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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE UNITED STATES OF AMERICA, *et al. ex rel.* DR. PAUL BELLMAN, Plaintiffs, v. GILEAD SCIENCES, INC., Defendant.	**COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA**
UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. GILEAD SCIENCES, INC., Defendant.	16 Civ. 6228 (PAE)

Plaintiff the United States of America (the "United States" or the "Government"), by its attorney, Jay Clayton, United States Attorney for the Southern District of New York, brings this action against Gilead Sciences, Inc. ("Gilead"), and alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States against Gilead under the False Claims Act, 31 U.S.C. §§ 3729-33 (the "FCA"), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the United States based on Gilead's violations of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), for paying kickbacks to doctors and other healthcare providers to induce them to prescribe certain Gilead drugs that were reimbursed by federal healthcare programs.

2. Gilead developed, marketed, and/or sold the following antiretroviral drugs primarily used to treat HIV: Stribild®, Genvoya®, Complera®, Odefsey®, Descovy®, and Biktarvy® (the "Gilead HIV Drugs"). These drugs are expensive—some can cost insurers over $4,000 for a one-month supply—and patients are supposed to take them indefinitely to suppress their HIV viral load.

3. From January 1, 2011, through November 17, 2017 (the "Relevant Time Period"), Gilead offered and paid remuneration in the form of honoraria payments, meals, and travel expenses to healthcare practitioners who spoke at or attended Gilead speaker events to induce them to prescribe the Gilead HIV Drugs and thereby caused, up to and through May 17, 2018, false claims for the Gilead HIV Drugs to be submitted to and paid by Medicare, Medicaid, TRICARE, and the AIDS Drug Assistance Program ("ADAP") in violation of the FCA.

4. As part of its marketing efforts and to increase sales, Gilead conducted events known as "HIV Speaker Programs" at which a healthcare provider involved in the treatment of

HIV ("HIV Speaker") was engaged to present a slide deck (prepared by Gilead) and facilitate discussion about one of the drugs or a topic concerning HIV (an "HIV Disease State Topic") to other healthcare providers involved in the treatment of HIV ("Attendees"). Gilead's HIV Speaker Programs were often held in the evening at restaurants ("HIV Dinner Programs"). These HIV Speaker Programs were typically organized by sales representatives in Gilead's HIV therapeutic area ("Sales Representatives"), at times in consultation with their direct supervisors ("Regional Directors").

5. Gilead conducted HIV Speaker Programs in order to promote and increase the sales of the Gilead HIV Drugs. In total, Gilead paid many high-volume prescribers of HIV drugs tens or hundreds of thousands of dollars in honoraria to prepare and present as HIV Speakers, in addition to paying for their meals and travel expenses.

6. The HIV Speaker Programs were supposed to be educational in nature and the cost of any meals provided was supposed to be modest. But in practice, Gilead held many HIV Speaker Programs: at restaurants that served extravagant meals and alcohol in contravention of Gilead's own policies; where the company repeatedly invited the same healthcare providers; and that were attended by individuals with little educational need to attend. Further, Gilead's compliance program failed to prevent these improper practices, even though Gilead knew that it had to comply with the AKS and the company's own data should have put Gilead on notice of many of these abuses.

7. Many healthcare providers who received these improper kickbacks then prescribed the Gilead HIV Drugs. As a result, federal healthcare programs paid millions of dollars in reimbursements for tainted prescriptions. Gilead therefore knowingly caused the submission of thousands of false claims for payment to federal healthcare programs—specifically, Medicare,

Medicaid, TRICARE, and ADAP. As a result, Gilead is liable under the FCA and the common law for damages and penalties for these claims for payment for the Gilead HIV Drugs, as discussed in detail below.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

9. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

10. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1391(c), because Gilead does business in this district and some of the false or fraudulent acts occurred in this District.

PARTIES

11. Plaintiff is the United States of America and is suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS"), and its component agencies, the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs, and the Health Resources and Services Administration ("HRSA"), which administers the ADAP program; and the Defense Heath Agency, which administers the TRICARE program.

12. Defendant Gilead is a corporation headquartered in Foster City, California. Gilead develops, manufactures, markets, and sells drugs used to treat infectious diseases, including the Gilead HIV Drugs. Gilead does business throughout the United States, including in the Southern District of New York.

