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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* STEVEN R.PEIKIN, M.D., *et al.*, Plaintiffs, v. SALIX PHARMACEUTICALS, INC., Defendant.	**COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA** 12 Civ. 3870 (DLC)
UNITED STATES OF AMERICA *et al. ex rel.* RASVINDER DHALIWAL, Plaintiffs, v. SALIX PHARMACEUTICALS, LTD., Defendant.	15 Civ. 706 (DLC)

UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. SALIX PHARMACEUTICALS, INC., Defendant.	12 Civ. 3870 (DLC) 15 Civ. 706 (DLC)

Plaintiff United States of America (the "United States" or the "Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, brings this action against Salix Pharmaceuticals, Inc. a/k/a Salix Pharmaceuticals, Ltd. ("Salix"), alleging upon information and belief as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States against Salix 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 Salix's violations of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b), for paying kickbacks to doctors to induce them to prescribe certain Salix pharmaceutical products that were paid for by federal health care programs. As set forth more fully below, from January 2009 through December 2013 (the "Covered Period"), Salix knowingly offered and paid remuneration, including monetary payments and lavish meals, to physicians and other health care professionals who spoke at or attended Salix's speaker programs to induce them to recommend, promote, and prescribe certain Salix drugs and medical devices — specifically, Xifaxan, Apriso, Relistor, MoviPrep, OsmoPrep, Solesta, and Deflux (the "Covered Products"). These speaker programs were often little or nothing more than social gatherings for the doctors and other health care

professionals. And the payments and meals that the doctors and other health care professionals received in connection with these events were kickbacks to induce them to write prescriptions for the Covered Products.

2. Salix's speaker programs on the Covered Products included in-person events and pre-recorded events. At in-person events, both the speaker and the attendees were present in person, and the speaker was supposed to provide an educational talk on a Covered Product to the attendees, using a slide presentation. At pre-recorded programs, the designated speaker did not appear in person. Instead, a Salix employee was supposed to use a laptop or other device to play for the attendees a pre-recorded video of a doctor delivering a slide presentation. At the end of the pre-recorded presentation, the Salix employee was supposed to call the designated speaker, who was to be available to answer any questions by telephone. Salix employees internally referred to these pre-recorded programs as "doc-in-the-box programs." For each of its speaker programs (whether in-person or pre-recorded), Salix paid the speaker an honorarium — ranging from $250 (for a doctor available on call to answer questions associated with a pre-recorded program) to $4,500 (for a doctor who spoke at an in-person program and had a specified level of experience and certain other credentials).

3. According to Salix's internal policies, each speaker program was supposed to involve the presentation of scientific or clinical information about the relevant Salix product. The venue for these programs was supposed to be "conducive" to the exchange of information. In addition, the cost of the meal was supposed to be "modest" by local standards of restaurant meals, and the attendees were supposed to consist entirely of health care professionals with a legitimate interest in the scheduled topic.

4. In practice, however, Salix held many speaker programs that were primarily social in nature and otherwise did not comply with Salix's internal policies. Such events occurred throughout the Covered Period and across the country. For example, in connection with the in-person speaker programs, there were numerous instances where:

- the designated speaker spent little or no time discussing the Covered Product;
- the required slide presentation was not shown at all or in its entirety;
- doctors attended multiple programs on the same exact topic within a short period of time;
- the programs were held in the main dining rooms of restaurants or other locations that were not conducive to an educational program;
- the programs were held at high-end restaurants (such as Nobu and Le Bernardin in New York City), with per-person costs exceeding $200 and even $300;
- Salix employees responsible for certain programs reported that certain physicians had attended the event even though they had not, in order to make the per-person cost of the event appear lower than it actually was;
- attendees included individuals other than health care professionals with a legitimate interest in the scheduled topic, such as a physician's spouse; and/or
- the programs were used as an opportunity to provide a physician's practice (in some cases including administrative staff) with a meal or a happy hour.

5. Additionally, with respect to the pre-recorded speaker programs, there were numerous instances where the Salix employee did not play the pre-recorded presentation, or the Salix employee played the pre-recorded presentation but placed the laptop or other viewing device in a location where it could not readily be seen or at a volume at which it could not readily be heard.

6. Thus, many of Salix's speaker programs were nothing more than social events at which Salix wined and dined doctors and other health care professionals, often at high-end

restaurants. Salix intended these sham speaker programs to be inducements to the participants to write prescriptions for the Covered Products. Indeed, in selecting the speakers for these sham events, Salix selected those health care professionals whom it had identified (1) as high prescribers of the Covered Products or (2) as having high prescription-writing potential. And it dropped as speakers those health care professionals who did not write a sufficient number of prescriptions.

7. Moreover, Salix's kickback scheme worked. On average, the doctors who Salix paid as speakers during the Covered Period increased their prescription writing for the Covered Products after Salix began paying them as speakers. Similarly, the doctors who Salix repeatedly invited to attend its speaker programs also increased their prescription writing for the Covered Products after they began attending the programs.

8. By giving its speakers and attendees kickbacks, Salix knowingly caused the submission of thousands of false claims for payment to federal health care programs — specifically, Medicare, Medicaid, TRICARE, and the Veterans Administration health care program. As a result, Salix is liable under the FCA and the common law for damages and penalties for these claims for payment for the Covered Products, as discussed in detail below.

