PREET BHARARA
United States Attorney for the
Southern District of New York
By: LI YU
REBECCA C. MARTIN
ELLEN M. LONDON
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007
Tel: (212) 637-2734/2714/2737
Fax: (212) 637-2686

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION and BIOSCRIP, INC., Defendants.	11 Civ. 8196 (CM) **AMENDED COMPLAINT-IN-INTERVENTION OF THE UNITED STATES** JURY TRIAL DEMANDED

The United States, by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, alleges for its complaint as follows:

PRELIMINARY STATEMENT

1. This is a civil action brought by the United States (the "Government") against Novartis Pharmaceuticals Corporations ("Novartis") and BioScrip, Inc. ("BioScrip), under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "FCA"), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the Government as a result of two kickback schemes involving Novartis's transplant drug Myfortic (orchestrated by Novartis), and Novartis's iron chelation drug Exjade (orchestrated by Novartis and BioScrip). First, under the Myfortic kickback scheme, Novartis paid kickbacks to numerous pharmacies in exchange for

the pharmacies switching transplant patients to Myfortic, or continuing to recommend and dispense Myfortic instead of cheaper, generic competitor drugs. Second, under the Exjade kickback scheme, Novartis provided kickbacks – in the form of patient referrals and "rebates" – to BioScrip in exchange for BioScrip recommending refills to Exjade patients. In connection with these two schemes, Novartis caused numerous pharmacies, including BioScrip, to submit false claims for Myfortic or Exjade shipments to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in reimbursements that should not have been paid.

2. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), expressly prohibits any individual or entity from offering, paying, soliciting or receiving any "remuneration," which "include[s] any kickback, bribe, or rebate," to "any person to induce such person" to purchase or recommend a drug or service that is covered by Medicare or Medicaid. *Id.* In that regard, to qualify for most Medicare and Medicaid payments, pharmacies must certify that they are complying with the AKS. Further, as early as 1994, the Government gave notice to pharmaceutical companies like Novartis that they could be in violation of the AKS by offering financial benefits to a pharmacy in exchange for recommending to physicians that they move patients from one prescription drug to another prescription drug or for directly marketing a prescription drug to patients under the guise of "educational" or "counseling contacts." *See* 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

3. Although Novartis and BioScrip knew that the AKS prohibited them from, respectively, giving and receiving kickbacks to promote switching patients to Myfortic and/or Exjade refills, they disregarded that prohibition, choosing instead to put sales growth and profits before their duty to comply with federal law.

4. As part of the Myfortic kickback scheme, and starting in 2005, Novartis offered

kickbacks to twenty or more pharmacies that could influence whether Myfortic or a competitor drug was prescribed to transplant patients, and disguised these kickbacks as "performance" rebates or discounts. In exchange for the kickbacks, these pharmacies agreed to disregard their professional independence, and use their influence to switch patients to Myfortic (which Novartis referred to as "conversion"), or to continue dispensing Myfortic instead of competitor drugs. For example, in early 2011, the owner of Twenty-Ten Prescription Pharmacy in Los Angeles told Novartis that, in exchange for "5% more" in rebates, Twenty-Ten would "do all the conversions" requested by Novartis. *See infra* at ¶ 119. Similarly, Novartis agreed to a kickback arrangement with Transcript Pharmacy in Flowood, Mississippi, after Transcript promised to recommend moving patients to Myfortic "*only if*" Novartis allowed Transcript to participate in the Myfortic kickback scheme. *See infra* at ¶ 104.

5. In furtherance of the Myfortic kickback scheme, Novartis and the pharmacies concealed key aspects of their relationships from physicians, patients, and the Government. First, when the pharmacies, in exchange for the kickbacks from Novartis, recommended switching patients to Myfortic or opposed the use of generic drugs, they presented those recommendations as unbiased professional opinions to physicians and patients, without disclosing that they stood to earn tens or hundreds of thousands of dollars from Novartis as a result of those recommendations. *See infra* at ¶¶ 67, 96-97. Second, although Novartis drafted rebate and discount contracts for the pharmacies to sign, invariably missing from these written agreements are the unlawful promises that Novartis extracted from the pharmacies in exchange for Novartis's payments — to switch patients to Myfortic or to keep recommending and dispensing Myfortic. *See infra* at ¶¶ 65-66, 73, 107. Finally, to ensure that it would reap the Myfortic sales produced by kickbacks, Novartis also ignored compliance issues raised by the kickback arrangement in violation of its own written policies and procedures. For example, in

2011, Novartis executives disregarded reporting requirements under the company's compliance policies and failed to report an obvious compliance issue raised by an effort to induce Walgreen's to convert patients to Myfortic in exchange for rebates. *See infra* at ¶¶ 130-141.

6. For Novartis, the Myfortic kickback scheme was highly lucrative. First, it resulted in rapid, sometimes exponential, growth in Myfortic sales. For example, in the first four years of its kickback relationship with Novartis, Bryant's Pharmacy in Arkansas drove its annual Myfortic sales "from $100,000 to over $1 million," by "work[ing] aggressively to increase [its] Myfortic utilization." *See infra* at ¶¶ 71-75. Further, as a Novartis account manager has admitted, this scheme is generating "an ongoing stream of revenue for" Novartis "going forward as long as the patient is still living and using [Myfortic]." Transplant patients and the public fisc, on the other hand, have borne the cost of the Myfortic kickback scheme. Specifically, hundreds, possibly thousands, of transplant patients have undergone switches in their medication as a result of recommendations from pharmacies that were based on undisclosed financial, rather than independent clinical, considerations. Further, Medicare and Medicaid paid tens of millions of dollars to pharmacies for Myfortic based on false claims that were never entitled to federal reimbursement. *See infra* at ¶¶ 142-143.

7. The Exjade kickback scheme similarly was based on Novartis's recognition that it could increase Exjade sales by offering kickbacks to BioScrip to induce the pharmacy to set aside its independent clinical judgment and promote Exjade refills for Novartis. Thus, Novartis leveraged its control over BioScrip's access to Exjade patient referrals to make BioScrip implement a program of calling Exjade patients and – under the guise of offering "education" or "counseling" – recommending that the patients order Exjade refills. Once this began to generate higher Exjade sales for Novartis, Novartis and BioScrip agreed on a bundle of extra incentives for BioScrip – in the form of more patient referrals and kickbacks in the guise of rebates – so that

the pharmacy would continue recommending Exjade refills to patients. *See infra* at ¶¶ 174-199.

8. Further, while Novartis and BioScrip understood that BioScrip's "top priority" in calling Exjade patients was to generate refill orders for Novartis and that BioScrip was giving patients biased advice that emphasized the benefits of getting Exjade refills while understating the drug's serious – potentially life-threatening – side effects, they concealed these facts from patients, prescribers, and the federal healthcare programs. Instead, Novartis and BioScrip promoted BioScrip's Exjade program as patient-focused and clinically sound. In addition, Novartis and BioScrip also withheld key dimensions of their kickback scheme from the written agreements that purported to reflect all material aspects of their relationship pertaining to Exjade. *See infra* at ¶¶ 200-226.