13. Relator Paul Bellman, M.D. is a physician who has treated patients diagnosed with HIV/AIDS. In August 2016, Dr. Bellman filed a complaint (subsequently amended in January 2020 and April 2021) in the United States District Court for the Southern District of New York under the *qui tam* provisions of the FCA, alleging, *inter alia,* that Gilead had violated the AKS and FCA by paying remuneration to doctors through its HIV Speaker Programs to prescribe the Gilead HIV Drugs.

RELEVANT BACKGROUND

I. The Anti-Kickback Statute and the False Claims Act

14. The FCA establishes liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B).

15. "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

16. In addition to treble damages, the FCA also provides for the assessment of a civil penalty for each violation or each false claim.

17. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Payments by a pharmaceutical company to doctors to induce them to write prescriptions for the company's pharmaceutical products that are ultimately

paid for by federal healthcare programs are examples of such illegal remuneration. A violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

18. The AKS arose out of congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, among other federal healthcare programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

19. The AKS defines remuneration to include anything of value, including "cash" or "in-kind" payments. 42 U.S.C. § 1320a-7b(b)(2).

20. As codified in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." Accordingly, a person or entity violates the FCA when they knowingly submit or cause to be submitted claims to federal healthcare programs that result from violations of the AKS.

21. By providing kickbacks to physicians to induce them to prescribe the Gilead HIV Drugs, Gilead has caused false claims to be submitted to federal healthcare programs.

II. The Relevant Federal Healthcare Programs

22. Generally, when a physician prescribes a Gilead HIV Drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits a claim for payment to the relevant federal healthcare program(s) for reimbursement.

23. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal healthcare program purchases the Gilead HIV Drug directly rather than reimbursing the pharmacy.

24. ***Medicare.*** Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program"). Medicare has several parts, including Part D, which 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. 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, CMS, contracts with private companies (often known as "sponsors") that are authorized to sell Part D insurance coverage. CMS regulates and subsidizes such companies 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.

25. Generally, after a physician 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 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 it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

26. Payments by CMS to a Part D Plan sponsor are conditioned on 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. 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.

27. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor 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.

28. The payments made by CMS 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).

29. 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.

30. By statute, all contracts between a Part D Plan sponsor and 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.

31. 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). In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2011 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 provision of § 1127B(b) of the Act."

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

33. Additionally, Medicare also enters into provider agreements with physicians to establish their eligibility to participate in the program. To be eligible for payment under the program, physicians must certify that they agree to comply with the AKS, among other federal healthcare laws.

34. On the Medicare provider enrollment agreement, 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." During the Relevant Time Period, those requirements included:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me . . . 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)…
>
> *****
>
> 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.

CMS Form 855I.

35. ***Medicaid.*** Medicaid is a joint federal-state program created in 1965 that provides healthcare benefits for certain groups, primarily the poor and disabled. 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). Among the states, the FMAP is at least 50 percent and is as high as 83 percent.

36. The Medicaid programs of all states reimburse for prescription drugs. 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 then generate funding requests to the state Medicaid programs. 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 then 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.

37. Claims arising from illegal kickbacks are not authorized to be paid under state law. For example, a relevant New York regulation provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse or mistake." N.Y. Comp. Codes R. & Regs. Title 18 § 518.1(c). "Unacceptable practice" is defined to include "[b]ribes and kickbacks," *id.* § 515.2(b)(5), and lists within this category both "soliciting or receiving," *id.* § 515.2(b)(5)(ii), and "offering or paying," *id.* § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether

in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," *id.* § 515.2(b)(5)(ii), (iv). New York's anti-kickback statute likewise forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366–d –f.

38. States also generally require certifications by physicians as a condition of providing Medicaid reimbursement for the prescriptions they write. These certifications include compliance with the AKS, among other federal healthcare laws.

39. A provider who participates in the Medicaid program must generally sign an agreement with his or her state that certifies 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.

40. ***TRICARE.*** TRICARE, administered by the Department of Defense ("DOD"), is part of the United States military's healthcare system, designed to maintain the health of active duty-service personnel, provide healthcare during military operations, and offer healthcare to non-active-duty beneficiaries, including dependents of active-duty personnel and military retirees and their dependents. The military health system 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. Military prescription drug benefits are provided through three programs: military treatment facility

outpatient pharmacies, TRICARE contractor retail pharmacies, and a national contractor's mail-order service.

41. TRICARE requires physicians to certify to compliance with the AKS, among other federal healthcare laws.

42. ***ADAP.*** ADAP is a federal program administered by HRSA that covers the costs, in whole or in part, of HIV/AIDS medications for the underinsured and uninsured. *See* 42 U.S.C. §§ 300ff-21 *et seq*. It is authorized under Part B of the Ryan White HIV/AIDS Program ("RWHAP"). RWHAP Part B provides funds to states and territories in order to, among other things, pay for HIV treatment, including the Gilead HIV Drugs, through ADAP. *See id.* ADAP is administered by states, similar to Medicaid.