JURISDICTION AND VENUE

9. 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.

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 Salix 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 suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS"), and its component agency, the Centers for Medicare and Medicaid Services ("CMS") (formerly known as the Health Care Financing Administration), which administers the Medicare program and is responsible for overseeing the Medicaid program; the Department of Defense, which administers the TRICARE/CHAMPUS program (TRICARE"); and the Department of Veterans Affairs ("VA").

12. Relator Steven Peikin is a physician, and the remaining relators, Seana Swierczek, Christine Moore, Paul Mastrella, and Rasvinder Dhaliwal are former employees of Salix. In May 2012, relators Peikin, Swierczek, Moore, and Mastrella filed an action under the *qui tam* provisions of the FCA, alleging, *inter alia*, that Salix had violated the AKS and FCA in connection with its speaker programs and with respect to certain of the Covered Products (specifically, Xifaxan, Apriso, and Relistor). In January 2015, relator Dhaliwal filed an action under the *qui tam* provisions of the FCA, alleging, *inter alia*, that Salix had violated the AKS and FCA in connection with its speaker programs and with respect to all of the Covered Products.

13. Defendant Salix is a specialty pharmaceutical company headquartered in Raleigh, North Carolina. Salix's products focus on the prevention and treatment of gastrointestinal ("GI") disorders.

FACTUAL ALLEGATIONS

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," § 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," § 3729(a)(1)(B).[1] "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate indifference. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

15. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] 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 health care programs are examples of such illegal remuneration. Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

16. The AKS arose out of congressional concern that remuneration given to those who can influence health care decisions would result in goods and services being provided that

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[1] In May 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to Salix's conduct for the entire time period alleged in the complaint by virtue of Section 4(f) of FERA. Section 3279(a)(1)(A), formerly Section 3729(a)(1) of the FCA prior to FERA, and as amended in 1986, applies to conduct on or after May 20, 2009. Section 3729(a)(1) of the pre-FERA FCA provides, in pertinent part, that:

> (a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval . . .
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> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .

are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the Medicare and Medicaid programs, among other federal health care programs, from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

17. 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]."

18. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

19. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal health care programs.

20. By providing kickbacks to physicians to induce them to prescribe the Covered Products, Salix has caused false claims to be submitted to federal health care programs.

21. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64

Fed. Reg. 47099, 47103 (1999), the FCA civil penalties are $5,500 to $11,000 for violations, such as those alleged here, occurring on or after September 29, 1999.

II. The Federal Health Care Programs

22. For the Covered Products at issue in this case, generally, when a physician prescribes a pharmaceutical product, 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.

23. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription products. In such cases, the federal health care program purchases the product 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"). 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. All persons enrolled in Medicare Part A and/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 (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.

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 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. 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.

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)(1).

32. 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 (§ 1127B(b) of the Act)."

33. 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).

34. In addition, Medicare enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician 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.
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> 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.

35. ***Medicaid.*** 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. 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.

36. 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. 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)(1).

37. 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.

38. Medicaid claims arising from illegal kickbacks are not authorized to be paid pursuant to the PPACA, 42 U.S.C. § 1320a-7b(g). Further, such claims are not payable under state regulatory regimes. For example, the New York regulatory regime 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 forbids kickbacks in similar terms. *See* N.Y. Soc. Serv. Law §§ 366–d –f.

39. 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.

40. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively certify, as a condition of payment of the claims submitted for reimbursement by Medicaid, compliance with applicable federal and state laws and regulations.

41. In New York, for example, 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."

42. ***TRICARE.*** TRICARE, (formerly known as CHAMPUS), 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.

43. TRICARE prescription drug benefits are provided through several different programs: military treatment facility outpatient pharmacies, TRICARE network and non-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.

44. 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.

45. 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.

46. TRICARE beneficiaries can also fill prescriptions through TRICARE's mail order pharmacy program as well. 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, which replenishes the PBM's inventory of pharmaceuticals after accumulated dispensings reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DOD's national prime vendor bills TRICARE directly for drug replenishment costs.

47. 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.

48. 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.* §§ 199.2(b), 199.9(c)(12).

49. ***Veterans Administration Health Care.*** 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.

50. 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. 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 ("PPV") for distribution of pharmaceuticals. The PPV fills the order for the facility, and then submits an invoice to the VA for payment, charging the VA the price set by the contract awarded by the VA to the drug manufacturer. The VA makes payment to the PPV. The PPV then seeks a chargeback from the drug manufacturer for any difference between the contract price paid by the VA and the PPV's acquisition price.

51. During the Covered Period, the VA had an FSS contract with Salix (the "Salix VA contract"), for the procurement of drugs. The Salix VA contract required Salix to comply

with all applicable Federal, State and local laws, executive orders, rules and regulations. The Salix VA contract expressly required Salix to comply with the AKS.

