IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

[UNDER SEAL], on behalf of the UNITED STATES OF AMERICA, *et al.*,

Plaintiffs/Relator,

v.

[UNDER SEAL],

Defendants.

Civil Action No.

COMPLAINT AND JURY DEMAND

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

FILED UNDER SEAL

HEALTH CHOICE ADVOCATES, LLC, on behalf of the UNITED STATES OF AMERICA; STATE OF ARKANSAS; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; DISTRICT OF COLUMBIA; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF IOWA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; STATE OF VERMONT; COMMONWEALTH OF VIRGINIA; and STATE OF WASHINGTON,

Plaintiffs/Relator;

v.

GILEAD SCIENCES, INC.; HEALTHSTAR COMMUNICATIONS, INC.; COVANCE, INC.; AEROTEK, INC.; and RANDSTAD NORTH AMERICA, INC.,

Defendants.

Civil Action No.

COMPLAINT AND JURY DEMAND

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

The United States of America (the "United States") and the Plaintiff States (the United States and Plaintiff States are collectively referred to herein as the "Government"), by and through their *qui tam* Relator Health Choice Advocates, LLC (the "Relator"), allege:

PRELIMINARY STATEMENT

1. This is a civil action brought on behalf of the Government under the Federal False Claims Act, 31 U.S.C. § 3729 – 3733 (the "False Claims Act" or "FCA") and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by and civil penalties

[1] The state statues are the: (1) Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 911 (as amended by 2017 Arkansas Laws Act 978 (S.B. 564)); (2) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (3) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (4) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (5) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (6) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (7) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (8) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (9) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (10) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (11) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (12) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (13) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (14) Maryland False Claims Act, Md. Code Ann. Health-Gen. §§ 8-101 – 111; (15) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (16) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615; (17) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16; (18) Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 416; (19) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (20) New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. §§ 167:61-b – 61-e; (21) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (22) New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 14-15; (23) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (24) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (25) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (26) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (27) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 1.1-9; (28) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (29) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (30) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (31) Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642; (32) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (33) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

and restitution owed to the Government as a result of a multi-tiered kickback scheme involving defendants Gilead Sciences, Inc. ("Gilead" or the "Company"); HealthSTAR Communications, Inc. ("Healthstar"); Covance Inc. ("Covance"); Aerotek, Inc. ("Aerotek"); and Randstad Healthcare, a division of Randstad North America, Inc. ("Randstad"). Collectively, Gilead, Healthstar, Covance, Aerotek, and Randstad are referred to herein as "Defendants."

2. Defendants' unlawful conduct involves Gilead's blockbuster products (1) Sovaldi (sofosbuvir); (2) Harvoni (ledipasvir/sofosbuvir); (3) Truvada (emtricitabine/tenofovir); and (4) Atripla (efavirenz/emtricitabine/tenofovir). Collectively, Sovaldi, Harvoni, Truvada, and Atripla are referred to herein as the "Covered Drugs."

3. To enrich themselves at the expense of the Government, Gilead, with substantial assistance from Healthstar, Covance, Aerotek, and Randstad, engaged in three intertwined, unlawful marketing schemes for the Covered Drugs. First, Gilead contracted with and paid remuneration to Healthstar to deploy nurse educators to recommend Sovaldi and Harvoni to Prescribers[2] and patients. While purporting to provide independent medical advice and disease-awareness information, the Healthstar nurses were in reality acting as undercover sales reps for Gilead, focused on the singular mission Gilead had paid them to accomplish: refer Sovaldi and Harvoni to Prescribers and patients. Second, with assistance from Covance, Aerotek, and Randstad, Gilead provided in-kind remuneration to Prescribers in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses. These reimbursement support services were provided to induce Prescribers to prescribe the Covered Drugs to their patients. Third, with assistance from Healthstar, Gilead provided in-kind remuneration to Prescribers in the form of free nursing services to induce them to prescribe

[2] As used herein, the term "Prescriber" refers to any physician or Advance Practice Provider authorized to write prescriptions, as well as their employers.

Sovaldi and Harvoni to their patients.

4. The federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting, or receiving any "remuneration," which includes "any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* Further, the U.S. Department of Health and Human Services (the "HHS") has repeatedly warned pharmaceutical companies that they should refrain from engaging in marketing or promotional activities that rely on individuals involved in the delivery of healthcare or on the provision of free services such as billing, nursing, or other staff services. *See, e.g.*, 56 Fed. Reg. 35952-01, 35981 (July 29, 1991); 59 Fed. Reg. 65372-01, 65376 (Dec. 19, 1994).

5. Although Gilead and its co-defendants knew that the AKS prohibited them from giving kickbacks to promote the Covered Drugs, Defendants disregarded the law, choosing instead to put sales growth and profits before their duties to comply with the law and ensure patient safety and integrity in the healthcare marketplace. Tens of thousands of patients were prescribed the Covered Drugs not based on clinical efficacy or patient-specific information, but rather as a result of the unlawful, substantial kickbacks Gilead offered Prescribers.

6. Based on Defendants' illegal marketing and promotion schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay billions of dollars in improper reimbursements.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the Government's claims pursuant to 28 U.S.C. §§ 1331 and 1345.

8. This Court may exercise personal jurisdiction over Gilead, Healthstar, Covance, Aero, and Randstad because a substantial part of the acts giving rise to the Government's claims

occurred within the State of Texas.

9. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c) because Gilead, Healthstar, Covance, Aero, and Randstad each transact business in this District and/or, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

THE PARTIES

10. Gilead is a publicly-traded pharmaceutical company headquartered in Foster City, California. Gilead sells pharmaceuticals throughout the United States.

11. Healthstar is a privately-held corporation headquartered in Mahwah, New Jersey. According to its website, Healthstar provides "a comprehensive portfolio of unique and traditional healthcare marketing services."[3] Among those services are marketing services for the pharmaceutical industry, including the provision of clinical educators. According to Healthstar, one of the goals of clinical educators is to "enhance the sales representatives' access to physicians and create a receptive audience for their message."[4]

12. Covance is a company headquartered in Princeton, New Jersey. According to its website, Covance offers services such as "[i]dentify[ing] prior authorization requirements to smooth the process for patients and providers."[5] The website also touts Covance's "Market

[3] HealthSTAR Communications, http://www.healthstarcom.com (last visited May 24, 2017).

[4] HealthSTAR Clinical Education Solutions, http://www.healthstarces.com/clinical.html (last visited May 24, 2017).

[5] Covance Patient Access Programs, http://www.covance.com/industry-solutions/healthcare/commercialization/patient-and-provider-services/patient-access-programs.html (last visited June 13, 2017).

Access Field Team" that provides "on-site assistance to healthcare professionals . . . ."[6] Covance is a subsidiary of Laboratory Corporation of America Holdings, a publicly-traded company headquartered in Burlington, North Carolina.

13. Aerotek is a company headquartered in Hanover, Maryland. According to its website, Aerotek provides staffing services.[7] Aerotek provided field reimbursement personnel to Covance. Aerotek is a subsidiary of Allegis Group, a privately-held company headquartered in Hanover, Maryland.

14. Randstad Healthcare is a company headquartered in Alpharetta, Georgia. According to its website, Randstad is a staffing company.[8] Randstad provided field reimbursement personnel to Covance. Randstad Healthcare is a division of Randstad North America, Inc. a privately-held company headquartered in Atlanta, Georgia.

15. Relator Health Choice Advocates, LLC is an affiliate of the National Healthcare Analysis Group ("NHAG"), a research organization based in New Jersey. Each year, NHAG representatives conduct hundreds of interviews of participants in the healthcare marketplace – nurses, sales reps, office managers, administrators, reimbursement support personnel, etc. – to form an understanding of industry practices.

16. Relator brings this action on behalf of the Government pursuant to the *qui tam* provisions of the federal False Claims Act, 31 U.S.C. § 3729 – 3733 and the false claims acts of the respective Plaintiff States.

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[6] *Id.*

[7] *See* Aerotek Staffing Services, https://www.aerotek.com/workforce-solutions/staffing-services (last visited June 13, 2017).

[8] *See* Randstad Healthcare Overview, http://healthcare.randstadusa.com/aboutRandstadHealthcare/overview.aspx (last visited June 13, 2017).