9. Novartis and BioScrip both reaped significant financial benefits from the Exjade kickback scheme. For example, a 2011 internal analysis showed that Novartis was realizing a 7.8:1 return on investment from its Exjade kickback relationship with BioScrip, *i.e.*, Novartis realized $7.8 in additional Exjade sales for each dollar it paid BioScrip in kickbacks. BioScrip, likewise, realized higher Exjade sales, greater Medicare and Medicaid reimbursements, larger dispensing fees, and more kickbacks from Novartis as a result of its participation in the Exjade kickback scheme. *See infra* at ¶¶ 199, 227.

10. Exjade patients and the federal healthcare programs, however, were subjected to the deleterious effects of the Exjade kickback schemes. Thousands of patients received biased advice concerning their Exjade therapy. Further, Medicare and Medicaid paid tens of millions of dollars for Exjade shipments based on false claims submitted by BioScrip that were never entitled to federal reimbursement. *See infra* at ¶¶ 227-232.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction over the Government's claims under

the FCA pursuant to 28 U.S.C §§ 1331 and 1345, and over the Government's common law claims pursuant to 28 U.S.C § 1345.

12. This Court may exercise personal jurisdiction over Novartis and BioScrip; and venue is proper in this District pursuant to 31 U.S.C. § 3732(a), as well as 28 U.S.C. §§ 1391(b) and 1391(c), because Novartis and BioScrip transact business in this District and, in furtherance of the fraudulent kickback schemes, submitted, caused to be submitted, or conspired to submit false claims in this District.

THE PARTIES

13. Plaintiff is the United States of America. Through its agency the United States Department of Health and Human Services ("HHS"), the Government administers the Medicare and Medicaid programs.

14. Defendant Novartis is a manufacturer and seller of pharmaceutical products. As relevant here, Novartis manufactures and sells the transplant drug, Myfortic (mycophenolic acid delayed-release tablets).

15. Defendant BioScrip is an independent pharmacy with its headquarters in Elmsford, New York. During all times relevant to the Exjade kickback scheme, BioScrip distributed Exjade through its specialty mail-order pharmacy group based in Columbus. Ohio.

THE APPLICABLE STATUTES

16. The AKS, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration given to those who can influence health care decisions would result in the provision of goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect patient and federal healthcare programs, including Medicare and Medicaid, 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, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

17. The AKS makes it illegal for individuals or entities to "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 pharmacies to induce them to recommend or purchase the company's drugs violate this statute to the extent that the drugs are reimbursed by a federal health care program. 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) and 42 U.S.C. § 1320a-7(b)(7).

18. As early as 1994, the Government made it clear that the AKS prohibits drug manufacturers from offering financial incentives to pharmacies to effectuate "product conversion" programs where even one purpose is to induce increased use of prescription drugs covered by federal healthcare programs. Specifically, HHS-OIG issued "Special Fraud Alerts" explaining that:

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

59 Fed. Reg. at 65,376 (Dec. 19, 1994). One of the examples provided was of a "product

conversion" program in which a drug company provided pharmacies cash awards for changing from a competitor's product to that drug company's product; in this scenario, "[t]he pharmacies were induced to help persuade physicians, who were unaware of the pharmacies' financial interest, to change prescription." *Id.* Another type of activity identified by HHS-OIG as raising AKS concerns involved a drug company "offer[ing] cash or other benefits" to pharmacies "in exchange for performing marketing tasks in the course of pharmacy practice related to Medicare or Medicaid," including, specifically, "sales-oriented 'educational' or 'counseling' contacts ... or patient outreach." *Id.*

19. In addition, to provide guidance on the AKS, HHS-OIG also offers interested parties with the opportunity to seek "formal advisory opinions" regarding, *inter alia*, the application of the AKS and the AKS safe harbor regulations to any existing or proposed business arrangement. *See generally* 42 C.F.R. Part 1008.

20. The FCA reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986). As relevant here, the FCA establishes treble damages liability to the United States for an individual or entity that:

> (i) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1) (2000) and, as amended, 31 U.S.C. § 3729(a)(1)(A);
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> (ii) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, *id.* § 3729(a)(1)(B); or
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> (iii) "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid," *id.* § 3729(a)(3)(1986), and, as amended, 31 U.S.C. § 3729(a)(1)(C).[1]

[1] On May 20, 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 defendants' conduct for the entire time period alleged in the complaint by virtue of Section 4(f) of FERA, while Sections 3279(a)(1) and 3279(a)(3) of the

"Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference. *Id.* In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.[2]

21. Falsely certifying compliance with the Anti-Kickback Statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. 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]."

THE FEDERAL HEALTH CARE PROGRAMS

22. ***Medicare***. Medicare is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq.* ("Medicare Program"). Part B of the Medicare Program provides supplemental benefits to participants to cover, among other things, physician services and prescription drugs. *See generally id.* §§ 1395j–1395w-4. Part D of the Medicare Program, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Part A or Part B are eligible to enroll in a prescription drug plan under Part D.

23. Medicare enters into provider agreements with providers and suppliers to establish their eligibility to participate in the program. During the relevant times, to be eligible

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FCA prior to FERA, and as amended in 1986, remain applicable here for conduct predating the effective date of FERA.

[2] 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.

for payment under Part A and/or Part B of the program, pharmacies must certify:

> I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare 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.

See, e.g., CMS Form-855S (04/06) at 26.

24. With regard to Medicare Part D, HHS, through its component agency the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. The Part D sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors, in turn, enter into subcontracts with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

25. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor (sometimes through a pharmacy benefit manager, or "PBM"). The pharmacy receives reimbursement from the Part D sponsor (or the PBM) for the portion of the drug cost not paid by the beneficiary.

26. The Part D sponsor then is 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 paid to the pharmacy, and whether the drug is covered under Medicare Part D. 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. Submitting PDE claims data to CMS, which is necessary for CMS to administer the Part D program and make payments to Part D Plan sponsors for qualified drug coverage, is a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322.

27. Under Medicare Part D, 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. *See* 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS then 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 submitted by 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 determines that it underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference; and if CMS determines that it overpaid the sponsor, it will recoup the overpayment from the sponsor.[3] 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).

28. In order to receive Part D funds from CMS, the Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to

[3] 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

comply with all applicable federal laws, regulations, and CMS instructions. 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. Further, CMS regulations expressly require Part D Plan sponsors to 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 False Claims Act and Anti-Kickback statute. *See* 42 C.F.R. § 423.505(h)(1).

