IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER, **Plaintiffs, **v.** **NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., CURASCRIPT, INC., CVS CAREMARK CORPORATION,** **Defendants.**	**THIRD AMENDED COMPLAINT** **CIVIL ACTION No. 11-8196 (McMahon, J.)** **JURY TRIAL REQUESTED**

THIRD AMENDED COMPLAINT
(False Claims Act)

SUMMARY STATEMENT

1. This lawsuit involves a scheme by Defendant Novartis Pharmaceuticals Corporation ("Novartis"), one of the largest manufacturers of pharmaceutical products in the world, to pay kickbacks to owners of specialty pharmacies, including, but not limited to Defendants Accredo Health Group, Inc. ("Accredo"), Curascript, Inc. ("Curascript"), and CVS Caremark Corporation ("Caremark"). Novartis paid kickbacks to induce these pharmacies to recommend that patients order Novartis specialty medications reimbursed by federal and state health care programs, including, but not limited to, the iron chelating drug Exjade, the myeloid leukemia, oral cancer drugs Gleevec and Tasigna, the cystic fibrosis drug Tobramycin Inhalation Solution ("TOBI"), and the organ transplant drug Myfortic.

2. In Novartis' own words, the pharmaceutical manufacturer seeks to "leverage" the "[r]ole of key influencers such as Specialty Pharmacies." Novartis "leverages" specialty pharmacies by offering them financial inducements, such as referrals of patients and cash "rebates" or "discounts" pegged to the pharmacy's "performance" in achieving Novartis' sales goals, in exchange for the specialty pharmacies' agreement to use pharmacists, nurses and other staff—perceived as objective and acting in the best medical interests of patients—to recommend and increase the sales and market share for Novartis specialty drug products thereby.

3. Novartis' scheme exploits for its own corrupt purposes the special trust that patients place in their pharmacists. Patients rely on the expertise and objectivity of their

pharmacists when seeking advice on whether to order, refill, discontinue or change medications. Unbeknownst to these patients, and to the public at large, Novartis has corrupted the objectivity of the specialty pharmacies with whom they do business by rewarding those pharmacies with kickbacks—including "rebate" payments and promises of future patient referrals—in exchange for the pharmacies' efforts to encourage their patients to increase orders of Novartis medications. This secret, illegal financial compensation induces pharmacists to increase sales of Novartis' targeted drugs that are often more expensive for payers like Medicare and Medicaid and less efficacious and safe, than other drugs sold by the competition. Neither Novartis nor the specialty pharmacies that participate in this scheme disclose to patients or physicians that the pharmacists are receiving financial inducements.

4. Publicly-funded health care programs are forbidden by law and by regulation from reimbursing pharmacies for medications that were ordered as a result of the payment of kickbacks.

5. As a result of this scheme, Novartis knowingly caused specialty pharmacies, including, but not limited to the Defendant pharmacies named in this complaint, to submit hundreds of millions of dollars in false claims to publicly-funded health care programs for reimbursement for orders of specialty medicines, including Exjade, Gleevec, Tasigna, TOBI, Myfortic, and others, that were ordered as a result of kickbacks from Novartis.

6. The Defendant pharmacies acted knowingly in submitting hundreds of millions of dollars in false claims to publicly-funded health care programs for medicines that were ordered as a result of kickbacks.

7. *Qui Tam* Plaintiff David M. Kester ("Kester" or "Relator"), a former Respiratory Account Manager II for Defendant Novartis, brings this civil action on behalf of and in the name of the United States of America ("United States") under the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and on behalf of and in the name of the state plaintiffs under analogous *qui tam* provisions in state false claims laws.

JURISDICTION AND VENUE

8. All Counts of this Complaint are civil actions by Relator, acting on behalf of and in the name of the United States and the state plaintiffs, against the Defendants under the federal False Claims Act, 31 U.S.C. §§ 3729-3733, and analogous state false claims laws.

9. This Court has jurisdiction over the claims brought on behalf of the United States pursuant to 28 U.S.C. §§ 1331 and 1345, and 31 U.S.C. § 3732(a).

10. This Court has jurisdiction over the state law claims alleged herein under 31 U.S.C. § 3732(b). In addition, the Court has supplemental jurisdiction over the claims brought on behalf of the state plaintiffs under 28 U.S.C. § 1367.

11. The False Claims Act provides that an action under 31 U.S.C. § 3730 may be brought "in any judicial district in which . . . any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred." 31 U.S.C. § 3732(a). The Defendants all transact business in this judicial district by, among other things, shipping specialty medications to customers residing in this judicial district. Indeed, the Borough of Manhattan is a large market for the specialized medications at issue in this complaint. Moreover, former defendant BioScrip owns and operates a pharmacy in Manhattan and has its corporate

headquarters in this judicial district. Accordingly, this Court has personal jurisdiction over the Defendants, and venue is appropriate in this district. 31 U.S.C. § 3732(a). Venue is also proper under 28 U.S.C. § 1391.

12. None of the allegations set forth in this Complaint is based on a public disclosure of allegations or transactions in a criminal, civil or administrative hearing, in a congressional, administrative or General Accounting Office report, hearing, audit or investigation, or from the news media. Relator David M. Kester has direct and independent knowledge of the information on which the allegations set forth in this Complaint are based. Moreover, prior to filing this lawsuit and prior to any public disclosures regarding this matter, Relator voluntarily provided the information set forth herein to agents of the United States Department of Justice.

13. None of the allegations or transactions set forth in this Complaint is substantially the same as allegations or transactions that have been publicly disclosed in a Federal criminal, civil or administrative hearing in which the Government or its agent is a party, or in a congressional, administrative or Government Accountability Office, or other Federal report, hearing, audit or investigation, or from the news media.

THE PARTIES

Relator David M. Kester

14. David Kester was born in Atlanta, Georgia. He received a Bachelor of Arts Degree in Chemistry from the University of North Carolina at Chapel Hill in 1981. Since then, he has worked in the area of sales and marketing for industrial chemical and pharmaceutical manufacturers. He has received multiple awards and repeated recognition for outstanding

performance during his career. For example, Morton Thiokol, Inc. named him Salesman of the Year in 1989 and 1990; Pharmacia recognized that he was 3rd of 23 managers in sales growth in 2003; and Chiron Corporation Biopharmaceuticals ranked him 7th in its President's Club Ranking in 2004 and 3rd in its Presidents Club Ranking through May 2005.

15. Relator was hired by Defendant Novartis in 2006 as an Area Sales Manager I. He subsequently worked for Novartis as an Area Sales Manager II with responsibility for managing nine sales representatives in North Carolina, Virginia, West Virginia, Maryland, South Carolina, Georgia, Florida, Alabama, Mississippi, Tennessee, Louisiana, Texas, Oklahoma, Arkansas, and Kentucky, who are assigned to market the cystic fibrosis drug TOBI. Beginning with his first full calendar year at the company, Novartis repeatedly has recognized Relator's exceptional management and sales ability. In 2007, he received the company's "Impact Award," an honor reserved for those managers who possess the confidence, competence, and accountability that impacts the productivity of one's team and drives results. In 2008, he received both the "Impact Award" and the President's Club Award for a Top Area; the latter is given to the manager with the highest area sales attainment versus goal for the year. In 2009, he was promoted. In 2010, he once again received the President's Club Award for a Top Area. On September 6, 2012, he was named Respiratory Account Manager II. On April 12, 2013, Relator resigned from his employment at Novartis, effective April 19, 2013.

16. On a number of occasions during his tenure at Novartis, Relator spoke up about Novartis practices that he felt were improper or illegal. Each time, he has suffered retaliation as a result. In August 2010, Relator voiced concerns through an intermediate-level manager to a

Novartis vice president about whether a sales pitch proposed by the vice president might be "off-label" and thus illegal. In response, the vice president challenged him in front of the entire sales team the next morning and aggressively disagreed with his position. In addition, despite record sales accomplishments in 2010, his merit raise in February 2011 was the lowest since he joined Novartis. The company provided an explanation that made no logical sense. Relator did not raise the matters alleged herein with company management because he was certain that his doing so would not lead to changes in practices, but rather would result in his facing serious retaliatory measures.

17. Relator currently resides in Raleigh, North Carolina.

Plaintiff United States Of America

18. Relator brings this action on behalf of the United States pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 *et seq*.

19. On behalf of the United States, Relator seeks recovery for damages to federally-funded health insurance programs, including, but not limited to, the federal-state Medicaid drug benefit program, established under Title XIX of the Social Security Act, 42 U.S.C. §1396 *et seq.*, and state laws; the Medicare Part D program, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395w-101 through 1395w-154; and the U.S. Department of Defense TRICARE and CHAMPUS health care programs, established pursuant to 10 U.S.C. § 1071 *et seq*.

20. The Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health & Human Services ("HHS") funds and oversees the joint federal-state

funded Medicaid Program for the financially needy. The state plaintiffs participate in the Medicaid program, under which they pay for pharmaceutical drugs in certain circumstances and for certain indigent individuals who are beneficiaries of such programs. Reimbursement for drugs covered by a state Medicaid program is made by each state's Medicaid program agency, which, in turn, seeks reimbursement for a portion of its expenditures from the federal government.

21. CMS funds and oversees the Medicare Part D program, which covers a portion of prescription drug expenses for individuals eligible for traditional Medicare who have voluntarily enrolled in a Part D plan. The enrollee must pay plan premiums, co-payments and co-insurance, and a deductible. In addition, the enrollee must pay 100% of his or her prescription drug expenditures when those expenditures for the year fall within a specified financial bracket (the so-called "donut hole"). All of the Defendant pharmacy corporations participated in the Medicare Part D program.

22. This complaint incorporates by reference Paragraphs 22-32 of the United States' Second Amended Complaint which set forth in detail how Medicare Part D pays for prescription medication.

23. In order to obtain payment from Medicare's Part D program, all the pharmacies that received kickbacks from Novartis (including, but not limited to, the Defendant pharmacies here) entered into contracts with so-called "Part D Plan Sponsors" in which they agreed to comply with all applicable law and to assume the obligations of the Part D sponsors, which their contracts expressly define to include compliance with federal anti-kickback law. ,

In order to obtain payment from state Medicaid programs, the pharmacies were also required to certify compliance with the federal and state anti-Kickback laws, regulations, and contract conditions. For instance, in New York, pharmacies must periodically sign a "Certification Statement for Provider Billing Medicaid," in which the provider certifies that claims submitted "to the State's Medicaid fiscal agent, for services or supplies furnished," "will be subject to the following certification. . . . I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations." Additional examples of express certifications are listed below, at paragraphs 52 to 72.

State Plaintiffs

24. Relator brings this action, in whole or in part, on behalf of the states of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland (with regard only to the claims on which Maryland has not declined to intervene), Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia and Wisconsin, and the District of Columbia ("the state plaintiffs"). Relator brings this action under the *qui tam* provisions of the following false claims laws of the state plaintiffs: California False Claims Law, Cal. Gov. Code § 12650 *et seq.*; Colorado Medicaid False Claims Act, Col. Rev. Stat. 25.5-4-303.5 through 25.5-4-310 (2010); Conn. Gen. Stat. § 17b-301d (2010); Delaware False Claims and Reporting Act, 6 Del. C. § 1201 *et seq.*; Florida False Claims Act, Fla. Stat. §§ 68-081-68.09; Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B; Hawaii

False Claims Law, HRS § 661-21 *et seq*.; Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq*.; Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5.-1 *et seq*.; Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq*.; Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611 (2010); Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq*.; Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq*.; Minnesota False Claims Act, Minn.Stat. § 15C.01 *et seq*.; Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq*.; Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq*.; the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*.; New York False Claims Act, NY State Finance Law, Art. 13, § 187 *et seq*.; North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*. (2010); Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 (2011) *et seq*.; Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010); Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185; Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq*.; Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*.; Wisconsin False Claims for Medical Assistance, Wis. Stat. § 20.931; and the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.

25. On behalf of the state plaintiffs, Relator seeks recovery for damages caused by the submission of false claims to state-funded health insurance programs, including but not limited to: a) the federal-state Medicaid programs that are jointly funded by the United States and the state plaintiffs; and b) other state health insurance programs, such as New York's Program for

Elderly Pharmaceutical Insurance Coverage, that cover some or all of the costs of prescription medication.

The Manufacturer Named As Defendant

Novartis Pharmaceuticals Corporation

26. Novartis Pharmaceuticals Corporation ("Novartis") researches, develops, manufactures and distributes medications. Novartis is owned, through a United States holding company, by Novartis International AG, a pharmaceutical manufacturer headquartered in Basel, Switzerland. Novartis' corporate headquarters in the United States are in East Hanover, New Jersey. In 2010, Novartis AG had total sales of $50.6 billion and net income of $3.4 billion, and it had 161,500 employees worldwide.

27. Novartis manufactures and sells a number of "specialty medications," *i.e.*, drugs that may be particularly costly or require special handling, administration or monitoring, and that are used to treat chronic, complex conditions.

28. Novartis entered into the kickback arrangements alleged herein while knowing that these kickbacks were prohibited by federal and state law, regulation, policy and contract condition. Novartis also knew that its kickbacks and other inducements would cause many pharmacies (including the Defendant pharmacies named herein) to submit claims to the federal and state governments which requested reimbursement for the cost of the Novartis drugs that the pharmacies had dispensed to patients. And Novartis knew that federal and state governments required, as a condition of paying any such claim for reimbursement, that the pharmacies not have violated any federal or state laws, regulations, or contract conditions that forbade them from accepting kickbacks.

The Specialty Pharmacies

29. Novartis has entered into illegal kickback schemes with numerous entities that own specialty pharmacies or operate specialty pharmacy franchise programs. Relator identifies herein four of those entities that handle particularly large number of prescriptions of the Novartis' specialty medications at issue in this Second Amended Complaint.

Accredo Health Group, Inc.