STATUTORY BACKGROUND

17. In relevant part, the FCA, 31 U.S.C. § 3729(a)(1)(A) – (C), establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; or
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to commit a violation of [the foregoing paragraphs].

Within the meaning of the FCA, "knowingly" is defined to include reckless disregard and deliberate ignorance. 31 U.S.C. § 3729(b)(1). In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

18. In relevant part, the AKS, 42 U.S.C. § 1320a-7b, provides as follows:

> (b) Illegal Remunerations.
>
> > (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
> >
> > > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > >
> > > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> > (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
> >
> > > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which

> payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

19. For purposes of the AKS, "remuneration" includes the transfer of anything of value, whether cash or in-kind consideration, directly or indirectly, covertly or overtly. Importantly, the statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

20. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry, and that healthcare professionals remain free of conflicts of interest that could impact treatment decisions.

21. To ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

22. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS constitute violations of the FCA. 42 U.S.C. § 1320a-7b(g). The PPACA also makes clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." Pub. L. No. 111-148, 124 STAT. 759 § 6402 (adding new section, § 1128J(h)).

23. Knowingly providing kickbacks to Prescribers to induce them to prescribe a drug (or to influence prescriptions) to individuals who seek reimbursement for the drug from a federal

Government healthcare program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA.

24. A violation of the AKS constitutes a felony. Any party convicted under the AKS must be excluded from federal health care programs for a term of at least five years. 42 U.S.C. § 1320a-7(a).

25. Compliance with the AKS is required for reimbursement of claims from federal health care programs, and claims made in violation of the law are actionable civilly under the FCA. 42 U.S.C. § 1320a-7b(g) (stating, in part, that "a claim that includes items or services resulting from a violation of . . . [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]"); *see also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 313 (3d Cir. 2011) (stating that "[c]ompliance with the AKS is clearly a condition of payment under Parts C and D of Medicare").

26. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect Defendants from liability for the conduct alleged herein.

27. Each of the Plaintiff States has enacted statutes that are parallel to the legislative scheme embodied in the FCA and the AKS.

AFFECTED HEALTH PROGRAMS

28. Generally, when a Prescriber prescribes one of the Covered Drugs, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

29. In certain circumstances, a federal program may also have pharmacy facilities that

directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

Medicare

30. Medicare is a federal program that provides federally-subsidized health insurance primarily for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program").

31. Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006.

32. All persons enrolled in Medicare Part A or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Center for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into subcontracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

33. Generally, after a Prescriber writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through the sponsor's pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to the CMS an electronic notification of the drug dispensing event, called the Prescription Drug Event

("PDE"), which contains data regarding the prescription claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

34. Payments to a Part D Plan sponsor are "conditioned upon the provision of information to CMS that is necessary" for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

35. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor's plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage, and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy

and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R. § 423.336.

36. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

37. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

38. By statute, all contracts between a Part D Plan sponsor and the HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112(b)(1).

39. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R. § 423.505(h)(l).

40. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply 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 (31 U.S.C. §§ 3729 *et seq.*), and the Anti-Kickback Statute (section 1128B(b) of the Act)." 42 C.F.R. § 423.505(h)(1).

41. CMS regulations further require that all subcontracts between Part D Plan sponsors and downstream entities (such as pharmacies and PBMs) contain language obligating the entities in question to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

42. A Part D Plan sponsor also is required to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.
>
> (2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.
>
> (3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under § 423.871(f)) are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

43. Compliance with the regulatory requirement that the PDE data submitted to CMS

is true, accurate, and complete is a condition of payment under the Medicare Part D program. *See id.* at 423.505(k)(1)

44. In accordance with this regulatory requirement, since the Part D program began, Medicare required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to

> certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

45. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

46. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

47. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. To be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . . The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the

> Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Medicaid

48. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program.

49. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

50. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(l).

51. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies generate funding requests to the state Medicaid programs.

52. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding each state will be

permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R. § 430.30.

53. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

54. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify compliance with applicable federal and state laws and regulations.

55. For example, in New York, physicians and 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."

TRICARE

56. TRICARE is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military

operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

57. TRICARE prescription drug benefits are provided through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies, and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

58. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information

regarding the prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

59. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE/DOD.CHAMPUS Medical Claim- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

60. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by the Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals. The PBM then submits a TED record to TRICARE to obtain administrative

fees. DLA bills TRICARE directly for drug replenishment costs.

61. Pursuant to 38 U.S.C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

62. Since March 2003, TRICARE has contracted with a pharmacy benefits manager, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

63. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

64. While some physicians enroll in the TRICARE program as network or participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with

TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* § 199.9(c)(12).

Veterans Administration Health Care

65. The Department of Veteran Affairs ("VA") maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are procured directly by the VA. A VA beneficiary can take a prescription to a VA medical facility, at which point the VA dispenses the medication to the VA beneficiary from its existing inventory. The VA also supports a mail service prescription program as part of its outpatient drug benefit. VA beneficiaries can submit prescriptions to that mail service program, and the VA then dispenses pharmaceuticals purchased by the VA directly to VA beneficiaries. The VA medical system serves approximately four million veterans.

66. The VA purchases the pharmaceuticals that it dispenses at its medical facilities and through its mail service prescription program through its Federal Supply Schedule ("FSS") program. Pursuant to Public Law 102-585, pharmaceutical manufacturers are required to enter into national contracts with the VA pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price. A VA facility that requires a supply of a particular medication (including a mail order facility) submits a purchase order to the VA's pharmaceutical prime vendor for distribution of pharmaceuticals.

67. Pursuant to the PPACA, among other things, all claims to Government reimbursed programs resulting from a violation of the AKS are also a violation of the FCA.

68. Moreover, the statutes and regulations set forth above concerning Medicare, Medicaid, TRICARE, and Veterans Administration Health Care, when viewed together, state

that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed.

69. Here, the claims submitted for the Covered Drugs violated the AKS because they stemmed from prescriptions that were tainted by kickbacks, while the participants in the scheme knew that claims for reimbursement would be submitted to the above programs. As such, and as more fully discussed below, the prescribing healthcare providers expressly and impliedly falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, TRICARE, and Veterans Administration Health Care.

70. In addition to falsely certifying compliance with the AKS, the healthcare providers also falsely certified compliance with contractual provisions that were conditions for payment.

RELATOR'S INVESTIGATION

71. To unmask Defendants' unlawful conduct, Relator and its representatives interviewed numerous individuals with knowledge of the scheme.

- Confidential Interviewee #1 ("CI-1") was employed by Healthstar, under its contract with Gilead, as a Hep-C nurse from May 2015 until January 2016. Her territory spanned the southeast region of the United States including Georgia, Mississippi, Alabama, and the Florida Panhandle.
- Confidential Interviewee #2 ("CI-2") was employed by Healthstar as a Hep-C nurse from March 2014 through January 2016. Her territory spanned all of Illinois and large parts of Wisconsin and Missouri.
- Confidential Interviewee #3 ("CI-3") was employed by Healthstar, under its contract with Gilead, as a Hep-C nurse from August 2013 until January 2016.

Her territory included Wyoming, Colorado, New Mexico, Arizona, Las Vegas, Nevada, and El Paso, Texas.

- Confidential Interviewee #4 ("CI-4"), was employed by Healthstar, under its contract with Gilead, as a Hep-C nurse from August 2013 until December 2015. Her territory included Houston, Texas to parts of Louisiana.
- Confidential Interviewee #5 ("CI-5") was employed by Gilead as a Hep-C drug rep from July 2013 until October 2014. His territory spanned the state of California.
- Confidential Interviewee #6 ("CI-6") is employed by Covance as a reimbursement services ("RS") field representative supporting Sovaldi and Harvoni, and has been employed since February 2016. Her territory includes the state of Missouri.
- Confidential Interviewee #7 ("CI-7") was employed by Aerotek, under its contract with Covance, as a RS field representative from July 2014 until December 2014. Her territory spanned the state of Illinois.
- Confidential Interviewee #8 ("CI-8") was employed by Randstad, under its contract with Covance, as a RS representative from October 2015 until April 2016.
- Confidential Interviewee #9 ("CI-9") was employed by Healthstar, under its contract with Gilead, as a Hep-C nurse from June 2014 until January 2015. Her territory spanned from Houston, Texas to Baton Rouge, Louisiana.
- Confidential Interviewee #10 ("CI-10") was employed by Healthstar, under its contract with Gilead as a Hep-C nurse from August 2013 until January 2016. Her territory spanned six states surrounding and including Missouri.