FACTUAL ALLEGATIONS

I. Gilead Used the HIV Speaker Programs to Increase Sales of the Gilead HIV Drugs

43. The Gilead HIV Drugs are antiretroviral drugs (*i.e.*, drugs that act against retroviruses such as HIV) used for the treatment of HIV. Doctors generally prescribe the Gilead HIV Drugs to be taken once a day for an indefinite period of time—potentially the entirety of the patient's life—in order to keep a patient's HIV viral levels at bay. These drugs are very expensive—Medicare typically paid well in excess of a thousand dollars for a one-month supply of Complera®, and significantly more for many of the other Gilead HIV Drugs.

44. From January 2011 to November 2017, Gilead conducted HIV Speaker Programs in order to promote and increase the sales of the Gilead HIV Drugs. Specifically, during this time period, Gilead held over 17,300 HIV Speaker Programs, over 9,500 of which were HIV Dinner Programs. At these HIV Speaker Programs, Gilead paid doctors an honorarium of, on average,

$1,500 to present a slide deck, prepared by Gilead, and facilitate discussion regarding either one of the drugs or an HIV Disease State Topic.

45. All told, during the Relevant Time Period, Gilead paid 548 healthcare providers who served as HIV Speakers a total of more than $23.7 million in honoraria payments ($13.7 million of which was for the HIV Dinner Programs). In addition to honoraria, Gilead also paid for the HIV Speakers' and the Attendees' meals and alcohol consumed at these events.

46. Gilead conducted the HIV Speaker Programs in order to encourage the HIV Speakers and Attendees to increase their prescriptions of the Gilead HIV Drugs. In furtherance of this goal, Gilead held an enormous number of HIV Speaker Programs and paid substantial remuneration to HIV Speakers. Indeed, Gilead paid hundreds of thousands of dollars to certain prescribers of the Gilead HIV Drugs. Specifically, Gilead paid approximately 60 healthcare providers who were involved in the treatment of HIV over $100,000 each in total honorarium payments, in addition to paying for their meals and any travel expenses; and most of these individuals prescribed a large volume of the Gilead HIV Drugs. For instance, one HIV Speaker, who received over $300,000 in total honorarium payments, wrote prescriptions for Gilead HIV Drugs that resulted in over $6 million in Medicare, Medicaid, and TRICARE payments.

47. Not only were the HIV Speaker Programs intended to increase the HIV Speakers' prescriptions of the Gilead HIV Drugs but, at times, Sales Representatives were encouraged to use particular doctors as HIV Speakers in an effort to increase the volume of their prescriptions too. For instance, a Gilead Regional Director's HIV business plan from 2012 noted that a particular HIV Speaker was a "must win" account whose prescriptions "need to increase" and that the Regional Director should "[c]apitalize on program opportunities" for the doctor "as a speaker and attendee."

II. Gilead Knew That It Had to Comply with the AKS But Its Compliance Program Did Not Prevent the Fraudulent Use of HIV Speaker Programs

48. During the Relevant Time Period, Gilead understood that it had to comply with the AKS and that the AKS "seeks to prohibit improper influences on healthcare decisions by making it illegal to pay anything of value to induce someone to purchase, prescribe, or recommend a product that is reimbursed under federal or state government healthcare programs." But Gilead's internal controls failed to prevent its sales force from improperly using its HIV Speaker Programs to try to influence healthcare providers' prescribing decisions.

49. In particular, during the Relevant Time Period, Gilead's policies and procedures failed to prevent Sales Representatives and Regional Directors in its HIV therapeutic area from improperly providing honoraria payments, meals, and travel expenses to healthcare providers who spoke at or attended HIV Speaker Programs to induce them to prescribe the Gilead HIV Drugs. For example, before 2016, Gilead did not place any limits on repeat attendance at HIV Speaker Programs or on whether HIV Speakers could repeatedly attend programs on the same topics they spoke on.

50. Gilead also had access to data that should have put Gilead on notice of the strong possibility that Gilead's employees were abusing the HIV Speaker Programs. In particular, during the Relevant Time Period, Gilead maintained or had access to data on its HIV Speaker Programs, including the venues used, the costs of the events, and the Attendees at its programs. However, Gilead failed to detect and adequately address instances of HIV Speaker Program abuses by Sales Representatives and Regional Directors that related to compliance with meal-spend limits, inappropriate venues, as well as excessive attendance by HIV Speakers and other healthcare providers at HIV Dinner Programs, despite the fact that such abuses were evident in the data.

