fully illustrated by these examples, that additional evidence is peculiarly within each Defendant's control and warrants that further discovery should proceed as to each drug identified in this Complaint, as well as other 340B Program drugs sold by each Defendant that failed to comply with the Ceiling Price formula.

1. AbbVie

132. AbbVie signed its PPA with HHS on January 4, 1993 and its PPA Addendum on December 13, 2016. As noted above, these documents expressly required AbbVie "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug . . . , reduced by the rebate percentage," and to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price."

133. AbbVie has knowingly violated these legal obligations. Relator knows about AbbVie's fraud because of Relator's own private, non-public purchase transactions involving AbbVie's drugs, through which AbbVie charged Relator prices that far exceeded the actual Ceiling Prices for many years.

134. Beginning in Q2 2019—when the financial penalty regulation for failing to provide accurate Ceiling Prices went into effect—these prices suddenly and dramatically dropped to $0.01 per unit,[1] the Ceiling Price which AbbVie was required to charge all along, overcharging Covered Entities by as much as 40,903%:

Drug Name	NDC[2]	340B Package Price		Overcharge
		Q1 2019	Q2 2019	
Namzaric 21 mg-10 mg Capsule	00456122130	$122.71	$0.30	40,903%
Namzaric 28 mg-10mg Capsule	00456122830	$122.58	$0.30	40,860%
Fetzima ER 80 mg Capsule	00456228030	$87.62	$0.30	29,207%
Fetzima ER 20 mg Capsule	00456222030	$87.60	$0.30	29,200%
Fetzima ER 120 mg Capsule	00456221230	$87.58	$0.30	29,193%
Fetzima 20-40 mg Titration Pack	00456220228	$73.48	$0.28	26,243%
Fetzima ER 40 mg Capsule	00456224030	$62.93	$0.30	20,977%
Linzess 145 mcg Capsule	00456120130	$19.07	$0.30	6,357%
Linzess 290 mcg Capsule	00456120230	$17.96	$0.30	5,987%
Depakote ER 500 mg Tablet	00074712611	$42.95	$1.00	4,295%
Depakote ER 500 mg Tablet	00074712613	$42.95	$1.00	4,295%
Depakote ER 500 mg Tablet	00074712653	$214.75	$5.00	4,295%
Depakote ER 250 mg Tablet	00074382611	$36.88	$1.00	3,688%
Depakote ER 250 mg Tablet	00074382613	$36.88	$1.00	3,688%

[1] The illustrations in this Complaint contain pricing on a per-package basis rather than a per-unit basis. Some packages, such as a bottle of pills or a vial of medication, contain multiple dosage units. In these circumstances, a per-unit penny price will result in a package price greater than $0.01—*e.g.*, a bottle of thirty pills at $0.01 per pill is accurately priced at $0.30 per bottle. Other packages, such as a pen-style injector or inhaler, might contain only one unit. In these circumstances, the package price of $0.01 will match the unit price of $0.01.

[2] NDC stands for National Drug Code, a unique identifier for each pharmaceutical product.

135. For several of its drugs, AbbVie failed to follow the statutory Ceiling Price formula until Q3 2019, when there was a similar sudden and dramatic drop to $0.01 per unit, the Ceiling Price which AbbVie was required to charge all along:

Drug Name	NDC	340B Package Price		Overcharge
		Q2 2019	Q3 2019	
Latisse 0.03% Eyelash Solution	00023361605	$14.90	$0.05	29,800%
Latisse 0.03% Eyelash Solution	00023361670	$8.94	$0.03	29,800%
Zenpep DR 15,000 Unit Capsule	00023611101	$17.00	$1.00	1,700%
Lexapro 10 mg Tablet	00456201001	$6.00	$1.00	600%
Lexapro 20 mg Tablet	00456202001	$6.00	$1.00	600%
Lexapro 5 mg Tablet	00456200501	$6.00	$1.00	600%

136. These sudden price decreases are not the result of market forces—*i.e.*, AbbVie did not suddenly decrease its prices across large swaths of its drug line in Q2, Q3, and Q4 2019. Nor did the Ceiling Price formula change in 2019: the 2019 regulation added civil monetary penalties, but it did not alter the formula, which has remained constant since 1992. Moreover, AbbVie's independent contractual obligation to comply with the Ceiling Price formula through its PPA and PPA Addendum did not change in 2019.

137. Rather, the 340B Ceiling Prices AbbVie began charging in 2019 are the Ceiling Prices it was required to charge all along. These sudden shifts demonstrate that AbbVie's previous (much higher) prices had been inflated and did not reflect accurate 340B Ceiling Prices.

138. Relator bolstered this conclusion by providing its data to several leading experts in pharmacoeconomics and 340B Program pricing, who conducted a sophisticated analysis of AbbVie's pricing decisions. This expert analysis confirmed that the only plausible explanation for the sudden shifts in pricing across numerous of its products at issue in this Complaint is that AbbVie systematically refused to comply with the statutory Ceiling Price formula until it was faced with civil monetary penalties for doing so beginning in 2019.

139. This sudden compliance is also highly probative evidence of AbbVie's scienter, showing that when it was faced with financial penalties starting in 2019, AbbVie knew exactly how to properly calculate the Ceiling Prices for its drugs, thereby demonstrating that its previous violations were undertaken knowingly.

140. Furthermore, despite knowing that it had, for years, expressly violated the statutory Ceiling Price formula to the detriment of the government programs cited herein, AbbVie has, to date, knowingly failed to reimburse those government programs for these inflated Ceiling Prices. This failure triggers the so-called "reverse false claims" theory of FCA liability, which imposes liability on a defendant who, after becoming aware that it caused financial loss to a government program, fails to make the government whole. *See, e.g.*, 31 U.S.C. 3730(a)(1)(G) and its State FCA analogs.

a. Depakote ER

141. AbbVie's drug Depakote ER, used to treat seizure disorders, mental/mood conditions (such as manic phase of bipolar disorder), and to prevent migraine headaches, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2012 to 2016, Medicaid programs paid $109,691,448 for Depakote ER.

142. Depakote ER comes in two strengths: 250 mg tablets and 500 mg tablets.

143. Prior to Q2 2019, and at least as far back as Q1 2015, AbbVie charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Depakote ER 250 mg ranging from $4.99 (Q1 2016) to $36.88 (Q1 2019) per package, or as high as 3,688% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did AbbVie begin charging the statutorily mandated Ceiling Price ($1.00 per package).

144. Prior to Q2 2019, and at least as far back as Q1 2015, AbbVie charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing,

unlawfully inflated prices for Depakote ER 500 mg ranging from $14.95 or $74.73, depending on package size (Q4 2016) to $51.24 or $256.19, depending on package size (Q3 2018) per package, or as high as 5,124% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did AbbVie begin charging the statutorily mandated Ceiling Price ($1.00 or $5.00 per package, depending on package size).

145. AbbVie has not refunded the aforementioned Depakote ER overcharges to Covered Entities, or to Medicare or Medicaid programs using 340B pricing.

b. Fetzima

146. AbbVie's drug Fetzima, an antidepressant used to treat major depressive disorder in adults, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2012 to 2016, Medicaid programs paid $83,544,817 for Fetzima.

147. Fetzima comes in five strengths: Fetzima 20-40 mg titration pack, Fetzima ER 20 mg capsule, Fetzima ER 40 mg capsule, Fetzima ER 80 mg capsule, and Fetzima ER 120 mg capsule.

148. From Q1 2016 (if not much earlier) through Q1 2019, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Fetzima 20-40 mg titration pack ranging from $91.51 (Q1 2016) to $73.48 (Q1 2019) per package, or as high as 32,682% of the statutorily mandated Ceiling Price of $0.01 per unit. Not until the second quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.28 per package).

149. From Q1 2016 (if not much earlier) through Q1 2019, Allergan charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Fetzima ER 20 mg capsule ranging from $105.16 (Q1 2016) to $87.60 (Q1 2019) per package, or as high as 35,053% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did Allergan

begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

150. From Q1 2016 (if not much earlier) through Q1 2019, Allergan charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Fetzima ER 40 mg capsule ranging from $80.31 (Q1 2016) to $62.93 (Q1 2019) per package, or as high as 26,770% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

151. From Q1 2016 (if not much earlier) through Q1 2019, Allergan charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Fetzima ER 80 mg capsule ranging from $106.11 (Q1 2016) to $87.62 (Q1 2019) per package, or as high as 35,370% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

152. From Q1 2016 (if not much earlier) through Q1 2019, Allergan charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Fetzima ER 120 mg capsule ranging from $103.94 (Q1 2016) to $87.58 (Q1 2019) per package, or as high as 34,647% of the statutorily mandated penny Ceiling Price. Not until the second quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

153. AbbVie has not refunded the aforementioned Fetzima ER overcharges to Covered Entities, or to Medicare or Medicaid programs using 340B pricing.

c. Lexapro

154. AbbVie's drug Lexapro, mainly used to treat major depressive disorder or generalized anxiety disorder, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2012 to 2016, Medicaid programs paid $179,024,817.90 for Lexapro.

155. Lexapro comes in three strengths: 5 mg, 10 mg, and 20 mg tablets.

156. From Q1 2016 (if not much earlier) through Q2 2019, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Lexapro 5 mg tablets ranging from $45.39 (Q1 2016) to $6.00 (Q2 2019) per package, or as high as 4,539% of the statutorily mandated penny Ceiling Price. Not until the third quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($1.00 per package).

157. From Q1 2016 (if not much earlier) through Q2 2019, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Lexapro 10 mg tablets ranging from $46.39 (Q1 2016) to $6.00 (Q2 2019) per package, or 4,639% of the statutorily mandated penny Ceiling Price. Not until the third quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($1.00 per package).

158. From Q1 2016 (if not much earlier) through Q2 2019, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Lexapro 20 mg tablets ranging from $48.55 (Q1 2016) to $6.00 per package, or 4,855% of the statutorily mandated penny Ceiling Price. Not until the third quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($1.00 per package).

159. Allergan (now owned by AbbVie) has not refunded the aforementioned Lexapro overcharges to Covered Entities, or to Medicare or Medicaid programs using 340B pricing.

d. Linzess

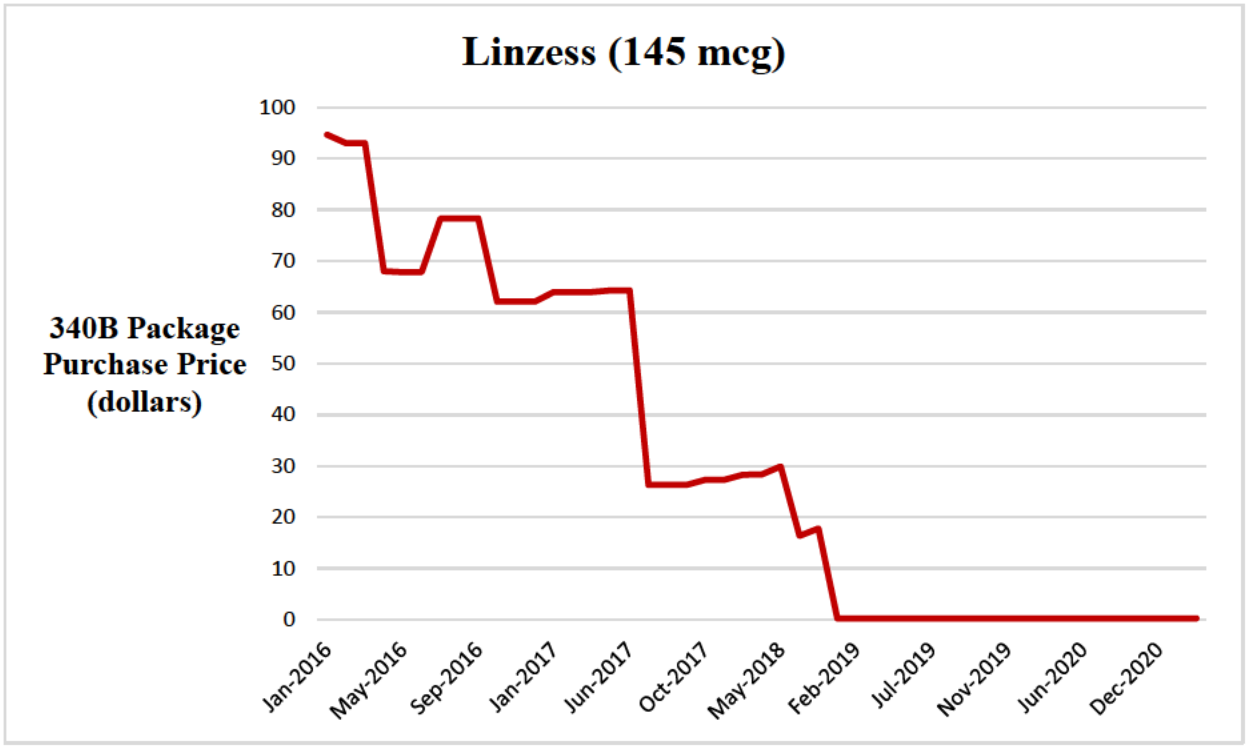
160. AbbVie's drug Linzess, used to treat irritable bowel syndrome, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. Between 2016 and 2018, Medicaid programs paid $311,050,240 for Linzess.

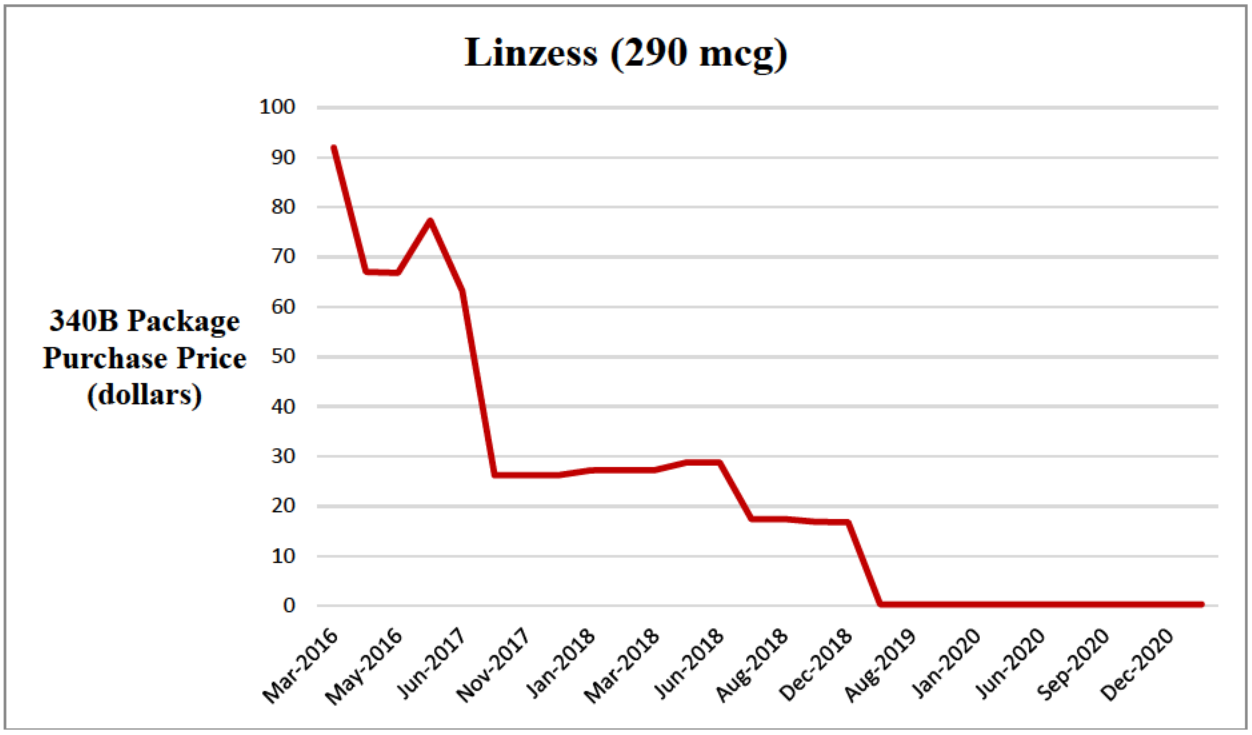
161. Linzess is supplied in 3 different product strengths: 145 mcg and 290 mcg, available since 2012, and a 72-mcg strength, which was introduced in 2017.