- Confidential Interviewee #11 ("CI-11") was employed by Covance, under its contract with Gilead, as a RS representative from October of 2014 until February 2015.
- Confidential Interviewee #12 ("CI-12") was employed by Gilead as an HIV drug rep from 2012 until 2014. Her territory spanned New York, NY and the surrounding area.

THE FRAUDULENT SCHEMES

72. Based on Relator's investigation, there is overwhelming evidence that Gilead, with substantial assistance from Healthstar, Covance, Aerotek, and Randstad, engaged in a complex, multi-part scheme that involved the payment of kickbacks to Prescribers for the purpose of increasing prescriptions of the Covered Drugs.

73. In the first scheme, Gilead contracted with and paid remuneration to Healthstar to deploy nurse educators to recommend Sovaldi and Harvoni to Prescribers and patients, thereby blurring the lines between independent medical advice and sales.

74. In the second scheme, with assistance from Covance, Aerotek, and Randstad, Gilead provided in-kind remuneration in the form of reimbursement support services, saving Prescribers thousands of dollars in administrative expenses, to induce Prescribers to recommend Gilead's Covered Drugs.

75. In the third scheme, with assistance from Healthstar, Gilead provided free nursing services to doctors to induce them to recommend Sovaldi and Harvoni to their patients.

Scheme One: White Coat Marketing by Nurse Educators

76. Beginning in 2013, Gilead contracted with Healthstar to employ nurses to help promote Sovaldi and obtain easier access to Prescribers who oftentimes are skeptical of sales

reps and, as a consequence, restrict or deny access to such reps. Once Harvoni was launched in 2014, Healthstar nurses also began to promote Harvoni.

77. Healthstar touted its clinical educators' ability to "enhance the sales representatives' access to physicians and create a receptive audience for their message."[9] Gilead contracted with Healthstar and hired roughly two dozen nurses to help Gilead gain direct, unfettered access to Prescribers and patients. Gilead's purpose was quite simple: it wished to cloak itself in the uniforms of the Healthstar nurses and push Prescribers to prescribe and patients to request prescriptions for Sovaldi and Harvoni.

78. Gilead's relationship with Healthstar plainly involves the payment of a kickback – cash consideration – in return for services that ultimately led to prescriptions being filled and paid for with Government money.

79. In this case, Gilead paid remuneration to Healthstar to have nurse educators recommend Gilead drugs over competing drugs to Prescribers and patients. Gilead believed that the Healthstar nurses were likely to be viewed by Prescribers as better credentialed and more credible than traditional drug reps, and, thus, they were more likely to gain access to Prescribers and their staff.

80. The Office of Inspector General ("OIG") refers to utilizing healthcare providers, like nurses, to promote particular drugs as "white coat marketing," and has warned against the practice.

> The fraud and abuse risks are compounded where . . . a physician or other health care professional is involved in the marketing activity—a practice sometimes referred to as "white coat" marketing. White coat marketing is closely scrutinized under the anti-kickback statute because physicians and other health care professionals are in an

[9] HealthSTAR Clinical Education Solutions, http://www.healthstarces.com/clinical.html (last visited May 24, 2017).

> exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . . .[10]

81. As detailed below, Gilead paid Healthstar to hire nurse educators to *recommend* Gilead drugs to doctors and patients and drive sales. Thus, Gilead and Healthstar violated the AKS and, in turn, the FCA.

82. Gilead and Healthstar needed a clever approach to disguise this marketing strategy. After all, the nurses could not openly play the role of drug reps for at least three reasons. First, Prescribers would potentially limit nurse access, in the same manner that drug rep access was being limited. Second, if they knew that the nurses were nothing more than sales reps in disguise, Prescribers would discount the nurses' "recommendations" as biased. Third, the OIG has identified white coat marketing as particularly suspect and the AKS prohibits pharmaceutical companies from paying non-employees to "recommend" its drugs to others.[11] Since the nurses involved in this scheme were not Gilead employees, Gilead and Healthstar could not openly pay the nurses to exclusively recommend Gilead drugs. Gilead would be acting in violation of the AKS if it openly paid Healthstar to deploy nurses to recommend Gilead drugs. Similarly, Healthstar would be acting in violation of the AKS for being paid to recommend Gilead's Covered Drugs.

83. In an attempt to circumvent the law, Gilead and Healthstar contrived a disease awareness program that would act as a cover for the nurses, seemingly distinguishing them from drug reps and enabling them to appear to be independent. Gilead and Healthstar designated the nurses as "educators" who, instead of being paid to recommend drugs, were purportedly there to

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[10] *See, e.g.*, OIG Op. 11-08, at 6 (Jun. 14, 2011), https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf.

[11] 42 U.S.C. § 1320a-7b(b).

promote free educational services to Prescribers.

84. Although the nurses were called educators and employed by Healthstar, they were expected to and did recommend Gilead drugs. This conclusion is compelled by numerous facts Relator uncovered during its investigation.

85. ***The nurse "educators" received sales training from Gilead.*** Each of the nurses underwent a rigorous training program and learned sales techniques, similar to the program each Gilead drug rep undergoes. The sales training of nurses was a key component of the scheme because Gilead's ultimate goal was to drive sales and most nurses have little sales experience or training.

86. The nurses were trained over a period of multiple weeks. The majority of the training consisted of home-study, followed by training at Gilead headquarters in California, which also included Healthstar trainers. The nurses were taught skills needed to effectively "detail" Sovaldi and Harvoni – that is, market them to Prescribers in the same manner as a sales rep would. The nurse interviewees stated that each spent hours over many days practicing Gilead's sales techniques. Each engaged in role playing exercises with each other and professional sales trainers. The interviewees also stated that the nurses learned "tried and true" sales techniques such as methods to overcome office gatekeepers and respond to sales objections.

87. CI-2, CI-3 and CI-4 all confirmed that the nurses received Gilead sales training. CI-3 stated that part of her training included learning how to overcome objections and get past office gatekeepers. CI-4 stated that she participated in objection-handling workshops, which she found useful as clinical nurses do not usually perform sales functions. Furthermore, interviewees stated that nurses were trained to use a sales call tracking system, to meticulously record each encounter with a target Prescriber and report back to Gilead.

88. The fact that the Healthstar nurses received sales training from Gilead underscores that the true purpose of the scheme devised by Gilead was not to provide disease education, but rather to drive prescriptions for Sovaldi and Harvoni. If the true purpose of the nurse educators was to provide disease education, it made no sense for the Healthstar nurses to receive *sales* training, practice *sales* techniques, and receive *sale*s talking points from Gilead.

89. ***The nurse "educators" were actively used by Gilead to drive sales.*** Once trained, the nurses were selectively deployed to target Prescribers with high potential to prescribe Gilead drugs. The targeting activities were based on a Prescriber's prescribing trends and habits, which were identified through prescription data by Gilead. At the day-to-day level, each territory's nurses and drug reps would coordinate on sales calls to the targeted Prescribers.

90. CI-2, CI-3, and CI-4 confirmed that they received target lists from a drug rep. CI-4 explained that the target lists were based on each Prescriber's prescription potential. CI-2 explained that she was directed by the drug rep on which Prescribers to see.

91. The fact that the Healthstar nurses were deployed by Gilead for the particular purpose of targeting Prescribers with high potential to prescribe Gilead drugs underscores that the true motivation for Gilead's efforts was not to provide disease education, but rather to drive prescriptions for Sovaldi and Harvoni.

92. ***The nurse "educators" engaged directly with Prescribers.*** After gaining access to Prescribers purportedly to offer a disease education service, the nurses (*i.e.*, "white coated" clinicians) were now in an ideal position to exclusively recommend Sovaldi and Harvoni to Prescribers. The nurses were often armed with Gilead-branded materials, which they could use to promote Sovaldi and Harvoni. Every interaction with a Prescriber was a potential opportunity to obtain more prescriptions for Gilead products.

93. CI-2, CI-3, CI-4, and CI-5 all confirm that Healthstar's nurses gained access to Prescribers and promoted Sovaldi and Harvoni. CI-2 explained that when cold-calling Prescribers, she would identify and speak to the "gatekeeper." She indicated that getting past the gatekeeper "was all in how you present yourself. I would just say, 'hey, I am a clinical educator. I'm not sales. I'm clinical. I'm a nurse-by-background clinical educator.'" Of course, by playing the "clinical educator" card, the Healthstar nurses were able to obtain access to Prescribers and their staff and begin the sales pitches Gilead had trained the nurses to deliver.