30. Defendant Accredo Health Group, Inc. ("Accredo"), headquartered in Memphis, Tennessee, is a wholly-owned subsidiary of Medco Health Solutions, Inc. ("Medco"). Accredo is one of the largest specialty pharmacies and, as of 2010, was the largest mail order pharmacy in the United States. Through so-called Therapeutic Resource Centers, Accredo provides specialty pharmacy and related services for individuals with complex and chronic health conditions. According to the company's website, Accredo's "pharmacists and other healthcare professionals talk frequently with patients over the phone, helping them follow their treatment and educating them about their condition." Accredo further maintains on its website that its "therapy management consists of clinically based protocols developed for each of the medication categories for which we provide services. Accredo's clinical protocols help to provide optimal clinical outcomes for you, the patient." Accredo also assures drug manufacturers that the pharmacy engages in "[r]egular communication with physician offices" with pharmacy teams providing "regular updates to physicians, alerting them to adherence issues, adverse events and other anomalies." Accredo dispenses approximately 200 specialty drugs from approximately 83 dispensing pharmacies nationwide.

31. Pursuant to kickback arrangements alleged herein, Accredo has distributed Exjade, TOBI, Gleevec and Tasigna.

32. On or about April 2012, Accredo's parent company, Medco, was acquired by Express Scripts.

BioScrip Corporation

33. BioScrip Corporation ("BioScrip"), a former defendant herein, is headquartered in Elmsford, New York. BioScrip owns 34 specialty pharmacies across the country, including both community pharmacies and mail service facilities. The company specializes, among other things, in providing specialty pharmaceutical products for patients with chronic and acute health care conditions. BioScrip owns a community pharmacy located at 197 8th Avenue in New York, N.Y. In its 2010 Annual Report, BioScrip states as follows: "[W]e proactively contact patients in instances of missed refills and alert physicians and other health care providers when the patient can't be located." The company boasts in its annual report that it achieves "higher compliance rates [*i.e.*, taking medications properly] as compared to industry averages and other documented and available metrics [*i.e.*, refill rates]."

34. Through the kickback arrangements alleged herein, Bioscrip sold Exjade, one of the specialty drugs at issue herein.

Curascript, Inc.

35. Defendant Curascript, Inc. ("Curascript"), a wholly-owned subsidiary of Express Scripts, Inc., is a specialty pharmaceutical services company headquartered in Orlando, Florida. The company supplies specialty medications through mail order pharmacies and operates

specialty care management programs that focus on improving patient compliance and adherence to drug therapy.

36. Through the kickback arrangements set forth herein, Curascript sells and distributes the Novartis drugs Gleevec, Tasigna, and TOBI.

CVS Caremark Corporation

37. Defendant CVS Caremark Corporation ("Caremark"), which is headquartered in Woonsocket, Rhode Island, and incorporated in Delaware, is the largest provider of prescription medications and the largest owner and operator of specialty pharmacies in the United States. In 2010, the company's net income exceeded $3.4 billion. Caremark fills or manages more than one billion prescriptions per year.

38. At approximately 66 retail and 18 mail order "specialty pharmacy stores," Caremark dispenses "specialty medications" and provides related counseling." Caremark defines "specialty medications" as ones that treat "complex conditions" and which "may be injectable and infused, high cost, [and/or] have special delivery and storage requirements." Caremark maintains on its website that patients enrolled at one of its specialty pharmacies are "assigned to a clinician-led CareTeam" that is "experienced in helping people with serious medical conditions get the most out of their health care through disease education and counseling."

39. Defendant Caremark owns Theracom, LLC, a unit that provides "commercialization support services" to the biopharmaceutical, device, diagnostic and vaccine manufacturing communities. Theracom maintains on its website that it helps pharmaceutical and other

manufacturers assure successful product commercialization by, among other things, "removing barriers to access ... providing responsive, quality care to patients, and offering the highest levels of service to patients, physicians, specialty pharmacies, product distributors and other care providers." Moreover, the company bills itself as working on behalf of the manufacturer "often as an extension of the manufacturer's brand, to deliver services that will lead to successful product uptake and support the ultimate dispensing or distribution of the product on a patient-by-patient basis." Amerisource Bergen purchased the unit for $257.2 million in November 2011.

40. Through the kickback transactions alleged herein, Caremark sells and distributes the Novartis drugs Gleevec, Tasigna, and TOBI. Relator asserts claims against Defendant Caremark only for the time period after March 2010.

STATUTORY BACKGROUND

The Federal Health Care Program Anti-Kickback Statute

41. The Federal Health Care Program Anti-Kickback Statute ("AKS"), enacted as Section 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b), prohibits persons from offering, paying, soliciting, or receiving illegal remunerations "in return for . . . arranging for or recommending purchasing, leasing or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(1)(B) and (2)(B). The types of illegal remuneration covered specifically include kickbacks, rebates, and bribes, whether paid directly or indirectly, overtly or covertly, in cash or in kind. 42 U.S.C. § 1320a-7b(b)(1) and (2). The terms "good" and "item" as used in the statute include prescription medication. Several of the states have analogous anti-kickback statutes. *See*, *e.g.*,

Fla. Stat., Ch. 409.920(2)(e).

42. Federal regulations, codified at 42 C.F.R. 1001.952, identify certain narrowly defined financial transactions known as "safe harbors" that do not come within the prohibitions of the AKS. Persons or entities relying on the safe harbor exceptions to avoid liability under the AKS have the burden of affirmatively proving their strict compliance with all conditions set forth in the statutory exceptions. None of the "safe harbors" covers the violations of the AKS described in this Complaint.

43. The AKS covers any arrangement in which one purpose of the remuneration is to induce another to recommend or arrange for the purchasing, leasing or ordering of goods or items that will be paid for by a federal health program, even if other motivations are also present.

44. The HHS Office of Inspector General has identified several characteristics of arrangements among sellers, sales agents, and purchasers that appear to be associated with an increased potential for program abuse, particularly overutilization and excessive program costs. These characteristics include the following, each of which is present in the Novartis scheme at issue in this complaint:

- Compensation based on percentage of sales;
- Direct billing of a Federal health care program by the Seller for the item or services sold by the sales agent;
- Direct contact between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;
- Direct contact between the sales agent and Federal health care program beneficiaries;

- Use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients; and,

- Marketing of items or services that are separately reimbursable by a Federal health care program (*e.g.*, items or services not bundled with other items or services covered by a DRG payment), whether on the basis of charges or costs.

Advisory Request No. 99-3; Advisory Request No. 98-10.

45. In August 1994, the HHS Office of Inspector General issued a Special Fraud Alert, that was later published in the Federal Register, warning pharmaceutical companies and pharmacies that it had learned of certain aggressive, pharmaceutical marketing practices in which drug manufacturers made payments to pharmacies and physicians and that these practices would implicate the criminal anti-kickback statute if "one purpose of any of these marketing schemes is to induce the provision of a prescription drug item reimbursable by Medicaid. There is no statutory exception or 'safe harbor' to protect such activities." 94 Fed. Reg. 31,157 (Dec. 19, 1994). One of the three practices the HHS Office of Inspector General singled out for special mention was a "conversion" program in which a drug manufacturer made cash payments to pharmacies in exchange for the pharmacies persuading physicians to switch patients from a competitor's drug to the manufacturer's drug. The HHS Office of Inspector General pointed out the public safety concerns at issue:

> Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product.

59 Fed. Reg. 65372.

AKS Compliance as Condition of Payment

46. "[A] claim that includes items or services resulting from a violation" of the AKS "constitutes a false or fraudulent claim for purposes of [the civil False Claims Act]." 42 U.S.C. § 1320a-7b (g).

47. Compliance with the AKS is a necessary condition to the right of all health care providers, including pharmacies, to receive or retain payments from the Medicare, Medicaid, or TRICARE programs.

48. The U.S. Department of Defense regulations for the CHAMPUS program provide that: "Providers seeking payment from the Federal Government through programs such as CHAMPUS have a duty to familiarize themselves with, *and comply with*, the program requirements." 32 C.F.R. §199.1(a)(4) (emphasis added). Those program requirements, in turn, provide for mandatory suspension or exclusion from CHAMPUS for those found liable for civil fraud against CHAMPUS, or convicted of criminal fraud against any federal health care program; they expressly state that fraud includes: "[a]rrangements by providers with employees, independent contractors, suppliers, or others which appear to be designed primarily to overcharge the CHAMPUS through various means (such as commissions, fee-splitting, and kickbacks) used to divert or conceal improper or unnecessary costs or profits." 32 C.F.R. §199.1(c)(12) and (i)(B) and (D) (emphasis added). Per 32 CFR 199.17(r), all fraud, abuse, and conflict of interest requirements for the basic CHAMPUS program, as set forth in Part 199, are applicable to the TRICARE program.

Express Certifications of Compliance with the AKS

Medicare Part D

49. Pharmacies billing Medicare Part D must expressly certify their compliance with the AKS. Thus, the regulations governing Medicare Part D require that pharmacies billing Part D enter into contracts with sponsors in which they agree to "comply with the Medicare Part D sponsor's contractual obligations" when providing services. 42 C.F.R. § 423.505(i)(3)(iii). Those obligations include compliance with "Federal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to applicable provisions of Federal criminal law, the False Claims Act . . . and the anti-kickback statute." 42 C.F.R. § 423.505(h)(1) (setting forth requirements for sponsors' annual contracts). In addition, pharmacies contracting with Part D sponsors must agree in their contracts to "comply with all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(3)(iv).

Medicaid

49. In order for a pharmacy to be eligible to bill and obtain payment from Medicaid, the state Medicaid programs require the pharmacy to abide by applicable federal and state law, including federal and/or state anti-kickback law. State programs require compliance with such laws as a precondition of payment. For example, in Illinois, in order to bill Medicaid, a pharmacy must first enter into an agreement in which it acknowledges that "compliance with such laws and handbook provisions [regarding services] is a condition of payment for all claims submitted." (Agreement for Participation in the Illinois Medical Assistance Program (available at: http://www.hfs.illinois.gov/assets/hfs1413t.pdf) (accessed on October 19, 2011).) The

referenced handbook provides in turn as follows: "Providers are subject to State and federal laws pertaining to penalties for vendor fraud *and kickbacks*." (Illinois Handbook for Providers of Medical Services, Chapter 100 – General Policy & Procedures, Section 136 (available at: http://www.hfs.illinois.gov/assets/100.pdf) (accessed on October 19, 2011) (emphasis added).) In Michigan, pharmacies billing Medicaid agree to comply with the policies and procedures for the Michigan Medical Assistance Program contained in the Medicaid Provider Manual. (Michigan Medical Provider Enrollment & Trading Partner Agreement (available at: http://www.michigan.gov/documents/Dch-1625_Provider_EnrollmentAgreement1659467.pdf) (accessed on October 19, 2011).) The Michigan Provider Manual expressly states that "receiving kickbacks" is an example of prohibited "Medicaid fraud." (Michigan Department of Community Health Medicaid Provider Manual, pp. 40-41 (available at: http://www.mdch.state.mi.us/dch-medicaid/manuals/ MedicaidProviderManual.pdf) (accessed on October 19, 2011).) In Florida, pharmacies agree that they must be in compliance with federal, state and local law before Florida "may make payments for medical assistance." (Florida Non-Institutional Medicaid Provider Agreement (available at: http://www.doh.state.fl.us/demo/BrainSC/Medicaid/MPA_Non-Inst_ July_081.pdf) (accessed on October 19, 2011).) The Provider Handbook then sets forth the Florida Anti-Kickback Statute as an example of a law with which providers must comply. (Agency for Health Care Administration Florida Medicaid Provider General Handbook, Chapter 2, p. 42. (available at:https://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/HANDBOOKS/GH_09_ 090204_Provider_General_Hdbk_ver1.3.pdf) (accessed on October 19, 2011).)

50. Relator hereby incorporates by reference the Second Amended Complaint of the United States, including but not limited to Paragraphs 35 through 118 of that Complaint which set forth the laws, rules and other program requirements which have required pharmacies during the time period covered by the United States' complaint to certify compliance with anti-kickback law before they may bill the Medicaid programs of the following twenty-nine states: Arizona, California, Colorado, Connecticut, the District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, Nevada, New York, Oklahoma, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Virginia, Washington, West Virginia, and Wisconsin.

51. The remaining twenty-one of the fifty states, during the time period covered herein, also have conditioned Medicaid payment on providers certifying compliance with anti-kickback law or all "applicable" law, which necessarily includes the AKS and, in the case of some states, also includes state anti-kickback statutes made specifically applicable to Medicaid providers.

52. *Alabama*: In Alabama, the Alabama Medicaid Provider Agreement states explicitly that it is "subject to all state and federal laws and regulations relating to fraud and abuse in health care and the Medicaid program." Alabama Medicaid Provider Enrollment Application, §1.2.3 (Nov. 2004). Since at least 2004 and 2008, respectively, the Alabama Enrollment package and the Medicaid Provider Manual have specified that, by submitting Medicaid claims, the provider certifies that it has abided by the policies and procedures of the Program as reflected in the Alabama Medicaid Agency Administrative Code. That Code, in turn,

forbids kickbacks. Ala. Admin. Code R. 560-X-4-.04 (West 2014) (effective 1996). Moreover, like federal law, Alabama state law makes it a felony offense to offer, pay, solicit, or receive a "kickback, bribe, or rebate." Ala. Code § 22-1-11(b) (West 2014) (effective 1996).

53. *Alaska*: In Alaska, providers enrolling in Alaska Medicaid, in order to be paid under the program, must expressly certify that they will comply with all federal and state laws as they apply to providing health care or related services to Medicaid recipients in the state. Alaska Admin. Code tit. 7, § 105.210(b)(3) (West 2014) (effective Feb. 1, 2010). In addition, under Alaska law, the act of submitting a claim itself certifies that no kickbacks were paid. *Id.* § 105.220(a)(1) (effective Feb. 1, 2010) ("billing the department . . . constitutes agreement by the provider to comply with all applicable federal and state laws"). Accordingly, the Alaska Medical Assistance Program Provider Agreement requires a provider to certify that it "will abide by all Alaska laws, regulations, rules, written policies and billing manual instructions related to the Alaska Medical Assistance program, including, but not limited to, Alaska Statutes ("AS"), Alaska Administrative Code ("AAC"), Title XIX of the Social Security Act, the United States Code ("U.S.C.") and the Code of Federal Regulations ("C.F.R.") related to the Medicaid and CAMA programs." Moreover, like federal law, Alaska law defines "medical assistance fraud" to include the acts of "confer[ring], offer[ing] to confer, solicit[ing], agree[ing] to accept, or accept[ing] property, services, or a benefit to refer a medical assistance recipient to a health care provider." Alaska Stat. § 47.05.210(a)(3) (West 2014) (effective Sept. 2003).