III. Salix's Speaker Programs Were an Integral Part of Its Strategy for Increasing Its Sales of the Covered Products

52. Throughout the Covered Period, speaker programs were an important part of Salix's strategy for increasing its sales of the Covered Products, all of which are indicated for the treatment of various GI disorders. Indeed, from January 2009 through December 2013, Salix conducted approximately 10,000 speaker programs for the Covered Products. Approximately 8,000 of those speaker programs were for Xifaxan, Apriso and Relistor. Salix viewed Xifaxan in particular as key to its future success. During the Covered Period, Salix spent approximately $20 million on honoraria and meals for speaker programs for Xifaxan, Apriso and Relistor, and approximately $25 million on honoraria and meals for speaker programs for all of the Covered Products.

53. Members of Salix's sales force — referred to as "territory managers" or "sales representatives" (collectively, "sales representatives") — were encouraged to recruit new speakers and pressured to schedule speaker programs, with some supervisors setting goals for the number of programs sales representatives were expected to hold during a given period.

54. Moreover, Salix periodically monitored the prescription writing data of the health care professionals who spoke at and attended its speaker programs, and selected for future invites those doctors who prescribed comparatively more of Salix's drugs or who Salix identified as having the potential to be high prescribers.

55. During the Covered Period, Salix paid over 500 physicians honoraria in connection with its speaker programs on the Covered Products, with dozens of physicians earning more than $50,000, and several earning more than $100,000.

56. An email from a sales manager to his subordinate sales representatives, dated October 24, 2012, reflects (1) the pressure placed on sales representatives to schedule speaker programs, and (2) Salix's emphasis on using speaker programs as a driver of sales for the Covered Products. In the email, the sales manager wrote:

> I have attached a spreadsheet with your Xifaxan completed and approved speaker programs dating from 9-26-12 thru October 31. The expectations are that each of you complete a minimum of 3 programs for the month of October. I have sent several follow up emails reminding everyone of these expectations. I have also sent emails letting everyone know that I expect programs to continue through November up to December 15th. These programs should be completed with customers that you will get ROI [return on investment]. . . . As a Region we have completed 46 total programs and have 18 more on the books thru December 17. Let's shoot to get as close as we can to 100 total programs for PP3. . . . We all know that high activity on the right customers equals higher ranks which equals higher bonus payouts.

IV. Salix Was Well Aware That Its Speaker Programs Had to Be Legitimate Educational Events With Modest Meals

57. Throughout the Covered Period, Salix had internal policies that purported to place limits on its speaker programs. Those policies demonstrate that Salix knew that its speaker programs were required to be legitimate educational events with modest meals. Indeed, pursuant to Salix's internal policies, the venue for speaker programs — which were typically held in restaurants, and during which a meal was provided to the speaker and attendees — was supposed to be "conducive" to the exchange of information.

58. In addition, under Salix's policies, the cost of the meal was supposed to be "modest" by local standards of restaurant meals, and the attendees were supposed to consist entirely of health care professionals with a legitimate interest in the scheduled topic.

59. And, pursuant to Salix's internal policies, speaker programs were supposed to involve the presentation of scientific or clinical information about the relevant Salix product.

60. Salix thus understood how its speaker programs were supposed to be conducted: they were supposed to be legitimate educational events with modest meals. Nevertheless, as set forth below, Salix regularly flouted its internal policies. Throughout the Covered Period, Salix conducted many speaker programs that had little or no educational value and/or through which it provided the speaker and the attendees with lavish meals at high-end restaurants.

V. Salix Created Incentives for Sales Representatives to Use Speaker Programs as Kickbacks and Had Insufficient Controls to Prevent Kickbacks from Occurring

61. Sales representatives had a budget for speaker programs, which they were expected to spend. A former sales representative from Michigan described being told, in connection with speaker programs, to "spend, spend, spend, spend, spend, spend." Similarly, in March 2012, a regional sales manager sent an email to his subordinate sales representatives, instructing them: "Let's make sure we are getting as many programs on the books as possible for April. . . . Programs, Programs, Programs. Utilization of this resource with the correct [health care professionals] will make a huge difference."

62. Sales representatives were expected to schedule so many speaker programs that, practically speaking, there was little or no way for them to avoid conducting programs where the same attendees attended the same programs over and over again.

63. Moreover, sales representatives were compensated in part based on the number of prescriptions written by doctors on their call lists (*i.e.*, the doctors in their geographic regions to whom they were assigned to market Salix's pharmaceutical products). This created an incentive for sales representatives to schedule as many speaker programs as possible and to use the programs as a vehicle to pay kickbacks to doctors — in the form of honoraria to speakers and free meals to attendees — to increase their compensation.

64. Speakers were paid each time that they spoke. Their compensation for each program, known as an honorarium, was based on such factors as their experience and credentials in the relevant therapeutic area. However, although these factors affected the level of the honorarium a speaker was paid for each program, a doctor could have minimal experience and credentials and still be chosen as a speaker for Salix. In fact, the qualification that often governed whether sales representatives used a doctor as a speaker was whether the doctor was a high prescriber of Salix's products or was viewed as having the potential to be a high prescriber.

65. Speakers were paid a significant sum for each program they conducted. A doctor who was available to answer questions associated with a pre-recorded program was paid $250 for each such program. And a doctor who spoke at an in-person program could earn up to $4,500 for each program.

66. In addition to choosing the speakers, sales representatives also selected the attendees at speaker programs and were responsible for inviting them to the programs. As in the case of speakers, sales representatives sought to select the doctors who were high prescribers of Salix's products or who were viewed as having the potential to be high prescribers.