29. Accordingly, 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." Further, CMS regulations also expressly require that all subcontracts between Part D Plan sponsors and downstream entities – including pharmacies – contain language obligating the pharmacies to comply with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(4)(iv).

30. CMS regulation further requires Part D Plan sponsors to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment," provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of

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what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

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

42 C.F.R. § 423.505(k). Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

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

> Pursuant to the contract(s) between the [CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
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> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event (PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated

> contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may result in Federal civil action and/or criminal prosecution.

All approved Part D Plan sponsors who received payment under Medicare Part D in benefit

years 2006 through the present date submitted these required Attestations in the same or similar format.

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

33. ***Medicaid***. Medicaid is a joint federal-state program created in 1965 that provides health care 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. *See* 42 U.S.C. § 1396d(b). Among the states, FMAP is at least 50 percent and is as high as 83 percent.

34. The Medicaid programs in all states reimburse for prescription drugs. Under the Medicaid Drug Rebate Statute, 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1), and in exchange for Medicaid coverage for their drugs, drug manufacturers like Novartis enter into national rebate agreements that require them to pay rebates to state Medicaid programs when their drugs are dispensed to Medicaid patients. 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). *See* 42 C.F.R. § 430.30.

35. Claims arising from illegal kickbacks are not authorized to be paid 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.

36. 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.

37. 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.

38. 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."

MYFORTIC'S REIMBURSEMENT STATUS AND COMPETITIVE POSITION

39. Myfortic is a delayed-release mycophenolic acid tablet that acts as a long-term immunosuppressant used to prevent organ rejection by solid organ transplant recipients. During the relevant times, the transplant division at Novartis was responsible for negotiating Myfortic rebate and discount contracts with pharmacies and transplant centers, promoting Myfortic to transplant physicians, and creating the marketing materials for Myfortic. Since at least 2009, Myfortic has been the most important drug in Novartis's portfolio of transplant drugs.

40. Pharmacies, including those receiving kickbacks from Novartis, purchase Myfortic sold by Novartis through wholesalers. After the pharmacies dispense Myfortic to patients, they submit claims for reimbursement on behalf of those patients to their insurers, including Medicare and Medicaid.

41. Medicare and Medicaid reimbursements provide a key source of funding for Myfortic. According to an analysis that Novartis obtained in 2011, Medicare and Medicaid coverage collectively accounted for 47% of total Myfortic sales by specialty pharmacies, including the pharmacies receiving kickbacks from Novartis. With respect to Medicare, immunosuppressive drugs such as Myfortic are generally reimbursed under Part B. Specifically,

Part B covers immunosuppressive drug therapy where Medicare covered the cost of the transplant and in other limited circumstances. Moreover, where Part B coverage is not applicable, payments for immunosuppressive drugs, like Myfortic, may be made under Part D for eligible beneficiaries. In addition, Medicaid, subject to restrictions imposed by the States, also reimburses claims for "covered outpatient drugs," which in general include drugs dispensed by prescription for medically indicated uses.[4] 42 U.S.C. § 1396r-8(k)(6).

42. Finally, as a mycophenolate-class immunosuppressant, Myfortic's main competitors are CellCept, a brand-name drug form Roche, and, since 2009, generic mycophenolate ("generic CellCept" or "generic MMF"). While the price of brand-name CellCept was generally comparable to Myfortic, generic CellCept was substantially cheaper than both brand-name CellCept and Myfortic. In 2011, for example, Medicare Part B reimbursement for generic CellCept was less than half of the Myfortic reimbursement.

EXJADE'S REIMBURSEMENT STATUS

43. During the relevant times, and as described in detail below, *see infra* at ¶¶ 162-167, BioScrip, along with two other specialty pharmacies, dispensed Exjade as part of a Novartis-created exclusive Exjade distribution network. As relevant here, BioScrip purchased Exjade directly from Novartis. After it dispensed Exjade to patients, BioScrip submitted claims for reimbursement on behalf of those patients to their insurers, including Medicare and Medicaid.

44. Even before it launched Exjade, Novartis expected Medicare and Medicaid reimbursements to be a key source of funding for Exjade. For example, in assessing the six

[4] The definition of "covered outpatient drug" does not include "a drug or biological product used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3). The statute defines "medically accepted indication" as a use that is FDA-

pharmacies seeking membership in the exclusive distribution network for Exjade, Novartis identified "Medicaid licensing" and "Part D capabilities" as a "key" criterion for selecting the participating pharmacies. Indeed, as an internal Novartis analysis from 2010 shows, Novartis knew that "Medicaid and Medicare constitute ~ 50% of Exjade" dispensed by BioScrip and the other two pharmacies participating in the Novartis-created Exjade distribution network.

NOVARTIS'S KNOWELDGE OF ITS DUTY OF AKS COMPLIANCE IN DEALING WITH PHARMACIES

I. Novartis's Awareness of Medicare and Medicaid Coverage for Myfortic and Exjade

45. At all relevant times, Novartis was well aware that Medicare and Medicaid covered a substantial percentage of the Myfortic sales made by the pharmacies to which it was paying kickbacks. For instance, many of the Myfortic rebate contracts drafted by Novartis expressly entitle the pharmacies to earn an additional "Medicare Part B Utilization Performance Benefit" if the pharmacies' Medicare utilization reaches a certain benchmark.

46. In addition, internal records show that Novartis knew, and was focused on, the scope of Medicare reimbursements for Myfortic sold by pharmacies that received kickbacks. For example, in an October 20, 2009, e-mail regarding his contract negotiations with Bryant's Pharmacy, a Novartis transplant account employee specifically reported that "73% of [Bryant's] patients are Medicare."

47. Similarly, Novartis was well aware that Medicaid reimbursed substantial amounts of Myfortic claims. As a general matter, Novartis has paid millions of dollars to State Medicaid agencies under the Medicaid Drug Rebate Statute based on Medicaid reimbursement for Myfortic.

48. Further, Novartis documents show that executives and managers in the

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approved or that is "supported by one or more citations" in a statutorily-identified compendium. *Id.* § 1396r-8(k)(6).

transplant division were specifically aware that Medicaid reimbursed claims for Myfortic submitted by the pharmacies that received kickbacks from Novartis. For example, in a March 2010 report, a Novartis transplant account manager advised her director that Twenty-Ten Pharmacy in Los Angeles was "working on conversions of Medic-Cal [California's Medicaid program]" patients to Myfortic from CellCept or generic CellCept.