54. *Arkansas*: In Arkansas, in exchange for the agreement by the Medicaid agency to pay for covered services, since at least 2008, providers have been required to certify that they

will "conform to all Medicaid requirements covered in Federal or State laws, regulations or manuals." Like federal law, the Arkansas Medicaid Fraud Act defines "Medicaid Fraud" to include purposely soliciting or receiving a kickback. Ark. Code Ann. 5-55-11(7)(A) (West 2014) (effective 1993).

55. *Delaware*: Delaware's "Contract for Items or Services Delivered to Delaware Medical Assistance Program Eligibles in the Department of Health & Social Services," requires providers to certify, as a condition of payment, that they will "abide by the rules, regulations and procedures" of the Delaware Medical Assistance Program and to acknowledge that "penalties may be imposed for failure to observe the terms of the Social Security Act." Delaware law criminalizes kickbacks in connection with public assistance programs covering medical goods and services. Del. Code Ann. tit. 31, § 1005 (West 2014) (effective 1986).

56. *Hawaii*: In Hawaii, since at least 2002, providers billing Medicaid, in order to get paid, have been required to certify that they "agree to abide by the applicable provisions of the Hawaii State Medicaid Program … and applicable provisions set forth in the Code of Federal Regulations (C.F.R.) related to the Medical Assistance Program." Hawaii State Medicaid Program Provider Agreement and Condition of Participation, DHS-1139 (Apr. 2003). The Code of Federal Regulations, in turn, provides penalties for those who violate the federal AKS. 42 C.F.R. 1003.102(b)(11) (West 2014). Finally, Hawaii law makes clear that AKS compliance is a condition of payment. Hawaii Medicaid regulations state that "[n]o payment shall be made where program rules are violated." Haw. Code R. § 17-1739.1-3(c) (West 2014) (effective 2005).

57. *Idaho*: In Idaho, the Department of Health and Welfare Medicaid Provider Agreement, as of December 2005, included a "Compliance" section where the provider certifies that it will "provide services in accordance with all applicable provisions of statutes, rules and federal regulations governing the reimbursement of services and items under Medicaid in Idaho." Idaho Dep't of Health and Welfare Medicaid Provider Agreement, at 1. The federal AKS is, of course, one such "statute," and federal regulations further provide penalties for those who violate the AKS. 42 C.F.R. 1003.102(b)(11) (West 2014). In the same Idaho Medicaid Provider Agreement, as a condition of reimbursement, the provider must agree that it will certify on its claims that "the items or services claimed were provided in accordance with . . . this agreement."

58. *Iowa*: In Iowa, since at least July 2007, pharmacies seeking payment from Medicaid have been required to sign the standard Iowa Medicaid Provider Agreement, Form 470-2965, in which they expressly certify that they will "comply with all applicable Federal, State and local laws, regulations, administrative rules and written policies of the Iowa Medicaid program, including but not limited to . . . the Federal anti-kickback statute . . . ." They further agree, in the Section entitled "Reimbursement," that they understand that the Iowa Medicaid agency will pay only for those goods and services "rendered by Provider in accordance with Federal and State law."

59. *Louisiana*: In order to obtain payment from Louisiana Medicaid, providers, since at least January 2009, have been required to certify, in a Provider Agreement, that they will "conduct their activities/actions in accordance with the [Louisiana] Medical Assistance Program Integrity Law . . . ." That law, in turn, prohibits kickback arrangements in connection with

claims for Medicaid goods and services. La. Rev. Stat. Ann. § 46:438.2 (West 2014) (effective 1997).

60. *Maine*: The MaineCare Benefits Manual, since at least June 2009, has provided that in order to bill MaineCare, providers must certify that they comply with "the provisions of the Federal and State laws related to Medicaid . . . ." Consistent with the Manual's requirement, the Medicaid Program's Provider Agreement, which pharmacies must sign in order to be paid, expressly prohibits violations of the federal AKS and provides that reimbursement of claims is "contingent" on the provider complying with all applicable federal and state laws and regulations and the terms of the Provider Agreement. In the Provider Agreement, since at least January 2009, a provider must certify, in a section entitled "Certifications," that neither it nor any of its employees are engaging in violations of the AKS, and, if the provider subsequently learns of such violations, that it will notify Maine's Medicaid agency within one business day.

61. *Mississippi*: In Mississippi, a Medicaid Provider must certify, before it may be paid by Medicaid, that it will "abide by federal and state laws and regulations affecting delivery of services." Mississippi Medicaid Assistance Participation Agreement § C-1, ¶2. Mississippi law, in turn, prohibits kickbacks in the state Medicaid program. Miss. Code Ann. § 43-13-207 (West 2014) (effective May 15, 1984).

62. *Montana*: In enrolling in Montana Medicaid, "in consideration of Medicaid payments," providers, since at least 2005, have had to certify that they agree "to comply with all applicable laws, rules and written policies pertaining to the Montana Medicaid Program (Medicaid), including but not limited to Title XIX of the Social Security Act, the Code of

Federal Regulations (CFR), Montana Codes Annotated (MCA), Administrative Rules of Montana (ARM) and written Department of Public Health and Human Services (Department) policies . . . ." Like federal law, Montana law defines "Medicaid fraud" to include the offering, paying, solicitation or acceptance of kickbacks for recommending items or services to be paid for under the state Medicaid program. Mont. Code Ann. 45-6-313(1)(b) (West 2014) (effective April 11, 1995).

63. *Nebraska*: In Nebraska, as a prerequisite to obtaining payments from Medicaid, since at least 2006, providers have had to certify, as a condition of payment, "[t]hat the policies and procedures of the Nebraska Health and Human Services System in the administration of the Nebraska Medical Assistance Program will be followed." Among those policies is the state's anti-kickback statute, the False Medicaid Claims Act. Neb. Rev. Stat. Ann. § 68-938 (West 2014) (effective 2006) (forbidding providers from "receiv[ing] anything of value in addition to the amount legally payable under the medical assistance program in connection with a provision of such good or service"). Since at least 2010, Nebraska's Medicaid Provider Agreement has also required providers to certify "[f]ull compliance with all applicable Federal statutory and regulatory law." Moreover, in addition to violating the foregoing express certifications, claims tainted by kickbacks are also impliedly false under Nebraska's False Medicaid Claims Act. Since at least 2006, "a claim submitted with regard to a good or service is deemed to be false" if the person submitting the claim has accepted a kickback. Neb. Rev. Stat. Ann. § 68-938.

64. *New Hampshire*: In New Hampshire, since at least March 2012, providers seeking to bill and be paid by Medicaid must certify in provider agreements that they "agree to

abide by all rules, regulations, billing manuals, bulletins and notices promulgated by the US Department of Health and Human Services, the State of NH, or the NH Department of Health and Human Services pertaining to the provision of care or services under NH Title XIX and the claiming of payments for those services." New Hampshire law in turn, prohibits the offering, paying, solicitation or acceptance of kickbacks for recommending items or services to be paid for under the state Medicaid program. N.H. Rev. Stat. Ann. 167:61-a(I)(i) (West 2014).

65. *New Mexico*: In New Mexico, from at least 2003, providers have had to certify, as a condition of receiving Medicaid payment, that they "[a]bide by all federal, state, and local laws, rules, and regulations, including but not limited to, those laws, regulations, and policies applicable to providers of medical services under Title XIX (Medicaid) and Title XXI (SCHIP) of the Social Security Act and other health care programs administered by [the state Medicaid agency]." Moreover, since at least 2003, New Mexico has defined "Medicaid fraud" to include the offering, paying, solicitation or acceptance of kickbacks for recommending items or services to be paid for under the state Medicaid program. N.M. Stat. Ann. § 30-44-7 (West 2014) (effective 2003).

66. *North Carolina*: In North Carolina, since at least 2007, providers enrolling in Medicaid have had to certify, in the Provider Administrative Participation Agreement, that they will "comply with federal and state laws, regulations, state reimbursement plan and policies governing the services authorized under the Medicaid Program and this agreement (including, but not limited to, Medicaid provider manuals and Medicaid bulletins published by the Division of Medical Assistance and/or its fiscal agent)." Since August 3, 2010, North Carolina's

Medicaid fraud law has forbidden kickbacks. N.C. Gen. Stat. § 108A-63 (West 2014) (effective Aug. 3, 2010).

67. *Rhode Island*: In Rhode Island, since at least 2003, to bill and receive payment from Medicaid, providers have had to certify that they will "follow all laws, rules, regulations, policies and amendments that govern the Rhode Island Medical Assistance Program as specified by the Federal Government and the State of Rhode Island." This certification is required by state law. R.I. Code R. § 0301.01 (West 2014) (as amended Aug. 2014) (requiring this certification). Rhode Island law, like federal law, prohibits kickbacks. R.I. Gen. Laws §§ 40-8.2-3(a)(2) & 5-48.1-3(a), (b) (West 2014) (effective 1993).

68. *South Dakota*: In South Dakota, in order to bill and be paid by Medicaid, since at least September 2007, providers have had to certify that they will "comply with all Federal and State laws, regulations and rules applicable to Provider's participation in the medical assistance program." Like federal law, South Dakota law forbids kickbacks. S.D. Codified Laws § 22-45-4 (West 2014) (effective 1986).

69. *Tennessee*: In Tennessee, in the Network Participation Agreement for specialty pharmacy providers that has been in place since at least 2008, a pharmacy must certify that it "shall comply fully with all applicable laws and regulations."

70. *Utah*: The Utah Medicaid Provider Agreement, since at least 2002, has required providers, as a condition of payment, to certify that they will "comply with all appropriate and applicable state and federal rules and regulations." Utah law, like federal law, prohibits kickbacks. Utah Code Ann. § 26-20-4 (West 2014) (effective Apr. 30, 2007).

71. *Vermont*: In Vermont, providers must certify, in the Vermont Health Programs Provider Agreement that has been in effect since August 2007, that they will "conform to all applicable Federal and State laws and regulations." Since April 1, 1999, Vermont's Medicaid regulations have provided that providers may be sanctioned for "failing to meet and maintain substantial compliance with all State and Federal regulations." Vt. Code. R. §12-7-1:7106, at 7106.2(11) (West 2014).

72. *Wyoming*: The Wyoming Medicaid Provider Participation Agreement, in effect since January 2007, requires providers, as a condition of receiving payment from Wyoming Medicaid, to certify that they will "[c]omply with applicable state and federal law, including: the Social Security Act (42 USC 1936 et seq.); the Wyoming Medical Assistance and Service Act (Wyo. Stat. § 42-4-101 et seq.); the regulations of the Centers for Medicare & Medicaid Services (CMS); the United States Department of Health and Human Services (HHS) (42 CFR Subchapter C); section 6032 of the Deficit Reduction Act of 2005 (Employee Education About False Claims Recovery); and the Wyoming Department of Health (WDH) Wyoming Medicaid Rules and policies."

73. The federal False Claims Act, as amended in June 2009, imposes liability on anyone who, *inter alia*, "knowingly and improperly avoids . . . . an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). The statute defines the term "obligation" to mean "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." 31

U.S.C. § 3729(b)(3).

74. The Social Security Act imposes an affirmative duty on health care providers who bill Medicare or Medicaid to disclose any Medicare or Medicaid overpayments they identify to the government health care program within 60 days of discovery, or, in the case of providers who submit cost reports (pharmacies do not do so), by the deadline for submission of their cost report. 42 U.S.C. § 1320a-7k(d). This statute expressly states that the duty it imposes is an obligation as that term is used in Section 3729(b)(3) of the federal False Claims Act. *Id.* (d)(3).

75. Federal law and regulations require that any health care provider who furnishes health care services that may be reimbursed under Medicare, Medicaid, or TRICARE must ensure that, to the extent of his or her authority, those services are provided "only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 1004.10. This requirement makes the health care provider the "gatekeeper" who, through the exercise of his objective, unbiased medical judgment, plays a critical role in determining what services will be reimbursed with federal funds. If the gatekeeper's medical judgment is corrupted – for example, by the receipt of kickbacks from a party who would benefit from the gatekeeper's decision to purchase and use that party's products in the course of patient care – then the federal health insurance system is at risk of paying for services that were not really medically necessary. The AKS was enacted to address this risk.

THE FRAUDULENT SCHEME

Overview

76. Beginning in or about January 2007 and continuing through the current time, Novartis management has employed a scheme to increase sales of certain specialty medications by corrupting the medical objectivity of pharmacists who are responsible for counseling patients on the most appropriate medication for their conditions. Novartis does so by paying Accredo, Bioscrip, Curascript, and Caremark and other specialty pharmacies valuable rewards—including patient referrals and cash payments styled as "performance rebates" or "performance discounts" —for recommending to patients, physicians, and other healthcare managers the ordering or refilling of Novartis medications and for taking other steps to increase sales of Novartis' specialty drugs. Novartis maintains scorecards of the pharmacies' performance in meeting sales goals and pays rebates or "discounts" pegged to each pharmacy's success, if any, in increasing the quantity of sales to agreed-upon benchmark levels.

77. In a November 4, 2009, internal document entitled "Pharmacy Management Program/The Untapped Opportunity," Novartis explained that the increasingly influential role of pharmacists in patient and physician decisions on medication means that pharmacists are in a position to drive Novartis' sales through their recommendations:

> For many patients, especially the less affluent, the pharmacist is often the first point of contact when they feel unwell. Research findings (on NSAID therapeutics) from South Africa revealed that as many as 30% of patients consult a pharmacist without having a prescription. Even if patients then go on to consult a physician, the pharmacist retains the position of "gatekeeper" by guiding patient purchases. The same research showed that 30% of patients with a prescription ask the pharmacist for a cheaper brand, and 80% of

> these patients accept the pharmacist's recommendation. In the end this results in 36% of patients following the pharmacist's recommendation.
>
> . . . [P]harmacists are now taking on the role of counselor and caregiver, in addition to that of dispenser. Many pharmacists even perform laboratory analysis, such as liver function tests, so that they can monitor patients' progress. The role of the pharmacist as "counselor" and "caregiver" is also supported by a study, undertaken in the US, which states that 72% of recommendations made by pharmacists to physicians on therapeutic interchanges are accepted.
>
> Pharmacists have a new role in today's competitive markets and are in a position to drive sales through recommendation/switching between the products.