94. CI-2 further believed that nurse educators were effective at influencing a Prescriber's choice of drug treatments because their medical background gave them more credibility. CI-2 gave an example where the Prescriber's office refused to see drug reps. However, CI-2 was able to go in because she was a nurse. She then educated the doctor on the medication, and was able to introduce the drug rep to the Prescriber. CI-2 also confirmed that she exclusively recommended Sovaldi and Harvoni when discussing Hep-C medications since, pursuant to instructions received from Gilead, she "can't talk about a competitor's drugs."

95. Similarly, CI-3 explained that Healthstar's nurses helped Gilead's drug reps gain access to Prescribers. CI-3 stated that she was an extension of the drug reps. "If they had problems or needed to . . . seal the deal, [the drug reps] would bring me in and say, 'Hey, this is an additional resource for you, Dr. Smith. If you need anything clinical, call her. She's available to you.'" CI-3 further stated, "I don't give [Prescribers] drug options. I can't. I'm an employee of Gilead Science, so I am not promoting another drug." "I am there [] solely educating on Sovaldi or Harvoni."

96. Along the same lines, CI-4 explained that her method of gaining access to Prescribers entailed using her nurse credentials. She said that in instances where she did not

speak directly with the Prescriber, she had other options, "you know the mid-levels [medical assistants and nurses] were more open because usually they have a nursing background as well." When directly asked if she was promoting education or Gilead drugs, CI-4 conceded that in addition to promoting education, "I guess you could say [we were] promoting the drug too because you're not in there promoting someone else's drug . . . ."

97. CI-5, a drug rep, "strongly agree[d]" that Healthstar's nurses can gain access where drug reps cannot. CI-5 also agreed that the nurse educators were effective in influencing a Prescriber's choice of potential drugs because of "the branding, the repetition of messaging." He also stated that it was "no coincidence that . . . the way [nurse educators] phrase things are very much in line, almost synonymous with, what [drug reps] are saying. For the subliminal messaging definitely being given by the nurse educator, it's just again more influenced."

98. The fact that the Healthstar nurses worked closely with the Gilead sales reps to target Prescribers underscores that the true motivation for Gilead's efforts was not to provide disease education, but rather to drive prescriptions for Sovaldi and Harvoni.

99. ***The nurse "educators" engaged directly with patients.*** Even more disturbing is the fact that the Healthstar nurses promoted Sovaldi and Harvoni directly to patients. By offering to educate patients and gaining direct access to individuals suffering from Hep-C, white coated nurse clinicians were in a prime position to recommend and promote Gilead's products directly to these patients. Importantly, these encounters were direct nurse-to-patient contacts, which were used to actively convert patients from their current medications and products to Gilead products.

100. Medications are an essential part of Hep-C disease management. Thus, nurses cannot truly educate patients about Hep-C without also including a discussion of the medications

available to treat that disease. However, when the topic of medications came up during any patient education session, pursuant to Gilead's directive, the nurses generally were not permitted to discuss any medication other than Sovaldi and Harvoni.

101. To reach out directly to patients, Gilead deployed Healthstar nurses to community events to educate Hep-C sufferers. CI-1, CI-2, CI-3, and CI-4 each personally conducted these educational events, referred to as "community organizations."

102. CI-4 explained that some community organizations were held at AIDS service organizations, where patients were HIV-positive and there was also a high infection rate of Hep-C. During these hour-long presentations, Healthstar nurses would present a PowerPoint-like slide deck. CI-4 confirmed that sometimes the slide presentations were "branded," meaning they were Gilead-product specific. Similarly, CI-3 performed community organization events. CI-3 explained that these sessions were "strictly on the disease of Hepatitis C, transmission, how it was cured . . . .," as opposed to about particular drugs. However, she conceded that, if a patient asked about a Hep-C medication during a general disease awareness presentation, she would answer: "You know, if you were my mom, *I'd want you to be on Harvoni*."

103. Similarly, CI-2 confirmed that she also conducted Hep-C education in the community, including at addiction centers and HIV clinics. She stated that patients often were unaware that they have been infected with Hep-C. After she began conducting these education meetings, CI-2 was told by the sales rep that there was an increase in the number of sales.

104. Moreover, CI-1 explained that physician calls and new patient training metrics were used to determine Healthstar's nurse bonuses, thereby *tying their compensation to the volume or value of referrals*. Sales calls to Prescribers and the number of patient training sessions are sales metrics. These metrics do not measure, in any meaningful way, patient health

outcomes or treatment efficacy, but rather relate to new patient prescriptions and prescription refills.

105. The fact that the compensation of the Healthstar nurses was tied to the number of prescriptions resulting from their supposed "disease education" program underscores that the true motivation for Gilead's efforts was not to provide disease education, but rather to drive prescriptions for the Gilead products.

Scheme Two: Reimbursement Support Services

106. To induce recommendations of the Covered Drugs over competing drugs, Gilead sales reps offered a second type of kickback: free reimbursement support services for Prescribers who wrote prescriptions for the Gilead Covered Drugs. This remuneration was a tangible, in-kind benefit that greatly reduced, and in some instances eliminated, Prescribers' administrative costs related to prescribing Gilead's Covered Drugs. Gilead referred to this remuneration as coverage determination and/or reimbursement support services, but in practice, the services were intended to induce Prescribers to choose Gilead's Covered Drugs over a competitor's drugs. For Sovaldi and Harvoni, the services were offered under a branded program called "Support Path."

107. Over at least the last three years, Gilead contracted with Covance who hired and trained dozens of skilled workers to provide free coverage determination and reimbursement support for Sovaldi, Harvoni, Atripla, and Truvada prescriptions. The services included activities like patient insurance benefit verification services, patient prior authorization services, and coverage appeals (collectively, "Support Services").

108. Gilead's drug reps and Covance's field reps marketed the Support Services in order to increase the likelihood that Prescribers would prescribe Gilead's Covered Drugs. Put simply, in exchange for prescribing Gilead's Covered Drugs, Gilead, through Covance, would

assume and underwrite the Prescribers' administrative responsibilities and costs associated with starting a patient on Gilead's Covered Drugs. The more a Prescriber prescribed Gilead's Covered Drugs as a percentage of its overall prescription volume, the greater the Prescriber's savings, as time and money spent on Support Services for the Covered Drugs would now be handled by Gilead. Gilead's Support Services were the "carrot" (*i.e.,* remuneration) dangled to induce Prescribers to recommend Gilead's drugs to their patients.

109. Support Services have a tangible value to Prescribers because these services reduce, and in some instances eliminate, the administrative costs associated with prescribing drugs. These services also help increase profitability, particularly for office-based Prescribers, who derive most of their revenue from billing 15, 30, and 45-minute units of service provided to patients during office visits.

110. The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

111. When an office-based Prescriber receives payment for an E/M service, the payment is intended to compensate the Prescriber for the actual medical care given *and* administrative tasks associated with that patient's care. These tasks include conducting a patient's prescription drug insurance "benefit verification," determining if the drug is on the formulary lists and tiers, seeking a coverage determination, determining co-pays and deductibles, conducting telephone calls to patients, responding to patient complaints, returning messages and faxes, handling prescription refill requests and, where necessary, obtaining "prior

authorizations"[12] in addition to managing the resulting paper trail.[13] Despite these enormous administrative costs and expenses,[14] office-based Prescribers are not permitted to directly charge patients a fee for any of these services. Instead, Prescribers get paid for these services indirectly through the E/M unit charge.

112. Since a Prescriber's E/M reimbursement for each office visit is fixed per unit, Prescribers are continuously seeking ways to combat overhead costs and reduce expenses in order to earn more profit from each E/M unit billed. One way to do so is to reduce the administrative costs associated with prescribing drugs. If a Prescriber can reduce this cost, each E/M unit will be more profitable. These economics have a direct impact on a provider's prescribing behavior. Providers are less likely to prescribe a drug that imposes an undue burden on support staff because doing so would mean a decrease in profitability resulting from the need to hire more staff or reduce the number of patients that can be seen in a day. Conversely, a

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[12] A study of 12 primary care practices published in the Journal of the American Board of Family Medicine put the mean annual projected cost per full-time equivalent physician for prior authorization activities between $2,161 and $3,430. The study's authors concluded that "preauthorization is a measurable burden on physician and staff time." *See* Christopher P. Morley, et al., *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, 26 J. Am. Bd. Fam. Med. 93-95 (Jan.-Feb. 2013).