49. Likewise, Novartis also knew that Medicare and Medicaid were key payors for the Exjade shipments dispensed by BioScrip. For example, in seeking membership in the exclusive Exjade distribution network, BioScrip "expressed" to Novartis that it had "significant experience with large Medicaid populations." Further, after it began offering kickbacks to BioScrip in 2007 in exchange for recommending refills to Exjade patients, Novartis remained well aware of the importance of Medicare and Medicaid coverage for Exjade. Thus, in a 2008 internal presentation, Novartis noted that the Exjade patient population involved a "[d]iverse payor mix: Medicaid, Commercial, Medicare." Similarly, in a 2009 presentation to Novartis, BioScrip discussed increasing the Medicare/Medicaid patient base and how Novartis and BioScrip could get Medicare Part D patients to choose plans that covered Exjade.

II. Novartis's Knowledge of Its Obligation to Comply with the AKS

50. Novartis knew that it was required to comply with the AKS in promoting Myfortic to health care professionals, including pharmacies. First, as a matter of written policy, Novartis recognized that "any member of the . . . pharmacy . . . profession" is a healthcare professional, and that Novartis should not interfere with the pharmacy's independence by offering anything "intended to have an inappropriate influence on the [pharmacy's] decision to [] dispense, recommend, purchase, supply, or administer products." *See* Novartis Pharma Principles & Practices for Professionals at 2-4.

51. More specifically, Novartis's Ethics and Compliance Policies ("Novartis E&C

Policies"), first issued in 2003 and reissued in 2006, 2008, 2010, and 2011, have provided that:

> The Federal Anti-kickback Statute makes it illegal to knowingly and willfully provide any "remuneration" in return for:
>
> (1) referring a person to another person for items or services covered under federal health care programs; or
>
> (2) purchasing or recommending the purchase of any good or service which is paid for by federal health care programs.
>
> "Remuneration" is defined very broadly and includes any item of value which is provided with the intent to induce the actions described above. Essentially, this law, and similar state statutes, prohibits bribes and kickbacks. The federal statute applies to payments made under virtually any federal healthcare program – not just Medicare and Medicaid ([TRICARE], VA benefits, etc.). Note again that many state statutes similarly prohibit such activities.
>
> Under the Anti-kickback Statute, it is illegal to solicit (ask for) or receive kickbacks, as well as to offer to pay a kickback. Any of these actions constitutes a felony and is punishable by a fine up to $25,000 per violation and imprisonment up to five years, or both. In addition, the government may impose civil fines and may terminate an entity's right to provide products and services to patients whose care is paid for by government programs.

52. Further, since at least 2008, the E&C Policies have highlighted the fact that HHS-OIG has "identified a number of specific risk areas for pharmaceutical manufacturers" like Novartis. As relevant here, those include:

- "Discounts and other remuneration to purchasers;" and
- "Relationships with physicians and other persons and entities in a position to make or influence referrals (*e.g.*, ***potential conflicts of interest, prescription switching arrangements***, . . .)."

(Emphasis added).

53. In addition, the Novartis E&C Policies have specified that "[j]udicial and administrative interpretations of this law have been very broad" and that "[t]he statute is violated if even one purpose (as opposed to a primary or sole purpose) is to induce the Healthcare Provider to prescribe its product."

54. Finally, as the executives at Novartis responsible for overseeing the promotion

of Myfortic have admitted, they understood that the AKS applied to Novartis's relationships with pharmacies that dispensed Myfortic to transplant patients and that it was part of their job responsibilities to ensure that those relationships complied with the AKS.

III. Novartis's Additional Compliance Obligations Under Its 2010 Corporate Integrity Agreement

55. In September 2010, and following the filing of several civil actions alleging AKS violations and other healthcare fraud claims, Novartis entered into a settlement with the Government and several states. The civil settlement provided, in relevant parts, that Novartis violated the AKS by giving "illegal remuneration . . . to health care professionals to induce them to promote and prescribe" certain Novartis drugs. Concurrently, Novartis pled guilty to a criminal information, admitting to violating the misbranding provision of the Food, Drug, and Cosmetics Act, 21 U.S.C. § 331(a).

56. In conjunction with the resolution of the criminal and civil cases, Novartis entered into a Corporate Integrity Agreement (the "Novartis CIA") with the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG") in September 2010.

57. The Novartis CIA requires Novartis, among other things, to "ensure that [its] Policies and Procedures address . . . appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including . . . the federal anti-kickback statute . . . and the False Claims Act . . . ." Novartis CIA at § III(B)(3)(c).

58. In addition, the Novartis CIA mandated that executives in key positions throughout Novartis submit annual certifications to HHS-OIG to attest to their compliance with federal laws, the CIA's requirements, and Novartis policies. *Id.* at § III(A)(4).

59. Finally, to facilitate prompt detection of unlawful activities, the Novartis CIA requires Novartis to notify HHS-OIG, in writing, of all probable violations of criminal, civil, or

administrative laws applicable to any federal health care program, including violations of the AKS. *Id.* at § III(H).

THE MYFORTIC KICKBACK SCHEME

I. The Basic Structure of the Myfortic Kickback Scheme

60. At its core, the Myfortic kickback scheme consisted of a basic, and unlawful, *quid pro quo* between Novartis and the pharmacies receiving kickbacks. Novartis offered the pharmacies the opportunity to earn tens or hundreds of thousands of dollars in "rebates" and "discounts" by "moving business" for Novartis. In exchange, the recipient pharmacies agreed to jettison their independent professional judgment, and, instead, become Novartis's proxies in promoting the use of Myfortic over its competitor drugs, brand-name CellCept and generic CellCept.

61. Practically, the Myfortic kickback relationships typically involved five steps. First, before offering a pharmacy the opportunity to participate in the scheme, Novartis ascertained that the pharmacy had sufficient influence over whether transplant patients received Myfortic or a competitor drug. Thus, although Myfortic is sold through hundreds of pharmacies, the kickback scheme only involved approximately twenty-some pharmacies that were both willing to sell their recommendations and able to "drive the [Myfortic] business" for Novartis.

62. For example, prior to authorizing a rebate offer for Transcript Pharmacy in Mississippi, senior executives at Novartis's transplant division directed account managers to determine whether Transcript had sufficient influence either to lower Myfortic sales by recommending that transplant patients move from Myfortic to generic CellCept, or to "grow the [Myfortic] business" by switching patients to Myfortic.

63. Second, after it confirmed that a pharmacy had the requisite influence over the choice of transplant drug, Novartis sought an explicit agreement from the pharmacy as to how it

would promote Myfortic, in terms of switching transplant patients to Myfortic or preventing the use of competitor drugs. Indeed, prior to approving an offer of financial incentives to a pharmacy, senior Novartis executives required account managers to present a "business case" showing how the activities promised by the pharmacy would affect Myfortic sales.