78. At a November 2009 international gathering of its sales staff in Dubai, Novartis' office of Global Consumer Access and Affordability once again highlighted the critical new role pharmacies play in Novartis' marketing efforts, and specifically advocated the use of "discount for refill" provisions in contracts with specialty pharmacies. These Novartis personnel noted that "traditional business models" involving marketing Novartis products to doctors were no longer as successful due, in part, to regulations designed to safeguard patients and taxpayer dollars. On a PowerPoint document, they then highlighted several ways in which Novartis can "leverage the influence of the pharmacy" to increase Novartis product sales, including:

> Reminders & Discounts: provide patients on chronic therapy with reminders and services from pharmacies to maintain compliance; offer discounts to drive refills.

79. In this PowerPoint, Novartis observed that the potential effectiveness of using "pricing/discounting to incentivize adherence" was "high." Similarly, Novartis stated that the potential effectiveness of an "intervention program" to "leverage pharmacy to remind patients or

reinforce the importance of adherence" was "high." Novartis personnel use the term "adherence" to mean "refills" -- even though increasing refills does not mean that patients will take the refilled medication on schedule and, as a result, "adhere" to the prescribed regimen.

80. Novartis' Head of U.S. Management Markets and Mature Products, Don DeGolyer, has trained Novartis sales representatives that the pharmacists Novartis seeks to influence have certain "unmet needs," including, in particular, specialty pharmacies "looking for pharmaco [pharmaceutical company] reimbursement for services (*e.g.*, compliance programs.)" In using the phrase "compliance programs" in this context, DeGolyer was not referring to a compliance program designed to ensure adherence to applicable law. Rather, he was using the phrase to refer to a "medication compliance program," a term that Novartis defines in training materials for its sales force as "the extent to which a patient acts in accordance with the prescribed interval, and the dose of a dosing regimen." In practice, Novartis personnel use the phrases "compliance programs" and "adherence programs" to reference programs in which specialty pharmacies use clinical staff and sales personnel to drive up sales of Novartis products, by, among other things, contacting customers to encourage them to order Novartis' specialty medications.

81. The first aspect of Novartis' kickback scheme involves Novartis channeling a new patient -- *i.e.*, a patient who has been prescribed the Novartis specialty medication for the first time -- to Novartis web sites or call centers, or to so-called "Novartis reimbursement hubs," for guidance with insurance reimbursement and information on where and how to fill their prescription.

82. The "reimbursement hubs," in coordination with Novartis and under the oversight of Novartis employees, steer patients to specialty pharmacies to fill their prescriptions for specialty medications.

83. The reimbursement hubs are run on behalf of Novartis by outside entities, such as Defendant Caremark's subsidiary, Theracom, LLC, and Amerisource Bergen's "LASH" consulting services group, that specialize in improving patient access to medications and increasing product sales. Pursuant to their contracts with Novartis, these hubs not only provide insurance advice to patients and doctors, but also direct patients to fill their prescription at one of a select group of specialty pharmacies that are part of the "Novartis specialty pharmacy network." The Defendant pharmacies are part of this network.

84. As set forth in greater detail below, unbeknownst to the patients ordering Novartis medications, the specialty pharmacies to which they are directed by Novartis web sites, call centers and reimbursement hubs are pharmacies that are paid by Novartis for their success in shifting market share from the competitors' products to the Novartis product by getting new patients onto the Novartis product and maximizing the number of orders, refills, and doses of the Novartis product per existing patient.

85. The second aspect of the scheme involves Novartis' selection of a limited number of specialty pharmacies for possible inclusion in its specialty pharmacy network. To be considered for inclusion, the specialty pharmacy must demonstrate that it will use effective techniques to maximize the quantity of the drug dispensed, including calling patients to encourage them to order or re-order the Novartis medication. Novartis only admits a pharmacy

into its network if the pharmacy agrees: (a) to continue using these techniques; (b) to be benchmarked against its peers through a scorecard reflecting pharmacy achievement of performance metrics relating to drug sales, such as market share and quantity of drug dispensed per patient; and (c) to send Novartis' reimbursement hub the names of patients who are not refilling their orders of the Novartis drug at issue.

86. This second aspect of the scheme also involves Novartis' Specialty Pharmacy Team entering into contracts with those pharmacies that have been selected to be part of the network. These contracts include (a) financial incentives to the pharmacies that reward the pharmacies for taking actions that increase Novartis' market share and/or increase the total quantities of the drug sold per patient, and (b) provisions requiring the pharmacies to submit detailed data on sales to Novartis so they can be assessed vis-à-vis the other specialty pharmacies in Novartis' distribution network on monthly "scorecards" and other provisions that incentivize the pharmacies to increase patient orders of the Novartis product. These contracts, which have been signed by each of the Defendant pharmacies, have been negotiated by Novartis Associate Directors for Specialty Pharmacy and by Novartis employees within the Oncology business unit. These Associate Directors, who have included, among others, Andrea Vogels, Steve Davis, Robert Rindini, Monica Carlson, Sue Severin and Dawnya Bieller, have reported to John Mandala, Senior Director, U.S. Managed Markets and Market Access/Specialty Pharmacy Account Manager, who, in turn, has reported to Novartis' Vice-President for Managed Markets & Market Access, United States.

87. Novartis' contracts with specialty pharmacies typically offer base-level payments characterized as discounts or rebates in the range of one to three percent of Novartis' sales prices. The pharmacies earn what is known within Novartis as a "first category rebate" or "adherence support" by undertaking to call patients to educate them about the Novartis product and the underlying disease that it treats, to provide advice on the drug's side effects and to encourage patients to remain on the Novartis product.

88. Pursuant to many of Novartis' contracts with specialty pharmacies, including contracts with the Defendant pharmacies, the pharmacy can also earn what is known within Novartis as a "second category rebate" by achieving performance metrics specified in the contract. These second category rebates, which are sometimes characterized as "performance discounts," are paid based on the quantity of the Novartis drug dispensed or the increased market share obtained for the Novartis product; they are not paid merely because of the pharmacy's purchase of the product. As such, they are performance-based payments rather than classic volume rebates. In other words, Novartis conditions its continued payment of performance-based discounts or rebates to specialty pharmacies on the pharmacy's success in convincing patients and their physicians to order and reorder Novartis medication and in pushing up the total quantity of Novartis medication dispensed.

89. To supplement the contractual, financial incentives, Novartis also uses the reimbursement hubs' control over patient referrals to the specialty pharmacies in Novartis' distribution network to incentivize the specialty pharmacies to increase the sales of Novartis medications. Specifically, when a new patient's health insurer has not designated a specific

pharmacy, Novartis, through its control of the reimbursement hub, has control over the referral of that patient to one of the various specialty pharmacies in its distribution network. Novartis sometimes will direct the reimbursement hub to channel such "undesignated patients" on an evenly rotating basis. When some pharmacies are doing better than others at increasing the sales of the Novartis specialty medication, however, Novartis sometimes will direct the hub to reward the better performing pharmacies, and penalize the lagging pharmacies, by sending more patients to the higher performing pharmacies than to the others.

90. The specialty pharmacies that participate in these kickback arrangements have agreed with Novartis to engage in a number of coordinated initiatives to achieve Novartis' goals regarding market share and the quantity of drug to be dispensed per patient.

91. The pharmacies' market-share-focused initiatives have included a number of proactive efforts by the pharmacies to get new patients onto the Novartis drug, such as initiatives: to "ensure ALL appropriate patients" are on Novartis' immunosuppressive drug Myfortic; to get patients to switch off Novartis' oncology drug Gleevec sooner than they would otherwise and placed on Novartis' second-line oncology drug Tasigna rather than on one of the competing, second-line treatments; and, to dispense Novartis' cystic fibrosis drug TOBI instead of the less expensive, compounded tobramycin product.

92. To increase the amount of drug dispensed per patient, the pharmacies have launched initiatives to use nurses with perceived professional competence and objectivity, as well as other pharmacy staff perceived by patients to be acting on behalf of the pharmacy's professional staff, to "intervene" with patients and recommend that patients reorder the Novartis

product. These programs have included "High Touch Specialty Care" programs launched to increase sales of Novartis' oncology products Exjade, Gleevec and Tasigna and cystic fibrosis drug TOBI. Novartis personnel have actively participated in designing these programs, and have at times provided "scripts" for the pharmacy personnel to follow when making calls to patients. In addition, to further increase the amount of Novartis product dispensed per patient, the pharmacies have undertaken coordinated campaigns to recommend that patients increase their dosing of Novartis products to the highest approved dose. Pharmacies have undertaken such dosing initiatives with regard to Gleevec and Exjade, for example.

93. The Novartis reimbursement hubs run by third parties also pressure patients to refill or request additional prescriptions of Novartis products by having their own telemarketers place calls to patients urging them to do so and by notifying physicians when patients decline to do so.

94. Novartis sometimes requests that pharmacy companies that have both retail and specialty pharmacies channel their customers who are on Novartis specialty drugs from their retail to their specialty pharmacies. Novartis does this because specialty pharmacies interact more often with patients and consequently are better positioned to intervene with patients and recommend Novartis products. Novartis sometimes employs this tactic when it wishes the specialty pharmacies to help switch patients from one Novartis product to another Novartis product that treats the same condition. There are a number of reasons why it is sometimes in Novartis' financial interest to switch patients from one Novartis product to another. For example, the first Novartis product may be about to lose its patent protection, or may have less of

a competitive advantage than a second, newer Novartis product. In addition, sometimes patients become resistant to or intolerant of a Novartis drug and have to switch to another treatment for medical reasons; Novartis would prefer that the patient switch to an alternative Novartis product than to a competitor's product. Novartis uses specialty pharmacies to intervene with patients in each of these circumstances to maximize the changes that they will switch over to a second Novartis product. Novartis uses the euphemism "patient journey" to describe these decision points in a patient's pharmaceutical regimen. Novartis has used its contracts with Defendants Accredo, Caremark and Curascript to channel patients from the pharmacy chains' retail stores to their specialty stores so that these pharmacies can then recommend to patients, physicians and caregivers that the patients switch from Novartis' oncology drug Gleevec to Novartis' oncology drug Tasigna, and from Novartis' cystic fibrosis drug TOBI, which is going off patent in the near future, to Novartis' new brand cystic fibrosis product, TOBI Podhaler (TIP).

95. Novartis' contracts with specialty pharmacies provide for preparation of monthly scorecards evaluating the success of the specialty pharmacy in achieving the performance metrics, which Novartis compares against the scorecards of the pharmacy's competitors. The pharmacies know they are being compared with their competitors. They are aware that they may lose the right to participate in Novartis' specialty pharmacy network, and to receive lucrative patient referrals and compensation, if they fall short on order numbers compared to their competitors. Removal from the Novartis specialty pharmacy network not only means deprivation of the lucrative rebate opportunities that Novartis offers to pharmacies in the

network, but also, and perhaps even more importantly, means that Novartis' reimbursement hub will no longer be referring any future patients to the pharmacy.

96. Novartis personnel use the term "adherence" or "compliance" to describe the results of "high touch" specialty pharmacy programs that involve: (a) calls by pharmacists, nurses and other pharmacy staff to patients urging them to order the Novartis product; and, (b) other steps to increase the sales of Novartis products. In reality, however, Novartis's contracting efforts are focused on increasing the quantities of the drug dispensed regardless of whether that leads to greater patient "compliance" with or "adherence" to a drug regimen. While Novartis, the pharmacies and the health plans track the quantity of medication dispensed to given patients, they do not track whether the patients actually take the medication dispensed to them. A greater amount of medication dispensed to a patient does not necessarily translate into greater patient adherence to or compliance with a prescription medication regimen. Often, and especially when little or no co-payment is required from the patient, a patient will order medication simply because he is asked to do so and not because he intends to continue on the medication. Consequently, Novartis personnel internally refer to the "adherence" aspect of the specialty pharmacy program by its true function, *i.e.*, as a "refill program."

97. The Novartis performance-based contracts corrupt the disinterested, objective clinical advice that otherwise would be provided by specialty pharmacies to patients. There are many different medications made by different companies that are available to treat the illnesses treated by Novartis medications. Some are safer or more effective than others, depending on the patient's unique health profile. Some are less expensive for the payer, and if there is any co-pay,

"donut hole" or deductible involved, some are less expensive for the patient. Moreover, in some cases, the best medical approach may not require taking prescription medication. Patients may wish to discontinue a Novartis medication because of the drug's serious side effects, or because the drug is not working as expected. They want objective advice from their pharmacist about whether they should consider a different medication or medical approach. In counseling a patient on whether to fill a Novartis medication, a pharmacist has an ethical duty to listen objectively to the patient's description of his or her health condition, including any side effects that might be arising from the medication, and then provide objective advice on whether to stay on the Novartis drug or consider switching over to a different medication or another medical approach. See American Pharmacists Ass'n, Code of Ethics, *available at* http://www.pharmacist.com/code-ethics. When the pharmacy is being compensated for its success in meeting the manufacturer's dispensing goals, however, that objectivity is compromised and, often, lost. Rather than providing disinterested clinical advice, the pharmacy provides advice driven by its own financial considerations.

98. As set forth more fully below, Novartis induces pharmacists to recommend Novartis specialty medications that often are more expensive for payers, and/or less efficacious and safe for patients.

99. Novartis does not disclose to health plans, patients or physicians that it pays financial incentives to the specialty pharmacies based on the pharmacies' performance in driving up sales of Novartis' products. Nor do the specialty pharmacies disclose to patients that Novartis pays them based on their success in increasing the quantity of Novartis drugs dispensed.

Accordingly, the health plans, patients and doctors incorrectly assume that the pharmacies, when calling patients about their medication needs, are complying with their legal and professional obligations to provide objective clinical advice. The patients and physicians rely on this incorrect assumption in deciding whether to adopt the pharmacy's recommendations concerning the appropriate medication for the patient.