51. Furthermore, although Gilead conducted live monitoring of its HIV Speaker Programs from July 2013 through the end of the Relevant Time Period, only a very small percentage of the HIV Speaker Programs were actually monitored. Additionally, for a certain time period, Gilead required the monitor to provide advance notice to the Sales Representatives hosting the event and the HIV Speaker that their program would be monitored. Although Gilead later implemented "unannounced" monitoring visits in 2015, these too did not prevent the fraudulent use of HIV Speaker Programs. For example, one such unannounced monitor who attended a 2016 dinner at the James Beard House failed to report the "800 wine glasses" at the event, as noted by a Sales Representative in a text message. Instead, this monitor's internal report incorrectly stated that the program was "by the book."

III. Gilead Selected HIV Speakers Based on Revenue Considerations and Pressured Sales Representatives to Hold HIV Speaker Programs

52. Gilead selected some healthcare providers as HIV Speakers because of their potential to write more prescriptions of the Gilead HIV Drugs. Indeed, Gilead's sales force strongly influenced Gilead's decisions concerning HIV Speaker selections and, in turn, which prescribers potentially received tens or hundreds of thousands of dollars in honoraria.

53. Specifically, Gilead's Regional Directors could nominate individuals to become HIV Speakers in Gilead's HIV Speaker Bureau. Frequently, Regional Directors would nominate potential HIV Speakers at the recommendation of a Sales Representative. Further, although Gilead's Medical Affairs and Business Conduct groups—which were responsible for approving HIV Speaker nominations—could reject a Regional Director's nomination, these groups rarely did so.

54. Some Sales Representatives recommended, and Regional Directors selected for nomination, HIV Speakers based on whether they were already high prescribers of Gilead HIV

Drugs or had the potential to be. For example, in March 2017, a Miami-based Regional Director texted one of their Sales Representatives the following about a newly approved HIV Speaker: "[They're] going to give you great ROI [return on investment] . . . . [They] can sell genvoya over and over to [them]self." Similarly, a California Regional Director responded to a Sales Representative's text message that an individual had increased their prescribing and several individuals "are [the] only ones higher than [this individual]!!!" by stating: "Amazing. We need to add [them]" as an HIV Speaker.

55. In internal Gilead documents, Gilead Regional Directors concealed their motives for these programs through the use of coded terms. For example, in 2013 and 2016 business plans, two Regional Directors discussed the need to push HIV Speakers to get more "experience" with the Gilead HIV Drugs in order to increase the HIV Speakers' speaking opportunities and credibility with the Attendees. But, as Sales Representatives knew, "experience" was, in fact, a euphemism for "prescribing" the Gilead HIV Drugs. Indeed, a New York City Sales Representative stated in a text message that an HIV Speaker had "[n]ot [] freakin . . . written" enough prescriptions for one of the Gilead HIV Drugs and that, as a result, the Sales Representative was "going to pull the speaker clinical experience bit" when meeting with the HIV Speaker.

56. Gilead also pressured its Sales Representatives to hold HIV Speaker Programs and rewarded Sales Representatives for holding these events. Specifically, Gilead provided its Sales Representatives with budgets to hold HIV Speaker Programs, and it evaluated the Sales Representatives' performance, in part, based on whether they spent their entire budget for HIV Speaker Programs.

57. For example, performance evaluations across regions evaluated Sales Representatives based on whether they "[m]aximized speaker program budget spend" and

"[m]anage[d] speaker budget adherence to within 1% on annual basis." One Regional Director nominated a Sales Representative for an award in 2015 partly because of their "execution of large numbers of . . . speaker programs." The same Regional Director informed their team of Sales Representatives in August 2016: "I don't want to leave any money on the table" regarding HIV Speaker Programs.

58. Gilead Sales Representatives complained that Gilead held too many HIV Speaker Programs, had too many HIV Speakers on its roster, and that it was, at times, hard to find individuals who would attend these programs. For instance, in one text message chain, Sales Representatives noted Gilead's "ridonkulous speaker budgets" for HIV Speaker Programs, that "it's crazy running around with these programs that no one wants to go to," and that "Gilead expects you to do a lot of programs and has too many speakers."