162. From Q1 2016 (if not much earlier) through Q4 2018, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicaid and Medicare programs using 340B prices, unlawfully inflated prices for Linzess 145 mcg ranging from $99.96 (Q1 2016) to $19.07 (Q4 2018) per package, or as high as 33,320% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

163. From Q1 2016 (if not much earlier) through Q4 2018, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicaid and Medicare programs using 340B prices, unlawfully inflated prices for Linzess 290 mcg ranging from $98.79 (Q1 2016) to $17.96 (Q4 2018) per package, or as high as 32,930% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

164. AbbVie's illegal conduct is further illustrated by the following graphs that tracks Relator's confidential, non-public purchase data:





165. AbbVie has not refunded the aforementioned Linzess overcharges to Covered Entities, or to Medicare or Medicaid programs using 340B pricing.

e. Zenpep DR

166. AbbVie's drug Zenpep DR, used in conditions where the pancreas cannot make or does not release enough digestive enzymes into the small intestines to digest the food, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2015 to 2019, Medicaid programs paid $325,094,458 for Zenpep.

167. From Q4 2018 through Q2 2019, Allergan (now owned by AbbVie) charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Zenpep DR 15,000-unit capsule ranging from $15.32 (Q4 2018) to $17.00 (Q2 2019) per package, or as high as 1,700% of the statutorily mandated penny Ceiling Price. Not until the third quarter of 2019 did Allergan begin charging the statutorily mandated penny Ceiling Price ($1.00 per package) for Zenpep DR 15,000 unit capsule.

168. AbbVie has not refunded the aforementioned Zenpep DR overcharges to Covered Entities, or to Medicare or Medicaid programs using 340B pricing.

2. AstraZeneca

169. Zeneca Pharmaceuticals (predecessor to AstraZeneca) signed its PPA with HHS on January 4, 1993 and its PPA Addendum on December 6, 2016. Astra Pharmaceuticals LP (predecessor to AstraZeneca) signed its PPA with HHS on January 27, 1993 and its PPA Addendum on January 31, 2017. As noted above, these documents expressly required AstraZeneca "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug . . . , reduced by the rebate percentage," and to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price."

170. AstraZeneca has knowingly violated these legal obligations. Relator knows about AstraZeneca's fraud because of Relator's own private, non-public

purchase transactions involving AstraZeneca's drugs, through which AstraZeneca charged Relator prices that far exceeded the actual Ceiling Prices for many years.

171. After Q1 2019—when the financial penalty regulation for failing to provide accurate Ceiling Prices went into effect—these prices suddenly and dramatically dropped to $0.01 per unit, the Ceiling Price which AstraZeneca was required to charge all along.

Drug Name	NDC	340B Package Price		Overcharge
		Q4 2018	Q1 2019	
Tudorza Pressair	00310080060	$51.59	$0.01	515,900%
Byetta 5 mcg Dose Pen Injector	00310651201	$17.86	$0.01	178,600%
Pulmicort 180 mcg Flexhaler	00186091612	$5.42	$0.01	54,200%
Symbicort 160-4.5 mcg Inhaler	00186037220	$51.68	$0.10	51,680%
Symbicort 160-4.5 mcg Inhaler	00186037028	$30.40	$0.06	50,667%
Pulmicort 90 mcg Flexhaler	00186091706	$3.80	$0.01	38,000%
Bydureon 2 mg Vial	00310652004	$15.14	$0.04	37,850%
Symlinpen 60 Pen Injector	00310661502	$11.34	$0.03	37,800%
Byetta 10 mcg Dose Pen Injector	00310652401	$7.30	$0.02	36,500%
Symbicort 80-4.5 mcg Inhaler	00186037228	$21.47	$0.06	35,783%
Symbicort 80-4.5 mcg Inhaler	00186037220	$31.75	$0.10	31,750%
Farxiga 10 mg Tablet	00310621030	$59.00	$0.30	19,667%
Farxiga 5 mg Tablet	00310620530	$58.48	$0.30	19,493%
Symlinpen 120 Pen Injector	00310662702	$8.21	$0.05	16,420%
Onglyza 5 mg Tablet	00310610590	$114.69	$0.90	12,743%
Onglyza 5 mg Tablet	00310610530	$38.23	$0.30	12,743%
Crestor 20 mg Tablet	00310075290	$42.59	$0.90	4,732%
Crestor 10 mg Tablet	00310075190	$42.57	$0.90	4,730%
Crestor 5 mg Tablet	00310075590	$42.38	$0.90	4,709%
Crestor 40 mg Tablet	00310075430	$14.07	$0.30	4,690%
Kombiglyze XR 5-500 mg Tablet	00310613530	$11.66	$0.30	3,887%
Kombiglyze XR 5-1,000 mg Tablet	00310614530	$11.25	$0.30	3,750%
Nexium DR 10 mg Packet	00186401001	$8.60	$0.30	2,867%
Kombiglyze XR 2.5-1,000 mg Tablet	00310612560	$10.55	$0.60	1,758%
Nexium DR 20 mg Packet	00186402001	$4.39	$0.30	1,463%
Onglyza 2.5 mg Tablet	00310610090	$4.15	$0.90	461%
Onglyza 2.5 mg Tablet	00310610030	$1.38	$0.30	460%
Nexium DR 40 mg Packet	00186404001	$0.95	$0.30	317%

172. For two of its drugs, AstraZeneca failed to follow the statutory Ceiling Price formula until Q3 2019, when there was a similar sudden and dramatic drop to $0.01 per unit, the Ceiling Price which AstraZeneca was required to charge all along:

Drug Name	NDC	340B Package Price		Overcharge
		Q2 2019	Q3 2019	
Xigduo CR 5 mg-500 mg Tablet	00310625030	$25.63	$0.30	8,543%
Xigduo CR 5 mg-1,000 mg Tablet	00310626060	$29.14	$0.60	4,857%

173. These sudden price decreases are not the result of market forces—*i.e.*, AstraZeneca did not suddenly decrease its prices across large swaths of its drug line in Q2, Q3, and Q4 2019. Nor did the Ceiling Price formula change in 2019: the 2019 regulation added civil monetary penalties, but it did not alter the formula, which has remained constant since 1992. Moreover, AstraZeneca's independent contractual obligation to comply with the Ceiling Price formula through its PPA and PPA Addendum did not change in 2019.

174. Rather, the 340B Ceiling Prices AstraZeneca began charging in 2019 are the Ceiling Prices it was required to charge all along. These sudden shifts demonstrate that AstraZeneca's previous (much higher) prices were inflated and did not reflect accurate 340B Ceiling Prices. Relator bolstered this conclusion by providing its data to several leading experts in pharmacoeconomics and 340B Program pricing, who conducted a sophisticated analysis of AstraZeneca's pricing decisions. This expert analysis confirmed that the only plausible explanation for the sudden shifts in pricing across the products at issue in this Complaint is that AstraZeneca systematically refused to comply with the statutory Ceiling Price formula until it was faced with civil monetary penalties for doing so beginning in 2019.

175. This sudden compliance is also highly probative evidence of AstraZeneca's scienter, because it shows that when AstraZeneca was faced with financial penalties starting in 2019, AstraZeneca knew exactly how to properly

calculate the Ceiling Prices for its drugs, thereby demonstrating that its previous violations were undertaken knowingly.

176. Furthermore, despite knowing that it had, for years, expressly violated the statutory Ceiling Price formula to the detriment of the government programs cited herein, AstraZeneca has, to date, knowingly failed to reimburse those government programs for these inflated Ceiling Prices. This failure triggers the so-called "reverse false claims" theory of FCA liability, which imposes liability on a defendant who, after becoming aware that it caused financial loss to a government program, fails to make the government whole. *See, e.g.*, 31 U.S.C. 3730(a)(1)(G) and its State FCA analogs.

a. Byetta

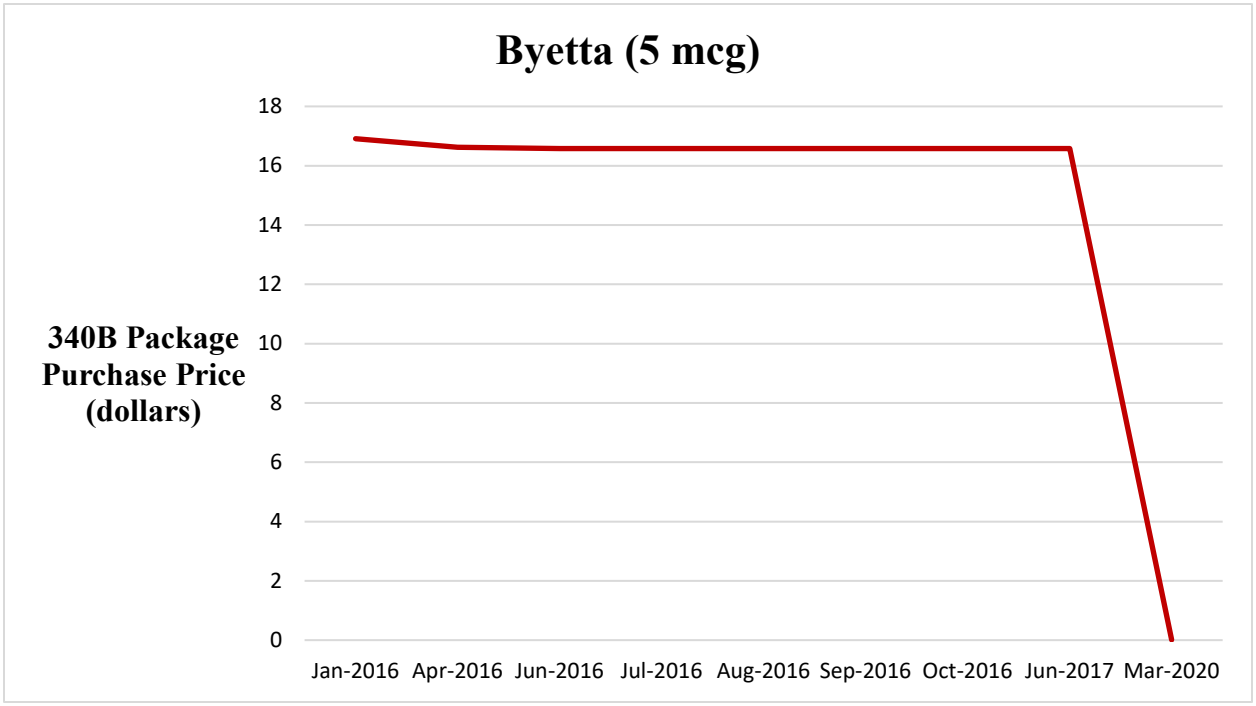
177. AstraZeneca's drug Byetta, an injectable drug pen used to control blood sugar in people with type 2 diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $129,857,897 for Byetta.

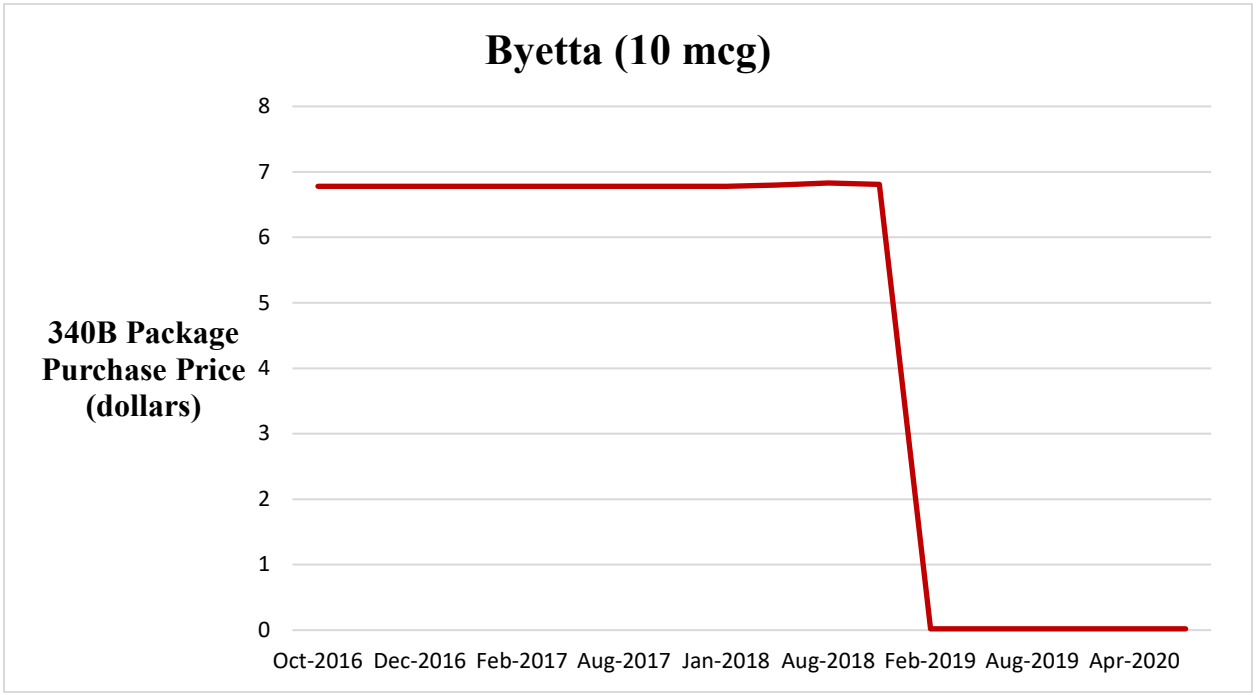
178. Byetta comes in two strengths: 5 mcg and 10 mcg.

179. From Q1 2015 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for the 5-mcg formulation of Byetta of $17.86 per package, or 178,600% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.01 per package).

180. From Q1 2015 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for the 10-mcg formulation of Byetta of $7.30 per package, or 36,500% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.02 per package).

181. AstraZeneca's illegal conduct is further illustrated by the following graphs that tracks Relator's confidential, non-public purchase data of Byetta 5 mcg and Byetta 10 mcg:





182. AstraZeneca has not refunded any of the aforementioned Byetta overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

b. Bydureon

183. AstraZeneca's drug Bydureon, used to treat type 2 diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $292,938,292 for Bydureon.

184. From Q1 2018 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Bydureon 2 mg vial ranging from $12.53 (Q1 2018) to $15.14 (Q4 2018) per package, or as much as 37,850% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.04 per package).

185. AstraZeneca has not refunded any of the aforementioned Bydureon overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

c. Crestor

186. AstraZeneca's drug Crestor, used to prevent cardiovascular disease and treat abnormal lipids, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 through 2018, Medicaid programs paid $334,244,639 for Crestor.