67. At all times relevant to the complaint, sales representatives also selected the topic, date, and venue for each program. There was little or no oversight with respect to the venues that the sales representatives chose. Accordingly, sales representatives frequently chose the high-end restaurants in the relevant community.

68. Moreover, for most of the Covered Period, Salix placed no limit on the number of programs a doctor could attend or how often a doctor could attend the same program. Indeed, for most of the Covered Period, there were no controls to prevent a sales representative from repeatedly selecting the same doctors on his call list as attendees at speaker programs on exactly

the same topics. Nor were there any controls to prevent a sales representative from arranging for the same doctors to take turns speaking and attending each other's programs repeatedly.

69. Moreover, although Salix's internal policy required attendance by at least two health care professionals who were not part of the speaker's medical practice, numerous speaker programs took place with less than two health care professionals in attendance. And, a number of programs took place with no one in attendance except members of the speaker's own practice.

70. As set forth above, the vast majority of Salix's speaker programs were held in restaurants. Although Salix's internal policies required the venues for these programs to be "conducive" to the exchange of information and the cost of the meal to be "modest" by local standards of restaurant meals, in practice Salix did not prohibit holding programs at restaurants that were high-end for the particular community in which they were located. Indeed, a significant number of Salix's speaker programs were held in high-end restaurants with costs exceeding $200 and even $300 per person.

71. Moreover, Salix did not require that a restaurant have a private room to be an acceptable venue for a speaker program. Nor did Salix require that the restaurant have a quiet atmosphere. This resulted in speaker programs frequently being held in the main dining rooms of noisy restaurants, as well as in other locations that were not conducive to a legitimate educational event.

72. Salix also had few checks on whether sales representatives reported truthfully on who attended the speaker programs they hosted. For example, for most of the Covered Period, Salix did not require that the speaker or the attendees at its programs sign attendance sheets.

73. Sales representatives' supervisors were made aware of each speaker program a sales representative hosted, the attendees who were purportedly present, and other details

regarding the program. First line supervisors, called district managers, and second-line supervisors, called regional managers, had access to the speaker program databases where this information was maintained, and received reports regarding speaker programs. These databases reflected numerous red flags of speaker program abuses, including instances where (1) the same doctors repeatedly attended programs (within a short period of time) where the same exact topic was supposed to be discussed, (2) doctors attended programs with their spouses, (3) the speaker and all of the attendees were from the same medical practice, (4) the programs were attended by very few and sometimes zero attendees, and (5) the per-person spend for programs was above $200 and even $300.

VI. Many Salix Speaker Programs Were Social Events that Lacked Any Legitimate Educational Purpose

A. Pre-Recorded Speaker Programs

74. During the Covered Period, Salix conducted more than 1,800 pre-recorded speaker programs. As set forth above, for those programs, a Salix sales representative was supposed to use a laptop or other device to play for the attendees a pre-recorded video of a doctor delivering a slide presentation. At the end of the pre-recorded presentation, the Salix sales representative was supposed to call the designated speaker, who was typically paid $250 to be available to answer any questions by telephone. As set forth above, Salix employees internally referred to these programs as "doc-in-the-box programs."

75. Many of these doc-in-the-box programs were little more than a mechanism to provide the attendees with extravagant dinners and an opportunity to socialize, and the speaker with $250 per event for doing little or nothing. Sales representatives often would not play the pre-recorded programs. And if the programs were played, the laptop or other device on which they were played was placed in a location where it could not be seen or at a volume at which it

could not be heard. The "speakers" typically were not called during these programs, and if they were called, it was usually to tell them that there were no questions.

76. Doctors from around the country participated in sham doc-in-the-box programs. For example:

- a doctor from Stafford, Virginia, was the speaker for at least 12 doc-in-the-box programs and was never called;
- a doctor from Providence, Rhode Island, was the speaker for at least 8 doc-in-the-box programs and was called only once or twice and then was told there were no questions;
- a doctor from Martinsburg, West Virginia, was the speaker for at least 9 doc-in-the-box programs and was never called;
- a doctor from Philadelphia, Pennsylvania, was the speaker for at least 8 doc-in-the-box programs and was called only once and told there were no questions;
- a doctor from Atlanta, Georgia, was the speaker for more than 30 doc-in-the-box programs and was called only about 20% of the time;
- a doctor from New York, New York, was the speaker for at least 5 doc-in-the-box programs and was never called; and
- a doctor from Rochester, New York, was the speaker for more than 30 doc-in-the-box programs and was rarely called, and in the few instances he was called, it was generally to say there were no questions.

77. Similarly, sales representatives from around the country organized and presided over sham doc-in-the-box speaker programs. For example:

- a former sales representative covering the New York City metro area did not bother showing the video — even in a perfunctory manner — approximately half the time, and never called the "speaker";
- a former sales representative covering various locations in Arizona and New Mexico played only a portion of the video at many events, including multiple events where, according to Salix's own data, the same attendees allegedly watched the same video within the span of a few months; and

- a former sales representative covering the Washington, D.C., area presided over seven to eight sham pre-recorded events for which she did not play the video or call the "speaker."