IV. Gilead's HIV Speaker Programs Provided Valuable Renumeration to Healthcare Providers

59. Gilead's HIV Speaker Programs and, in particular, Gilead's HIV Dinner Programs, were a conduit for Gilead to provide remuneration to HIV Speakers and Attendees. As detailed above, Gilead's HIV Speakers earned approximately $1,500 in honoraria per event, with some HIV Speakers earning hundreds of thousands of dollars in total. Further, Gilead's HIV Speaker Programs also funneled improper remuneration to healthcare providers by: holding HIV Dinner Programs at high-end restaurants that were wholly inappropriate for educational events; allowing Attendees to attend HIV Dinner Programs on the exact same topic again and again and, thereby, obtain free lavish meals for events that held minimal educational value for them; and paying for HIV Speakers to travel to speak at desirable destinations—at times at the HIV Speaker's request.

A. Lavish Restaurants

60. Gilead's Sales Representatives organized HIV Speaker Programs at high-end restaurants across the country. By way of example, a significant percentage of the HIV Speaker Programs held in New York City were held at expensive restaurants, such as the James Beard House, Del Posto, Asiate, Palma, Vaucluse, Ilili, and Limani.

61. At HIV Speaker Programs held at the James Beard House, Gilead provided Attendees and HIV Speakers with a meal that typically included approximately six courses, prepared by a guest chef, with alcoholic beverage pairings accompanying each course.

62. Even more, Gilead Sales Representatives, Regional Directors, HIV Speakers, and Attendees all knew, or plainly should have known, that the amount of alcohol served at HIV Speaker Programs held at the James Beard House was not conducive to an educational program. However, the James Beard House was one of Gilead's most used venues, as it hosted approximately 157 different HIV Dinner Programs, and it was a consistently popular venue—Sales Representatives knew that the venue was a draw for both HIV Speakers and Attendees.

63. Further, Gilead managers knew, or at minimum should have known, that the cost of a meal at the James Beard House exceeded the amount in Gilead's internal policies that limited the cost of food and beverage at HIV Dinner Programs to $125 per person. And the James Beard House was not the only such venue used by Gilead that provided meals that exceeded this cap. In fact, Gilead's Sales Representatives conducted numerous HIV Speaker Programs where the meals served exceeded the $125 per person threshold.

64. In certain instances, Gilead's Sales Representatives circumvented the $125 per person limit by including the cost of food and beverages in the reported "room fee" (*i.e.*, the cost charged to rent the room), thereby concealing the true cost of the meal and making it appear like

the per person cost was below $125 when it was actually significantly higher. For example, at one luxury restaurant in New York City, Sales Representatives and their Regional Director, in agreement with the restaurant, moved any costs associated with food or beverages that would make the per person cost exceed $125 to "room rental" fees that would be charged to Gilead.

B. Repeat Attendance

65. Many healthcare providers who prescribed a high volume of the Gilead HIV Drugs attended a large number of HIV Speaker Programs, frequently at high-end restaurants. In fact, approximately 160 doctors and other healthcare providers who prescribed the Gilead HIV Drugs attended or spoke at more than 50 HIV Speaker Programs.

66. Although the HIV Speaker Programs were supposedly designed by Gilead to educate healthcare providers, Sales Representatives repeatedly invited numerous doctors and other healthcare providers to attend the same HIV Speaker Programs over and over. Many repeatedly attended HIV Speaker Programs covering the exact same topic, often within a short period of time. In total, over 250 prescribers of the Gilead HIV Drugs attended HIV Dinner Programs on the same topic three times or more within a six-month period. And over 80 of them attended five or more HIV Dinner Programs on the same topic within a six-month period.

67. For instance, a nurse practitioner in New York City attended 75 HIV Dinner Programs. This nurse practitioner attended 40 HIV Dinner Programs on the same topic three times or more within a six-month period. That nurse practitioner often brought their sibling—a pediatric nurse practitioner and non-prescriber of the Gilead HIV Drugs—to the programs. Similarly, a physician assistant in Miami attended 60 HIV Dinner Programs, with 32 repeat attendances, often attending with their spouse who was a pharmacist, on the same topic three times or more within a six-month period.

68. Further, many healthcare providers who were paid to be HIV Speakers on a particular topic also attended HIV Dinner Programs on exactly the same topic, often within less than six months after speaking. In certain instances, the same group of doctors repeatedly attended the same HIV Speaker Programs together at various restaurants.