187. Crestor comes in four strengths: 5 mg, 10 mg, 20 mg, and 40 mg.

188. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Crestor 5 mg of $42.38 per package, or 4,709% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

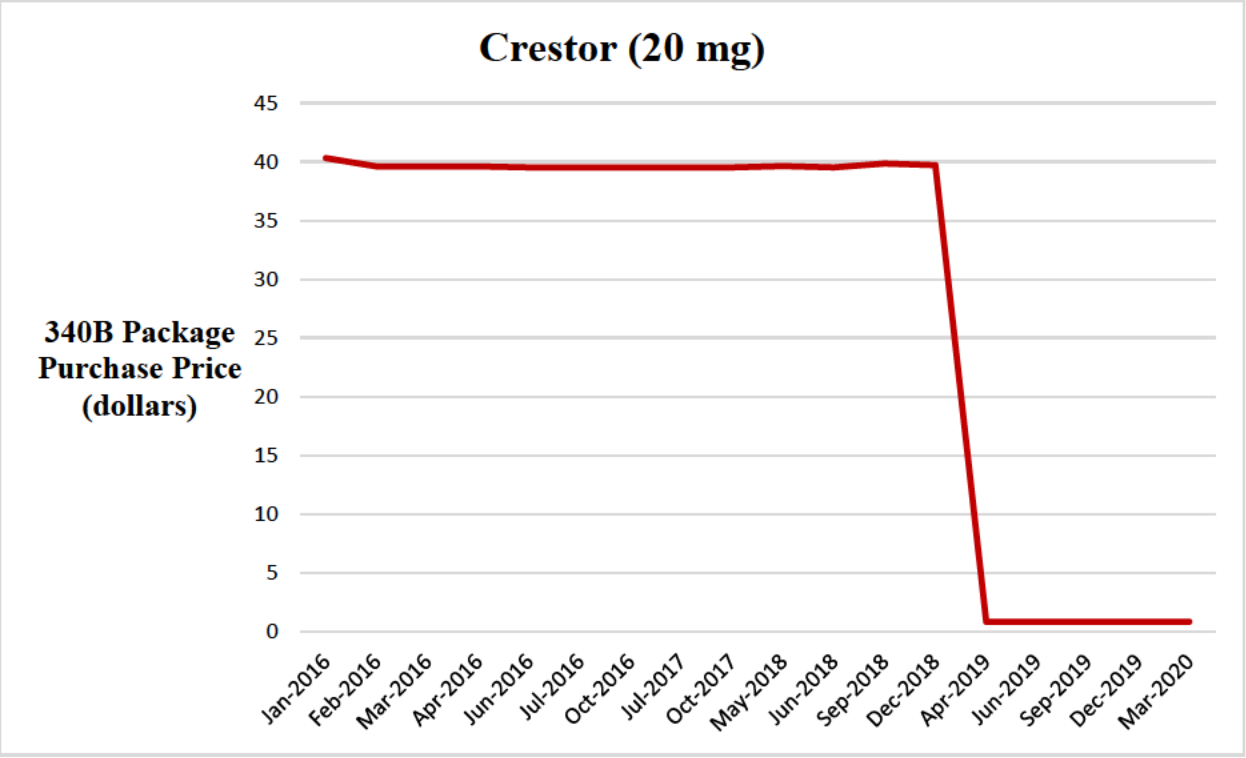
189. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Crestor 10 mg of $42.57 per package, or 4,730% of the statutorily

mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

190. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Crestor 20 mg of $42.59 per package, or 4,732% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.90 per package) for Crestor 20 mg.

191. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Crestor 40 mg of $14.07 per package, or 4,690% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package) for Crestor 40 mg.

192. AstraZeneca's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data of Crestor 20 mg:



193. AstraZeneca has not refunded any of the aforementioned Crestor overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

d. Farxiga

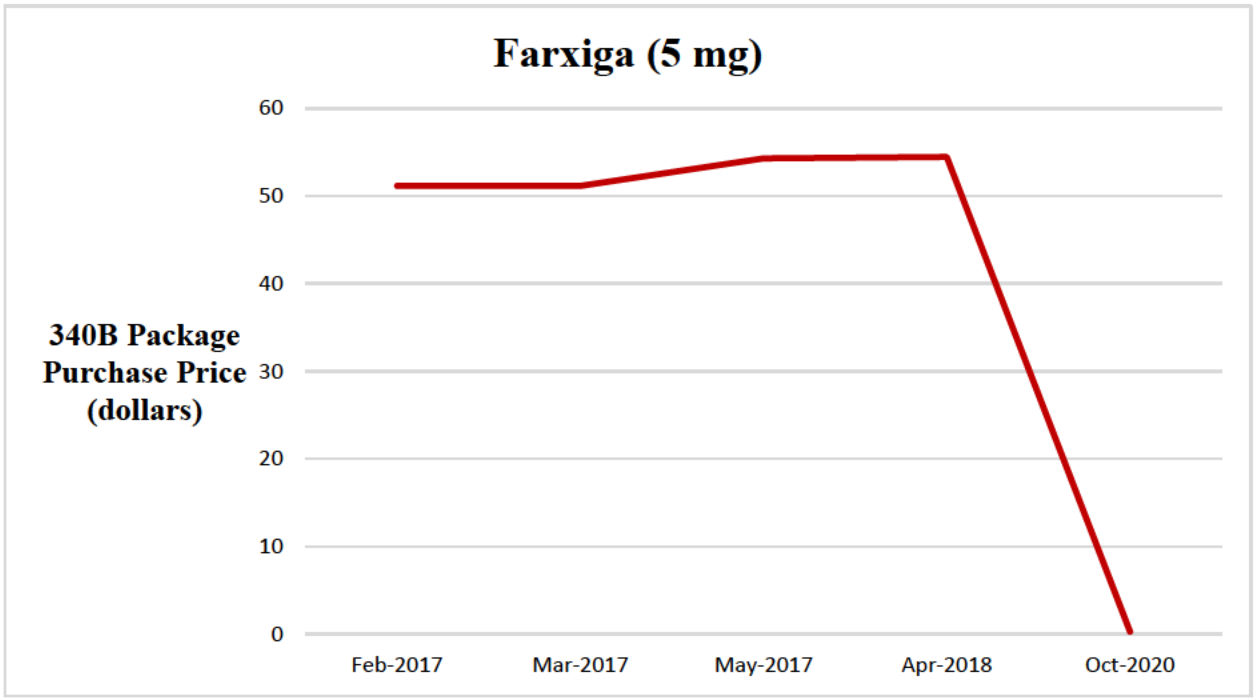
194. AstraZeneca's drug Farxiga, used to treat type 2 diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. In 2017 and 2018, Medicaid programs paid $85,722,285 for Farxiga.

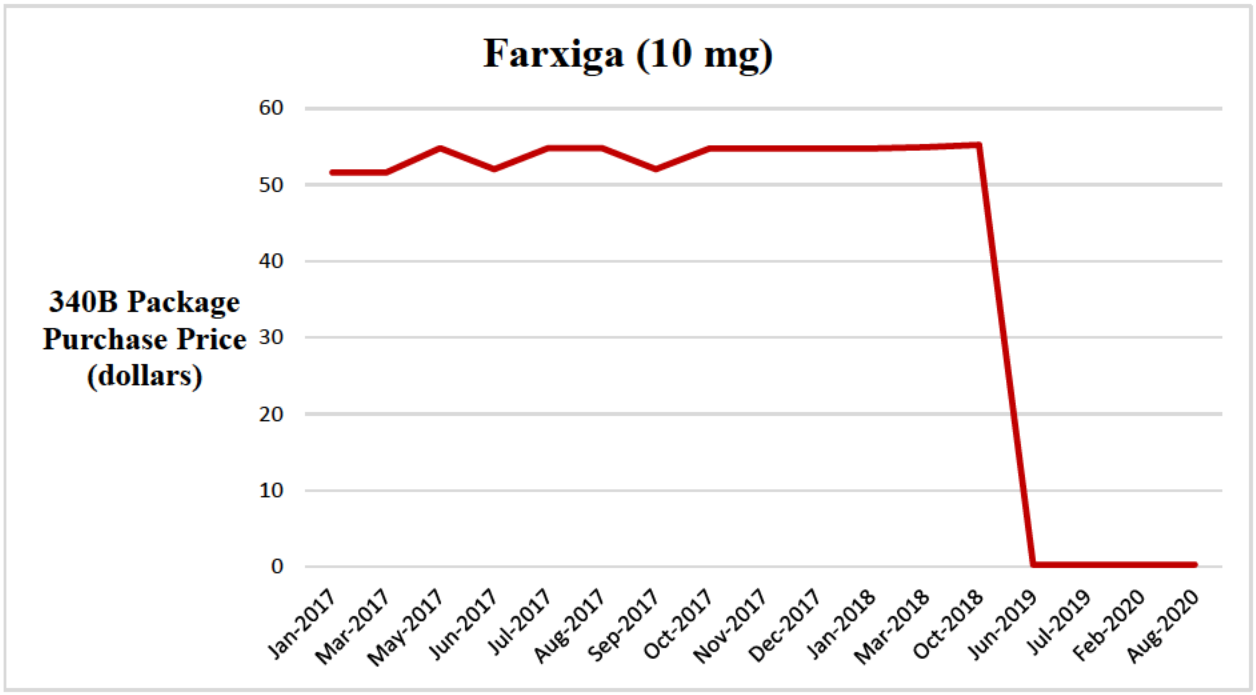
195. There are two strengths of Farxiga: 5 mg and 10 mg.

196. From Q1 2017 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Farxiga 5 mg ranging from $69.72 (Q1 2017) to $58.48 (Q4 2018) per package, or as high as 23,240% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package) for Farxiga 5 mg, a price that has stayed consistent through the second quarter of 2021.

197. From Q1 2017 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Farxiga 10 mg ranging from $70.23 (Q1 2016) to $59.00 (Q4 2018) per package, or 23,410% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package) for Farxiga 10 mg, a price that has stayed consistent through the second quarter of 2021.

198. AstraZeneca's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data of Farxiga 5 mg and Farxiga 10 mg:





199. AstraZeneca has not refunded any of the aforementioned Farxiga overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

e. Kombiglyze XR

200. AstraZeneca's drug Kombiglyze XR, used to control high blood sugar in people with type 2 diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $69,571,857.78 for Kombiglyze XR.

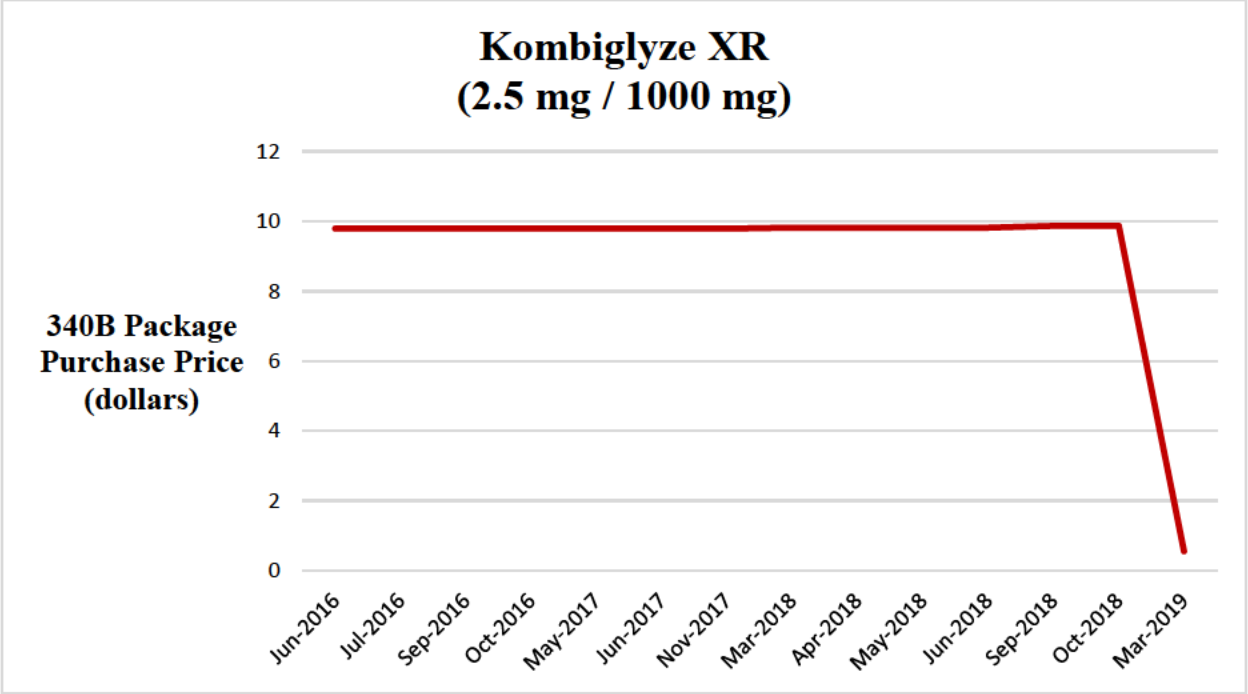
201. Kombiglyze XR comes in three strengths: 2.5-1,000 mg tab, 5-1,000 mg tab, and 5-500 mg tab.

202. From Q4 2015 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Kombiglyze 2.5-1,000 mg tab that ranged from $11.25 (Q3 2016) to $10.55 (Q4 2018) per package, or as much as 1,875% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.60 per package).

203. From Q1 2016 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Kombiglyze 5-1,000 mg tab of $11.25 per package, or 3,750% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

204. From Q1 2016 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Kombiglyze 5-500 mg tab of $11.66 per package, or 3,887% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

205. AstraZeneca's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Kombiglyze 2.5-1000 mg:



206. AstraZeneca has not refunded any of the aforementioned Kombiglyze overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

f. Nexium

207. AstraZeneca's drug Nexium, used to reduce stomach acid, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 through 2018, Medicaid programs paid $834,531,644 for Nexium.

208. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Nexium DR 10 mg packet of $8.60 per package, or 2,867% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

209. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Nexium DR 20 mg packet of $4.39 per package, or 1,463% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

210. From Q1 2014 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Nexium DR 40 mg packet of $0.95 per package, or 317% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

211. AstraZeneca has not refunded any of the aforementioned Nexium overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

g. Onglyza

212. AstraZeneca's drug Onglyza, used for the treatment of type 2 diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2015 to 2019, Medicaid programs paid $188,467,785 for Onglyza.

213. Onglyza comes in two strengths: 2.5 mg and 5 mg.

214. From Q1 2015 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Onglyza 2.5 mg tablet of $1.38 per package, or 460% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

215. From Q1 2015 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Onglyza 5 mg tablet of $38.23 per package, or 12,743% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

216. AstraZeneca has not refunded any of the aforementioned Onglyza overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

h. Pulmicort Flexhaler

217. AstraZeneca's drug Pulmicort Flexhaler, used in used in the long-term management of asthma and chronic obstructive pulmonary disease, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $101,142,754 for Pulmicort Flexhaler.