78. In addition, the same doctors were repeatedly invited to the same doc-in-the-box programs, which simply served as opportunities for them have an evening out with their colleagues paid for by Salix. An email from a former Maryland sales representative to a Washington, D.C., doctor, dated September 28, 2012, reflects the sham nature of the pre-recorded speaker programs. In the email, the sales representative wrote to the doctor: "I'm showing the Xifaxan video at the Suburban GI journal club next Wednesday, can you be available at 6:00 if there are any questions that arise? (considering this is the third time I've shown this video to them, I doubt they will have any questions this time either) ha-ha."

B. In-Person Speaker Programs

79. Many of Salix's in-person speaker programs — at which the speaker was supposed to go through a formal slide presentation and give an educational talk to the attendees — were also primarily or exclusively social events with little or no educational purpose. As set forth below, many of Salix's in-person speaker programs had one or more of the following characteristics (with a significant number of programs having multiple of the characteristics): there was little or no medical discussion; the same doctors attended the same exact event multiple times within a short time period (with the attendees often being members of the same medical practice); non-health care professionals (such as spouses and administrative staff) were allowed to attend; the events were staff outings or parties (rather than legitimate educational events); the events were attended by very few and sometimes zero attendees (such that there were instances where doctors were paid honoraria for events that did not occur or merely to have dinner with the organizing sales representative); and the events had an excessive per-person

spend. Many of Salix's above-referenced doc-in-the-box programs also had one or more of these very same characteristics, thus further reinforcing the sham nature of those programs.

1. Little or No Medical Discussion

80. Throughout the Covered Period, there were numerous instances where speakers were paid to speak at events where there was little or no medical discussion, much less discussion of the Salix product that was supposed to be the subject of the events. For example:

- A doctor from New York, New York, was the paid speaker for numerous events during the Covered Period, earning more than $30,000 in honoraria. At a typical event for which this doctor was the speaker, there was little or no discussion of the relevant Salix product or the condition it was meant to treat, and slides were not shown. Moreover, only a small percentage of a given event involved any type of medical discussion. Most of the events consisted of the attendees socializing with one another.

- A doctor from Martinsburg, West Virginia, was the paid speaker for numerous events during the Covered Period, earning more than $14,000 in honoraria. The events were primarily social in nature with 10-15 minutes of medical discussion (sometimes less), and typically no slides.

- A doctor from Providence, Rhode Island, was the paid speaker for numerous events during the Covered Period, earning more than $190,000 in honoraria. For approximately half of these events, the medical discussion lasted 15 minutes or less, including multiple events that were entirely social in nature with no medical discussion. The events were primarily a get together for the attendees, who in many instances knew each other and even practiced together. On multiple occasions, the sales representative announced that the attendees could just have dinner.

- A doctor from Lancaster, California was the paid speaker for approximately 20 events during the Covered Period, many of which took place in the main dining room of high-end restaurants (*e.g.*, Nobu) and were attended by individuals who had previously attended the same lecture. These events were very informal, included a very short presentation, and were primarily social in nature.

- A doctor from Atlanta, Georgia, was the paid speaker for numerous events during the Covered Period, including more than 25 breakfast and lunch events, for which he was paid between $1,500 and $2,900 per event. For these breakfast and lunch events, there was frequently little or no medical discussion. These events were catered and took place at different medical

practices. The physicians in the practice often would spend only a few minutes in the room designated for the event, and the discussion was primarily social.

- A doctor from Rochester, New York, was the paid speaker for numerous events, earning more than $200,000 in honoraria. According to the doctor, many of these events were primarily social in nature, and various sales reps instructed the doctor not to do the slide presentation. There were multiple instances where the sales reps announced that they were just going to have dinner that night.

2. Same Topic and Repeat Attendees

81. Salix conducted a significant number of speaker programs during the Covered Period where the same doctors were scheduled to make the same presentation to the same attendees multiple times within a short period of time. At these events, the speaker and attendees were often from the same medical practice or otherwise knew each other, and attended these events to socialize with one another. Not surprisingly, these events ended up being primarily social in nature, with little or no medical discussion.

82. Salix's sales representatives were generally responsible for inviting the speaker and attendees, and would invite the same people knowing full well that the events would be a sham. Moreover, on some occasions, sales representatives would allow the speakers to invite the attendees, and the speakers often invited other members of their practice, as well as significant others and friends, with the expectation that the events would be primarily social in nature.

83. It was well-known within Salix that doctors frequently attended the same events over and over. Indeed, frequent attendees were referred to internally by Salix employees as "plate lickers."

84. Moreover, Salix's speaker program data — to which the companies' management had access — revealed numerous instances of this same topic/frequent attendee phenomenon.

Indeed, below are a few of the many examples where Salix's speaker program data evidences doctors repeatedly attending the same events within a short period of time.

- **Example 1.** According to Salix's data, a doctor from Providence, Rhode Island, repeatedly "spoke" to the same two doctors on the same topic over and over again throughout 2012, as set forth below. These events included little or no medical discussion.