69. For instance, a "cluster" of ten doctors in Manhattan spoke at or attended together approximately 384 HIV Dinner Programs (at which others were in attendance). Over 300 of these 384 HIV Dinner Programs were led by one of these 10 doctors. Each of the doctors repeatedly attended HIV Speaker Programs within 90 days of themselves speaking on the same topic. In many instances, they attended an HIV Dinner Program less than two weeks after speaking on the same topic.

70. Gilead also held many HIV Speaker Programs with few to no prescribers in attendance and/or programs populated with repeat attendees, whom some Sales Representatives referred to as "seat fillers." Due to the difficulty, at times, in finding individuals to attend HIV Dinner Programs, Sales Representatives would text each about the need for "seat fillers" so that the programs had enough attendees to go forward. For example, Sales Representatives in New York City commented to each other in text messages "[i]f you have any foodies or seat fillers that might be interested please invite," "[b]ring any fillers you can," "[a]ll 4 fillers are coming," and "[h]ave plenty of seat fillers, needs providers now." In California, a Sales Representative asked an HIV Speaker to help recruit Attendees, stating "I need some peeps lol . . . Anyone you can send."

C. Speaker Travel

71. Gilead Regional Directors and Sales Representatives also believed that by covering the travel costs for HIV Speakers to desirable travel destinations, these HIV Speakers would, in

turn, prescribe more of the Gilead HIV Drugs. For instance, in May 2016, after arranging for an HIV Speaker to travel to speak in Denver and then Alaska, a Seattle Sales Representative wrote to their Regional Director that the HIV Speaker "would love me forever!" and that the HIV Speaker "may stop writing" a competitor's drug.

72. On many occasions, Gilead covered the travel costs of HIV Speakers who traveled long distances to speak at HIV Speaker Programs at desirable travel destinations, such as Hawaii, Miami, and New Orleans. This was sometimes in response to an HIV Speaker's request to be booked for an event in that city.

73. For instance, a Sales Representative asked their Regional Director if they knew any Sales Representatives in Manhattan because a California-based HIV Speaker "needs a favor . . . [they] would like a lunch program on May 10. [They are already in New York] for a [Continuing Medical Education program]." When the Regional Director asked if the HIV Speaker was willing to go to the "outer boroughs" (*e.g.* Brooklyn) the Sales Representative responded "[they] want[] Manhattan." This program took place on May 10, 2016, and Gilead paid the HIV Speaker an honoraria at an increased amount due to the travel and covered some of the HIV Speaker's travel costs.

FIRST COUNT

Violations of the False Claims Act: Causing False Claims for Payment to Be Presented (31 U.S.C. § 3729(a)(1)(A))

74. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

75. The United States seeks relief against Gilead under 31 U.S.C. § 3729(a)(1)(A).

76. As a result of Gilead's kickbacks to induce doctors and other healthcare providers to prescribe the Gilead HIV Drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. §

1320a-7b(b)(2), false and fraudulent claims for payment based on these prescriptions were made to federal healthcare programs. Accordingly, Gilead knowingly caused to be presented false or fraudulent claims for payment or approval to federal healthcare programs in violation of 31 U.S.C. § 3729(a)(1)(A).

77. By reason of the false or fraudulent claims, the United States has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

SECOND COUNT

Violations of the False Claims Act: Causing False Statements to Be Made and Used (31 U.S.C. § 3729(a)(1)(B))

78. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

79. The United States seeks relief against Gilead under the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

80. As a result of Gilead's kickbacks to induce doctors and other healthcare providers to prescribe the Gilead HIV Drugs in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Gilead knowingly caused, among others, physicians, pharmacies, and Part D sponsors, to make false records or statements that were material to false or fraudulent claims for payment submitted to federal healthcare programs.

81. By reason of these false records or statements, the United States has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

THIRD COUNT

Unjust Enrichment

82. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

83. The United States paid claims submitted to federal healthcare programs for reimbursement for the Gilead HIV Drugs based on false statements submitted to federal healthcare programs as a result of Gilead's violations of applicable federal and state laws and regulations, including the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. The circumstances of Gilead's receipt of payments based on the prescriptions written by healthcare providers who received kickbacks are such that, in equity and good conscience, Gilead should not retain those payments, the amount of which is to be determined at trial.

WHEREFORE, the United States respectfully requests judgment against Gilead as follows:

a. On Counts One and Two (FCA) a judgment against Gilead for treble damages and civil penalties for the maximum amount allowed by law;

b. On Count Three (common law) a judgment for damages to the extent allowed by law.

Dated: April 24, 2025
New York, New York

JAY CLAYTON
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