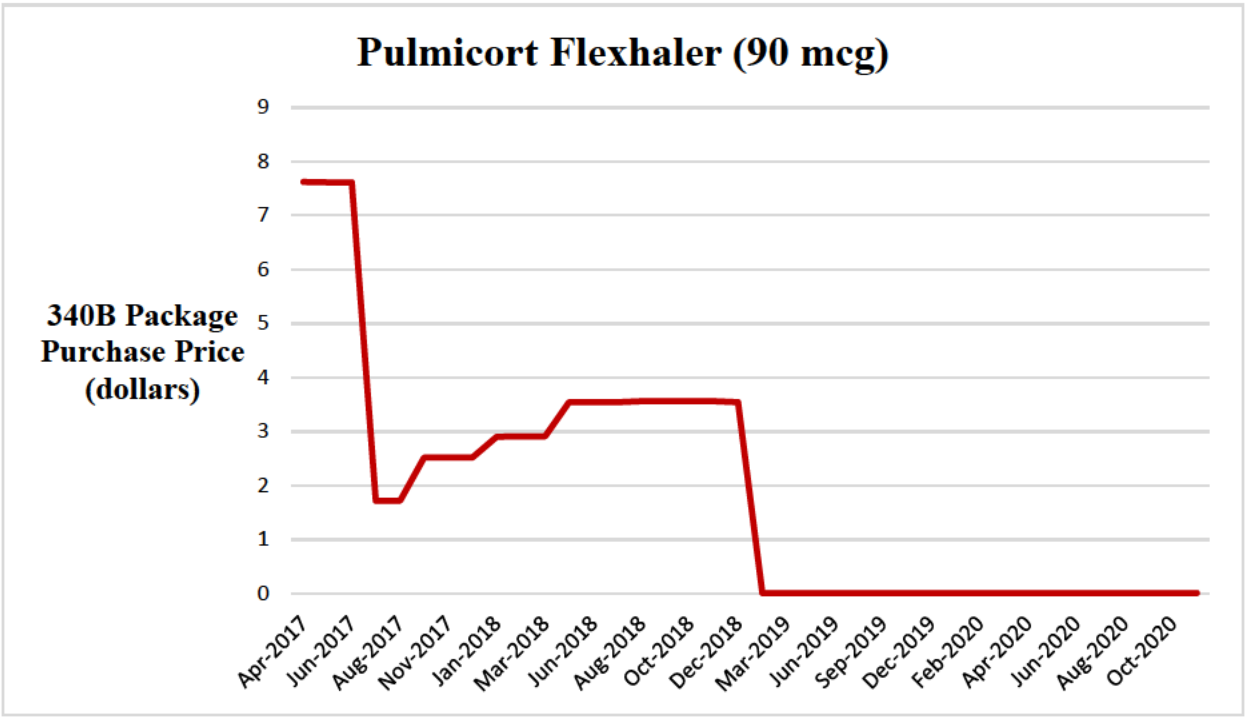
218. Pulmicort Flexhaler comes in two strengths: the 90 mcg Flexhaler and the 180 mcg Flexhaler.

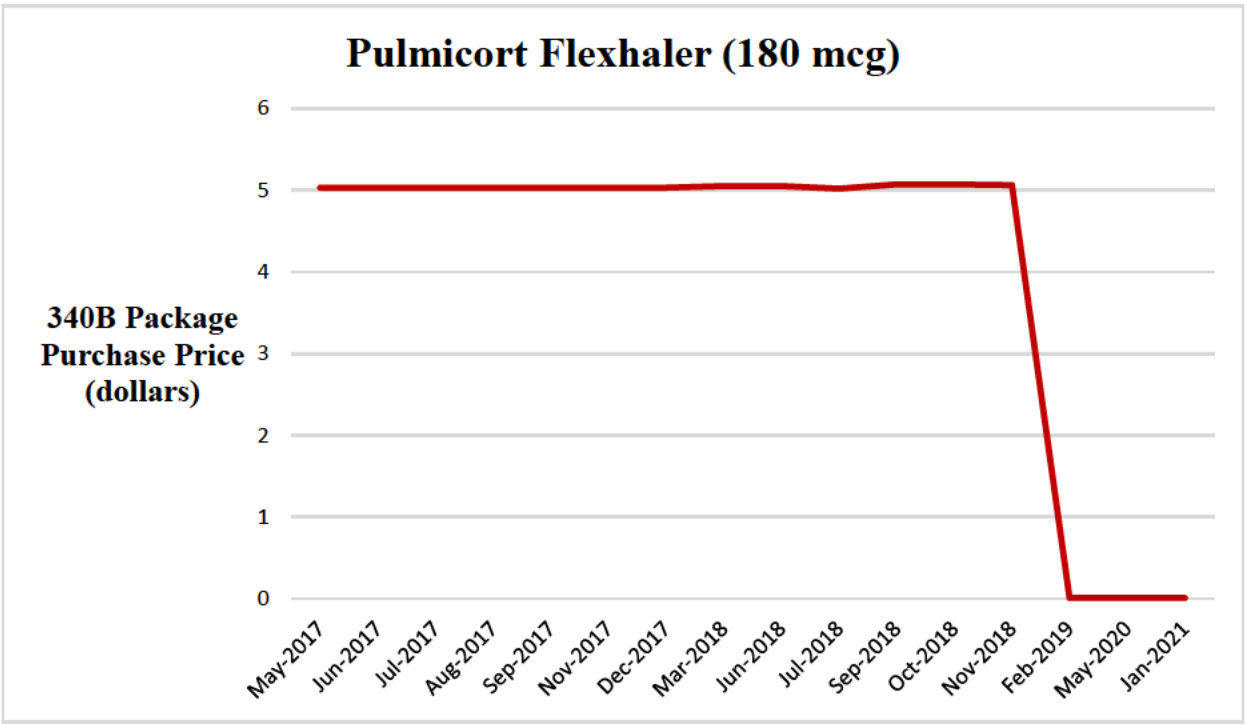
219. Prior to Q1 2019, and at least as far back as Q1 2016, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Pulmicort 90 mcg Flexhaler that ranged from $32.54 (Q1 2016) to $3.80 (Q4 2018) per package, or 325,400% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.01 per package).

220. From Q1 2016 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Pulmicort 180 mcg Flexhaler that ranged from $38.05 (Q 2016) to $5.42 (Q4 2018) per package, or 380,500% of the statutorily mandated penny

Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.01 per package).

221. AstraZeneca's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data of Pulmicort 90 mcg Flexhaler and Pulmicort 180 mcg Flexhaler:





222. AstraZeneca has not refunded any of the aforementioned Pulmicort Flexhaler overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

i. Symbicort

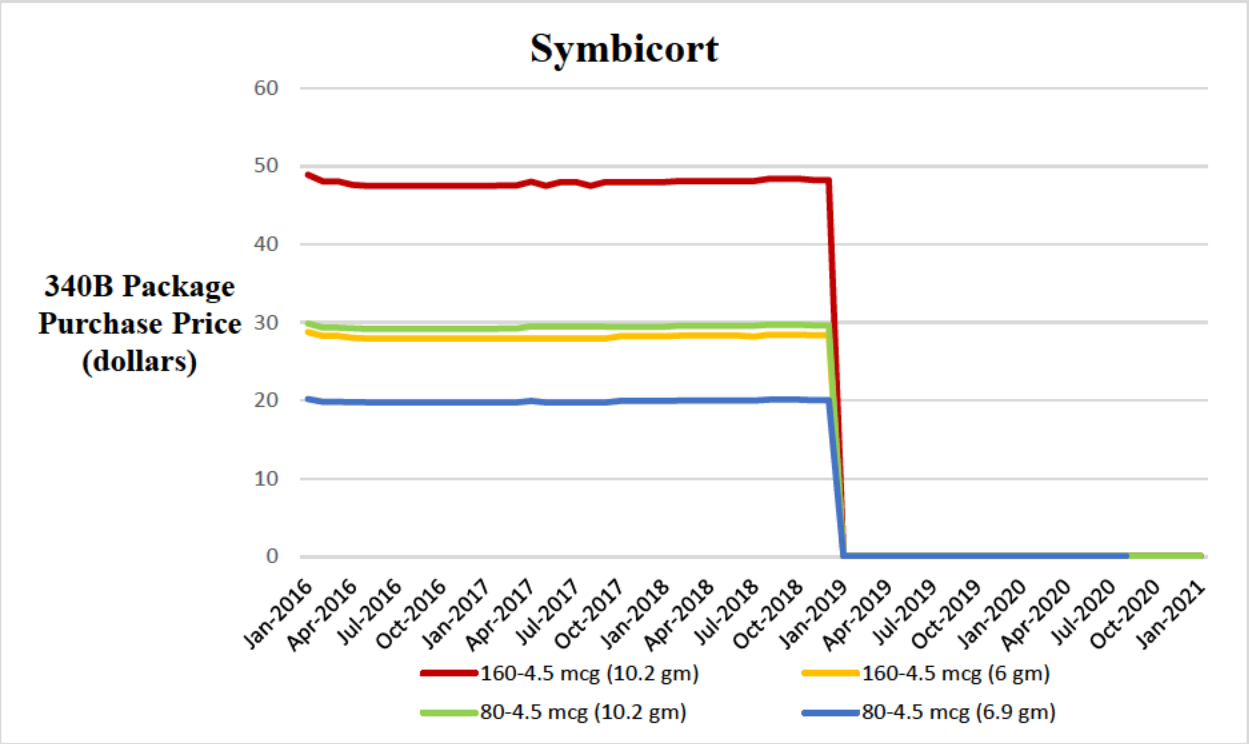
223. AstraZeneca's drug Symbicort, used in the management of asthma or COPD, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2016 to 2018, Medicaid programs paid $1,696,946,106 for Symbicort.

224. Symbicort comes in two strengths: 160 mcg budesonide/4.5 mcg formoterol and 80 mcg budesonide/4.5 mcg formoterol).

225. From Q1 2016 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Symbicort 80-4.5 mcg inhaler of $31.75 per package, or 31,750% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.10 per package).

226. From Q1 2016 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Symbicort 160-4.5 mcg inhaler of $51.68 per package, or 51,680% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.10 per package).

227. AstraZeneca's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data of Symbicort 80-4.5 mcg inhaler and Symbicort 160-4.5 mcg inhaler:



228. AstraZeneca has not refunded any of the aforementioned Symbicort overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

j. Tudorza Pressair

229. AstraZeneca's drug Tudorza Pressair, used as a maintenance treatment for chronic obstructive pulmonary disease, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2015 to 2019, Medicaid programs paid $134,325,581 for Tudorza Pressair.

230. From Q1 2018 through Q4 2018, AstraZeneca charged Covered Entities, as well as Medicare and Medicaid programs using 340B prices, unlawfully inflated prices for Tudorza Pressair of $51.59 per unit, or 515,900% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did AstraZeneca begin charging the statutorily mandated penny Ceiling Price ($0.01 per unit).

231. AstraZeneca has not refunded any of the aforementioned Tudorza Pressair overcharges to Covered Entities, or to Medicare and Medicaid programs using 340B pricing.

k. Examples of False Claims

232. By engaging in its fraudulent scheme, AstraZeneca directly submitted false claims to government-funded Covered Entities. Moreover, AstraZeneca caused Covered Entities, including Relator, to submit false claims to the Medicaid and Medicare Programs.

233. For example, on or about January 19, 2015, Patient M.S. was treated at Adventist Health Bakersfield—a Disproportionate Share Hospital and Covered Entity operated by Relator in Bakersfield, California—and was prescribed Crestor 20 mg (NDC 00310075239). M.S. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Crestor 20 mg was subject to a Ceiling Price of $0.01 per unit. On or about February 19, 2015, Adventist Health Bakersfield submitted a claim to Medi-Cal. Based on AstraZeneca's fraudulent overcharge, AstraZeneca caused Adventist Health Bakersfield to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of S.M.'s prescription, or $17.21 per package. In other words, AstraZeneca drastically overcharged Adventist Health Bakersfield for this drug, which caused Adventist Health Bakersfield to submit a false claim for reimbursement to Medi-Cal.

234. As another example, on or about February 19, 2015, Patient F.T. was treated at Adventist Health Bakersfield—a Disproportionate Share Hospital and Covered Entity operated by Relator in Bakersfield, California—and was prescribed Crestor 10 mg (NDC 00310075139). F.T. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Crestor 10 mg was subject to a Ceiling Price of $0.01 per unit. On or about July 27, 2015, Adventist Health Bakersfield submitted a claim to Medi-Cal. Based on

AstraZeneca's fraudulent overcharge, AstraZeneca caused Adventist Health Bakersfield to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of F.T.'s prescription, or $20.08 per package. In other words, AstraZeneca drastically overcharged Adventist Health Bakersfield for this drug, which caused Adventist Health Bakersfield to submit a false claim for reimbursement to Medi-Cal.

235. As another example, on or about March 5, 2015, Patient O.A. was treated at Adventist Health Bakersfield—a Disproportionate Share Hospital and Covered Entity operated by Relator in Bakersfield, California—and was prescribed Crestor 10 mg (NDC 00310075139). O.A. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Crestor 10 mg was subject to a Ceiling Price of $0.01 per unit. On or about April 20, 2015, Adventist Health Bakersfield submitted a claim to Medi-Cal. Based on AstraZeneca's fraudulent overcharge, AstraZeneca caused Adventist Health Bakersfield to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of O.A.'s prescription, or $17.21 per package. In other words, AstraZeneca drastically overcharged Adventist Health Bakersfield for this drug, which caused Adventist Health Bakersfield to submit a false claim for reimbursement to Medi-Cal.

236. As another example, on or about August 16, 2017, Patient J.H. was treated at Adventist Health Bakersfield—a Disproportionate Share Hospital and Covered Entity operated by Relator in Bakersfield, California—and was prescribed one tablet of Crestor 20 mg (NDC 00310075239). J.H. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Crestor 20 mg was subject to a Ceiling Price of $0.01 per unit. On or about September 21, 2017, Adventist Health Bakersfield submitted a claim to Medi-Cal. Based on AstraZeneca's fraudulent overcharge, AstraZeneca caused Adventist Health Bakersfield to report an inflated actual acquisition cost for the

drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of J.H.'s prescription, or $0.45. In other words, AstraZeneca drastically overcharged Adventist Health Bakersfield for this drug, which caused Adventist Health Bakersfield to submit a false claim for reimbursement to Medi-Cal.

237. By way of further example, a Federally Qualified Health Center (FQHC) in Illinois that is a 340B Covered Entity submitted the following claims to the Illinois Medicaid program where the Illinois FQHC should, but did not, receive the penny pricing Ceiling Price from AstraZeneca. In these examples, the Illinois FQHC charged the Illinois Medicaid program the same rate that it had paid to obtain the drug. Accordingly, AstraZeneca's misconduct resulted in the Illinois FQHC's unwitting submission of reimbursement claims to the Illinois Medicaid program at the increased rate, rather than the penny pricing Ceiling Price.

238. On or about January 10, 2017, Dr. E.R. wrote a prescription for Symbicort 160/4.5mcg Aero (NDC 00186037020) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about January 10, 2017. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $50.19 and received reimbursement from Illinois Medicaid at the same rate. As described above, Symbicort 160/4.5mcg Aero is manufactured by AstraZeneca and was subject to a penny pricing Ceiling Price; however, AstraZeneca drastically overcharged Covered Entities like the Illinois FQHC for this drug.

239. On or about March 28, 2017, Dr. E.R. wrote a prescription for Byetta 5mcg (NDC 00310651201) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about March 28, 2017. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $17.52 and received reimbursement from Illinois Medicaid at the same rate. As described above, Byetta 5mcg is manufactured by AstraZeneca and was subject to a penny pricing Ceiling Price; however,

AstraZeneca drastically overcharged Covered Entities like the Illinois FQHC for this drug.

240. On or about February 27, 2018, Dr. R.O. wrote a prescription for Byetta 10mcg (NDC 00310652401) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about February 27, 2018. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $7.17 and received reimbursement from Illinois Medicaid at the same rate. As described above, Byetta 10mcg is manufactured by AstraZeneca and was subject to a penny pricing Ceiling Price; however, AstraZeneca drastically overcharged Covered Entities like the Illinois FQHC for this drug.

241. On or about March 5, 2018, Dr. J.R. wrote a prescription for Symbicort 80/4.5mcg (NDC 00186037220) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about March 5, 2018. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $31.25 and received reimbursement from Illinois Medicaid at the same rate. As described above, Symbicort 80/4.5mcg is manufactured by AstraZeneca and was subject to a penny pricing Ceiling Price; however, AstraZeneca drastically overcharged Covered Entities like the Illinois FQHC for this drug.