	1/18/12	4/19/12	5/11/12	5/15/12	5/18/12	6/15/12	6/22/12
Doctor 1	X	X	X	X	X	X	X
Doctor 2	X	X					X

	7/31/12	8/27/12	9/18/12	10/15/12	11/28/12	12/3/12	12/17/12
Doctor 1		X	X		X	X	
Doctor 2	X	X	X	X	X		X

- **Example 2.** According to Salix's data, two doctors from New York, New York, repeatedly attended events on the same exact topic. These events were primarily social in nature, and included instances where there were no slides and little or no discussion of the relevant Salix drug.

	12/20/10	2/1/11	2/13/11	3/29/11	6/9/11	6/16/11	7/14/11
Doctor 1	X		X	X			X
Doctor 2	X		X	X	X	X	X

	7/22/11	7/29/11	9/12/11	10/19/11	1/12/12	4/26/12	6/4/12
Doctor 1			X		X	X	X
Doctor 2	X	X	X	X			

	6/18/12	7/10/12	7/17/12	7/25/12	11/1/12	12/10/12	12/13/12
Doctor 1		X		X		X	
Doctor 2	X		X		X		X

- **Example 3.** According to Salix's data, a doctor from Lancaster, California, repeatedly "spoke" to one or more doctors from his own practice on the same exact topic, including on 7/7/10, 9/14/10, 12/7/10, and 4/14/11. These events were primarily social in nature with little or no medical discussion.

- **Example 4.** According to Salix's data, a doctor from Bethesda, Maryland, repeatedly "spoke" to the same three doctors on the same topic, as set forth below. At most or all of these events, there were no slides and the discussion of the relevant drug was limited to 15 minutes or less.

	10/3/12	12/5/12	1/9/13	2/13/13	3/13/13	5/8/13
Doctor 1	X	X	X	X	X	X
Doctor 2	X	X	X	X		X
Doctor 3	X	X		X	X	X

- **Example 5.** According to Salix's data, a doctor from Washington, D.C., repeatedly "spoke" to the same three doctors on the same topic, as set forth below. At most or all of these events, there were no slides and the discussion of the relevant Salix drug was limited to 5-10 minutes.

	9/1/11	10/13/11	12/14/11	1/26/12	11/13/12	2/6/13
Doctor 1	X	X	X	X	X	X
Doctor 2		X	X	X	X	X
Doctor 3	X	X	X			

- **Example 6.** According to Salix's data, a doctor from Philadelphia, Pennsylvania, repeatedly "spoke" to three other doctors from his practice on the same topic, as set forth below. At most or all of these events, there were no slides and little if any medical discussion.

	7/17/12	11/1/12	12/13/12	4/25/13
Doctor 1	X	X	X	X
Doctor 2	X		X	X
Doctor 3	X	X		X

3. Improper Attendees

85. During the Covered Period, Salix often allowed individuals to attend its speaker programs who lacked a legitimate educational interest in the Salix products that were the purported subjects of the programs. Such improper attendees included (1) spouses of the speakers and the doctor attendees (these spouses were not health care professionals or practiced in areas unrelated to the Salix products that were supposed to be the subjects of the events); (2) friends of the speakers and the doctor attendees; and (3) administrative staff who worked for the speakers and the doctor attendees.

86. The following are examples of the many speaker programs that included improper attendees:

- Five doctors from New York, New York, frequently attended speaker programs with their spouses. Two of the spouses were not health care professionals, and the other spouses practiced in areas unrelated to the Covered Drugs that were supposed to be the subject of the events. Most or all of these events were social in nature, with little if any medical discussion.

- Four doctors from Providence, Rhode Island, frequently attended events with their spouses, three of whom were not health care professionals. Most or all of these events were social in nature, with little if any medical discussion.

- A doctor from Martinsburg, West Virginia, was the paid speaker at numerous events that were primarily social in nature, and his spouse — a dentist with no legitimate interest in the Covered Products — attended several of these events.

87. Moreover, sales representatives often encouraged doctors to bring improper attendees to Salix's speaker programs. For example, in an email dated July 25, 2011, a former sales representative emailed a doctor from Vineland, New Jersey, telling the doctor that he should "pick a place, ANYWHERE[,] so we could have a talk on Moviprep/Xifaxan." The sales representative invited the doctor to "bring the wife too," stating "[t]hat would be sponsored by Salix" and "[y]ou leave when you're ready."

4. Staff Events and Parties

88. There were numerous instances where Salix used its speaker programs as a vehicle to treat a doctor's medical practice to a free meal, happy hour, and even holiday party, in order to induce the doctor and other health care professionals in his or her practice to prescribe the Covered Products. To mask its payment for these events, Salix classified the events as speaker programs and paid honoraria to the designated "speakers," even though there was little if any medical discussion at these events.

89. The following are examples of instances where Salix paid for staff events and parties under the guise of speaker events:

- A doctor from Bethesda, Maryland, was paid $4,000 to "speak" at two events that were attended only by members of his own practice, had no presentation on the

relevant Salix drug, and had at most only 10-15 minutes of general medical discussion.

- A doctor from Providence, Rhode Island, was paid $1,800 for a speaker program at which there was no medical discussion and the attendees were all office staff from another doctor's practice. The doctor from that practice did not attend.

- At the request of a doctor from New Jersey, a former Salix manager arranged for Salix to fund a graduation party at a New Jersey restaurant for fellows who had been instructed by the doctor. Another doctor was paid to "speak" at this sham event, which contained at most 10-15 minutes of medical discussion and no slide presentation.