[13] In 2006, primary care providers spent a mean of 1.1 hours per week on authorizations, primary care nursing staffs spent 13.1 hours, and primary care clerical staff spent 5.6 hours, according to a 2009 study published in Health Affairs. The study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually. *See* Lawrence P. Casalino, et. al., *What Does it Cost Physician Practices to Interact with Health Insurance Plans?,28* Health Affairs 533-543 (May 14, 2009). http://content.healthaffairs.org/content/28/4/w533.full.

[14] A 2011 study published in Health Affairs found that providers spend an annual average of nearly $83,000 of overhead staff time and costs associated with coverage issues plans. With approximately 835,000 physicians practicing in the nation, this translates to over $69 billion annually. *See* Dante Morra, et. al., *US Physician Practices Versus Canadian; Spending Nearly Four Times as Much Money Interacting with Payers*, 30 Health Affairs 1443-1450 (Aug. 3, 2011) http://content.healthaffairs.org/content/30/8/1443.full.pdf+html.

Prescriber is much more likely to prescribe a drug if it can be prescribed with little or no administrative burden. Thus, the Prescriber's relative cost and burden in prescribing one company's drug when compared to another company's drug can directly influence which drug a Prescriber will recommend to a patient.

113. The costs Prescribers incur to obtain reimbursement support are certainly known to pharmaceutical manufacturers like Gilead. As such, Gilead, through Covance, developed Support Services that are marketed to Prescribers in order to increase the likelihood that Prescribers will choose to recommend Gilead's Covered Drugs. While these services cost millions of dollars to provide, Gilead readily incurred this expense, knowing that these services would act as a powerful inducement to Prescribers to recommend Gilead's Covered Drugs over a competitor's drugs.

114. While pitching Prescribers, Gilead sales reps emphasized that, if the Prescribers prescribed Gilead products, Gilead would provide the services and resources of a full reimbursement support team to manage the administrative tasks associated with prescribing the drug. Gilead sales reps further emphasized that the cost and expenses normally associated with managing a patient's prescription would be shifted to Gilead, thereby increasing the Prescriber's bottom line.

115. This value proposition was a powerful tool in the hands of Gilead's drug reps and Covance's field reps, and was used to induce Prescribers to recommend Gilead drugs. CI-5 (drug rep), and CI-8 and CI-11 (Covance call center employees), each confirmed that part of the pitch to market Sovaldi and Harvoni included an offer to outsource Support Services without any cost to the Prescriber. Similarly, CI-12, (HIV drug rep), confirmed that her pitch to market Atripla and Truvada also included an offer to outsource Support Services.

116. Gilead and Covance specifically targeted Prescribers who could *benefit* from the reimbursement services offered. CI-6 (a Covance field rep), explained that she was directed to call on specific Prescribers identified by Gilead drug reps. She described how she was directed to call on small offices, particularly those that do not have adequate staff to dedicate to reimbursement functions. CI-6 was also provided with a list of all specialists and primary care physicians in her territory, whom she then contacted.

117. CI-6 described herself to Prescribers as a middle-man between Covance's call center personnel and the Prescriber, explaining that if an issue became too complicated, difficult, or time- consuming to be handled via telephone, she would personally go to the office to assist. Furthermore, CI-6 explained that she tracked her sales efforts by entering sales call notes into sales software.

118. CI-7 (a Covance field rep) estimated that 70% of the Prescribers in her area utilized Covance's Support Services.

119. CI-5 (a drug rep) said his message to Prescribers included a reference to "the overhead that you [Prescribers] are paying to have [staff] . . . on the phone all day trying to get prior authorizations, rather than doing what you hired [them] to do, which is patient care. . . . Just send everything over to our reimbursement specialists, let them do all the prior authorizations. Let them deal with the headaches with the insurance companies. . . . You guys take care of all the patients. You provide the health care. Let us deal with the administrative side of things."

120. Because many drugs are expensive, most, if not all patients, cannot afford therapy unless it is covered by insurance. For example, Gilead's Hep-C drugs, Sovaldi and Harvoni, cost an individual about $84,000 per year. As a result, successfully starting patients on a drug therapy typically requires an initial determination to verify whether the patient has adequate

prescription drug coverage. This step is called "benefit verification." For most Prescribers, the verification of a patient is performed by staff and it is a time consuming task. It can take multiple calls lasting up to and sometimes over an hour just to determine the nature and extent of the patient's coverage. However, if the Prescriber recommends Gilead's Drugs, the verification task for the Gilead drug is handled by Covance, rather than the Prescriber's staff.

121. Each day, Covance's office receives requests from Prescribers to perform benefit verifications for their patients. These requests are immediately assigned to a Covance staff member who has training, education, and experience in determining patients' prescription drug benefits. First, the Covance specialist verifies the source of the patient's primary and secondary insurance benefits (*i.e.,* private insurance, Medicare, TRICARE, and/or Medicaid). Next, the Covance specialist contacts the insurer to verify the nature and extent of the patient's drug benefit coverage. In cases of Medicare and Medicaid, this is called a "coverage determination." For Medicare patients, coverage determinations tend to be particularly cumbersome and time consuming given the complexity of many Part D plans.

122. In addition to verifications and coverage determinations, Gilead also provides prior authorization services. Many insurance carriers require a Prescriber to obtain a prior authorization before prescribing certain medications. Further, if a medication receives an authorization, that authorization may only be valid for a limited time, such as one year or a month. After that, the Prescriber must start the prior authorization process over again. The cumbersome process often causes Prescribers to choose less expensive medications that do not require a prior authorization. Indeed, Part D carriers use the prior authorization process as a means to contain costs associated with expensive medications, like Gilead's Covered Drugs. Thus, if a Prescriber wants to recommend expensive drugs, the Part D carriers require the

Prescriber to go through the administrative process and make the case for prescribing the drug over a less expensive option. However, Gilead has relieved Prescribers of that burden in order to induce them to prescribe Gilead's Covered Drugs over competing medications.

123. Gilead also offers a service to appeal authorization and coverage denials. If a patient's carrier denies coverage for Gilead Covered Drugs or denies the prior authorization request, Gilead, through Covance, takes steps to reverse the adverse determination.

124. Prior authorizations and coverage appeals take time and experienced personnel. The processes of obtaining a prior authorization and appealing a denial require direct input from the Prescriber regarding the patient's medical history, clinical and laboratory findings, and other information to establish the patient's medical necessity for a particular drug. The Prescriber and his or her staff must also develop specialized knowledge about each carrier's unique prior authorization and coverage criteria.

125. Interviewees confirm that Covance's reimbursement support field reps directly assist Prescribers who prescribe Gilead drugs. The Covance field reps provide these services free of charge. CI-6 explained that field reps' responsibilities include "helping providers with linkage" to Sovaldi and Harvoni, such as helping staff complete and prepare insurance forms, communicating with Covance's reimbursement support call center employees, and helping to resolve any and all coverage issues. According to CI-6, this assistance included preparing and providing form template letters which can be used for either a prior authorization or coverage appeal. CI-11 (a Covance call center employee) stated that the form templates contain the *Prescriber's letterhead* at the top, while the body of the letter contains standardized form text drafted by Covance reimbursement specialists. The standard language contains medical necessity buzzwords that Covance employees know will result in approval for the drug.

126. The Support Services deliver significant value to Prescribers. Without them, Prescribers would have to use their own staff and resources or outsource the Support Services to a private vendor. Importantly, the payer-provider contracts with Medicare, Medicaid, and private insurers prohibit the Prescriber from charging patients a fee for these administrative services separate from the E/M unit charge. Gilead offers Prescribers a means to "outsource" this function without any direct or indirect cost to the Prescriber, but *only if* the Prescriber chooses to recommend Gilead's Covered Drugs. By offering these in-kind services as a means to induce Prescribers to recommend Gilead's Covered Drugs, Gilead and Covance violated the AKS.