3. Novartis

242. Novartis signed its PPA with HHS on December 30, 1992 and its PPA Addendum on December 14, 2016. As noted above, these documents expressly required Novartis "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug . . . , reduced by the rebate percentage," and to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price."

243. Novartis has knowingly violated these legal obligations. Relator knows about Novartis's fraud because of Relator's own private, non-public purchase transactions involving Novartis's drugs, through which Novartis charged Relator prices that far exceeded the actual Ceiling Prices for many years.

244. After Q1 2019—when the financial penalty regulation for failing to provide accurate Ceiling Prices went into effect—these prices suddenly and dramatically dropped to $0.01 per unit, the Ceiling Price which Novartis was required to charge all along.

Drug Name	NDC	340B Package Price		Overcharge
		Q4 2018	Q1 2019	
Gleevec 400 mg Tablet	00078064930	$614.32	$0.30	204,773%
Omnitrope 10 mg/1.5 mL cartridge	00781300407	$26.72	$0.02	133,600%
Omnitrope 5 mg/1.5 mL cartridge	00781300107	$25.61	$0.02	128,050%
Focalin XR 20 mg Capsule	00078043205	$77.67	$1.00	7,767%
Focalin XR 10 mg Capsule	00078043105	$61.98	$1.00	6,198%
Focalin XR 15 mg Capsule	00078049305	$32.74	$1.00	3,274%
Gleevec 100 mg Tablet	00078040134	$28.82	$0.90	3,202%
Diovan 320 mg Tablet	00078036034	$26.33	$0.90	2,926%
Exforge 10-160 mg Tablet	00078048915	$6.17	$0.30	2,057%
Lotrel 5-20 mg Capsule	00078040605	$18.61	$1.00	1,861%
Tegretol XR 200 mg Tablet	00078051105	$15.21	$1.00	1,521%
Lotrel 5-10 mg Capsule	00078040505	$11.65	$1.00	1,165%
Diovan 80 mg Tablet	00078035834	$9.60	$0.90	1,067%
Diovan 40 mg Tablet	00078042315	$2.85	$0.30	950%
Diovan Hct 80-12.5 mg Tablet	00078031434	$4.93	$0.90	548%
Diovan Hct 160-25 mg Tablet	00078031534	$3.39	$0.90	377%

245. For several of its drugs, Novartis failed to follow the statutory Ceiling Price formula until Q2 2019, when there was a similar sudden and dramatic drop to $0.01 per unit, the Ceiling Price which Novartis was required to charge all along:

Drug Name	NDC	340B Package Price		Overcharge
		Q1 2019	Q2 2019	
Focalin XR 5 mg Capsule	00078043005	$69.42	$1.00	6,942%
Focalin XR 30 mg Capsule	00078043305	$55.00	$1.00	5,500%
Tegretol XR 400 mg Tablet	00078051205	$7.11	$1.00	711%

246. For several of its drugs, Novartis failed to follow the statutory Ceiling Price formula until Q3 2019, when there was a similar sudden and dramatic drop to $0.01 per unit, the Ceiling Price which Novartis was required to charge all along:

Drug Name	NDC	340B Package Price		Overcharge
		Q2 2018	Q3 2019	
Trileptal 600 mg Tablet	00078045705	$11.81	$1.00	1,181%
Trileptal 300 mg Tablet	00078033705	$6.78	$1.00	678%
Trileptal 150 mg Tablet	00078045605	$3.60	$1.00	360%

247. These sudden price decreases are not the result of market forces—*i.e.*, Novartis did not suddenly decrease its prices across large swaths of its drug line in Q2, Q3, and Q4 2019. Nor did the Ceiling Price formula change in 2019: the 2019 regulation added civil monetary penalties, but it did not alter the formula, which has remained constant since 1992. Moreover, Novartis's independent contractual obligation to comply with the Ceiling Price formula through its PPA and PPA Addendum did not change in 2019.

248. Rather, the 340B Ceiling Prices Novartis began charging in 2019 are the Ceiling Prices it was required to charge all along. These sudden shifts demonstrate that Novartis's previous (much higher) prices were inflated and did not reflect accurate 340B Ceiling Prices. Relator bolstered this conclusion by providing its data to several leading experts in pharmacoeconomics and 340B Program pricing, who conducted a sophisticated analysis of Novartis's pricing decisions. This expert analysis confirmed that the only plausible explanation for the sudden shifts in pricing across the products at issue in this Complaint is that Novartis systematically refused to comply with the statutory Ceiling Price formula until it was faced with civil monetary penalties for doing so beginning in 2019.

249. This sudden compliance is also highly probative evidence of Novartis's scienter, because it shows that when Novartis was faced with financial penalties starting in 2019, Novartis knew exactly how to properly calculate the Ceiling Prices for its drugs, thereby demonstrating that its previous violations were undertaken knowingly.

250. Furthermore, despite knowing that it had, for years, expressly violated the statutory Ceiling Price formula to the detriment of the government programs cited herein, Novartis has, to date, knowingly failed to reimburse those government programs for these inflated Ceiling Prices. This failure triggers the so-called "reverse false claims" theory of FCA liability, which imposes liability on a defendant who, after becoming aware that it caused financial loss to a government program, fails to make the government whole. *See, e.g.*, 31 U.S.C. 3730(a)(1)(G) and its State FCA analogs.

a. Diovan

251. Novartis' drug Diovan, used to treat high blood pressure, heart failure, and diabetic kidney disease, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $129,598,813 for Diovan.

252. There are two versions of Diovan, each with multiple strengths: original (40 mg, 80 mg, and 320 mg) and HCT (80 mg valsartan/12.5 mg hydrochlorothiazide and 160 mg valsartan/12.5 mg hydrochlorothiazide).

253. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Diovan 40 mg tablets of $2.85 per package, or 950% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

254. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Diovan 80 mg tablets of $9.60 per package, or 1,067% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

255. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Diovan 320 mg tablets of $26.33 per package, or 2,926% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

256. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Diovan HCT 160-25 mg tablet of $26.33 per package, or 2,925% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

257. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Diovan HCT 80-12.5 mg tablet of $4.93 per package, or 548% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

258. Novartis has not refunded the aforementioned Diovan HCT overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

b. Focalin XR

259. Novartis' drug Focalin XR, used to treat attention deficit hyperactivity disorder (ADHD), has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $1,512,523,342 for Focalin XR.

260. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing,

unlawfully inflated prices for Focalin XR 10 mg ranging from $110.40 (Q1 2016) to $61.98 (Q4 2018) per package, or as high as 11,040% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($1.00 per package).

261. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Focalin XR 15 mg ranging from $95.66 (Q2 2016) to $32.74 (Q4 2018) per package, or as high as 9,566% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($1.00 per package) for Focalin XR 15 mg.

262. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Focalin XR 20 mg ranging from $77.69 (Q1 2016) to $77.67 (Q4 2018) per package, or as high as 7,769% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($1.00 per package) for Focalin XR 20 mg.

263. Novartis has not refunded the aforementioned Focalin XR overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

c. Gleevec

264. Novartis' drug Gleevec, used to treat cancer, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $1,696,946,106 for Gleevec.

265. In Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Gleevec 400 mg tablet of $614.32 per package, or 204,773% of the statutorily mandated

penny Ceiling Price. Not until Q1 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.30 per package).

266. From Q1 2016 through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Gleevec 100 mg tablet of $28.82 per package, or 3,202% of the statutorily mandated penny Ceiling Price. Not until Q1 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

267. Novartis has not refunded the aforementioned Gleevec overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

d. Omnitrope

268. Novartis' drug Omnitrope, a growth hormone used to treat children's growth disorders and adult growth hormone deficiency, and marketed by Novartis' subsidiary Sandoz, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $241,594,807 for Omnitrope.

269. Omnitrope is marketed in two strengths: 5 mg and 10 mg.

270. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Omnitrope 5 mg ranging of $25.61 per package, or 128,050% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.02 per package).

271. From Q1 2016 (if not much earlier) through Q4 2018, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Omnitrope 10 mg of $26.72 per package, or 133,600% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($0.02 per package).

272. Novartis has not refunded the aforementioned Omnitrope overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

e. Trileptal

273. Novartis' drug Trileptal, used to treat epilepsy and bipolar disorder, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $209,794,631 for Trileptal.

274. From Q1 2016 (if not much earlier) through Q2 2019, Novartis charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Trileptal 600 mg ranging from $61.02 (Q1 2016) to $11.81 (Q2 2019) per package, or as high as 6,102% of the statutorily mandated penny Ceiling Price. Not until Q3 2019 did Novartis begin charging the statutorily mandated penny Ceiling Price ($1.00 per package).

275. Novartis has not refunded the aforementioned Trileptal overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

f. Examples of False Claims

276. By engaging in its fraudulent scheme, Novartis directly submitted false claims to government-funded Covered Entities. Moreover, Novartis caused Covered Entities, including Relator, to submit false claims to the Medicaid and Medicare Programs.

277. For example, a Federally Qualified Health Center (FQHC) in Illinois that is a 340B Covered Entity submitted the following claims to the Illinois Medicaid program where the Illinois FQHC should, but did not, receive the penny pricing Ceiling Price from Novartis. In these examples, the Illinois FQHC charged the Illinois Medicaid program the same rate that it had paid to obtain the drug. Accordingly, Novartis' misconduct resulted in the Illinois FQHC's unwitting submission of reimbursement claims to the Illinois Medicaid program at the increased rate, rather than the penny pricing Ceiling Price.

278. On or about August 30, 2017, Dr. M.S. wrote a prescription for Focalin XR 20mg (NDC 00078043205) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about September 2, 2017. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $0.83 and received reimbursement from Illinois Medicaid at the same rate. As described above, Focalin XR 20mg is manufactured by Novartis and was subject to a penny pricing Ceiling Price; however, Novartis drastically overcharged Covered Entities like the Illinois FQHC for this drug.

279. On or about January 9, 2018, Dr. E.S. wrote a prescription for Focalin XR 15mg (NDC 00078049305) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about January 10, 2018. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $32.13 and received reimbursement from Illinois Medicaid at the same rate. As described above, Focalin XR 15mg is manufactured by Novartis and was subject to a penny pricing Ceiling Price; however, Novartis drastically overcharged Covered Entities like the Illinois FQHC for this drug.

280. On or about October 4, 2018, Dr. J.R. wrote a prescription for Focalin XR 10mg (NDC 00078043105) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about October 4, 2018. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $60.80 and received reimbursement from Illinois Medicaid at the same rate. As described above, Focalin XR 10mg is manufactured by Novartis and was subject to a penny pricing Ceiling Price; however, Novartis drastically overcharged Covered Entities like the Illinois FQHC for this drug.

4. Sanofi

281. Sanofi signed its PPA with HHS on December 29, 1992 and its PPA Addendum on August 14, 2016. As noted above, these documents expressly required Sanofi "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug . . . , reduced by the rebate percentage," and to "offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price."

282. Sanofi has knowingly violated these legal obligations. Relator knows about Sanofi's fraud because of Relator's own private, non-public transactions involving Sanofi's drugs, through which Sanofi charged Relator prices that far exceeded the actual Ceiling Prices for many years.

283. After Q1 2019—when the financial penalty regulation for failing to provide accurate Ceiling Prices went into effect—these prices suddenly and dramatically dropped to $0.01 per unit, the Ceiling Price which Sanofi was required to charge all along.

Drug Name	NDC	340B Package Price		Overcharge
		Q4 2018	Q1 2019	
Apidra Solostar 100 Units/mL	00088250205	$201.53	$0.15	134,353%
Apidra 100 Units/mL Vial	00088250033	$104.32	$0.10	104,320%
Lantus Solostar 100 Unit/mL	00088221905	$133.38	$0.15	88,920%
Lantus 100 Unit/mL Vial	00088222033	$88.92	$0.10	88,920%
Renvela 0.8 gm Powder Packet	58468013202	$583.38	$0.90	64,820%
Renvela 2.4 gm Powder Packet	58468013102	$563.08	$0.90	62,564%
Ambien 10 mg Tablet	00024542131	$585.10	$1.00	58,510%
Ambien 5 mg Tablet	00024540131	$585.10	$1.00	58,510%
Renagel 800 mg Tablet	58468002101	$750.85	$1.80	41,714%
Renvela 800 mg Tablet	58468013001	$576.88	$2.70	21,366%
Renagel 400 mg Tablet	58468002001	$750.85	$3.60	20,856%
Amaryl 2 mg Tablet	00039022210	$158.03	$1.00	15,803%
Amaryl 1 mg Tablet	00039022110	$96.98	$1.00	9,698%

284. For several of its drugs, Sanofi failed to follow the statutory Ceiling Price formula until Q2 2019, when there was a similar sudden and dramatic drop to $0.01 per unit, the Ceiling Price which Sanofi was required to charge all along:

Drug Name	NDC	340B Package Price		Overcharge
		Q1 2019	Q2 2019	
Ambien CR 6.25 mg Tablet	00024550131	$6.83	$1.00	683%
Zolpidem Tartrate ER 6.25 mg Tablet	00228348111	$6.83	$1.00	683%
Ambien CR 12.5 mg Tablet	00024552131	$4.70	$1.00	470%
Zolpidem Tartrate ER 12.5 mg Tablet	00228348211	$4.70	$1.00	470%

285. These sudden price decreases are not the result of market forces—*i.e.*, Sanofi did not suddenly decrease its prices across large swaths of its drug line in Q2, Q3, and Q4 2019. Nor did the Ceiling Price formula change in 2019: the 2019 regulation added civil monetary penalties, but it did not alter the formula, which has remained constant since 1992. Moreover, Sanofi's independent contractual obligation to comply with the Ceiling Price formula through its PPA and PPA Addendum did not change in 2019.

286. Rather, the 340B Ceiling Prices Sanofi began charging in 2019 are the Ceiling Prices it was required to charge all along. These sudden shifts demonstrate that Sanofi's previous (much higher) prices were inflated and did not reflect accurate 340B Ceiling Prices. Relator bolstered this conclusion by providing its data to several leading experts in pharmacoeconomics and 340B Program pricing, who conducted a sophisticated analysis of Sanofi's pricing decisions. This expert analysis confirmed that the only plausible explanation for the sudden shifts in pricing across the products at issue in this Complaint is that Sanofi systematically refused to comply with the statutory Ceiling Price formula until it was faced with civil monetary penalties for doing so beginning in 2019.

287. This sudden compliance is also highly probative evidence of Sanofi's scienter, because it shows that when Sanofi was faced with financial penalties

starting in 2019, Sanofi knew exactly how to properly calculate the Ceiling Prices for its drugs, thereby demonstrating that its previous violations were undertaken knowingly.