- A doctor from Stafford, Virginia, was the paid speaker for at least 12 in-person speaker programs, only one or two of which had any attendees from outside of his own practice. The doctor and the members of his practice treated these events as an opportunity for staff bonding, and the events were predominantly, if not exclusively, social in nature.

- A former sales representative covering various areas in North Carolina organized a dinner at Ruth's Chris Steakhouse where the only attendees were a doctor and the doctor's staff.

- On multiple occasions, Salix treated a doctor from New York, New York, and 20-25 members of his medical practice to lavish dinners at restaurants such as Tao and Abe & Arthur's.

90. Receipts from Salix's speaker programs — which were approved by managers — evidence the existence of speaker programs that were quite clearly happy hours. For example, the receipt for a speaker program at "Firebirds" in Newark, Delaware, dated September 14, 2011, reflects that Salix paid $190 for the attendees to order drinks and appetizers. The receipt also reflects that this "dinner" program ended at or around 5:13 pm.

91. In addition, emails from certain sales representatives to doctors reflect the sales representatives encouraging the doctors to bring their staff to speaker programs. For example, in an email dated December 8, 2010, a former sales representative covering various locations in New Jersey emailed a doctor stating, "Let me know if you want to join me for this Thursday night[']s dinner at Nicholas. Cocktails at 6:30 and you can bring staff."

5. Phantom Attendees and No Attendees

92. Certain Salix sales representatives also created phony records for speaker programs to make it appear that they were legitimate educational programs — with an appropriate number of attendees and an appropriate per-person spend — even though they were not. Indeed, there were numerous instances where sales representatives added non-existent attendees to Salix's speaker program records either: (1) to make lavish events that exceeded Salix's per person spend limit appear to be within the per person limit; or (2) to make it look like an educational program actually took place when it did not to justify paying the "speaker" an honorarium.

93. For example, a former sales representative covering various locations in New Jersey repeatedly reported that health care professionals attended particular events when they did not to avoid exceeding the per person cap for the events. Similarly, a former sales representative covering the Washington, D.C., area entered a completely fictitious set of names into Salix's records for a pre-recorded event that did not occur in order to justify paying the "speaker" an honorarium.

94. There were also instances where Salix sales representatives identified doctors who were high prescribers of Salix's products (or who were thought to have the potential to be high prescribers) and took them out for lavish dinners. The sales representatives justified paying for the events and paying the doctors an honorarium by classifying the events as speaker programs. For example, a doctor from New York, New York, confirmed that he was paid $2,000 to speak at multiple events at which there were no attendees other than Salix employees. Likewise, a doctor from Martinsburg, West Virginia, confirmed that he was paid $1,800 to speak at one event at

which there were no attendees, as well as numerous other events that were primarily social in nature.

6. Excessive Per-Person Spends

95. Rather than being "modest" by local standards of restaurant meals — and complying with Salix's per person spending limits — many of Salix's speaker programs were held at high-end restaurants and had excessive per person costs. Indeed, there were numerous programs where the per-person costs exceeded $200 and even $300.

96. In addition, many speaker programs were not conducted in private rooms, either because the restaurant did not have one or because Salix chose not to conduct the programs in a private room. This made it difficult or impossible to hear the "speaker" or show the slides (for in-person programs) or play the pre-recorded video (for pre-recorded programs). When speaker programs occurred in the public space of a restaurant it was common practice not to show the slides or play the pre-recorded video. The fact that many speaker programs were not held in private rooms shows that the motivation for these programs was not to educate, but to wine and dine the participants.

VII. Salix's Compliance Program Was Inadequate to Prevent Fraud with Respect to Its Speaker Programs

97. As set forth above, during the Covered Period, Salix did not have sufficient policies in place to prevent speaker programs from being used as a vehicle for kickbacks to doctors through the payment of honoraria and lavish dinners. For example, for much of the relevant period, there was no policy aimed at preventing sales representatives from hosting programs at which the same doctors were scheduled to speak repeatedly to the same attendees on exactly the same topic.

98. Nor did Salix have effective procedures in place to conduct after-the-fact audits of its speaker programs. Among other things, insufficient efforts were made to review the data and other information that Salix compiled on its speaker programs to police against speaker programs being used as kickbacks. Indeed, as set forth above, there were numerous instances where the per-person spending limits that Salix internally set for its speaker programs were significantly exceeded. Any reasonable effort to review the information in Salix's speaker program databases would have revealed these instances.

99. Similarly, any reasonable effort to review the information in Salix's speaker program databases would have revealed that doctors were repeatedly being scheduled to speak to the same attendees on the same exact topics. Salix simply did not care how often doctors were scheduled to present the same program to the same attendees.

100. In addition, Salix failed to address known abuses of its speaker programs. On certain occasions, sales managers and other supervisors attended speaker programs where there was little or no medical discussion, as well as events where the meal cost was excessive. Yet they did not reprimand or counsel the sales representatives who had organized the events or the doctors who had attended the events.

VIII. Salix's Sham Speaker Programs Were Intended to Be Kickbacks

101. Through its sham speaker programs, Salix intended to provide kickbacks to doctors and other health care professionals to increase their prescription writing for the Covered Products.