127. Relator's investigation also revealed that while carrying out these Support Services, Covance violated Medicare regulations regarding patient privacy and duty of care. CI-11 (a Covance call center employee) explained that when he performs these services and contacts a patient's insurance benefit drug plan representative, he has been trained to identify himself as "calling *on behalf of [a] patient from the Prescriber's office.*" Similarly, CI-8 (a Covance call center employee) explained that when she calls a patient's insurance benefit drug plan representative, she identified herself as "*calling at the request of the doctor's office and on behalf of the patient.*"

128. These statements are a blatant misrepresentation of Covance's role as Covance reps are neither a patient's "appointed representative" nor "calling from the doctor's office," and circumvent Medicare privacy rules regarding the coverage determination and appeal processes.

129. Medicare rules give patients the right to prompt coverage determinations and the right to seek a reconsideration of an adverse coverage determination. These rights are afforded to all patients seeking prescription coverage for drugs, including Hep-C and HIV patients who

have been prescribed Gilead's Covered Drugs. As is detailed above, the coverage determination requires contacting the patient's Part D carrier and/or Medicaid carrier and conveying medical information about the patient and the patient's particular need for the medication. Because of privacy and HIPAA concerns, Medicare rules only permit three parties to seek a coverage determination: 1) the patient; 2) the prescribing physician; and 3) the patient's appointed representative.[15] In truth, however, Covance is neither the patient nor the prescribing physician. Further, Covance is also not the patient's "appointed representative."

130. Medicare regulations define "appointed representative" as follows:

> Appointed representative means an individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in this subpart, the appointed representative has all of the rights and responsibilities of an enrollee in filing a grievance, obtaining a coverage determination, or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of this chapter.[16]

131. There are typically stringent State rules regarding the form and manner in which this appointment can be made.

132. Neither Gilead nor Covance follow these rules; therefore neither can claim to be the patient's representative. Since Covance is not the patient, the prescribing physician, nor the patient's appointed representative, it lacks the legal authority to engage in the Support Services offered to induce Prescribers to recommend Gilead's Covered Drugs. Such conduct raises significant privacy and patient care concerns.

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[15] 42 C.F.R. 423.566.

[16] 42 C.F.R .423.560.

Scheme Three: Free Nurse Services

133. In addition to offering kickbacks to nurse "educators" to recommend its products and paying Covance to provide Support Services, Gilead offered a third type of kickback: free nurse education and patient management services to Prescribers in exchange for those Prescribers recommending Gilead's Sovaldi and Harvoni over competitors' drugs.

134. Hep-C patients often require extra office time and resources to manage their disease. Most Prescribers typically allocate between 10 and 15 minutes to see routine patients. However, industry research demonstrates that Hep-C patients require much more time. Only the largest and most profitable clinics and Prescribers could afford to employ and pay for their own certified nurse educators to manage their patients. Smaller and less profitable Prescribers were unlikely to incur the cost of a nurse educator, which typically costs $50,000 to $100,000 in annual salary, or an average hourly wage of $40.00 per hour.

135. Seeking an advantage over its competitors, Gilead attempted to meet the needs and challenges that Prescribers face in managing their practice and patients. Accordingly, Gilead developed a marketing strategy that involved furnishing nurse support services to Hep-C Prescribers in an attempt to induce them to choose Gilead's Hep-C drugs over competing drugs. Gilead's nursing support services included: (i) assisting Prescribers increase practice efficiency; (ii) training staff on care; (iii) eliminating the expense of educating patients; and (iv) being on call to answer a patient's questions. Gilead provided these support services through Healthstar nurses free of charge. In typical *quid pro quo* fashion, in order to obtain these support services, Prescribers would in turn have to prescribe Gilead's drugs.

136. It was in this manner that, rather than promoting and marketing Gilead drugs based upon patient outcomes and efficacy, Gilead, through Healthstar, added incentives for Prescribers to recommend Gilead drugs over competing drugs. The interviewees confirm that

the nurse educator services saved staff time, money, and resources and "eliminate[d] an expense that the physician would have otherwise incurred" – the very type of conduct the OIG has flagged as suspect.[17] Such in-kind remuneration, given to induce a recommendation for Gilead drugs, is an unlawful kickback under the AKS, and justifies action under the FCA.

137. Healthstar Nurses offered Hep-C Prescribers direct nurse-to-patient education during "lunch and learns." Gilead drug reps and Covance field reps also induced Prescribers to recommend Sovaldi and Harvoni by offering free nurse services to any patient that was prescribed Sovaldi or Harvoni.

138. CI-2, CI-3, and CI-4 confirmed that nurse services were offered as a means to induce Prescribers to recommend Sovaldi and Harvoni. CI-3 explained, "You can get the buy-in with the staff and let them know that you're going to be their patients' primary resource for education. It frees them up to allow them to do other things." CI-4's pitch to Prescribers included giving Prescribers "the full patient presentation, like I would present to a patient, so that they [Prescribers] would know exactly what their patients were being told . . . ."

139. Gilead, through Healthstar, offered potential Prescribers the services of a nurse with Hep-C expertise, who would interact directly with a Prescriber's Hep-C patients, saving the Prescribers time and money. Healthstar nurses conducted one-on-one and group sessions with patients, during which patients were taught generally about Hep-C, as well as how to administer Sovaldi and Harvoni.

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[17] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, Dep't of Health & Human Servs., 68 Fed. Reg. 23731-01, 23737 (May 5, 2003), https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf (if "services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (*i.e.*, have independent value to the physician) . . . the arrangement may be problematic if the arrangement is tied directly or indirectly to the generation of federal health care program business for the manufacturer").

140. Interviewees confirm that Healthstar Hep-C nurses would directly care for Hep-C patients thereby freeing up Prescribers to care for other patients. In busy practices, it was commonplace for Healthstar deployed nurses to manage the Prescriber's patients without any staff members being present. Sales reps encouraged potential Prescribers to offload their Hep-C patients to the Healthstar nurses to manage. Healthstar nurses would manage patients through education sessions in the Prescriber's office or at another local venue, thereby freeing office staff to work in other areas. Patients were also given Healthstar nurses' telephone numbers and encouraged to call them directly instead of calling the Prescriber's office.

141. Generally, the nurse-patient education sessions would last about an hour. The sessions served as both classes and forums where Hep-C patients could ask questions, learn more about Hep-C and other health issues, and discuss treatments. As CI-4 explained, "[patients] who came month after month, [ ]didn't want the same [ ] presentation so they would have me do disease awareness one month, and then medication [Sovaldi and/or Harvoni] the next month." These education sessions saved Prescribers time and money by relieving the office of the burden of patient education, answering patient calls and questions, and general patient management.

142. During these patient education sessions, the Healthstar nurse would cover important topics such as side effects and how antacids interfere with Harvoni's efficacy. CI-2 explained that Hep-C-infected patients can disrupt Harvoni's mechanism of action if they also take antacids, which limit the drug's effectiveness. Oftentimes, nurses would spend considerable time with a patient reviewing their diet and other medications to ensure that the patient was not inadvertently ingesting any antacid. These tasks, such as reviewing a drug's contraindication and mechanism of action with a patient, are ordinarily performed by a patient's Prescriber. Here, Prescribers were able to outsource the task to Healthstar nurses – free of charge – for all patients

for whom Sovaldi and Harvoni were recommended.

143. Healthstar nurses would also cover how to administer and combine certain medications. For example, CI-3 stated that Sovaldi is prescribed with Ribavirin, a generic oral medication, and either Pegasys or Peg-Intron, injectable medications. Thus, CI-3 performed training on self-injection, a task normally performed by the Prescriber.

144. CI-2, CI-3, CI-4, and CI-5 each agreed that Healthstar nurses provide a tangible benefit to Prescribers.

145. CI-2 said Healthstar nurses "definitely" brought value to the Prescriber because when she educated patients on the disease and drugs, patients would spend less time seeking this information during a routine office visit. This, in turn, saved the Prescribers money because "if they were going to bring the patients back in [for education], they [Prescribers] don't get paid. They do not get reimbursed for that. So they can't charge for that time." CI-2 would explain to potential Prescribers that if they chose Gilead, they would save time during routine office visits, as the nurse would answer the majority of the patients' questions. She said, "how we would kind of word it is, 'look, you're going to get less, your office will get less phone calls because hopefully by the time we are through educating them [patients], we will have an answer to the majority of their questions.'" CI-2 would give out her phone number to patients in order to keep them from calling the Prescribers' office. She said, "I used to give my number to them, to *my patients*."