64. For example, to help upper management in the transplant division assess whether to offer a kickback, in the form of a discount, to the outpatient pharmacy at Baylor Hospital in Dallas, a Novartis account manager e-mailed the director of the Baylor pharmacy on January 29, 2010, asking the pharmacy to specify (i) "the total number of [transplant] patients involved;" (ii) the "percentage of [such] patients [that Baylor was] committing to convert" to Myfortic; and (iii) "the time line for conversion." The vice president heading Novartis's transplant division then approved offering financial incentives to the pharmacy at Baylor because it was "committing to convert patients to Myfortic" for Novartis.

65. Third, once Novartis and a pharmacy agreed on both the financial terms of their kickback relationship and how the pharmacy would promote Myfortic for Novartis, they signed a rebate or discount contract with certain standard terms created by Novartis.

66. Those agreements, however, only memorialized one side of the bargain. Specifically, the rebate or discount contracts drafted by Novartis showed the financial terms of the bargains, including the rebate amounts (in terms of percentages of Myfortic sales by the pharmacies) and when the payments were due (if the pharmacies met certain Myfortic market share or volume hurdles). By contrast, the promises or commitments that Novartis extracted from the pharmacies – to "convert" transplant patients to Myfortic or to prevent the use of generic CellCept – invariably were left out of the contracts, even though they were pivotal to Novartis's decision to offer financial inducements to the pharmacies. Indeed, as the former vice president in charge of Novartis's transplant business has admitted, those illicit commitments by

the pharmacies were never recorded in a written instrument.

67. Fourth, once the kickback relationships were in place, the pharmacies carried out their end of the bargain. Specifically, numerous pharmacies helped Novartis "drive the business" by recommending to physicians that they switch transplant patients to Myfortic. In addition, other pharmacies, such as Bryant's Pharmacy in Arkansas, helped Novartis "protect" Myfortic sales by opposing the use of the less costly generic CellCept. Further, to ensure the efficacy of these efforts, the pharmacies concealed their true motive – to earn kickbacks from Novartis – from the physicians, and acted as if they were exercising unbiased clinical judgment.

68. For example, in late July 2011, and just a week after Novartis agreed to include Transcript Pharmacy in Mississippi in the Myfortic kickback scheme, Transcript sent faxes to physicians to recommend that they switch patients from generic CellCept to Myfortic. These faxes presented the recommendation as an exercise in clinical judgment, without disclosing the pharmacy's financial interest in the outcome. In fact, however, Transcript made the recommendation entirely as a matter of economic calculation. As a Novartis account manager has admitted, the owner of Transcript told Novartis during negotiations that Transcript would make the recommendation "*only if*" Novartis offered Transcript financial inducements.

69. Finally, Novartis and the pharmacies earned hefty profits from their kickback scheme. For Novartis, it was highly profitable to pay pharmacies 10% or even 20% in kickbacks in exchange for switching transplant patients to Myfortic. In the words of a Novartis manager, it was like "using a short term cost to gain a[] long term annuity." This is because, as that manager stated, each "maintenance conversion" gives Novartis "an ongoing stream of revenue going forward as long as the patient is still living and using [Myfortic]."

70. As discussed more fully below, pharmacies also profited handsomely from selling their influence and integrity. The pharmacies earned substantial kickbacks for doing

Novartis's bidding. For example, from 2005 to 2009, Novartis gave Bryant's Pharmacy more than $370,000 in kickbacks as a reward for the pharmacy's effort to convert almost all of its transplant patients to Myfortic.

II. Specific Examples of the Myfortic Kickback Relationships

A. Bryant's Pharmacy

71. Over the course of their kickback relationship starting in January 2005, Novartis directed more than $650,000 in kickbacks to Bryant's Pharmacy ("Bryant") and its owner; and the owner, in exchange, helped Novartis obtain more than $5.5 million in Myfortic sales. This relationship, as discussed below, had two basic phases. First, as a Novartis manager noted in a March 1, 2010 report, from 2005 until late 2009, the kickbacks caused Bryant's owner to "aggressively work[] to increase his Myfortic utilization." Second, since the introduction of generic CellCept in 2009 changed the competitive landscape, the kickbacks ensured that Bryant remained a "staunch ally" to Novartis in terms of promoting the use of Myfortic and opposing the use of generic CellCept.

72. This kickback relationship arose from Novartis's recognition that Bryant's owner "was very influential" in the transplant community in Arkansas due to his relationship with "the State Board of Pharmacy [and] the State Kidney Commission" and his membership on "the formulary committee for the largest MCO [managed care organization] in the State." Thus, Novartis offered Bryant the opportunity to earn up to 15% of its Myfortic sales in rebates and discounts if the pharmacy would "move patients from CellCept to Myfortic."

73. Consistent with Novartis's standard practice, however, the written contracts for Bryant were silent on what the pharmacy would do for Novartis in exchange for the financial benefits it stood to earn. Instead, those agreements simply state the amount of the upfront discount and the amount of a "performance" rebate tied to Bryant achieving a series of specific

market share hurdles.

74. Once the kickback relationship began, Bryant's owner – as he promised Novartis – used his influence to promote Myfortic for Novartis, but did so without disclosing to physicians or patients his financial incentive in increasing Myfortic sales. Specifically, according to a March 1, 2010 report by a Novartis account manager, "in 3 months," Bryant's owner was able "to convert all [of his transplant] patients from CellCept to Myfortic." Further, he also relied on his standing with "the doctors in the area" to "control [Myfortic] market share" on an ongoing basis and to continue "to increase [] Myfortic utilization."

75. For Novartis, the result of the first phase of its kickback relationship with Bryant – from 2005 to 2009 – was exemplary. As a Novartis account manager explained to his supervisor, "in the [first] four years since [the] relationship began," the pharmacy drove its annual Myfortic sales up tenfold – "from $100,000 to over $1 million."

76. In April 2009, the second phase of this kickback arrangement began with the introduction of generic CellCept, which changed both the competitive landscape for Myfortic and Novartis's kickback relationship with Bryant. In this phase, Novartis had to accept limits on Bryant's ability to control Myfortic sales because a transplant physician in Arkansas preferred generic CellCept, which was far less costly, to Myfortic.

77. When that physician suggested moving patients to generic CellCept, Bryant's owner "argued against" the idea, emphasizing that "continuation of care" required patients already on Myfortic to remain on Myfortic. Ultimately, the physician agreed to continuing to prescribe Myfortic for previously transplanted, or "maintenance," patients, while using generic CellCept for newly transplanted patients.

78. Bryant's owner argued against the use of generic CellCept, however, not out of a clinical concern for patients' health, but to keep earning kickbacks from Novartis.

Specifically, the pharmacy owner knew that earning rebate payments depended on his keeping transplant patients on Myfortic. Indeed, in October 2009, and after he realized that he stood to lose substantial payments under the existing terms of the kickback arrangement, the owner made clear to Novartis that, unless Novartis agreed to renegotiate those terms, he would stop advocating for Myfortic and instead "convert current Myfortic patients to generic [CellCept]."