100. More often than not, physicians will follow the recommendation of a pharmacist concerning the best medication for a patient. As Novartis has informed its sales and marketing personnel, a recent study shows that physicians adopt the recommendations of community pharmacists more than 70% of the time.

101. Novartis has employed the foregoing scheme for the following specialty medications, among others: Exjade, Gleevec, Tasigna, TOBI, and Myfortic. The specialty pharmacies that are part of Novartis' network, including the specialty pharmacies identified herein, submit claims for these medications to publicly-funded health care programs, including claims for reimbursement for medication refill orders that were obtained as a result of recommendations the pharmacies made to patients and physicians. This is done in exchange for the kickbacks paid for by Novartis in violation of the AKS.

102. The pharmacies identified herein and the other specialty pharmacies that are part of Novartis' distribution networks for Exjade, Gleevec, Tasigna, TOBI and Myfortic, as well as other specialty medications, have signed Medicaid provider agreements in the states in which they do business. These agreements require compliance with all federal and state laws, regulations and program guidance applicable to the Medicaid program, which include, *inter alia*,

the AKS. These pharmacies have been required to sign the provider agreements as a condition of billing and receiving payment from Medicaid. In signing these agreements, these specialty pharmacies knowingly have falsely represented such compliance.

Exjade, Gleevec, and Tasigna

103. The Second Amended Complaint of the United States asserts claims against Defendant Novartis that are based on transactions between Novartis and Bioscrip with regard to Exjade. The states that have intervened in this action assert claims against Defendant Novartis that are based on transactions between Novartis and Bioscrip with regard to Exjade. All of the allegations in the aforementioned complaints are incorporated herein by reference. The additional allegations set forth in this complaint that concern transactions between Novartis and Accredo, Bioscrip or US Bioservices with regard to Exjade, and between Novartis and Accredo, Caremark or Curascript with regard to Gleevec and Tasigna, are set forth in support of the claims that Relator asserts on behalf of the United States and all state government plaintiffs herein, with the exception of Maryland, a state that does not permit qui tam plaintiffs to proceed with declined claims, and Washington, on whose behalf the relator has not brought suit.

104. Since approximately 2007, Novartis has used the kickback scheme herein described to market Exjade, an iron-chelating medication approved by the FDA in 2005 that is used to remove excessive amounts of iron from the blood. Exjade is prescribed for patients with an underlying illness, such as Sickle Cell Disease or Thalassemia, which often leads to excessive levels of blood iron. Since approximately 2007**,** Novartis also has employed the scheme set forth above to market Gleevec, a medication for leukemia and other blood cancers approved by the

FDA in 2001. Since approximately 2008**,** Novartis has also used the scheme for Tasigna, a drug that the FDA approved for the treatment of leukemia in October 2007. Tasigna is often prescribed as a "second line treatment" for leukemia patients who do not do well on Gleevec, either because of intolerable side effects or because the drug stops working for them.

105. Gleevec, Exjade, and Tasigna are "blockbuster" medications. In 2010 alone, Novartis' net sales of Gleevec, Exjade and Tasigna exceeded $1.284 billion, $263 million and $133 million, respectively. Novartis documents indicate that approximately 40% of Exjade sales are reimbursed by Medicaid, Medicare or other government health programs. Public health programs, including Medicare and Medicaid, likewise reimburse significant percentages of Gleevec and Tasigna sales. In the first quarter of 2011, Florida Medicaid data indicates that the average reimbursement per claim was $5,144 for Gleevec 400 mg., $5,378 for Exjade 500 mg., and $7,664 for Tasigna 150 mg.

106. The FDA-required product insert for Gleevec warns clinicians of the following complications that can arise from Gleevec: Dermatologic Toxicities, Fluid Retention and Edema, Gastrointestinal Disorders, Hemorrhage, Hematologic Toxicity, Hepatotoxicity, and Hepatic Impairment. The label also warns of the possibility of "Toxicities from Long-Term Use."

107. Tasigna's label includes a "black box warning" cautioning physicians and patients that the drug poses cardiovascular risks, including the risk of death, because the drug can prolong a phase of the heart's electrical cycle called the "QT interval." Tasigna is significantly less safe than its main competitor, the Bristol-Myers Squibb medication Sprycel (dasatinib), which, like Tasigna, is approved as a second-line treatment for chronic myelogenous leukemia. While

Tasigna has a black box warning on its label, Sprycel does not. Moreover, a thirty-day supply of Tasigna 150 mg is no less expensive than a thirty-day supply of Sprycel; indeed, in at least some states, Tasigna is marginally more expensive for Medicaid. Thus, a thirty-day supply of Tasigna 150 mg currently costs Florida Medicaid $8,181, while a thirty-day supply of Sprycel 100 mg. currently costs Florida Medicaid $7,882.

108. Exjade's label includes a black box warning advising doctors and patients that the drug can cause renal or hepatic failure or gastrointestinal hemorrhage. Exjade is a non-preferred medication on the formularies of some health care programs, including, for example, California Medicaid and Florida Medicaid.

109. Novartis uses the term "EPASS," which stands for "Exjade Patient Assistance and Support System," to describe its distribution network for Exjade, a system composed of a reimbursement hub operated by Amerisource Bergen's LASH Group and three specialty pharmacies: US Bioservices, Bioscrip and Accredo. In a first quarter 2008 update for the Oncology National sales team**,** Novartis employee Paul Pochtar, Vice President for Oncology Managed Markets, listed the oncology division's innovative actions to "[l]everage Specialty Pharmacy capabilities." These actions included the addition of a "performance component to EPASS pharmacies to achieve adherence targets" for Exjade. The update characterized "adherence" as one of the four "core pillars" to drive sales of Exjade." The update also identified "New Patient Starts" and "Dose" as issues and opportunities for Exjade, and identified "Specialty Pharmacy" as a "Key Tactic/Action" to drive "Competitive Position" and "Dose Optimization."

110. The first quarter 2008 update for the Oncology National sales team also discussed implementation of a "Big3 Specialty Pharmacy Initiative" for Gleevec and Tasigna that would "transition Retail to Specialty" and "[e]nhance patient care & adherence." It referenced as "innovative actions" efforts to "Strengthen Alignment with Franchises" through "Good integration of Customer Marketing in working with Business Franchise structure, such as "Exjade, Gleevec/Tasigna, Sandostatin LAR - Specialty Pharmacy initiatives." (Within Novartis' organizational structure, the term "franchise" refers to a Novartis business unit focused on a specific therapeutic area.) "Dose Optimization" was specifically identified as an issue and opportunity for Gleevec.

111. In an April 2008 webcast, Novartis management informed employees that it also would utilize specialty pharmacies as a "key tactic" to "push for an early switch" from Gleevec. Novartis aimed to achieve a "preferred 2nd line position" for Tasigna by getting patients who were not responding well to Gleevec to switch off Gleevec earlier than they would otherwise and then start on Tasigna rather than Sprycel or another second-line treatment.

112. In March 2009, Richard Andes, Novartis Director of Multiple Sclerosis Brand Managed Markets, presented training to the Novartis sales force. In the training, he noted the resounding success of Novartis' specialty pharmacy model in the oncology area. His PowerPoint slides illustrated this through a table showing Gleevec's "adherence" (*i.e.*, refill) rates at both specialty and retail/mail pharmacies. For Defendant Accredo, refill rates were 58% at retail/mail pharmacies, and 78% at specialty pharmacies. For Defendant Caremark, refill rates

were 63% at retail/mail pharmacies, and 92% at specialty pharmacies. For Defendant Curascript, they were 53% at retail/mail pharmacies, and 65% at specialty pharmacies.

113. As of September 14, 2009, Novartis had entered into specialty pharmacy contracts with the following specialty pharmacies to compensate the pharmacies for efforts to increase sales of Gleevec and Tasigna as part of the "Specialty Pharmacy Initiative": Defendants Accredo, Caremark and Curascript. In these contracts, Novartis and these Defendant pharmacies agreed that Novartis would pay the pharmacies to implement "High Touch Nurse" programs designed to increase sales of Gleevec and Tasigna through contacts made by pharmacy staff to patients, physicians and other health provider staff. The purpose of the calls was to recommend that patients start or continue on Gleevec or Tasigna. In these contracts, Defendants Accredo, Caremark and Curascript further agreed with Novartis to submit detailed data to Novartis on their Gleevec and Tasigna sales so that Novartis could "benchmark" them against their peers. Following this scorecarding, Novartis' policy, which was made to clear to these Defendant pharmacies, was to assess whether it was necessary to take further measures to improve the pharmacy's sales "metrics" so that they met Novartis' sales objectives.

114. The Novartis team supporting renewals of these contracts as of September 2009 included Novartis employees Carol Vuceta, Michael Mignogna, Beth Shields, AnnMarie Redmond, Ken Olsen, Emily Chee, Jie Bian, Matt Magestro, Stacey Helfant, Paul Amaral, Sue Gleason, John Badolato, Anni Varughese, Mark Sims and Ahmed Rabie.

115. To earn the financial compensation and patient referrals offered by Novartis as an inducement to increase sales of Gleevac and Tasigna, Defendants Accredo, Caremark, and

Curascript implemented "High Touch Nurse" programs that involved one-on-one contact between pharmacy staff on the one hand, and patients, physicians and other health care provider staff on the other hand, in which the pharmacy staff deceptively purported to provide disinterested "counseling" and "education" on the appropriate medication regimen for patients. To make these contacts with patients, physicians and other health care provider staff, these Defendants employed personnel who lacked the education, clinical experience, training or other qualifications to provide skilled counseling or education on the appropriate medication regimen. Caremark, for example, only required that such employees have a high school degree. In reality, these programs were simply call centers from which these unqualified pharmacy staff took steps to maintain regular contact with Gleevec and Tasigna patients. At the call centers, unqualified personnel took calls from patients and made calls to patients at least monthly, and also contacted physicians, and other health care providers; the employees purported to provide disinterested, objective clinical advice on the best medication regimen for patients. In reality, these employees aimed to sell more Novartis products and earn additional rebates by recommending Gleevac or Tasigna, a product with a "black box" warning. Defendants Accredo, Caremark, and Curascript did not disclose to patients, physicians, or other caregivers that they were receiving inducements from Novartis in return for recommending the use of these Novartis drugs.

116. Through their implementation of the High Touch Nurse Programs, which encouraged patients to rely on specialty pharmacy staff rather than their physicians and their physicians' staff for advice on the best medication regimen, Defendants Accredo, Caremark, and

Curascript violated the Anti-Kickback Statute, while also placing patients at serious risk. Approximately one-third of patients using Gleevec have a recurrence of cancer while on the treatment. These Defendants' "High Touch Nurse" employees who were receiving calls from patients, and who were also making calls to patients, physicians and other health care providers, lacked the education, experience and training to identify the symptoms of such a recurrence. Moreover, Tasigna has a "black box" warning because it can increase the heart's "QT interval," and both Gleevec and Tasigna use can lead to serious, sometimes life-threatening, side effects. These Defendants' "High Touch Nurse" program employees lacked the education, experience and training to identify and advise patients with regard to such side effects. Moreover, Novartis requested that specialty pharmacies in its network avoid asking open-ended questions that might elicit information about a serious side effect experienced by the patient.

117. According to Novartis, as a result of the specialty pharmacy contracts in place as of September 2009, the specialty pharmacies were making "[p]ro-active outbound calls to physicians prescribing > 300mg" of Gleevec. This led to Gleevec patients treated by specialty pharmacies having a higher level of "adherence" than patients treated by retail pharmacies. Moreover, 8,000 patients of the specialty pharmacies dispensing Gleevec and Tasigna were receiving "high touch specialty care"—an increase from the 5,000 patients in January 2008.

118. Beginning in approximately 2009, patients were directed to contact the Novartis-managed programs MyCMLCircle or MyGISTcircle for assistance with regard to Gleevec and Tasigna prescriptions. In addition, prior to September 2010, patients were instructed to contact

the Novartis websites www.cmlalliance.com and www.gistalliance.com for assistance with such prescriptions.

119. By February 2011, Novartis' specialty pharmacy contracts with Defendants Accredo, Caremark and Curascript pertaining to Gleevec and Tasigna included "Network incentives/penalties in place based on performance" and "SPP Network participants regularly scorecarded vs. their peers." The network "performance" incentives used by Novartis were rebate payments pegged to a pharmacy's success in achieving orders or refills of a product. The network "performance" penalties used by Novartis included reducing referrals from the patient reimbursement hub when a pharmacy fell substantially short of Novartis' sales objectives. Novartis used the scorecards derived from the data submitted by Accredo, Caremark and Curascript to determine the appropriate incentive payments and penalties for each pharmacy, if any.

120. In a January 22, 2013 training presentation to Novartis regional account managers, held at the Novartis campus in New Jersey, Rahul Bhatia, Novartis' Director of Sales Strategy and SFE, in the Division of US Managed Markets and Market Access, stated in a presentation attended by Relator that Novartis was using score-carding and performance-based incentives in the contracts with the specialty pharmacies that Novartis had selected to be part of a special "network" to distribute Novartis' specialty products, and that Novartis had entered into such contracts for all of its specialty products. At the time, Defendants Accredo, Caremark and Curascript continued to be part of the Novartis specialty network that distributed Gleevec and Tasigna. Bhatia explained that Novartis' score-carding measured "PDC's, or "Proportion of

Days Covered" and that Novartis then rewarded pharmacies based on their success on this metric. Bhatia further explained that Novartis used the scorecards as the basis for "a discussion" with each pharmacy.

121. As of September 14, 2009, Defendant Accredo, BioScrip, and US Bioservices Corporation (US Bioservices), an Amerisource Bergen company, were part of the EPASS Network that dispensed Exjade. As of September 14, 2009, these specialty pharmacies were subject to "Performance Driven" referral of patients with new prescriptions, *i.e.*, Novartis was directing its reimbursement hub, when referring new patients, to discriminate in favor of the pharmacy that had achieved the greatest success in meeting Novartis' sales goals. Moreover, by this date, Accredo, Bioscrip and US Bioservices had each instituted "High Touch Nurse" programs to contact patients on a regular basis for "education" and "counseling" that was secretly designed to keep patients on Exjade so that the pharmacy could earn performance incentive payments, and had included approximately 7,000 patients in these High Touch programs. As a result, according to Novartis, there had been a "[s]ignificant improvement" in these pharmacies' "performance."