288. Furthermore, despite knowing that it had, for years, expressly violated the statutory Ceiling Price formula to the detriment of the government programs cited herein, Sanofi has, to date, knowingly failed to reimburse those government programs for these inflated Ceiling Prices. This failure triggers the so-called "reverse false claims" theory of FCA liability, which imposes liability on a defendant who, after becoming aware that it caused financial loss to a government program, fails to make the government whole. *See, e.g.*, 31 U.S.C. 3730(a)(1)(G) and its State FCA analogs.

a. Apidra

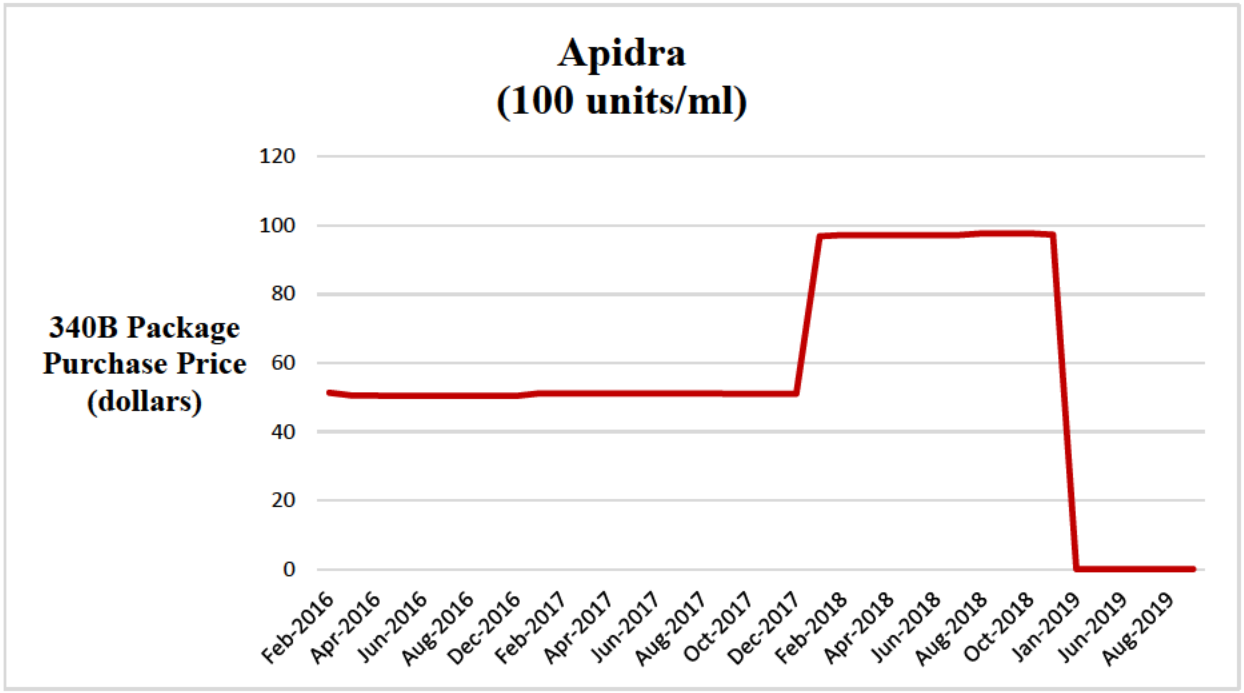
289. Sanofi's drug Apidra, a rapid-acting insulin analog, is available in two versions (100 units/ml vial and solostar 100 units/ml). Apidra has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $357,807,253 for Apidra.

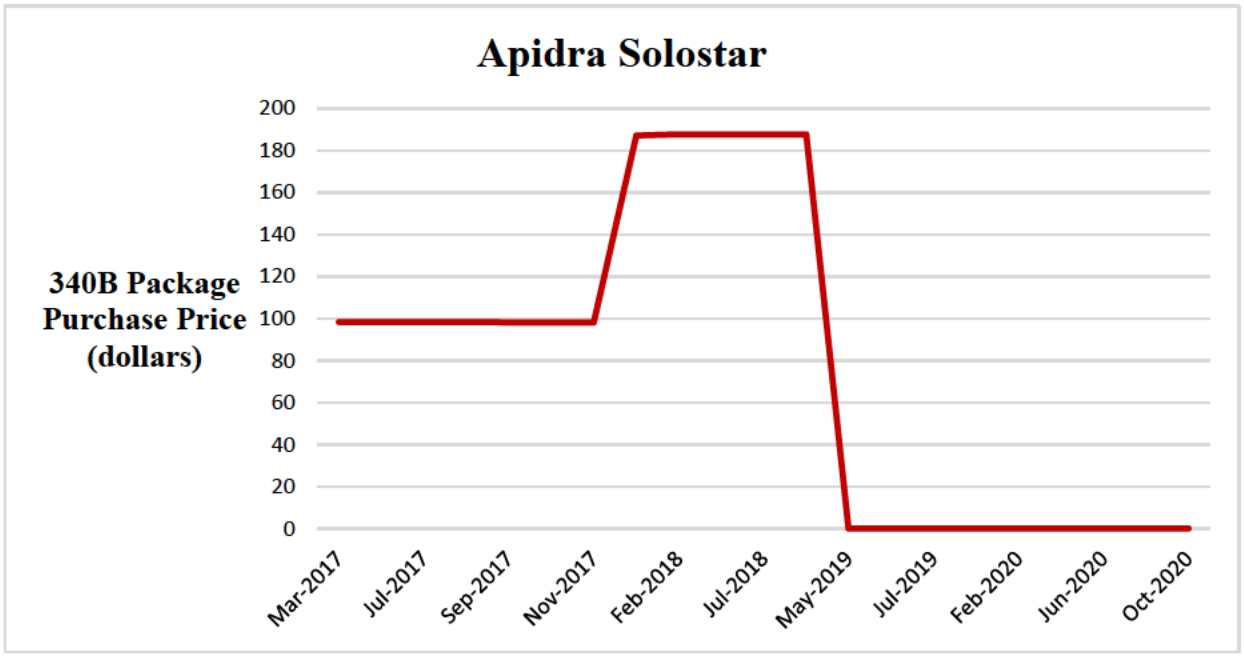
290. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Apidra 100 units/ml vial ranging from $54.25 (Q1 2016) to $104.32 (Q4 2018) per package, or as high as 104,320% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.10 per package).

291. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Apidra solostar 100 units/ml ranging from $104.35 (Q1 2016) to $201.53 (Q4 2018) per package, or as high as 134,353% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did

Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.15 per package).

292. Sanofi's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Apidra 100 units/ml vials and Apidra solostar 100 units/ml:





293. Sanofi has not refunded the aforementioned Apidra overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

b. Lantus

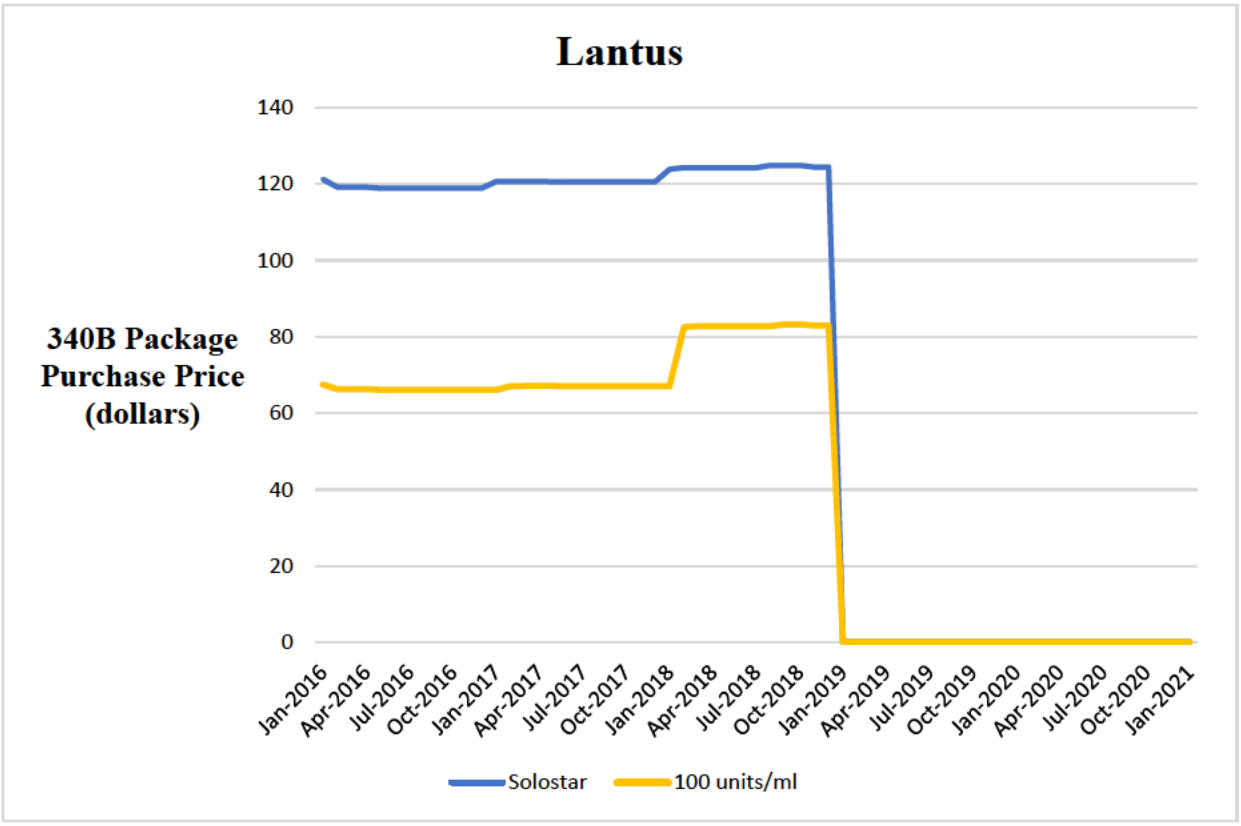
294. Sanofi's drug Lantus, a long-acting insulin used to treat diabetes, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $5,996,158,862 for Lantus.

295. Lantus is available in two versions (100 units/ml vial and solostar 100 units/ml).

296. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Lantus ranging from $71.19 (Q1 2016) to $88.92 (Q4 2018) per package of Lantus 100 units/ml, or as high as 88,920% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.10 per package).

297. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Lantus ranging from $128.00 (Q1 2016) to $133.38 (Q4 2018) per package of Lantus Solostar 100 units/ml, or as high as 88,920% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.15 per package).

298. Sanofi's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Lantus 100 units/ml and Lantus Solostar 100 units/ml:



299. Sanofi has not refunded the aforementioned Lantus overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing for either form of Lantus.

c. Renagel

300. Sanofi's drug Renagel (acquired when Sanofi bought Genzyme), used to treat hyperphosphatemia in patients with chronic kidney disease, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2012 to 2016, Medicaid programs paid $326,235,033 for Renagel.

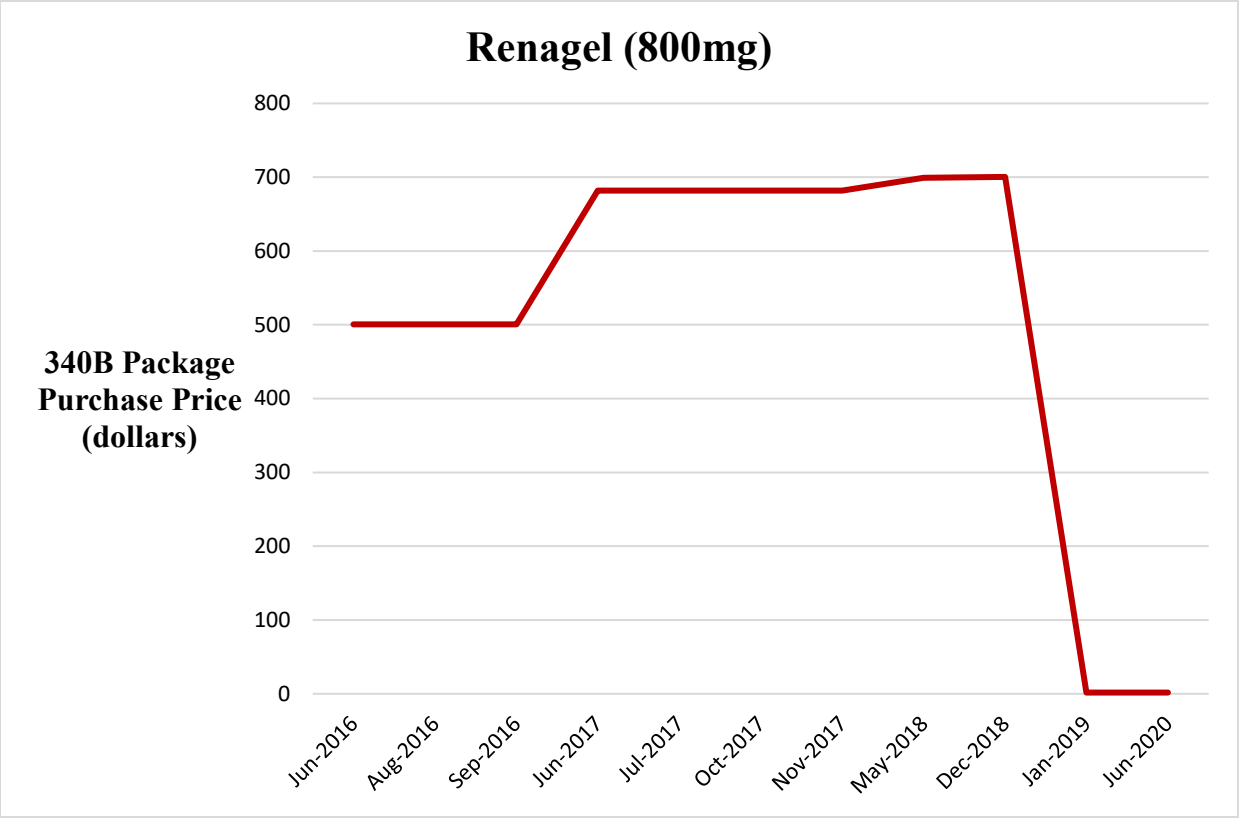
301. There are two strengths of Renagel available: 400 mg and 800 mg.

302. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing,

unlawfully inflated prices for Renagel 400 mg ranging from $539.07 (Q1 2016) to $750.85 (Q4 2018) per package, or as high as 20,856% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($3.60 per package).

303. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Renagel 800 mg ranging from $541.06 (Q1 2016) to $750.85 (Q4 2018) per package, or as high as 41,714% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($1.80 per package).

304. Sanofi's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Renagel 800 mg:



305. Sanofi has not refunded the aforementioned Renagel overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

d. Renvela

306. Sanofi's drug Renvela (acquired when Sanofi bought Genzyme), used to treat patients with chronic kidney disease, has been heavily used by 340B Covered Entities, as well as Medicare and Medicaid programs using 340B pricing. From 2014 to 2018, Medicaid programs paid $349,607,013 for Renvela.

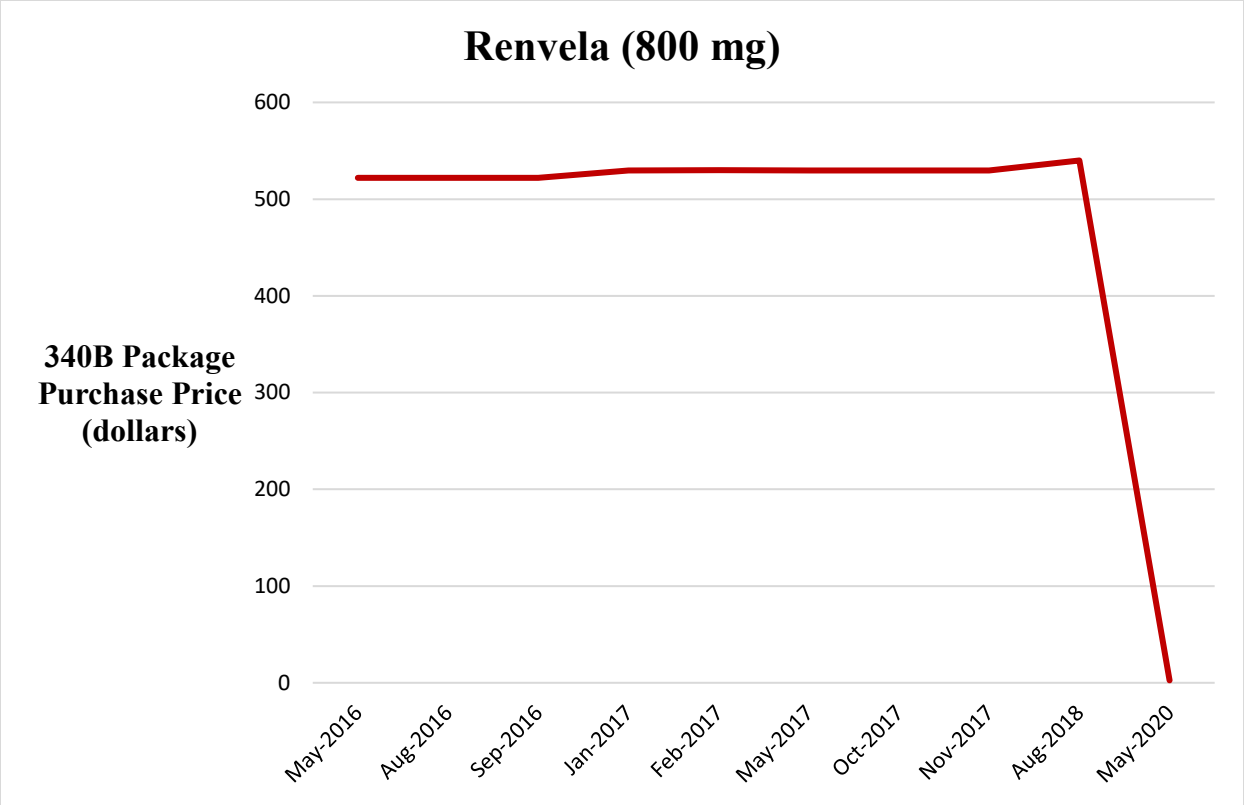
307. Renvela is available in three versions: powder packets (0.8 gm and 2.4 gm) and tablets (800 mg).

308. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Renvela 0.8 gm ranging from $562.44 (Q1 2016) to $583.38 (Q4 2018) per package, or as much as 64,820% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

309. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Renvela 2.4 gm ranging from $562.44 (Q1 2016) to $563.08 (Q4 2018) per package, or as much as 62,564% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($0.90 per package).

310. From Q1 2016 (if not much earlier) through Q4 2018, Sanofi charged Covered Entities, as well as Medicare and Medicaid programs using 340B pricing, unlawfully inflated prices for Renvela 800 mg tablet ranging from $562.44 (Q1 2016) to $576.88 (Q4 2018) per package, or as much as 21,366% of the statutorily mandated penny Ceiling Price. Not until the first quarter of 2019 did Sanofi begin charging the statutorily mandated penny Ceiling Price ($2.70 per package).

311. Sanofi's illegal conduct is further illustrated by the following graph that tracks Relator's confidential, non-public purchase data for Renvela 800 mg tablets:



312. Sanofi has not refunded the aforementioned Renvela overcharges to Covered Entities or to Medicare and Medicaid programs using 340B pricing.

e. Examples of False Claims

313. By engaging in its fraudulent scheme, Sanofi directly submitted false claims to government-funded Covered Entities. Moreover, Sanofi caused Covered Entities, including Relator, to submit false claims to the Medicaid and Medicare Programs.

314. For example, on or about August 17, 2015, Patient R.P. was treated at Adventist Health Tillamook—a Critical Access Hospital and Covered Entity operated by Relator in Tillamook, Oregon—and was prescribed Lantus Solostar 100 units/ml (NDC 00088221905). R.P. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus Solostar 100 units/ml was subject to a Ceiling Price of $0.01 per unit ($0.15 per package). On or

about April 22, 2016, Adventist Health Tillamook submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Tillamook to report an inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of R.P.'s prescription, or $40.98 for sixty units. In other words, Sanofi drastically overcharged Adventist Health Tillamook for this drug, which caused Adventist Health Tillamook to submit a false claim for reimbursement to Medicare.

315. As another example, on or about March 1, 2016, Patient V.B. was treated at Adventist Health Bakersfield—a Disproportionate Share Hospital and Covered Entity operated by Relator in Bakersfield, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). V.B. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about March 8, 2016, Adventist Health Bakersfield submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Bakersfield to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of V.B.'s prescription, or $6.78 for forty units. In other words, Sanofi drastically overcharged Adventist Health Bakersfield for this drug, which caused Adventist Health Bakersfield to submit a false claim for reimbursement to Medi-Cal.

316. As another example, on or about March 28, 2016, Patient J.H. was treated at Adventist Health Tillamook—a Critical Access Hospital and Covered Entity operated by Relator in Tillamook, Oregon—and was prescribed Lantus Solostar 100 units/ml (NDC 00088221905). J.H. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus Solostar 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about May 11, 2017, Adventist Health Tillamook submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Tillamook to report an

inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of J.H.'s prescription, or $65.19 for sixty units. In other words, Sanofi drastically overcharged Adventist Health Tillamook for this drug, which caused Adventist Health Tillamook to submit a false claim for reimbursement to Medicare.

317. As another example, on or about May 11, 2016, Patient C.C. was treated at Adventist Health Glendale—a Disproportionate Share Hospital and Covered Entity operated by Relator in Glendale, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). C.C. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about May 18, 2016, Adventist Health Glendale submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Glendale to report an inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of C.C.'s prescription, or $41.47 for forty units. In other words, Sanofi drastically overcharged Adventist Health Glendale for this drug, which caused Adventist Health Glendale to submit a false claim for reimbursement to Medicare.

318. As another example, on or about June 18, 2016, Patient M.T. was treated at Adventist Health Castle—a Disproportionate Share Hospital and Covered Entity operated by Relator in Kailua, Hawaii—and was prescribed Lantus 100 units/ml (NDC 00088222033). M.T. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about June 27, 2016, Adventist Health Castle submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Castle to report an inflated actual acquisition cost for the drug, and Medicare provided reimbursement at the fraudulently inflated cost of M.T.'s prescription, or $15.13 for twenty units. In other words, Sanofi drastically overcharged Adventist Health Castle for this drug, which

caused Adventist Health Castle to submit a false claim for reimbursement to Medicare.

319. As another example, on or about December 1, 2016, Patient F.H. was treated at Adventist Health Howard Memorial—a Critical Access Hospital and Covered Entity operated by Relator in Willits, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). F.H. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about December 31, 2016, Adventist Health Howard Memorial submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Howard Memorial to report an inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of F.H.'s prescription, or $20.21 for nineteen units. In other words, Sanofi drastically overcharged Adventist Health Howard Memorial for this drug, which caused Adventist Health Howard Memorial to submit a false claim for reimbursement to Medicare.

320. As another example, on or about November 8, 2017, Patient M.R. was treated at Adventist Health St. Helena—a Disproportionate Share Hospital and Covered Entity operated by Relator in St. Helena, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). M.R. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about November 15, 2017, Adventist Health St. Helena submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health St. Helena to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of M.R..'s prescription, or $6.65 for three units. In other words, Sanofi drastically overcharged Adventist Health St. Helena for this drug, which caused Adventist Health St. Helena to submit a false claim for reimbursement to Medi-Cal.

321. As another example, on or about January 27, 2018, Patient D.P. was treated at Adventist Health Clear Lake—a Critical Access Hospital and Covered Entity operated by Relator in Clearlake, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). D.P. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about February 5, 2018, Adventist Health Clear Lake submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Clear Lake to report an inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of D.P.'s prescription, or $4.23 for eight units. In other words, Sanofi drastically overcharged Adventist Health Clear Lake for this drug, which caused Adventist Health Clear Lake to submit a false claim for reimbursement to Medicare.

322. As another example, on or about February 28, 2018, Patient C.B. was treated at Adventist Health Clear Lake—a Critical Access Hospital and Covered Entity operated by Relator in Clearlake, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). C.B. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about June 12, 2018, Adventist Health Clear Lake submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Clear Lake to report an inflated cost for the drug, and Medi-Cal provided reimbursement at 101% of the fraudulently inflated cost of C.B.'s prescription, or $17.21 for fifteen units. In other words, Sanofi drastically overcharged Adventist Health Clear Lake for this drug, which caused Adventist Health Clear Lake to submit a false claim for reimbursement to Medi-Cal.

323. As another example, on or about March 13, 2018, Patient P.G. was treated at Adventist Health Sonora—a Disproportionate Share Hospital and Covered Entity operated by Relator in Sonora, California—and was prescribed Lantus 100

units/ml (NDC 00088222033). P.G. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about March 20, 2018, Adventist Health Sonora submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Sonora to report an inflated actual acquisition cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of P.G.'s prescription, or $7.70 for four units. In other words, Sanofi drastically overcharged Adventist Health Sonora for this drug, which caused Adventist Health Sonora to submit a false claim for reimbursement to Medi-Cal.

324. As another example, on or about April 13, 2018, Patient C.L. was treated at Adventist Health Clear Lake—a Critical Access Hospital and Covered Entity operated by Relator in Clearlake, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). C.L. was a beneficiary of Medicare and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about April 20, 2018, Adventist Health Clear Lake submitted a claim to Medicare. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Clear Lake to report an inflated cost for the drug, and Medicare provided reimbursement at 101% of the fraudulently inflated cost of C.L.'s prescription, or $12.96 for six units. In other words, Sanofi drastically overcharged Adventist Health Clear Lake for this drug, which caused Adventist Health Clear Lake to submit a false claim for reimbursement to Medicare.

325. As another example, on or about May 17, 2018, Patient S.L. was treated at Adventist Health Howard Memorial—a Critical Access Hospital and Covered Entity operated by Relator in Willits, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). S.L. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about

August 30, 2018, Adventist Health Howard Memorial submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Howard Memorial to report an inflated cost for the drug, and Medi-Cal provided reimbursement at 101% of the fraudulently inflated cost of S.L.'s prescription, or $11.34 for eight units. In other words, Sanofi drastically overcharged Adventist Health Howard Memorial for this drug, which caused Adventist Health Howard Memorial to submit a false claim for reimbursement to Medi-Cal.

326. As another example, on or about June 15, 2018, Patient M.V. was treated at Adventist Health Clear Lake—a Critical Access Hospital and Covered Entity operated by Relator in Clearlake, California—and was prescribed Lantus 100 units/ml (NDC 00088222033). M.V. was a beneficiary of California Medicaid (Medi-Cal) and received their prescription directly from the hospital. At the time, Lantus 100 units/ml was subject to a Ceiling Price of $0.01 per unit. On or about June 22, 2018, Adventist Health Clear Lake submitted a claim to Medi-Cal. Based on Sanofi's fraudulent overcharge, Sanofi caused Adventist Health Clear Lake to report an inflated cost for the drug, and Medi-Cal provided reimbursement at the fraudulently inflated cost of M.V.'s prescription, or $9.62 for six units. In other words, Sanofi drastically overcharged Adventist Health Clear Lake for this drug, which caused Adventist Health Clear Lake to submit a false claim for reimbursement to Medi-Cal.

327. By way of further example, a Federally Qualified Health Center (FQHC) in Illinois that is a 340B Covered Entity submitted the following claim to the Illinois Medicaid program where the Illinois FQHC should, but did not, receive the penny pricing Ceiling Price from Sanofi. In this example, the Illinois FQHC charged the Illinois Medicaid program the same rate that it had paid to obtain the drug. Accordingly, Sanofi's misconduct resulted in the Illinois FQHC's unwitting submission of reimbursement claims to the Illinois Medicaid program at the increased rate, rather than the penny pricing Ceiling Price.

328. By way of further example, on or about March 7, 2017, Dr. J.L. wrote a prescription for Lantus Vial 100 U/ml (NDC 00088222033) for an Illinois Medicaid beneficiary, who received their prescription directly from the Illinois FQHC on or about on or about April 19, 2017. The Illinois FQHC submitted a reimbursement claim for the prescription to Illinois Medicaid at a per-package rate of $70.86 and received reimbursement from Illinois Medicaid at the same rate. As described above, Lantus Vial 100 U/ml is manufactured by Sanofi and was subject to a penny pricing Ceiling Price; however, Sanofi drastically overcharged Covered Entities like the Illinois FQHC for this drug.

VIII. CAUSES OF ACTION

COUNT I

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

329. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

330. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for reimbursement of the cost of their drugs, in violation of 31 U.S.C. § 3729(a)(1)(A).

331. Because of each Defendant's actions, the United States of America has been, and continues to be, severely damaged.

COUNT II

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

332. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

333. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made

or used false records or statements material to the payment of false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B).

334. The United States of America, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid for drugs provided to recipients of health care programs funded by the United States.

335. Because of each Defendant's actions, the United States of America has been, and continues to be, severely damaged.

COUNT III

(Violation of False Claims Act, 31 U.S.C. § 3729(a)(1)(G))

336. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

337. Each Defendant: (i) knowingly made, used, or caused to made or used, a false record or statement material to an obligation to pay or transmit money or property to the United States, or (ii) knowingly concealed, avoided, or decreased an obligation to pay or transmit money or property to the United States.

338. Because of each Defendant's actions, the United States of America has been, and continues to be, severely damaged.

COUNT IV

(Violation of California False Claims Act)

339. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

340. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented, and is still presenting or causing to be presented false or fraudulent claims for payment or approval in violation of Cal. Gov't Code § 12651(a)(1).

341. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Cal. Gov't Code § 12651(a)(2).

342. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of California or its political subdivisions, in violation of Cal. Gov't Code § 12651(a)(7).

343. The State of California or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continues to pay, for their drugs provided to recipients of health care programs funded by the State of California.

344. Because of each Defendant's actions, the State of California and its political subdivisions have been, and continue to be, severely damaged.

COUNT V

(Violation of Colorado Medicaid False Claims Act)

345. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

346. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented, or caused to be presented to an officer or employee of the State of Colorado or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Colo. Rev. Stat. § 25.5-4-305(a).

347. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Colo. Rev. Stat. § 25.5-4-305(b).

348. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado or its political subdivisions, in violation of Colo. Rev. Stat. § 25.5-4-305(f).

349. The State of Colorado or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health care programs funded by the State of Colorado.

350. Because of each Defendant's actions, the State of Colorado and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT VI

(Violation of Connecticut False Claims Act for Medical Assistance Programs)

351. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

352. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and is still presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of Conn. Gen. Stat. § 4-275(a)(1).

353. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid, in violation of Conn. Gen. Stat. § 4-275(a)(2).

354. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions, in violation of Conn. Gen. Stat. § 4-275(a)(7).

355. The State of Connecticut or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health care programs funded by the State Connecticut.

356. Because of each Defendant's actions, the State of Connecticut and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT VII

(Violation of Delaware False Claims and Reporting Act)

357. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

358. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Delaware or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Del. Code tit. 6, §1201(a)(1).

359. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Delaware or its political subdivisions, in violation of Del. Code tit. 6, §1201(a)(2).

360. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the State of Delaware or its political subdivisions, in violation of Del. Code tit. 6, § 120l(a)(7).

361. The State of the State of Delaware or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health care programs funded by the State of Delaware.

362. Because of each Defendant's actions, the State of Delaware and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT VIII

(Violation of District of Columbia False Claims Act)

363. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

364. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented, or caused to be presented to an officer or employee of the District of Columbia, false or fraudulent claims for payment or approval, in violation of D.C. Code § 2-381.02(a)(l).

365. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be used, false records or statements to get false claims paid or approved by the District of Columbia, in violation of D.C. Code § 2-381.02(a)(2).

366. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District of Columbia, in violation of D.C. Code § 2-381.02(a)(6).

367. The District of Columbia, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and continues to pay, for their drugs provided to recipients of health insurance programs funded by the District.

368. Because of each Defendant's actions, the District of Columbia has been, and continues to be, severely damaged.

COUNT IX

(Violation of Florida False Claims Act)

369. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

370. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Florida or its agencies, false or fraudulent claims for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

371. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity

of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or its agencies, in violation of Fla. Stat. § 68.082(2)(b).

372. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or its agencies, in violation of Fla. Stat. § 68.082(2)(g).

373. The State of Florida or its agencies, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance plans funded by the State of Florida or its agencies.

374. Because of each Defendant's actions, the State of Florida and/or its agencies have been, and continue to be, severely damaged.

COUNT X

(Violation of Georgia False Medicaid Claims Act)

375. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

376. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval, in violation of Ga. Code § 49-4-168.1(a)(1).

377. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made

or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program, in violation of Ga. Code § 49-4-168.1(a)(2).

378. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Georgia or its political subdivisions, in violation of Ga. Code § 49-4-168.1(a)(7).

379. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of Medicaid.

380. Because of each Defendant's actions, the State of Georgia and/or political subdivisions have been, and continue to be, severely damaged.

COUNT XI

(Violation of Hawaii False Claims Act)

381. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

382. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Hawaii or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(l).

383. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made and used, false records or statements to get false or fraudulent claims paid or

approved by the State of Hawaii or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(2).

384. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii or its political subdivisions, in violation of Haw. Rev. Stat. § 661-21(a)(7).

385. The State of Hawaii or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

386. Because of each Defendant's actions, the State of Hawaii and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XII

(Violation of Illinois False Claims Act)

387. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

388. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for payment or approval, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(A).

389. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to get false or fraudulent claims paid or

approved by the State of Illinois or its political subdivisions, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(B).

390. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois or its political subdivisions, in violation of 740 Ill. Comp. Stat. § 175/3(a)(1)(G).

391. The State of Illinois or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

392. Because of each Defendant's actions, the State of Illinois and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XIII

(Violation of Indiana False Claims and Whistleblower Protection Act)

393. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

394. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented false claims to the State of Indiana or its political subdivisions, for payment or approval, in violation of Ind. Code § 5-11-5.5-2(b)(l).

395. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, false records or statements to obtain payment or approval of false claims from

the State of Indiana or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(2).

396. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana or its political subdivisions, in violation of Ind. Code § 5-11-5.5-2(b)(6).

397. The State of Indiana or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of those claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

398. Because of each Defendant's actions, the State of Indiana and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XIV

(Violation of Iowa False Claims Act)

399. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

400. Each Defendant, in reckless disregard or deliberate ignorance for the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of Iowa Code § 685.2(1)(a).

401. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Iowa Code § 685.2(1)(b).

402. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Iowa or its political subdivisions, in violation of Iowa Code § 685.2(1)(g).

403. The State of Iowa or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

404. Because of each Defendant's actions, the State of Iowa and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XV

(Violation of Louisiana Medical Assistance Programs Integrity Law)

405. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

406. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented, or caused to be presented false or fraudulent claims, in violation of La. Rev. Stat. § 46:438.3(A).

407. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and is still engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of La. Rev. Stat. § 46:438.3(C).

408. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity

of the information, knowingly make, use, or cause to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the medical assistance programs, or to knowingly conceal, avoid, or decrease an obligation to pay or transmit money or property to the medical assistance programs, in violation of La. Rev. Stat. § 46:438.3(C).

409. The State of Louisiana, its medical assistance programs, political subdivisions, and/or the Department, unaware of the falsity of the claims and/or statements made by each Defendant, or their actions as set forth above, acted in reliance, and continue to act in reliance, on the accuracy of each Defendant's claims and/or statements in paying for their drugs provided to medical assistance program recipients.

410. Because of each Defendant's actions, the State of Louisiana, its medical assistance programs, political subdivisions, and/or the Department have been, and continue to be, severely damaged.

COUNT XVI

(Violation of Massachusetts False Claims Act)

411. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

412. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for payment or approval, in violation of Mass. Gen. Laws ch. 12 § 5B(1).

413. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to obtain payment or approval of claims by the

Commonwealth of Massachusetts or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(2).

414. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or its political subdivisions, in violation of Mass. Gen. Laws ch. 12 § 5B(8).

415. The Commonwealth of Massachusetts or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

416. Because of each Defendant's actions, the Commonwealth of Massachusetts and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XVII

(Violation of Michigan Medicaid False Claims Act)

417. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

418. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made or caused to be made, and is still making or causing to be made, false statements or false representations of material facts in an application for Medicaid benefits, in violation of Mich. Comp. Laws § 400.603(1).

419. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity

of the information, knowingly and intentionally made or caused to be made false statements or false representations of a material fact for use in determining rights to a Medicaid benefit, in violation of Mich. Comp. Laws § 400.603(2).

420. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and is still concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit, or the initial or continued right of any other person on whose behalf each Defendant has applied for or is receiving a benefit with intent to obtain a benefit to which each Defendant were not entitled or in an amount greater than that to which each Defendant were entitled, in violation of Mich. Comp. Laws § 400.603(3).

421. Each Defendant, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly and intentionally made, presented, or caused to be made or presented, and is still making, presenting, or causing to be presented, to an employee or officer of the State of Michigan or its political subdivisions, false claims under the Social Welfare Act, Mich. Comp. Laws §§ 400.1-400.122, in violation of Mich. Comp. Laws § 400.607(1).

422. The State of Michigan or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of Medicaid.

423. Because of each Defendant's actions, the State of Michigan and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XVIII

(Violation of Minnesota False Claims Act)

424. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

425. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Minnesota or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

426. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claim paid or approved by the State of Minnesota or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(2).

427. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota or its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

428. The State of Minnesota or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs.

429. Because of each Defendant's actions, the State of Minnesota and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XIX

(Violation of Montana False Claims Act)

430. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

431. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Montana or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Mont. Code § 17-8-403(1)(a).

432. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Montana or its political subdivisions, in violation of Mont. Code § 17-8-403(1)(b).

433. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana or its political subdivisions, in violation of Mont. Code § 17-8-403(1)(g).

434. The State of Montana or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

435. Because of each Defendant's actions, the State of Montana and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XX

(Violation of Nevada False Claims Act)

436. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

437. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false claims for payment or approval, in violation of Nev. Rev. Stat. § 357.040(1)(a).

438. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to obtain payment or approval of false claims, in violation of Nev. Rev. Stat. § 357.040(1)(b).

439. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada or its political subdivisions, in violation of Nev. Rev. Stat. § 357.040(1)(g).

440. The State of Nevada or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

441. Because of each Defendant's actions, the State of Nevada and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXI

(Violation of New Jersey False Claims Act)

442. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

443. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented or caused to be presented to an employee, officer, or agent of the State of New Jersey, or to any contractor, grantee, or other recipient of State funds, false or fraudulent claims for payment or approval, in violation of N.J. Stat. § 2A:32C-3(a).

444. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to made or used, false records or statements to get false or fraudulent claims paid or approved by the State of New Jersey or its political subdivisions, in violation of N.J. Stat. § 2A:32C-3(b).

445. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Jersey or its political subdivisions, in violation of N.J. Stat. § 2A:32C-3(g).

446. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of Medicaid.

447. Because of each Defendant's actions, the State of New Jersey and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXII

(Violation of New York False Claims Act)

448. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

449. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for payment or approval, in violation of N.Y. State Fin. Law § 189(1)(a).

450. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of N.Y. State Fin. Law § 189(1)(b).

451. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to an obligation to pay or transmit money to the State of New York or its political subdivisions, in violation of N.Y. State Fin. Law § 189(1)(g).

452. The State of New York or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

453. Because of each Defendant's actions, the State of New York and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXIII

(Violation of North Carolina False Claims Act)

454. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

455. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented, false or fraudulent claims for payment or approval, in violation of N.C. Gen. Stat. § 1-607(a)(1).

456. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of N.C. Gen. Stat. § 1-607(a)(2).

457. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina or its political subdivisions, in violation of N.C. Gen. Stat. § 1-607(a)(7).

458. The State of North Carolina or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of health insurance programs funded by the state or its political subdivisions.

459. Because of each Defendant's actions, the State of North Carolina and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXIV

(Violation of Oklahoma Medicaid False Claims Act)

460. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

461. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Oklahoma or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Okla. Stat. tit. 63, § 5053.1(B)(1).

462. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made or caused to be made, and is still making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Oklahoma or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(2).

463. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Oklahoma or its political subdivisions, in violation of Okla. Stat. tit. 63, § 5053.1(B)(7).

464. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of Medicaid.

465. Because of each Defendant's actions, the State of Oklahoma and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXV

(Violation of Rhode Island False Claims Act)

466. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

467. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the State of Rhode Island or a member of Rhode Island's National Guard, false or fraudulent claims for payment or approval, in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

468. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made or caused to be made, and is still making or causing to be made, false records or statements to get false or fraudulent claims paid or approved by the State of Rhode Island or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

469. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Rhode Island or its political subdivisions, in violation of R.I. Gen. Laws § 9-1.1-3(a)(7).

470. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of Medicaid.

471. Because of each Defendant's actions, the State of Rhode Island and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXVI

(Violation of Tennessee Medicaid False Claims Act)

472. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

473. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to the State of Tennessee or its political subdivisions, false or fraudulent claims for payment under the Medicaid program, in violation of Tenn. Code § 71-5-182(a)(1)(A).

474. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false or fraudulent records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee or its political subdivisions, in violation of Tenn. Code § 71-5-182(a)(1)(B).

475. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false or fraudulent records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee or its political subdivisions, relative to the Medicaid program, in violation of Tenn. Code § 71-5-182(a)(1)(D).

476. The State of Tennessee or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of the Medicaid program.

477. Because of each Defendant's actions, the State of Tennessee and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXVII

(Violation of Texas Medical Assistance Program, Damages, and Penalties Act)

478. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

479. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made or caused to be made, and is still making or causing to be made, false statements or misrepresentations of material fact that permitted each Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Tex. Hum. Res. Code § 36.002(1).

480. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed—and is still concealing or failing to disclose, or causing to be concealed or not disclosed—information that permitted each Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Tex. Hum. Res. Code § 36.002(2).

481. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, caused to be made, induced, or sought to induce, and is still making, causing to be made, inducing, or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a Federal or state law, rule, regulation or

provider agreement pertaining to the Medicaid program, in violation of Tex. Hum. Res. Code § 36.002(4)(B).

482. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, and is still making, claims under the Medicaid program for products that were inappropriate, in violation of Tex. Hum. Res. Code § 36.002(7)(C).

483. The State of Texas or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for prescription drugs for recipients of Medicaid.

484. Because of each Defendant's actions, the State of Texas and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXVIII

(Violation of Vermont False Claims Act)

485. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

486. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made or caused to be made, and is still making or causing to be made, false statements or misrepresentations of material fact that permitted each Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the benefit or payment that was authorized, in violation of Vt. Stat. tit. 32, § 631(a)(1)-(2).

487. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, or caused to be concealed or not disclosed—and is still concealing or failing to disclose, or causing

to be concealed or not disclosed—information that permitted each Defendant to receive a benefit or payment under the Medicaid program that was not authorized or that was greater than the payment that was authorized, in violation of Vt. Stat. tit. 32, § 631(a).

488. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, caused to be made, induced, or sought to induce, and is still making, causing to be made, inducing, or seeking to induce, false statements or misrepresentations of material fact concerning information required to be provided by a Federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program, in violation of Vt. Stat. tit. 32, § 631(a)(2).

489. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, and is still making, claims under the Medicaid program for products that were inappropriate, in violation of Vt. Stat. tit. 32, § 631(a).

490. The State of Vermont or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance on the accuracy of these claims and/or statements, paid, and continue to pay, for prescription drugs for recipients of Medicaid.

491. Because of each Defendant's actions, the State of Vermont and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXIX

(Violation of Virginia Fraud Against Taxpayers Act)

492. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

493. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented to an officer or employee of the Commonwealth of Virginia or its political subdivisions, false or fraudulent claims for payment or approval, in violation of Va. Code § 8.01-216.3(A)(1).

494. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth of Virginia or its political subdivisions, in violation of Va. Code § 8.01-216.3(A)(2).

495. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Virginia or its political subdivisions, in violation of Va. Code § 8.01-216.3(A)(7).

496. The Commonwealth of Virginia or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

497. Because of each Defendant's actions, the Commonwealth of Virginia and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXX

(Violation of Washington Medicaid False Claims Act)

498. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

499. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for payment of approval, in violation of Wash. Rev. Code § 74.66.020(1)(a).

500. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of Wash. Rev. Code § 74.66.020(1)(b).

501. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Washington or its political subdivisions, in violation of Wash. Rev. Code § 74.66.020(1)(g).

502. The State of Washington or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

503. Because of each Defendant's actions, the State of Washington and/or its political subdivisions have been, and continue to be, severely damaged.

COUNT XXXI

(Violation of False Claims to Government of Puerto Rico Programs, Contracts, and Services Act)

504. Relator incorporates by reference the preceding paragraphs of this Complaint as though fully set forth herein.

505. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally presented or caused to be presented false or fraudulent claims for payment of approval, in violation of P.R. Laws tit. 32, § 2934(1)(a).

506. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements material to false or fraudulent claims, in violation of P.R. Laws tit. 32, § 2934(1)(b).

507. Each Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly and intentionally made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Puerto Rico or its political subdivisions, in violation of P.R. Laws tit. 32, § 2934(1)(d).

508. The Commonwealth of Puerto Rico or its political subdivisions, unaware of the falsity of the claims and/or statements made by each Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and continue to pay, for their drugs provided to recipients of state funded health insurance programs.

509. Because of each Defendant's actions, the Commonwealth of Puerto Rico and/or its political subdivisions have been, and continue to be, severely damaged.

IX. PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against each Defendant as follows:

a. That each Defendant be ordered to cease and desist from submitting any more false claims, or further violating the federal FCA and State FCAs.

b. Three times the amount of damages to the United States and the Whistleblower States;

c. The maximum per-violation civil penalties as provided under federal FCA and the State FCAs; including a per-violation civil penalty of not less than $13,508 or more than $27,018 per false claim, as adjusted for inflation as provided by 31 U.S.C. § 3729(a) and 15 C.F.R. § 63(a)(3);

d. That each Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

e. That judgment be granted for Relator against each Defendant for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator in the prosecution of this suit;

f. Any other recoveries or relief provided for under the federal FCA and the State FCAs, including prejudgment and post-judgment interest;

g. That the Court issue an order enjoining each Defendant from continuing to engage in the fraudulent conduct alleged herein; and

h. That this Court award such further relief as it deems just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all claims so triable in this action.

Dated: November 7, 2023 By: Kenneth Capesius

Kenneth D. Capesius (SBN 347555)*
kcapesius@baronbudd.com
W. Scott Simmer (admitted *pro hac vice*)
ssimmer@baronbudd.com
Noah M. Rich (admitted *pro hac vice*)
nrich@baronbudd.com
BARON & BUDD, P.C.
600 New Hampshire Ave. NW, 10th Floor
Washington, DC 20037
Telephone: 202.333.4562
Facsimile: 214.523.6600

Roland Tellis (SBN 186269)
rtellis@baronbudd.com
Mark Pifko (SBN 228412)
mpifko@baronbudd.com
BARON & BUDD, P.C.
15910 Ventura Blvd., Suite 1600
Encino, CA 91436
Telephone: 818.839.2333
Facsimile: 214.520.1181

William H. von Oehsen (admitted *pro hac vice*)
William.vonOehsen@PowersLaw.com
Ronald S. Connolly (admitted *pro hac vice*)
Ron.Connelly@PowersLaw.com
POWERS PYLES SUTTER & VERVILLE PC
1501 M Street NW, 7th Floor
Washington, DC 20005
Telephone: 202.872.6765
Facsimile: 202.785.1756

*Admitted only in California

Attorneys for Relator