79. Novartis recognized that it would "loose [sic] much more" in Myfortic sales if Bryant stopped its efforts to limit the use of generic CellCept than it would from renegotiating the terms of its kickback arrangement with the pharmacy. Specifically, as a Novartis account manager advised his director in an October 16, 2009 e-mail, the probability that Bryant's owner could convince a transplant physician "to convert all Myfortic patients to generic is 100%." Thus, in December 2009, Novartis amended its agreement with Bryant by adding one percent to the rebate and simultaneously lowering the market share threshold by 20%, and further agreed to make those benefits available retroactively, starting on October 1, 2009.

80. By tailoring the terms of the kickback arrangement based on Bryant's demands, Novartis directed a steady stream of payments to the pharmacy throughout the course of their kickback relationship. This, in turn, ensured that Bryant has remained – in Novartis's view – "a staunch ally" in Novartis's efforts to limit the use of generic CellCept.

81. Medicare and Medicaid, however, have been the victims of this corrupt arrangement. Since the inception of its kickback relationship with Novartis, Bryant has submitted thousands of reimbursement claims to Medicare and Medicaid based on Myfortic it dispensed in connection with the Myfortic kickback scheme. Further, neither Novartis nor Bryant disclosed to Medicare or Medicaid the fact that, in exchange for the inducements from Novartis, Bryant had agreed to convert patients to Myfortic and to keep them on Myfortic.

82. Any Medicare or Medicaid claim submitted by Bryant for Myfortic dispensed in

connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, since 2005, Bryant has submitted more than 8,300 Myfortic claims to Medicare Part B alone and has obtained more than $3.2 million in reimbursement based on such false claims.

B. Baylor Hospital's Outpatient Pharmacy

83. The outpatient pharmacy at Baylor Hospital in Dallas, Texas, provides transplant drugs to approximately 200 patients who received their transplants at Baylor. Starting in February 2010, Novartis has given the Baylor pharmacy a 10% discount on all Myfortic sales. However, as Novartis e-mails show, that arrangement has been based on an unlawful *quid pro quo* — in exchange for the financial incentive, the Baylor pharmacy promised Novartis "a conversion of 200 CellCept patients [to Myfortic] by the end of May [2010]."

84. This kickback arrangement began in late January, when Baylor asked Novartis for "an incentive [on Myfortic] on [its] outpatient side," *i.e.*, the outpatient pharmacy.

85. To assess whether it would be profitable for Novartis to offer such an incentive to the pharmacy, the vice president in charge of Novartis's transplant division directed a transplant regional account manager ("TRAM") to extract a pledge from the Baylor pharmacy regarding how many patients it was "committing to convert [to Myfortic]" and "the time line for conversion."

86. During a telephone call on January 29, 2010, the TRAM and the director of the Baylor pharmacy discussed what Baylor would do in exchange for the financial "incentive" it was seeking from Novartis. Specifically, the pharmacy director told the TRAM that, as for the "approximately 200 patients currently treated in the outpatient pharmacy," Baylor pharmacy would be able to "have 25% of the patients converted [to Myfortic] by March and 100% conversion by the end of May."

87. As the then-head of the transplant division at Novartis has acknowledged, Novartis analyzed the Baylor pharmacy's offer to "convert patients to Myfortic" in exchange for a discount, and concluded that it "expected growth to occur" by offering the financial inducement that the pharmacy had requested. Thus, Novartis offered, and the Baylor pharmacy accepted, a 10% discount on Myfortic sales.

88. This arrangement was memorialized in a "letter of commitment" dated February 12, 2010. However, the unlawful *quid pro quo* that is at the core of this relationship, *i.e.*, Novartis offering the discount in exchange for the pharmacy's "commit[ment] to convert [its] patients to Myfortic," was not disclosed or even mentioned in that written document.

89. Moreover, once it agreed on the kickback arrangement with Novartis in February 2010, the Baylor pharmacy promptly fulfilled its side of the bargain. Specifically, Medicare claims data show that, in the year when the arrangement began, the amount of Myfortic reimbursement at Baylor pharmacy grew sevenfold — from approximately $110,000 in 2009 to more than $790,000 in 2010.

90. This corrupt arrangement has caused significant losses to Medicare and Medicaid. Since the inception of its kickback relationship with Novartis, the Baylor outpatient pharmacy has submitted thousands of reimbursement claims to Medicare and Medicaid based on Myfortic it dispensed in connection with the kickback scheme. Further, neither Novartis nor the Baylor pharmacy disclosed to Medicare or Medicaid the conversions that the Baylor pharmacy had agreed to do in exchange for the financial "incentive" from Novartis.

91. Any Medicare or Medicaid claim submitted by the Baylor pharmacy for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, since February 2010, the pharmacy has submitted more than 6,300

Myfortic claims to Medicare Part B and has obtained more than $3.7 million in Medicare reimbursement based on such false claims.

C. Kilgore's Medical Pharmacy

92. Kilgore's Medical Pharmacy ("Kilgore") in Columbia, Missouri, is another pharmacy that Novartis used to switch patients to Myfortic in exchange for rebate payments.

93. In Missouri, Kilgore was the exclusive provider of pharmacy services for all kidney transplant patients enrolled in a state initiative, the Missouri Kidney Program. In other words, Kilgore enjoyed privileged access to a large number of patients that Novartis sought to target for Myfortic sales.

94. Since 2006, Novartis has paid kickbacks to Kilgore under the guise of performance rebates in exchange for the pharmacy's efforts to convert patients to Myfortic. Specifically, as a co-owner of Kilgore admitted to Novartis in a March 22, 2011 e-mail, "the pool of candidates" that Kilgore could convert to Myfortic had become "very thin" by 2011, as result of "[Kilgore's] prior efforts to switch patients."

95. Nonetheless, in 2011, Novartis chose to use Kilgore to implement a new initiative for converting patients to Myfortic. Specifically, the initiative, as designed by Novartis, involved having Kilgore identify patients who were taking both a proton-pump inhibitor ("PPI") drug for gastrointestinal issues and CellCept or generic CellCept. Novartis then had Kilgore prepare a fax recommendation to those patients' physicians to suggest switching the patients to Myfortic based on a clinical study that Novartis provided to Kilgore.

96. To ensure the success of this initiative, the faxes from Kilgore disclosed neither the fact that Kilgore was making the recommendation at Novartis's behest nor the fact that, if Kilgore successfully converted a sufficient number of patients to Myfortic, it stood to earn tens of thousands of dollars from Novartis.

97. In other words, Kilgore's faxes presented the recommendations to switch patients to Myfortic as independent clinical opinions from a conscientious pharmacy. In fact, however, a monthly report from the Novartis account manager supervising Kilgore's implementation of this initiative makes clear that the real goals were to "get[] the account at a segment share [of Myfortic] greater than 75%" and to "get[] non-users [physicians] to move their patients to myfortic."