122. In a September 14, 2009 Novartis presentation titled "U.S. Oncology Town Hall – Field Web Cast," Novartis identified as key priorities, among others: "Dose Optimization" for Gleevec; "Seize 2nd line leadership" for Tasigna; and "New patient starts," "Treat at 1000," "Dose," and "Adherence" for Exjade.

123. Novartis directs physicians and patients to contact a reimbursement hub called "E-PASS Administrator" for assistance with regard to Exjade prescriptions and reimbursement.

According to PowerPoint slides presented in or about the fall of 2007 by Novartis managers Emily Chee (Director, Brand Managed Markets, Hematology Business Franchise) and Bill Conkling (Regional Business Director East, Oncology Business Franchise) the reimbursement hub E-PASS "refers [each] case to appropriate specialty pharmacy or PAP." E-PASS Administrator is operated by the LASH Group, which is part of Amerisource Bergen's Consulting Services division.

124. According to the Chee/Conkling PowerPoint presentation described above, a specialty pharmacy in the Novartis network for Exjade "calls patient monthly for refill and monitors compliance." To incentivize the pharmacy to make calls that increase the total Exjade refill orders, Novartis enters into a contract with the pharmacy that provides rebates based on the pharmacy's achievement of agreed-upon "performance metrics" relating to Exjade refills. The rebates are "[p]aid as fixed $ amt per shipment – approx $50 per shipment." Novartis and the pharmacy then conduct "[m]onthly discussions on report card performance." The Chee/Conkling PowerPoint notes that: "Monthly adherence scorecards allow Novartis and pharmacies to carefully monitor adherence." The Chee/Conkling presentation also states that nurses at one specialty pharmacy "have been able to address one of the key reasons for discontinuation – side effects" and that nurses have had a "significant impact on Exjade adherence." As evidence, the presentation points out that there had been a $1.4 million increase in Exjade sales and 17% increase in the number of shipments received by patients in first six months of therapy (the presentation equates shipments *received* to "better outcomes for patients"). The presentation further notes that two other specialty pharmacies were

"implementing Nurse programs and increasing patient contact in the early months of therapy." Patients, the presentation explained, were "more willing to open up to a nurse than a pharmacist." In 2008, Chee and Conkling were nominated for a Novartis Global Nexus Award for their "new, innovative, and breakthrough thinking" with regard to the Specialty Pharmacy High Touch Model they developed to market Exjade. The presentation identified BioScrip as the first specialty pharmacy to implement the High Touch Model. In connection with this nomination, Novartis management praised Chee and Conkling for the following aspects of the program for Exjade:

- Development of the patient adherence scorecards was an internal crossfunctional team effort involving Marketing, Market Research, Business Analysis and Customer Marketing.

- To provide a further incentive to our pharmacy partners in 2008, an incentive program ($320,000) will reward the pharmacies for hitting adherence targets.

Tobramycin Inhalation Solution ("TOBI")

125. In approximately 2007, Novartis decided to export the "specialty pharmacy" model to other specialty products outside the area of oncology. Since approximately 2008, Novartis has used financial incentives in contracts with specialty pharmacies, including the defendant pharmacy chains and networks, to compensate pharmacies for increasing patient orders of Tobramycin Inhalation Solution (TOBI), an inhaled antibiotic for cystic fibrosis patients.

126. TOBI, which Relator had marketed, was approved by the FDA on November 27, 1997. In 2010, Novartis' gross sales of the drug exceeded $ 280 million, with its net sales exceeding $196 million. Approximately 35% of TOBI sales are paid for by public health

programs. Medicaid reimburses approximately 31.1% of the public health program sales, with Medicare Part B and Part D covering the remaining 68.9%.

127. Like the oncology medications discussed above, TOBI is a very expensive drug. In Florida, Medicaid paid an average of $4,195 per claim for TOBI in the first quarter of 2011.

128. TOBI's package insert warns clinicians that TOBI can cause dangerous side effects, including Ototoxicity, Nephrotoxicity, Muscular Disorders, and Bronchospasm. The product label advises clinicians to monitor patients for these adverse reactions.

129. Novartis' brand product TOBI is significantly more expensive for payers than compounded generic tobramycin and other compounded generic products, which are also generally covered by Medicaid. There is no evidence that TOBI is more efficacious or safe than compounded generic tobramycin or the other compounded generic alternatives when prepared by a competent specialty pharmacy. Consequently, in many cases there may not be a legitimate justification for a specialty pharmacy to recommend TOBI over a compounded generic product.

130. In 2007, in internal business plans, Novartis contract managers first proposed paying specialty pharmacies who achieved certain performance metrics on a per patient/per dispense basis "similar to the Gleevec initiative" to operate a high touch program involving pharmacy outreach to patients encouraging refills. The Novartis contract managers proposed characterizing this kind of payment "as a rebate to ensure consistently [sic] throughout Novartis." Novartis contract personnel observed that patient "compliance rates," *i.e.*, refill rates, were significantly higher when specialty pharmacies were used by patients. For example, at

Caremark, only 70% of customers using retail or mail order pharmacies refilled their medication, while 88% of customers using specialty pharmacies did so.

131. Novartis' 2007 internal business plans for the marketing of TOBI contemplated a "per patient/per dispense" payment to specialty pharmacies of $34, $69, or $103, depending upon the pharmacy's ability to meet the performance metrics relating to "compliance," *i.e.*, prescription refill rates. The business plans indicated that the specialty pharmacies first would receive a "category 1 rebate" to allow them to "initiate programs supporting TOBI." These programs, also referred to within Novartis as "service initiatives," would require specialty pharmacies to "manage their 'own' TOBI patients to drive compliance, provide insights into care, and secure data insights." In other words, Novartis would pay the pharmacies in exchange for their undertaking regularly to contact patients encouraging them to fill existing TOBI prescriptions, inquiring about their health care, and transmitting the patients' health care information to Defendant Caremark's Theracom unit and Novartis. The pharmacies also would receive a "category 2 rebate" as reimbursement for achieving "higher compliance," the misnomer used within the Novartis contracting organization to describe higher ordering rates. Pursuant to a contract with Novartis, Caremark's Theracom unit would operate a reimbursement hub for TOBI called "TOBICARE." TOBICARE would steer patients to the specialty pharmacies in the Novartis network, and would assign referrals of new patients among the specialty pharmacies, according to criteria that Novartis set. Novartis managed these referrals in such a way as to reward pharmacies who achieved "higher compliance" with Novartis's goals for increasing sales and refills of Novartis drugs.

132. As of April 2010, Novartis documents indicate that a forthcoming "Specialty Pharmacy (SPP) Network" for TOBI would include Defendant Accredo, Aetna, A-Med, Armada, Defendant Caremark, CF Services, Cigna, Defendant Curascript, Precision Rx, Rx Solutions, and Walgreen SPP. These documents also stated that an objective of TOBICARE was to "increase TOBI refills through the Specialty Pharmacy."

133. On July 15, 2010, Mark Smith, Novartis Senior Director for U.S. Managed Markets, claimed in a discussion with Relator that Novartis' performance incentives for specialty pharmacies were legal under a safe harbor to the AKS because of high unmet medical needs of TOBI patients. There is no such safe harbor.

134. In a September 1, 2010, PowerPoint presentation, Novartis' Contract Operations Team for TOBI reported that they were negotiating a contract with Foundation Care that would provide a "performance rebate" on TOBI purchases based on "volume and market share requirements" along with "patient adherence support." "Patient adherence support" refers to a Novartis payment to a specialty pharmacy made in exchange for the pharmacy employing staff to encourage customers to refill their TOBI prescriptions, and, if they decline to do so, alerting the TOBICARE reimbursement hub run by Caremark's Theracom unit so that TOBICARE can follow-up with the person's physician. The stated contracting objectives were to "[g]row TOBI volume and market share" and "[i]mprove patient adherence by leveraging Foundation Care's Intervention Programs and Capabilities." As Novartis believed that Foundation Care advocated for a competitor drug, i.e., compounded tobramycin, the presentation stated that the goal was to "discourage this account from promoting and advocating compounded tobramycin."

135. At a March 21-24 meeting in San Diego, California, Novartis' Associate Director for Marketing, Kiery Jackson, admitted during a group discussion that the TOBICARE program is not really an adherence program, but rather is more of a "refill program." Present at the meeting were Chris Lyon and David Kester, both of whom pointed out that Novartis' customers would not like to hear this. In using the term "customers" in this setting, Lyon and Kester were referring to physicians and other health care providers.

136. On April 8, 2011, Novartis had active contracts with six owners of specialty pharmacies pursuant to which Novartis paid the pharmacies to increase TOBI refill numbers, using "category 1" rebates to launch a pharmacy's service initiative, and "category 2" rebates to reward pharmacies that achieved certain performance goals in terms of the number of TOBI refills ordered by patients. According to Max Stillwell, a Novartis Transplant Regional Account Manager, the six were Defendant Accredo, Defendant Caremark, Cigna Tel-Drug, Defendant Curascript/ESI, A-Med, and CF Services. Stillwell explained that the specialty pharmacies contact the patient seven to ten days before their refill would be due and ask the patient if the specialty pharmacy can ship a refill.

137. In addition, since approximately April 2010, TOBICARE has directed patients to specialized pharmacies rather than retail pharmacies so they will receive these follow-up calls requesting refill orders. TOBICARE also calls the patient to encourage refills, usually placing their calls six weeks before the next refill is due. According to Stillwell, specialty pharmacies only receive the rebate if they actually dispense TOBI. The pharmacy's mere purchase of the

drug from Novartis does not entitle them to a rebate unless that purchase leads to a refill, *i.e.*, an order for the drug. Many of these refill orders are reimbursed by public health programs.

138. On an April 28, 2011 call concerning TOBICARE, Oscar Urcia from Novartis' customer service department confirmed that the six specialty pharmacies mentioned in the preceding paragraph are "approved TOBICARE specialty pharmacies." Novartis used the term "approved specialty pharmacies" to refer to pharmacies with which Novartis has entered into contracts providing incentive rebates as a reward for increased refill numbers. Urcia stated on the call that TOBICARE employs three customer service agents that handle 50 to 75 calls per day, including calls in which they contact patients to check for insurance changes, check for any side effects or other issues relating to the patient's use of TOBI, and ask if the patients are ready for the next refill. If the patient does not want a refill, TOBICARE notifies the physician that the patient is off therapy.

139. On May 19, 2011, Steve Davis ("Davis"), Assistant Director of Novartis' Specialty Pharmacy Group – the group that negotiates contracts between Novartis and specialty pharmacies – spoke by telephone with Relator and other Novartis employees. During the call, Davis said that, since approximately 2008, Novartis has used the specialty pharmacy model for TOBI because the "high touch" approach of specialty pharmacies, which include calls by sales staff to customers concerning prescription refills, increases the percentage of prescriptions that ultimately are refilled by patients (and largely paid for by the taxpayer). At retail pharmacies, the average number of TOBI prescription fills is 2.1 per patient per year; at specialty pharmacies,

the average number of TOBI prescription fills is 4.1 per patient per year out of a maximum of 6.5 per year. (TOBI is taken twice a day every other month.)

140. Davis explained that Novartis uses two separate methods to maximize the number of patients who receive calls from specialty pharmacy staff encouraging refills. First, Novartis and Defendant Caremark drive patients towards specialty pharmacies for their prescription needs by asking patients and doctors to contact TOBICARE (the reimbursement hub run by Defendant Caremark's subsidiary, Theracom) for all questions on payer reimbursement for TOBI. Theracom in turn has been instructed to direct inquiring patients and doctors' offices to specialty pharmacies in the first instance. Second, Novartis offers special rebates to specialty pharmacies that adopt such a "high touch" approach; the rebates are directly correlated with the average number of TOBI refills achieved by the pharmacy per year. According to Davis, Novartis only pays the specialty pharmacies these rebates if the refills were actually shipped from a Specialty Pharmacy location. This places pressure on the pharmacy chains to channel retail patients into their specialty pharmacies where they will be solicited for refills.

141. According to additional comments made by Davis on the May 19th call, Novartis at that time was finalizing a contract with Foundation Care that similarly would provide the company's specialty pharmacies with a tiered rebate structure tied to "performance metrics" to "encourage growth of TOBI market share." Davis explained that, while Novartis is willing to negotiate such rebate provisions with Caremark's specialty pharmacies, it is not willing to do so with Caremark's regular retail stores.

142. The combination of Theracom's efforts to steer patients towards "high touch" specialty pharmacies, and the performance-based rebates that Novartis offers only to "high touch" specialty pharmacies, has led to a dramatic increase in the percentage of TOBI sales made by these specialized pharmacies. Davis noted on the May 19th call that the percentage of TOBI sales generated by specialty pharmacies increased from 11% of the total TOBI sales in 2007, to approximately 35% of the total TOBI sales in 2010.

143. As of August 1, 2011, Novartis had active contracts with at least seven owners of specialty pharmacies pursuant to which Novartis paid the pharmacies to increase TOBI refill numbers using category 1 rebates to launch a pharmacy's service initiative and category 2 rebates to reward pharmacies that achieved certain performance goals in terms of the number of TOBI refills ordered by patients. According to Rob Rindini, Novartis Associate Director for Specialty Pharmacy, as of August 2011, the "TOBI SPs" include CIGNA Home Delivery, Defendant Caremark, Defendant Curascript, Defendant Accredo, A-Med, CF Services and Walgreens Specialty Pharmacy.

144. Novartis' purpose in limiting the number of pharmacies permitted to distribute TOBI and Novartis' new, successor product TIP as part of Novartis' exclusive network, and in including in the contracts with these "TOBI network" pharmacies the "pay for performance" provisions described above, is to obtain the agreement of the pharmacies: i) to recommend TOBI and/or Novartis' new product TIP instead of competing products; and, ii) to discontinue offering the less expensive, competing product – compounded tobramycin. When contracting with a new

TOBI network pharmacy, Novartis expects that the pharmacy will recommend TOBI and/or TIP over competing products and discontinue compounding tobramycin.