146. CI-3 explained that her education sessions included disease awareness, how Hep-C is contracted, and the risks of leaving Hep-C untreated. CI-3 agreed that her services were a value to the Prescriber, particularly by saving Prescribers time. "They didn't have the extra time, or the amount of time to invest in these patients, because doctors have to see more patients to

supplement their income."

147. CI-4 explained the value to Prescribers by saying, "there's no way they would have an hour or hour and a half to sit with patients and explain stuff to them. It's just not possible." She continued, "I can go into more detail. I have the time to go into more detail than they [do]. So that would be the benefit." Further, CI-4 felt that by educating the patients she was "making them better patients," which in turn "makes it easier for the doctor to manage their care." [T]he provider just has to worry about basically writing the prescription and seeing [the patients] in follow-up . . . ."

148. CI-5 (a drug rep) acknowledged Healthstar nurses' value to Prescribers, explaining that nurse educators can provide "value to the provider because the nurse educator is taking that time . . . that overhead-off of [the provider's] staff." Providers can thus "focus on the patient care and not education . . . . [They] can re-direct the patient to the nurse educator." CI-5 further explained that having a Healthstar nurse helped him make sales. He stated, "The more presence you have in that office, the more your product is on the forefront of everyone's mind." And if "[t]hat drug is at the forefront of [the Prescriber's] mind, that's what he's writing."

149. As is set forth above, Gilead has unlawfully furnished to Prescribers, through Healthstar, the services of these nurses to work with the Prescribers' Hep-C patients. Gilead intended for these nurse services to act as an inducement to Prescribers in return for recommending Gilead's drugs to patients. When Prescribers received the benefits of the nurses' service, Gilead and Healthstar "eliminate[d] an expense that [the Prescriber] would have otherwise incurred"[18] if they employed the nurse or provided the services themselves. This conduct violates the AKS.

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[18] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, Dep't of Health & Human Servs., 68 Fed. Reg. at 23737.

150. Not only does Gilead's provision of free nurse services violate the AKS, but it also creates a disturbing conflict of interest for the nurses. This conflict can harm patients and vastly increase pharmaceutical spending.

151. In a normal nurse-to-patient relationship, the nurse has no allegiance to or affiliation with any drug or drug company and is able to make a decision based solely upon the best interests of the patient. During recent years, scholars have raised concerns that increased promotional spending by pharmaceutical companies on nurses (mostly in the form of small gifts, dinners, or drug samples) is creating a serious conflict, and have suggested that a ban or strong limitation on such conduct is needed to protect patients.[19] The conflict created by Gilead's use of Healthstar nurses, which extends *far* beyond simple gifts and drug samples, is much greater. Here, the nurses are actually contracted, through Healthstar, with Gilead. Gilead trains and directs these nurses to increase sales. Thus, the nurses have an inherent interest in the success of the Gilead drugs, which creates a conflict with their duty of care to patients. The nurses may consciously or subconsciously recommend Gilead drugs despite cheaper alternatives or more effective treatments, to the detriment of a patient.[20]

152. The conflict of interest manifests in two related situations, continuity of care[21]

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[19] Nancy J. Crigger, *Pharmaceutical Promotions and Conflict of Interest in Nurse Practitioner's Decision Making: The Undiscovered Country*, 17 J. Am. Academy of Nurse Practitioners 207-12 (May 27, 2005).

[20] Judith A. Erlen, *Conflict of Interest – Nurses at Risk!*, 27 Orthopaedic Nursing 135-39 (Mar. – Apr. 2008). Erlen argues that a nurse simply accepting small gifts (such as notepads and promotional items) or listening to a marketing pitch is enough to cloud their judgment and create a conflict of interest. *Id.* at 137. This is a far cry from the situation highlighted here where the nurse *is indirectly employed* by the drug manufacturer.

[21] Continuity of care is concerned with quality of care over time. It is the process by which the patient and his/her physician-led care team are cooperatively involved in ongoing health care management toward the shared goal of high quality, cost-effective medical care.

and medication adherence. A Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be based on patient outcomes. However, since the Healthstar nurses' interests are closely aligned with that of the drug company, they will promote that company's drugs when other drugs may be more appropriate.

153. CI-2 confirmed that she only recommended Sovaldi and Harvoni when discussing medications that treat Hep-C. As she put it, "Well, obviously since I was in a contract with Gilead, I would recommend the Gilead drugs." She additionally noted that she would not recommend a competitors drug as the medication of choice because she "cannot talk about competitor drugs." Similarly, CI-3 explained "I'm a little biased toward Harvoni." "I don't give [Prescribers] drug options. I can't. I'm an employee of Gilead Science, so I am not promoting another drug." CI-3 was supposed to perform unbranded education. But when asked about Hep-C medications during those presentations, her reply would be, "you know, if you were my mom, I'd want you to be on Harvoni." Similarly, CI-4 stated that she was "not in there promoting someone else's drug."

154. Regarding medication adherence, CI-4 stated that, "from an adherence standpoint," nurse educators were beneficial in "making sure that patients don't come off drugs because they have side effects and they don't know what to do." Patients "are getting . . . an understanding [of] the value and importance of staying on their treatment and not coming off . . . . [I]t helps with adherence and compliance." She continued, "the real benefit for them is . . . . the educators being the piece in the puzzle to adherence." In fact, CI-4 "would always hear that in meetings as well that [nurse educators] were an important piece of the puzzle as far as getting patients through therapy . . . ." CI-5, a drug rep, "strongly agree[d]" that Healthstar nurses are effective in influencing a patient to remain on therapy.

155. In the course of caring for patients, there may be times when a patient would have a potentially better outcome by switching to a more effective drug or a cheaper drug. Indeed, a Prescriber's decision to keep a patient on a certain drug or switch to a competing drug should be driven solely by patient outcomes. However, since these nurses' interests are aligned with that of the drug company, their independence is compromised. This conduct not only violates the AKS, but raises ethical and patient safety concerns for the nursing profession.

THE BREADTH OF GILEAD'S KICKBACK SCHEME

156. The evidence uncovered during Relator's investigation reveals a kickback scheme of truly breathtaking proportions.

157. The scheme encompasses every Prescriber that, since 2013, received a visit from a Healthstar clinical educator that purported to provide "education" concerning Hep-C.

158. The scheme encompasses every Prescriber that, since at least 2013, received Support Services from Covance.

159. The scheme encompasses every prescriber that, since at least 2013, received, directly or indirectly, "free nurse" services that were paid for by Gilead.

160. Gilead and its co-Defendants profited from the illegal schemes described in this Complaint, and Medicare, Medicaid, TRICARE, and Veteran Administration Healthcare were made to bear the costs.

161. Since at least 2013, Defendants' actions knowingly have caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries and others to submit millions of dollars in claims to Government programs for Gilead drugs provided to beneficiaries as a result of Defendants' illegal marketing and quid pro quo arrangements. Those false claims have caused the Government to disburse billions of dollars in reimbursements that were tainted by kickbacks and

should not have been paid.

**COUNT 1 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
PRESENTING FALSE CLAIMS FOR PAYMENT (31 U.S.C. § 3729(a)(1)(A))**

162. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

163. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

164. As a result of Gilead offering or paying, and Gilead's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of Gilead's Covered Drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

165. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

166. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**COUNT 2 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
USE OF FALSE STATEMENTS (31 U.S.C. § 3729(a)(1)(B))**

167. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

168. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

169. As a result of Gilead offering or paying, and Gilead's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering Gilead's Covered Drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

170. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for Gilead's Covered Drugs were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

171. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

172. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

COUNT 3 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE FALSE CLAIMS ACT:
CONSPIRING TO VIOLATE THE FALSE CLAIMS ACT (31 U.S.C. § 3729(a)(1)(C))

173. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

174. Relator seeks relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

175. As set forth above, Gilead conspired with Gilead's co-Defendants, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase, order, or recommend the purchasing or ordering of Gilead's Covered Drugs in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for Gilead's Covered Drugs dispensed in connection with the kickback scheme.

176. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

177. By reason of the Defendants conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT 4 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE ARKANSAS MEDICAID FRAUD FALSE CLAIMS ACT, ARK. CODE ANN. §§ 20-77-901 – 20-77-911

178. This is a claim for treble damages and civil penalties under the Arkansas Medicaid Fraud False Claims Act, Ark. Code Ann. §§ 20-77-901 – 20-77-911. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

179. Defendants violated the Arkansas Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Arkansas as described herein.

180. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Arkansas.