98. As Novartis's records show, Myfortic's market share among Kilgore's patients increased by approximately 8% after Kilgore implemented this initiative for Novartis. Novartis, in turn, paid Kilgore more than $120,000 in "performance" rebates in 2011. For Novartis, as noted above, having Kilgore implement the initiative as *quid pro quo* for higher rebates not only resulted in higher Myfortic sales, but also gave the company access to new transplant patients.

99. The corrupt relationship between Novartis and Kilgore has caused significant losses to Medicare and Medicaid. Since the inception of this kickback relationship, Kilgore has submitted thousands of reimbursement claims to Medicare and Medicaid based on Myfortic it dispensed in connection with the kickback scheme. Further, neither Novartis nor Kilgore disclosed to Medicare or Medicaid the fact that, in exchange for financial inducements from Novartis, Kilgore had agreed to "switch patients" to Myfortic.

100. Any Medicare or Medicaid claim submitted by Kilgore for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, since 2006, Kilgore has submitted more than 13,600 Myfortic claims to Medicare Part B and has obtained more than $4.6 million in reimbursement based on such false claims.

D. Transcript Pharmacy

101. Since July 2011, Novartis also has been orchestrating its kickbacks for

conversions scheme through Transcript Pharmacy in Flowood, Mississippi. Specifically, Novartis has offered and paid kickbacks to Transcript in the guise of rebates in exchange for the pharmacy sending recommendations to physicians to switch patients to Myfortic and not recommending the use of generic CellCept.

102. This unlawful arrangement originated from an e-mail that the owner of Transcript Pharmacy sent to Novartis on July 1, 2011, demanding rebates on Myfortic dispensed by Transcript. According to Transcript, it was entitled to those rebates from Novartis because it had driven "the conversion from CellCept to Myfortic at Tulane transplant" and "influence[d] University of Alabama – Birmingham a year later." Further, the e-mail made clear that, if Novartis did not agree to offer rebates to Transcript, the pharmacy would "move as many of the [patients on Myfortic] to generic CellCept as we can (with prescriber approval)."

103. To determine whether to agree to Transcript's demand, senior executives at the transplant division at Novartis directed account managers to find out (i) whether the pharmacy could help Novartis increase Myfortic sales, and (ii) whether Transcript in fact could sway transplant centers to prescribe generic CellCept by recommending generics over Myfortic.

104. In the first regard, the owner of Transcript told the Novartis account manager that Transcript would help Novartis "grow the [Myfortic] business" by sending letters to physicians to "recommend[] . . . moving [certain] patients to Myfortic" from generic CellCept, but "*only if*" Transcript received a rebate offer from Novartis. Further, Novartis also determined that, if Transcript chose to recommend the use of generic CellCept for patients already taking Myfortic, it likely would cause Novartis to lose more than $90,000 in Myfortic sales in the second half of 2011.

105. To profit from the Myfortic recommendations that Transcript promised to make in exchange for rebates, Novartis offered a kickback arrangement to the pharmacy on July 15,

2011.

106. That, in turn, induced Transcript to fulfill its end of the unlawful bargain. Specifically, starting in late July 2011, Transcript sent faxes to transplant centers to recommend that they switch patients from generic CellCept to Myfortic for a clinical reason. Those faxes, however, did not disclose that Transcript stood to earn thousands of dollars as a result of its recommendations. They likewise failed to indicate that, as Transcript had made clear to Novartis, the recommendations actually were based on financial, rather than clinical, considerations. Physicians, unaware of Transcript's true motive for sending those recommendations, switched numerous transplant patients to Myfortic.

107. In addition, the rebate contract drafted by Novartis that supposedly memorialized all aspects of Novartis's relationship with Transcript contained no mention of the fact that, as a *quid pro quo* for the payments from Novartis, Transcript had agreed to recommend switching patients to Myfortic. Moreover, as an additional kickback for Transcript, Novartis agreed to make payments retroactively starting on July 1, 2011, even though, as noted above, *see supra* at ¶ 82, there was no agreement between Novartis and Transcript at that point.

108. Medicare and Medicaid have been victims of the illegal kickback arrangement between Novartis and Transcript, as Transcript has submitted hundreds of reimbursement claims to Medicare and Medicaid for Myfortic it dispensed in connection with the kickback scheme. Further, neither Novartis nor Transcript disclosed to Medicare or Medicaid the fact that, in exchange for financial inducements from Novartis, Transcript had agreed to recommend moving patients to Myfortic.

109. Any Medicare or Medicaid claim submitted by Transcript for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data

shows that, between August 1, 2011, and February 28, 2013, Transcript submitted 614 Myfortic claims to Medicare Part B and obtained more than $354,000 in reimbursement based on such false claims.

E. Twenty-Ten Pharmacy

110. Yet another example of Novartis's scheme of using kickbacks to induce pharmacies to "convert" transplant patients to Myfortic from CellCept or generic CellCept involves the Twenty-Ten Pharmacy in Los Angeles. Twenty-Ten began to focus on the transplant patient population in 1985. By the early 2000s, it had become the main supplier of medications for patients from several transplant centers in Los Angeles, including the USC-Keck Hospital, the UCLA Medical Center, and the St. Vincent Medical Center.

111. Recognizing Twenty-Ten's influence in the transplant community in Los Angeles, Novartis entered into a series of rebate agreements with the pharmacy starting in 2004. Under those contracts, Twenty-Ten could earn up to 19% of its Myfortic sales as "performance" rebates, if Myfortic's market share or sales volume at the pharmacy reached certain thresholds.

112. The inconspicuous terms of those Novartis-drafted rebate contracts, however, concealed the unlawful promises that Novartis exacted from Twenty-Ten – that, in exchange for hundreds of thousands of dollars in rebates, Twenty-Ten agreed to "convert" hundreds of transplant patients to Myfortic from CellCept or generic CellCept. For example, between October 2009 and late 2011, Novartis used the potential for Twenty-Ten to earn a "balloon" or "bonus" rebate, in the amount of several hundred thousand dollars per year, to induce the pharmacy to agree to orchestrate "conversions" of entire groups of transplant patients to Myfortic.

113. Specifically, Novartis began to hatch those plans after the owner of Twenty-Ten asked Novartis to help his pharmacy address certain "cash flow issues" at a meeting in Los

Angeles in October 2009, and further explained that Twenty-Ten "ha[d] over $6 [million] in CellCept business he [was] willing to convert."

114. To profit from the potential conversions of those patients at Twenty-Ten, Novartis executives immediately began devising the means to offer additional kickbacks to Twenty-Ten – such as in the form of "a 'super' rebate" on top of the existing rebate arrangement – to induce it to switch patients to Myfortic and thereby "achieve exception [sic] growth."