Myfortic

145. The allegations of the United States with regard to the drug Myfortic, as set forth in the Second Amended Complaint of the United States, are incorporated herein by reference. The additional allegations set forth in this complaint with regard to the drug Myfortic are set forth in support of the claims that Relator asserts on behalf of the United States and all states named as plaintiffs herein, with the exception of the State of Maryland, a state whose false claims law does not permit private persons to proceed with claims declined by the state.

146. Novartis has also implemented a specialty pharmacy kickback scheme to increase the company's sales of Myfortic, an immunosuppressant prescribed following organ transplant. The FDA approved Myfortic in November 1997. In 2010, Novartis earned approximately $163 million from sales of this drug.

147. Myfortic is generally more expensive than the generic versions of its competitor, Cellcept (mycophenalate motefil), which gives Myfortic an immediate competitive disadvantage.

148. Like other immunosuppressants, Myfortic's product label contains a black box warning advising patients and physicians that the drug "may lead to increased susceptibility to infection and possible development of lymphomas and other neoplasms." The black box warning underscores the importance of particularly careful physician supervision of patient use of the drug, with all pertinent information on patient health transmitted to the physician: "Only physicians experienced in immunosuppressive therapy and management of organ transplant

recipients should use Myfortic . . . Patients receiving myfortic should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient." (Emphasis in original.)

149. To market Myfortic, Novartis must overcome the handicap of the product's relatively higher cost compared to the generic competition. To expand sales of the drug notwithstanding this price disadvantage, Novartis management, in an August 5, 2011, presentation entitled "XLR8: the myfortic® Acceleration Plan," announced the company's arrangements to: "Partner with SPs [specialty pharmacies] to ensure ALL appropriate patients are on myfortic." In other words, Novartis was entering into financial arrangements with specialty pharmacies to induce them to take proactive steps to move transplant patients onto Myfortic. Management disclosed the "[n]ew specialty pharmacy contracts designed to drive myfortic® net sales growth" with "risk mitigated: rebates paid only when performance hurdles achieved." Management clarified that the rebates would increase incrementally according to the specialty pharmacy's performance level. The document also stated that the specialty pharmacies with which Novartis had contracted in 2011 included Walgreens, OptumRx, TwentyTen, Transcript, Kings, and Kilgore.

150. In an August 22, 2011, email from Jim Niebanck, Director of Franchise Operations, Transplants, Relator was told that "[for] the SPs [specialty pharmacies] that we [Novartis] contract with, their performance rebates are based on their myfortic market share compared to the national market share."

151. Novartis' use of financial incentives to increase the market share of Myfortic compared to the competition directly affects the quality of patient care. The sales personnel that the specialty pharmacies employ to counsel patients to order Myfortic -- people with the equivalent of a high school diploma, and no professional training or licensing -- are unqualified to provide any medical advice to customers considering whether to order Myfortic. Moreover, unknown to the patient, any advice they provide is also biased by the financial incentives paid by Novartis. In the case of a drug with a black box warning, the potential consequences are particularly severe for a patient who might take the drug based on the urging of pharmacy sales staff, rather than on advice rendered by an objective health care practitioner skilled in immunosuppressive therapy and cognizant of the patient's full health profile.

THE FALSE CLAIMS

152. The false claims that form the basis for the Defendants' liability based on the allegations herein include all claims for Exjade, Gleevec, Tasigna, TOBI and Myfortic that have been billed by a specialty pharmacy to Medicare, Medicaid or another government health care program during a period of time in which Novartis used entry into its specialty pharmacy distribution networks, rebates or discounts, scorecarding and/or patient referrals to induce the billing pharmacy to recommend that patients start or continue on the Novartis drug.

153. Novartis closely tracked the distribution of Exjade, Gleevec, Tasigna, TOBI, Myfortic and other drugs on reports that contained specific information for each prescription, including date of first and last shipment, dispensing pharmacy and payer, and that consequently identify the prescriptions subject to kickbacks that were paid for by government health insurance.

Novartis created these reports from the detailed sales data that the network specialty pharmacies submitted to Novartis so that Novartis could create score cards to assess their performance. These reports, which are in Novartis' possession, contain detailed data on a prescription-by-prescription basis, concerning all sales of these specialty products through the network pharmacies.

154. For example, with regard to Exjade, Novartis created "EPASS Status Reports" that list by Exjade-prescribing physician key information on each prescription that the physician issued, including the date of the original order, the patient's diagnosis, the specialty pharmacy distributing the drug to the patient, the date of the last shipment of the drug to the patient, the reason for any discontinuation of the drug, and the payer. These reports consequently identify the specific prescriptions subject to the illegal kickbacks alleged herein, i.e., the prescriptions that were both dispensed by Bioscrip, US Bioservices or Accredo during the period of time in which kickbacks were paid and that were then paid for by Medicare, Medicaid or another government payer. For example, one such report reviewed by Relator during the course of his employment with Novartis - - a February 25, 2011, EPASS Status report in EXCEL format, reflects more than twelve thousand prescriptions that led to false claims on Medicare or Medicaid, including ones such as the following: i) in row 39, a prescription issued by a physician with Novartis ID 1744610 (physician names and addresses are found on the report but not included here for privacy reasons) for a patient with "other anemia," dispensed by Bioscrip and paid for by Medicare Part D; ii) in row 63, a prescription issued by a physician with Novartis ID 2019238 for a patient with Sickle Cell Disease, dispensed by Accredo and paid for by

Nevada Medicaid; iii) in rows 72 and 77, prescriptions issued by a physician with Novartis ID 2001152 for two patients with Sickle Cell Disease, dispensed by Accredo and paid for by New York Medicaid; iv) in row 144, a prescription issued by a physician with Novartis ID 2459205 for a patient with Sickle Cell Disease, dispensed by Accredo and paid for by Georgia Medicaid; v) in row 157, a prescription issued by a physician with Novartis ID 0430286 for a patient with Sickle Cell Disease, dispensed by Bioscrip and paid for by Florida Medicaid; vi) in row 202, a prescription issued by a physician with Novartis ID 0792509 for a patient with myelodysplastic syndrome (MDS), dispensed by US Bioservices and paid for by Medicare; vii) in row 217, a prescription issued by a physician with Novartis ID 1808639 for a patient with Sickle Cell Disease dispensed by US Bioservices and paid for by New York Medicaid; viii) in row 260, a prescription issued by a physician with Novartis ID 0678754 for a patient with "other anemia," dispensed by Accredo and paid for by Texas Medicaid; ix) in row 1016, a prescription issued by a physician with Novartis ID 1585680 for a patient with "other anemia," dispensed by Accredo and paid for by Medicare Part D; and, x) in row 3055, a prescription issued by a physician with Novartis ID 2011269 for a patient with "other anemia," dispensed by US Bioservices and paid for by Medicare Part D.

155. The Defendant pharmacies, and the government health care programs that they bill, maintain detailed records of the pharmacies' claims to government health care programs for Myfortic, Exjade, Gleevec, Tasigna, TOBI and TOBI Podhaler.

156. For example, the fact and significance of Curascript's Medicare and Medicaid billing for Gleevec can be determined by CuraScript's own publication, the 2010 Specialty Drug

Trend Report, which indicates the very substantial and increasing nature of Medicare Part D and Medicaid's cumulative payments to CuraScript for Gleevec that CuraScript dispensed in 2009 and 2010. On page 72, that report states that its data is based on a random sample of 650,000 Medicare and 2.15 million Medicaid beneficiaries, all of whom "used . . . CuraScript for specialty prescriptions." The report identifies Gleevec as a "specialty" medication. *Id.* at 58. The Trend Report—based on CuraScript's own claims data—reports that Medicare Part D's spending on Gleevec supplied by Curascript increased by 12.3% from 2009 to 2010. *Id.* As for Medicaid, the Trend Report—again, based on CuraScript's own claims data—states that Medicaid's spending on Gleevec placed Gleevec among the "Top 10 Medicaid Specialty Drugs" in 2010. *Id.* at 65. The federal and state governments also maintain detailed claims data regarding the hundreds of thousands of claims filed on the federal-state Medicaid program, Medicare Part D and TRICARE by the Defendant pharmacies for Exjade, Myfortic, Gleevec, Tasigna, TOBI and TOBI Podhaler during the period of time at issue in this action.

157. Gleevec and Tasigna are both indicated, according to their FDA-approved labels, for chronic myeloid leukemia (CML). According to statistics maintained by the American Cancer Society, "the average age at diagnosis of CML is around 64 years. Almost half of cases are diagnosed in people 65 and older. This type of leukemia mainly affects adults, and is only rarely seen in children." According to additional data of the American Cancer Society, imatinib (the generic name for Gleevec), a drug with hundreds of millions of dollars in annual sales, is "the standard treatment for CML patients." Similarly, according to the American Cancer Society, "Nilotinib (Tasigna) . . . can be used as a first treatment for CML, as well as for use in

people who can't take imatinib or whose CML no longer responds to it." Novartis sells hundreds of millions of dollars' worth of Tasigna each year. This data, considered cumulatively, evidences that the Defendant pharmacies inevitably are billing Medicare for Gleevec and Tasigna.

158. The following are examples of the hundreds of thousands of claims that Defendants Accredo, Caremark, and Curascript, through their specialty pharmacy arms, submitted to government health payers seeking payment for Gleevec, Tasigna, TOBI and TOBI Podhaler during the time period in which they were receiving the illegal remuneration from Novartis described herein. The referenced "Claim Nos." are claim-specific identifiers that permit either the government payer or the defendant pharmacy to retrieve the claim. To protect patient privacy, Relator includes no individually-identifiable health information herein. The following samples also serve to demonstrate the extremely high cost of individual prescriptions of these medications for the taxpayers: Claim No. 1039956025000, on which Curascript billed California Medicaid $5,405.64 for 30 units of Gleevec 400 mg., with date of service on February 8, 2011; Claim No. 1280952753400, on which Caremark billed California Medicaid $16,394.30 for 90 units of Gleevec 400 mg., with date of service on October 7, 2011; Claim No. 1165963312700, on which Accredo billed California Medicaid $4,198.27 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on June 14, 2011; Claim No. 1231961075300, on which Accredo billed California Medicaid $ 4,450.09 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on August 18, 2011; Claim No. 1140052108100, on which Curascript billed California Medicaid $ 4,513.04 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on March 4, 2011; Claim No. 1140052108200, on which Curascript billed California Medicaid

$4,513.04 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on April 22, 2011; Claim No. 1088950566200 on which Caremark billed California Medicaid $4,490.01 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on March 29, 2011; Claim No. 1222950499400 on which Caremark billed California Medicaid $4,759.71 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on August 10, 2011; Claim No. 1013955493800 on which Curascript billed California Medicaid $8,309.92 for 112 units of Tasigna 200 mg capsules, with date of service on January 13, 2011; Claim No. 1059956178900 on which Curascript billed California Medicaid $8,567.55 for 112 units of Tasigna 200 mg capsules, with date of service on February 28, 2011; Claim No. 1143954125500 on which Caremark billed California Medicaid $1,971.58 for 28 units of Tasigna 200 mg capsules, with date of service on May 21, 2011; Claim No. 1158953838200 on which Caremark billed California Medicaid $7,881.82 for 112 units of Tasigna 200 mg capsules, with date of service on June 7, 2011; Claim No. 110453319694004, on which Accredo billed Georgia Medicaid $4,506.29 for 280 units of TOBI 300mg/5mL, with date of service on February 14, 2011; Claim No. 201335428012203 on which Accredo billed Illinois Medicaid $7,674 for Gleevec 400 mg tablets with a date of service of December 20, 2013; Claim No. 201420628058536 on which Accredo billed Illinois Medicaid $10,056.90 for Gleevec 400 mg tablets with a date of service of July 25, 2014; Claim No. 201221328015580 on which Accredo billed Illinois Medicaid $8,983.99 for Tasigna 150 mg. capsules with date of service of July 31, 2012; Claim No. 201014128074888, on which Accredo billed Illinois Medicaid $8,124.72 for TOBI 300mg/5mL solution, with date of service on April 10, 2010; Claim No. 201032228018161, on which CuraScript billed Illinois Medicaid $5,147.99 for 30 units of

Gleevec 400 mg/capsule, with date of service on November 18, 2010; Claim No. 201215028095698, on which CuraScript billed Illinois Medicaid $8,983.99 for Tasigna 150 mg, with date of service on May 29, 2012; Claim No. 201317828054623, on which CuraScript billed Illinois Medicaid $6,648.67 for TOBI 300mg/5mL solution, with date of service on June 27, 2013; Claim No. 201333728174201, on which Caremark billed Illinois Medicaid $13,804.30 for 30 units of Gleevec 400 mg/capsule, with date of service on December 3, 2013; Claim No. 201306628080260, on which Caremark billed Illinois Medicaid $13,222.48 for TOBI 300 mg/5mL, with date of service on March 7, 2013; Claim No. 201419925147844, on which Caremark billed Illinois Medicaid $8,493.96 for Tasigna 150 mg/capsule, with date of service on January 15, 2014; Claim No. 31101902512495700 on which Caremark billed Maryland Medicaid $10,592.08 for 120 units of Gleevec 100 mg tablet with date of service of January 18, 2011; Claim No. 31102602510779700 on which Caremark billed Maryland Medicaid $9,542.05 for 30 units of Gleevec with date of service of January 24, 2011; Claim No. 31101902510998400 on which Curascript billed Maryland Medicaid $5,405.64 for 30 units of Gleevec with date of service of January 17, 2011; Claim No. P61115810131532000, on which Caremark billed Michigan Medicaid $15,886.83 for 180 units of Gleevec 100 mg. tablets, with date of service on June 7, 2011; Claim No. P61124110086215000, on which Caremark billed Michigan Medicaid $5,821.61 for 60 units of Gleevec 100 mg. tablets, with date of service on August 29, 2011; Claim No. P6111661015067900, on which Caremark billed Michigan Medicaid $1,5121.95 for 112 units of Tasigna 150 mg. tablets, with date of service on June 15, 2011; Claim No. P61119410157049000, on which Caremark billed Michigan Medicaid $1,5151.95 for 112 units

of Tasigna 150 mg. tablets, with date of service on July 13, 2011; Claim No. P61102710021092000, on which Caremark billed Michigan Medicaid $8,614.43 for 280 units of TOBI 300 mg/5 ML solution, with date of service on January 27, 2011; Claim No. P61103810112877000, on which Caremark billed Michigan Medicaid $5,254.99 for 280 units of TOBI 300 mg/5 ML solution, with date of service on February 7, 2011; Claim No. P61115910175346000, on which Accredo billed Michigan Medicaid for $5,781.30 for 30 units of Gleevec 400 mg. tablets, with date of service on June 8, 2011; Claim No. P61117810095409000, on which Accredo billed Michigan Medicaid for $4880.24 for TOBI 300 mg/5 ML solution, with date of service on June 30, 2011; Claim No. 201029550064473 on which Accredo billed New Jersey Medicaid $4,604.00 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on October 27, 2010; Claim No. 201112550106354, on which Caremark billed New Jersey Medicaid $5,220.00 for 280 units of TOBI 300 mg/5 ML Solution, with date of service on May 5, 2011; Claim No. 201114350068029, on which Caremark billed New Jersey Medicaid $4,878.05 for 30 units of Gleevec 400 mg capsules, with date of service on March 23, 2011; Claim No. 201135050045484, on which Caremark billed New Jersey Medicaid $15,122.93 for 112 units of Tasigna, 150 mg capsules, with date of service on December 16, 2011; Claim No. 201112550106354 on which Caremark billed New Jersey Medicaid for TOBI 300 MG/5 ML Solution with a date of service on May 5, 2011 and received payment in the amount of $4,309.68; Claim No. 201112550106 on which Caremark billed New Jersey Medicaid for TOBI 300 MG/5 ML Solution with a date of service on May 5, 2011 and received payment in the amount of $4,309.68; Claim No. 201025450303668 on which Caremark billed