102. In selecting speakers, sales representatives were pressured to focus on "return on investment" or "ROI." A number of sales representatives and managers tracked the prescription patterns of speakers and attendees following speaker programs to evaluate ROI.

103. Sales representatives were directed to select as speakers those doctors who either were high prescribers of the Covered Products or had high prescription writing potential, and to use speaker programs to induce them to continue writing or to start writing prescriptions for the Covered Products. For example:

- A sales representative covering the New York City metro area was told by his supervisor to pick three doctors who she believed could be paid off with dinners and lunches, and to take them out and stay for appetizers and then leave.

- Another sales representative covering the New York City metro area visited a doctor who was a high prescriber of a competitor drug to Apriso in order to convince the doctor to start writing for Apriso. During the visit, the sales representative's supervisor, who had accompanied the sales representative on this visit, told the doctor that Salix was going to make him a paid speaker. At the supervisor's direction, the sales representative also left a company credit card with the doctor's nurse so staff could order food and charge it to Salix. Thereafter, the doctor began prescribing Apriso.

- A sales representative covering various locations in New Jersey and Pennsylvania was instructed by her manager to make a particular doctor a paid speaker after the sales representative had had little success converting him to a Xifaxan 550 mg prescriber. Thereafter, the sales representative paid the doctor as a speaker for numerous dinner events that were primarily social in nature and at which the doctor did not give the required slide presentation.

104. Sales representatives were also directed to stop using doctors as speakers if they were not writing enough prescriptions. For example, a sales representative from New Jersey was told by her supervisor to stop scheduling speaker events with certain doctors because those doctors had not written a sufficient number of prescriptions for Salix drugs after being used as speakers. Similarly, a sales representative instructed an Apriso speaker from Washington, D.C., that the doctor needed to write more prescriptions for Apriso or she would not be used as a speaker again.

105. Salix thus used its speaker programs to drive prescriptions of the Covered Products, and doctors knew it. Sales representatives chose doctors to be speakers and attendees

based on their prescription-writing history, which the doctors had to maintain or increase in order to continue to be invited to speaker programs.

106. Moreover, Salix's kickback scheme was successful. On average, the doctors who Salix paid as speakers during the Covered Period increased their prescription writing for the Covered Products after Salix began paying them as speakers. Similarly, the doctors who Salix repeatedly invited to attend its speaker programs also increased their prescription writing for the Covered Products after they first began attending such programs.

IX. Salix Caused Thousands of False Claims to Be Submitted to and Paid for by Federal Health Care Programs

107. Salix caused many thousands of prescriptions to be written as a result of payments and/or other remuneration made in connection with speaker programs that were kickbacks to doctors. Salix paid hundreds of doctors kickbacks in the form of honoraria and/or other remuneration in conjunction with speaker programs on the Covered Products during the Covered Period. These doctors — who spoke at or attended sham speaker programs with little or no medical discussion and enjoyed lavish meals — wrote many thousands of dollars worth of prescriptions for these products that were paid for by federal health care programs.

108. Salix is liable to the federal government for damages based on the payment of the above claims and all other claims submitted to federal health care programs for prescriptions written by these physicians for the Covered Products beginning from the time they began receiving honoraria payments or other remuneration and running through the Covered Period, because the claims were the result of prescriptions induced by honoraria or other remuneration.

109. Compliance with the AKS is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements, and contracts.

110. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to physicians as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for prescriptions written by the doctors that took the kickbacks from Salix.

111. Claims for the Covered Products during the Covered Period arising from the kickbacks expressly and impliedly misrepresented compliance with a material condition of payment, *i.e.*, compliance with the AKS. Claims that include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the FCA. 42 U.S.C. § 1320a-7b(g).

112. By providing remuneration to physicians and other health care professionals, Salix intended to induce those physicians to prescribe the Covered Drugs. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to federal health care programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by federal health care programs.

FIRST COUNT

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

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

114. The United States seeks relief against defendant under 31 U.S.C. § 3729(a)(1) (2006) and, as amended, 31 U.S.C. § 3729(a)(1)(A).

115. As a result of Salix's kickbacks to induce health care professionals to prescribe the Covered Products 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 health care programs. Accordingly, Salix knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

116. 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: Use of False Statements
(31 U.S.C. § 3729(a)(2) (2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B))

117. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

118. The United States seeks relief against defendant under the False Claims Act, 31 U.S.C. § 3729(a)(2)(2006), and, as amended, 31 U.S.C. § 3729(a)(1)(B).

119. As a result of Salix's kickbacks to induce health care professionals to prescribe the Covered Products in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2), Salix knowingly caused health care providers, including physicians, pharmacies, PBMs and/or Part D sponsors, to make false records or statements that were material to false or fraudulent claims for payment submitted to federal health care programs.

120. 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

121. The United States incorporates by reference each of the preceding paragraphs as if fully set forth herein.

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

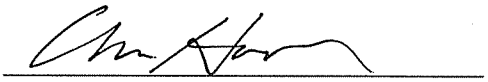
WHEREFORE, the United States respectfully requests judgment against Salix as follows:

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

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

Dated: June 2, 2016
New York, New York

PREET BHARARA
United States Attorney for the
Southern District of New York

By: 

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