181. The State of Arkansas, unaware of the false or fraudulent nature of these claims,

paid such claims which the State of Arkansas would not otherwise have paid.

182. By reason of these payments, the State of Arkansas has been damaged, and continues to be damaged, in a substantial amount.

COUNT 5 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT, CAL. GOV'T CODE §§ 12650 – 12656

183. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

184. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

185. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

186. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

187. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

COUNT 6 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE COLORADO MEDICAID FALSE CLAIMS ACT, COL. REV. STAT. ANN. §§ 25.5-4-303.5 – 25.5-4-310

188. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 – 25.5-4-310. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

189. Defendants violated the Colorado Medicaid False Claims Act by engaging in the

fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

190. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

191. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

192. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

COUNT 7 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS AND OTHER PROHIBITED ACTS UNDER STATE-ADMINISTERED HEALTH OR HUMAN SERVICES ACT ("CONNECTICUT FALSE CLAIMS ACT"), CONN. GEN. STAT. ANN. §§ 4-274 – 4-289

193. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274 – 4-289. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

194. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

195. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

196. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

197. By reason of these payments, the State of Connecticut has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 8 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE DELAWARE FALSE CLAIMS AND REPORTING ACT,
DEL. C. ANN. TIT. 6, §§ 1201 – 1211**

198. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

199. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

200. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

201. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

202. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 9 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE DISTRICT OF COLUMBIA
MEDICAID FRAUD ENFORCEMENT AND
RECOVERY AMENDMENT ACT OF 2012,
D.C. CODE ANN. §§ 2-381.01 – 2-381.10**

203. This is a claim for treble damages and civil penalties under District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

204. Defendants violated the District of Columbia Medicaid Fraud Enforcement and

Recovery Amendment Act of 2012 by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

205. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

206. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

207. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 10 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT, FLA. STAT. ANN. §§ 68.081 – 68.092

208. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

209. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

210. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

211. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

212. By reason of these payments, the State of Florida has been damaged, and

continues to be damaged, in a substantial amount.

COUNT 11 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE GEORGIA FALSE MEDICAID CLAIMS ACT, GA. CODE ANN. §§ 49-4-168 – 49-4-168.6

213. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

214. Defendant violated the Georgia False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

215. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

216. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

217. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 12 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE HAWAII FALSE CLAIMS TO THE STATE ACT, HAW. REV. STAT. §§ 661-21 – 661-31

218. This is a claim for treble damages and civil penalties under the Hawaii False Claims to the State Act, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

219. Defendants violated the Hawaii False Claims to the State Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

220. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

221. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

222. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

COUNT 13 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT, 740 ILL. COMP. STAT. ANN. §§ 175/1 – 175/8

223. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

224. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

225. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

226. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

227. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

COUNT 14 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE ANN. §§ 5-11-5.5-1 – 5-11-5.5-18

228. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

229. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

230. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

231. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

232. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 15 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE IOWA FALSE CLAIMS ACT, IOWA CODE ANN. §§ 685.1 – 685.7

233. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

234. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

235. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

236. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

237. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

COUNT 16 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. STAT. ANN. §§ 437.1 – 440.16

238. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

239. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

240. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

241. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

242. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 17 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MARYLAND FALSE HEALTH CLAIMS ACT, MD. CODE ANN., HEALTH-GEN. §§ 8-101 – 8-111

243. This is a claim for treble damages and civil penalties under the Maryland False Health Claims Act, Md. Code Ann., Health-General §§ 8-101 – 8-111. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

244. Defendants violated the Maryland False Health Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Maryland, as described herein.

245. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Maryland.

246. The State of Maryland, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Maryland would not otherwise have paid.

247. By reason of these payments, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount.

COUNT 18 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS LAW, MASS. GEN. LAWS ANN. CH. 12, §§ 5A – 5O

248. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

249. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

250. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

251. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

252. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

COUNT 19 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MICHIGAN MEDICAID FALSE CLAIM ACT, MICH. COMP. LAWS ANN. §§ 400.601 – 400.615

253. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

254. Defendants violated the Michigan Medicaid False Claim Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

255. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

256. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

257. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

COUNT 20 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT, MINN. STAT. ANN. §§ 15C.01 – 15C.16

258. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

259. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

260. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

261. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

262. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

COUNT 21 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. §§ 17-8-401 – 17-8-416

263. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

264. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Montana, as described herein.

265. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

266. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

267. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

COUNT 22 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEVADA SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL GOVERNMENT ACT, NEV. REV. STAT. ANN. §§ 357.010 – 357.250

268. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

269. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

270. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

271. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

272. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

COUNT 23 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS LAW, N.H. REV. STAT. ANN. §§ 167:61-B – 167:61-E

273. This is a claim for treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Law, N.H. Rev. Stat. Ann. §§ 167:61-b – 167:61-e. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

274. Defendants violated the New Hampshire Medicaid Fraud and False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Hampshire, as described herein.

275. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Hampshire.

276. The State of New Hampshire, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Hampshire would not otherwise have paid.

277. By reason of these payments, the State of New Hampshire has been damaged, and continues to be damaged, in a substantial amount.

COUNT 24 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT, N.J. STAT. ANN. §§ 2A:32C-1 – 2A:32C-18

278. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

279. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

280. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

281. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

282. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

COUNT 25 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT,
N.M. STAT. ANN. §§ 44-9-1 – 44-9-14,
AND THE NEW MEXICO MEDICAID FALSE CLAIMS ACT,
N.M. STAT. ANN. §§ 27-14-1 – 27-14-15

283. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14, and the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

284. Defendants violated the New Mexico Fraud Against Taxpayers Act and the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

285. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

286. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

287. By reason of these payments, the State of New Mexico has been damaged, and

continues to be damaged, in a substantial amount.

**COUNT 26 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT,
N.Y. FIN. LAW §§ 187 – 194**

288. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

289. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

290. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

291. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

292. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 27 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT,
N.C. GEN. STAT. ANN. §§ 1-605 – 1-618**

293. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

294. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

295. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

296. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

297. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

COUNT 28 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE OKLAHOMA MEDICAID FALSE CLAIMS ACT, OKL. STAT. ANN. TIT. 63, §§ 5053 – 5054

298. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okl. Stat. tit. 63, §§ 5053 – 5054. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

299. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

300. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

301. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

302. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 29 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE RHODE ISLAND STATE FALSE CLAIMS ACT,
R.I. GEN. LAWS ANN. §§ 9-1.1-1 – 9-1.1-9**

303. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

304. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

305. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

306. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

307. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 30 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT,
TENN. CODE ANN. §§ 4-18-101 – 4-18-108
AND THE TENNESSEE MEDICAID FALSE CLAIMS ACT,
TENN. CODE. ANN. §§ 71-5-181 – 71-5-185**

308. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108, and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

309. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including

knowingly causing false claims to be presented to the State of Tennessee, as described herein.

310. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

311. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

312. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

COUNT 31 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE TEXAS MEDICAID FRAUD PREVENTION LAW, TEX. HUM. RES. CODE ANN. §§ 36.001 – 36.132

313. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

314. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

315. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

316. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

317. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 32 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT,
VT. STAT. ANN. TIT. 32, §§ 630 – 642**

318. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630 – 642. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

319. Defendants violated the Vermont False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State as Vermont, as described herein.

320. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Vermont.

321. The State of Vermont, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Vermont would not otherwise have paid.

322. By reason of these payments, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount.

**COUNT 33 – AGAINST ALL DEFENDANTS,
FOR VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT,
VA. CODE ANN. §§ 8.01-216.1 – 8.01-216.19**

323. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

324. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

325. As a result of the misconduct alleged herein, Defendants knowingly made, used,

or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Commonwealth of Virginia.

326. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

327. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

COUNT 34 – AGAINST ALL DEFENDANTS, FOR VIOLATIONS OF THE WASHINGTON MEDICAID FRAUD FALSE CLAIMS ACT, WASH. REV. CODE ANN. §§ 74.66.005 – 74.66.130

328. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator realleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

329. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

330. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

331. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

332. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

Dated: June 14, 2017

Respectfully submitted,

/s/ Sam Baxter

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