New Jersey Medicaid for TOBI 300 Mg/5 ML Solution with a date of service on September 22, 2010, and received payment in the amount of $4,262.00; Claim No. 201135350024337 on which Caremark billed New Jersey Medicaid for Tasigna 150 mg. capsules with a date of service on December 19, 2011 and received payment in the amount of $7,573.44; Claim No. 201134650053087 on which Caremark billed New Jersey Medicaid for Gleevec 400 mg. capsules with a date of service of December 12, 2011 and received payment in the amount of $5,245.72; Claim No. 1100700007527301, on which Accredo billed New York Medicaid $5,506.20, and was paid $4,611.88, for 30 units of Gleevec 400 mg/capsule, with date of service on January 7, 2011; Claim No. 1307900192298701, on which Accredo billed New York Medicaid $8,012.17, and was paid $6,653.60, for 280 units of TOBI 300 mg/5 mL solution, with date of service on March 20, 2013; Claim No. 1102000070582701, on which Caremark billed New York Medicaid $7,062.60, and was paid $5,378.42, for 120 units of Gleevec 100 mg/capsule, with date of service on January 20, 2011; Claim No. 1109700082001301, on which Caremark billed New York Medicaid $10,082.48, and was paid $ 7,674.65, for 112 units of Tasigna 150mg/capsule, with date of service on April 5, 2011; Claim No. 1100500100190801, on which Caremark billed New York Medicaid $4,958.99, and was paid $4,126.95, for 280 units of TOBI 300 mg/5 mL solution, with date of service on January 5, 2011; Claim No. 1100600050858101, on which Curascript billed New York Medicaid $4,395.90, and was paid $4,392.90, for 30 units of Gleevec 400 mg/capsule, with date of service on January 6, 2011; Claim No. 1109700055644201, on which Curascript billed New York Medicaid $7,674.12, and was paid $7,671.12, for 112 units of Tasigna 200mg/capsule, with date of service on April 7,

2011; Claim No. 1116000099086101, on which Curascript billed New York Medicaid $4,567.32, and was paid $1,892.95, for 280 units of TOBI 300 mg/5 mL solution, with date of service on January 21, 2011; Claim No. 2511137300545 on which Curascript billed Oklahoma Medicaid $5091.68 for 30 units of Gleevec with dispensed date of May 17, 2011; Claim No. 311107001000 on which Curascript billed Washington Medicaid for $4,047.46 for 90 units of Gleevec with date of service of March 11, 2011; Claim No. 311135002023 on which Curascript billed Washington Medicaid $4,447.74 for 90 units of Gleevec with date of service of December 16, 2011; Claim No. 311118004014499000, on which Caremark billed Washington Medicaid $9,543.60 for 30 units of Gleevec with date of service on June 29, 2011; Claim No. 25140008029236 on which Accredo billed Wisconsin Medicaid $8,012.17 for 224 units of TOBI Podhaler with date of service of January 13, 2014; Claim No. 2514153053802 on which Caremark billed Wisconsin Medicaid $13,223.52 for 224 units of TOBI Podhaler with date of service on June 2, 2014; Claim No. 2512242014752, on which Caremark billed Wisconsin Medicaid $7,290.00 for Tasigna 200 mg/capsule, with date of service on August 29, 2012; Claim No. 2511357019875, on which Caremark billed Wisconsin Medicaid $10,470 for Gleevec 400 mg/capsule, with date of service on December 23, 2011.

159. The government health care programs reimbursed the sample false claims listed above, as well as hundreds of thousands of additional false claims submitted by the defendant pharmacies. The defendant pharmacies knew they were submitting false claims and knew they were receiving overpayments. Pursuant to 42 U.S.C. §1320a-7k(d), the pharmacies had an affirmative duty to disclose these overpayments to the relevant government health care program.

They knowingly and improperly avoided this obligation, failing to notify the government health plans of the overpayments they had received.

DAMAGES

160. Through the foregoing conduct, Defendant Novartis knowingly has caused specialty pharmacies to submit false claims to Medicaid, Medicare and other federal health care programs. Through the foregoing conduct, Defendants Accredo, Curascript and Caremark knowingly submitted false claims to Medicaid, Medicare and other federal and state health care programs. The claims are false because they seek payment for orders of prescription medication that are ineligible for reimbursement. The United States and the state Plaintiffs have been damaged by the amounts they have paid to reimburse specialty pharmacies in the Novartis network for orders of Gleevec, Exjade, Tasigna, TOBI, including TOBI Podhaler, and Myfortic marketed through the scheme set forth herein.[1]

COUNT I

(Federal False Claims Act, 31 U.S.C. § 3729 *et seq*.)

161. This is a civil action by Plaintiff David M. Kester, acting on behalf of and in the name of the United States, against the Defendants under the False Claims Act.

162. Plaintiff re-alleges and incorporates by reference paragraphs 1 through 160 as though fully set forth herein.

[1] In addition to the allegations contained herein, this complaint incorporates by reference the allegations contained in the United States' Second Amended Complaint.

163. Defendants Novartis, Accredo, Caremark and Curascript knowingly have presented or have caused to be presented false or fraudulent claims for payment by the United States, in violation of 31 U.S.C. § 3729(a)(1)(A) (post-May 2009 amendment) and 31 U.S.C. § 3729(a)(1) (pre-May 2009 amendment).

164. Defendants Novartis, Accredo, Caremark and Curascript knowingly have made or used, or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B) (post-May 2009 amendment) and 31 U.S.C. § 3729(a)(2) (pre-May 2009 amendment).

165. Defendants Novartis, Accredo, Caremark and Curascript have conspired with each other, as well as others, to defraud the Government by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(1)(C) (post-May 2009 amendments) and 31 U.S.C. § 3729(a)(3) (pre-May 2009 amendment).

166. Defendants Accredo, Caremark and Curascript have knowingly and improperly avoided obligations to pay or transmit money to the Government, in violation of 31 U.S.C. § 3729 (a)(1)(G) (2009).

167. Because of the Defendants' conduct set forth in this Count, the United States has suffered actual damages in the hundreds of millions of dollars, with the exact amount to be determined at trial.

COUNT TWO

(California False Claims Law, Cal. Gov. Code § 12650 *et seq*.)

168. Plaintiff re-alleges Paragraphs 1 through 160 inclusive.

169. Based on the foregoing allegations, the Defendants are liable under Cal. Gov. Code §12650 *et seq*.

COUNT THREE

(Colorado Medicaid False Claims Act, Col.Rev.Stat.25.5-4-303.5 through 25.5-4-310 (2010).)

170. Plaintiff re-alleges Paragraphs 1 through 160 inclusive.

171. Based on the foregoing allegations, the Defendants are liable under the Colorado Medicaid False Claims Act, Col.Rev.Stat. § 25.5-4-303.5 through 25.5-4-310 (2010).

COUNT FOUR

(Connecticut Gen. Stat. § 17b-301b (2010))

172. Plaintiff re-alleges Paragraphs 1 through 160 inclusive.

173. Based on the foregoing allegations, the Defendants are liable under Conn. Gen. Stat. § 17b-301b (2010).

COUNT FIVE

(Delaware False Claims & Reporting Act, 6 Del.C. §1201 *et seq*.)

174. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

175. Based on the foregoing allegations, the Defendants are liable under the Delaware False Claims & Reporting Act, 6 Del.C. § 1201 *et seq*.

COUNT SIX

(District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.)

176. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

177. Based on the foregoing allegations, the Defendants are liable under the District of Columbia False Claims Act, D.C. Code § 2-308.14 *et seq*.

COUNT SEVEN

(Florida False Claims Act, Fla. Stat. §§ 68-081-68.09)

178. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

179. Based on the foregoing allegations, the Defendants are liable under Florida False Claims Act, Fla. Stat. §§ 68-081-68.09.

COUNT EIGHT

(Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B)

180. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

181. Based on the foregoing allegations, the Defendants are liable under the Georgia State False Medicaid Claims Act, Georgia Code, Title 49, Ch. 4, Art. 7B.

COUNT NINE

(Hawaii False Claims Law, HRS § 661-21 *et seq*.)

182. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

183. Based on the foregoing allegations, the Defendants are liable under the Hawaii False Claims Law, HRS § 661-21 *et seq*.

COUNT TEN

(Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq*.)

184. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

185. Based on the foregoing allegations, the Defendants are liable under the Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq*.

COUNT ELEVEN

(Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5.-1 *et seq*. (2005))

186. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

187. Based on the foregoing allegations, the Defendants are liable under the Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 *et seq*.

COUNT TWELVE

(Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq*.)

188. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

189. Based on the foregoing allegations, the Defendants are liable under the Louisiana Qui Tam Action Act, La. R.S. 46:438:3 *et seq*.

COUNT THIRTEEN

(Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611(2010))

190. Based on the allegations set forth in the complaint of the State of Maryland, the Defendants Novartis and Bioscrip are liable under the Maryland False Health Claims Act, Md. Health-Gen. Code Ann. §§ 2-601 through 2-611(2010).

COUNT FOURTEEN

(Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq*.)

191. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

192. Based on the foregoing allegations, the Defendants are liable under the Massachusetts False Claims Law, ALM Ch. 12 § 5A-0 *et seq*.

COUNT FIFTEEN

(Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq*.)

193. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

194. Based on the foregoing allegations, the Defendants are liable under the Michigan Medicaid False Claims Act, Mich. Code 400.601 *et seq*.

COUNT SIXTEEN

(Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.)

195. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

196. Based on the foregoing allegations, the Defendants are liable under the Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq*.

COUNT SEVENTEEN

(Montana False Claims Act, Mon. Code Ann. § 17-8-401 *et seq*.)

197. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

198. Based on the foregoing allegations, the Defendants are liable under the Montana False Claims Act, Mon. Code Anno. § 17-8-401 *et seq*.

COUNT EIGHTEEN

(Nevada Submission of False Claims to State or Local Government Act,
Nev. Rev. Stat. Ann. § 357.010 *et seq*.)

199. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

200. Based on the foregoing allegations, the Defendants are liable under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq*.

COUNT NINETEEN

(New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.)

201. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

202. Based on the foregoing allegations, the Defendants are liable under the New Jersey False Claims Act, N.J. Stat. § 2A:32C-1 *et seq*.

COUNT TWENTY

(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*.)

203. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

204. Based on the foregoing allegations, the Defendants are liable under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*.

COUNT TWENTY-ONE

(New York False Claims Act, NY State Fin. Law, Art. 13)

205. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

206. Based on the foregoing allegations, the Defendants are liable under the New York False Claims Act, NY State Fin. Law, Art. 13.

COUNT TWENTY-TWO

(North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.)

207. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

208. Based on the foregoing allegations, the Defendants are liable under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq*.

COUNT TWENTY-THREE

(Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 *et seq*. (2011))

209. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

210. Based on the foregoing allegations, the Defendants are liable under the Oklahoma Medicaid False Claims Act, 63 Okla. St. § 5053.1 *et seq*. (2011).

COUNT TWENTY-FOUR

(Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010))

211. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

212. Based on the foregoing allegations, the Defendants are liable under the Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*. (2010).

COUNT TWENTY-FIVE

(Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185)

213. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

214. Based on the foregoing allegations, the Defendants are liable under the Tennessee Medicaid False Claims Act, 71-5-181 through 71-5-185.

COUNT TWENTY-SIX

(Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq*.)

215. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

216. Based on the foregoing allegations, the Defendants are liable under the Texas False Claims Act, Texas Human Resources Code, § 36.002 *et seq*.

COUNT TWENTY-SEVEN

(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*.)

217. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

218. Based on the foregoing allegations, the Defendants are liable under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq*.

COUNT TWENTY-EIGHT

(Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931)

219. Plaintiff re-alleges Paragraphs 1 through 160, inclusive.

220. Based on the foregoing allegations, the Defendants are liable under the Wisconsin False Claims for Medical Assistance Act, Wis. Stat. § 20.931.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff David M. Kester prays for the following relief:

1. On Counts One through Twenty-Eight, judgment for the United States or the State, as applicable, against the Defendants in an amount equal to three times the damages the federal or state plaintiff government, respectively, has sustained because of the Defendants' actions, plus a civil penalty of $11,000 for each violation, plus any available civil penalties under the state laws;

2. On Counts One through Twenty-Eight, an award to the Relator of the maximum allowed under the federal or state law under which suit is brought by the Relator on behalf of the federal or state plaintiff, respectively;

3. Against the Defendants, attorneys' fees, expenses and costs of suit; and

4. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands that this matter be tried before a jury.

Respectfully submitted,

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Dated: September 15, 2014