115. To ensure that Novartis would offer it additional financial benefits, Twenty-Ten, in turn, worked actively in 2010 to advocate with healthcare professionals at transplant centers for switching transplant patients to Myfortic from CellCept or generic CellCept. As a Novartis manager reported in an April 7, 2010 e-mail to her supervisor, Twenty-Ten's owner not only sought and "obtained approval from [a transplant surgeon] to start switching out [the surgeon's] maintenance patients to Myfortic," but also "called the head transplant coordinator at [the UCLA transplant center]" to recommend "switching [that center's] maintenance patients over to Myfortic."

116. By not disclosing to doctors and the clinical staff at transplant centers that his pharmacy stood to earn hundreds of thousands of dollars in rebates from Novartis for recommending Myfortic, Twenty-Ten was highly effective in securing Myfortic "conversions" for Novartis. In 2010, for example, Twenty-Ten increased its Myfortic sales by more than 34%. Indeed, Novartis viewed the owner of Twenty-Ten as "an amazing advocate for Myfortic" as well as a key partner.

117. In 2011, moreover, Novartis used the offer of a bonus rebate to induce Twenty-Ten to agree to carry out a Novartis-designed conversion initiative and convert 700 – 1000 patients to Myfortic. Specifically, Novartis directed Twenty-Ten to identify patients that

Novartis wanted to target for conversion, to contact the targeted physicians and patients to suggest conversion to Myfortic, and to take follow-up steps to complete the conversions.

118. As the owner of Twenty-Ten has admitted, he knew that it was "unethical" for a pharmacist like him to comply with Novartis's request and ask physicians to switch patients to Myfortic from CellCept or generic CellCept. Nonetheless, he agreed with a Novartis manager in January 2011 that, in exchange for "5% more" in Myfortic rebates, Twenty-Ten would "do all the conversions" suggested by Novartis. Indeed, as a Novartis account manager explained in her monthly report, Twenty-Ten even allowed Novartis to dictate the "Avg/Month and Avg/Day goals" that it needed to meet in terms of the number of patients it was converting to Myfortic.

119. To conceal the illegal and unethical *quid pro quo* central to this arrangement, Novartis left out from the rebate contract any reference to the conversion initiative to be executed by Twenty-Ten. Likewise, as Twenty-Ten's owner has acknowledged, Twenty-Ten did not disclose any aspect of its financial relationship with Novartis to any transplant center.

120. Finally, the unlawful kickbacks-for-conversions arrangement that Novartis orchestrated through Twenty-Ten has caused millions of dollars in damages to Medicare and Medicaid. Since the inception of this kickback relationship, Twenty-Ten has submitted thousands of reimbursement claims to Medicare and Medicaid based on Myfortic it dispensed in connection with the kickback arrangements. Further, neither Novartis nor Twenty-Ten disclosed to Medicare or Medicaid the *quid pro quo* arrangement between the pharmacy and Novartis.

121. Any Medicare or Medicaid claim submitted by Twenty-Ten for Myfortic dispensed in connection with its illegal arrangement with Novartis was false and ineligible for reimbursement because such a claim was tainted by kickbacks. In that regard, Medicare data shows that, since November 2009 alone, Twenty-Ten has submitted more than 8,800 Myfortic claims to Medicare Part B and has obtained more than $4.4 million in reimbursement based on

such false claims.

III. The Myfortic Kickback Scheme Was an Integral Part of Novartis's Overall Strategy for Myfortic

122. The kickback relationships summarized above were part of a strategy orchestrated by senior executives at Novartis. As discussed below, offering pharmacies financial inducements to switch patients to Myfortic, or to oppose the use of generic CellCept, has been a key plank in Novartis's overall plan for increasing Myfortic sales since at least 2005.

123. First, to seize market share from CellCept and generic CellCept, it has been a central element of Novartis's Myfortic strategy to acquire "maintenance conversions," *i.e.*, to have transplant patients already taking CellCept or generic be switched from those drugs to Myfortic. Specifically, Novartis has viewed its kickback relationships with pharmacies as a critical lever for obtaining such "maintenance conversions."

124. As a Novartis account manager has acknowledged, since he joined Novartis's transplant division in January 2005, it has been that division's strategy to leverage its rebate and discount relationships with pharmacies to have the pharmacies implement growth strategies designed to switch patients to Myfortic. Indeed, as discussed above, *see supra* at ¶¶ 71-75, Bryant's Pharmacy converted "all [of its] patients from CellCept to Myfortic" in 2005 in exchange for kickbacks from Novartis. Further, a January 2008 transplant strategy plan also specified that a key Novartis strategy for growing Myfortic was to partner with specialty mail order pharmacies on conversion. Similarly, in September 2009, and during a review of its relationships with pharmacies and transplant centers, the transplant division reiterated that to "grow [Myfortic] through conversion opportunities" at pharmacies was a "key strategy" for that division. And, in July 2011, the Novartis vice president heading the transplant division exhorted her staff to focus on the opportunity for "maintenance [] conversions at the Specialty Pharmacy"

to meet the annual sales target for Myfortic.

125. Second, since generic CellCept became available in 2009 at significantly lower prices, it also has been a key part of Novartis's Myfortic strategy to limit the impact of competition from generic CellCept by leveraging its kickback relationships with pharmacies.

126. For example, in an October 20, 2009 e-mail, a contracting executive at Novartis's transplant division posited that, as the use of generic CellCept was becoming more widespread, Novartis must "align our contracting with [pharmacies] that perform activities that drive and/or *protect* [Myfortic] business."

127. In short, the scope of Novartis's Myfortic kickback scheme was not limited to the specific examples detailed above, but instead encompassed all, or nearly all, of the twenty-some pharmacies to which Novartis paid kickbacks on Myfortic under the guise of "performance" rebates or discounts. Novartis records provide numerous other examples of such unlawful *quid pro quos*. For example, in late 2010, Novartis wanted Echo Specialty Pharmacy in Queens, New York, to "put in place suggested [Myfortic] growth drivers," *i.e.*, to take "targeted actions" that "would help Novartis grow the market share of Myfortic" among Echo's transplant patients. To induce Echo to take these actions, Novartis offered Echo tens of thousands of dollars in incentives by lowering the market share Echo had to achieve to earn kickbacks.

128. In each of these cases, Novartis offered rebates or discounts to induce the pharmacy to further Novartis's overall Myfortic strategy by recommending that patients switch to Myfortic and/or opposing the use of generic CellCept.

IV. Novartis Carried Out the Myfortic Kickback Scheme in Knowing Disregard of Its Duty to Comply with the AKS and by Ignoring the Requirements of Its Own Compliance Policies and Procedures

129. As executives responsible for supervising Novartis's Myfortic promotional

activities have admitted, Novartis was well aware that the AKS applied to its use of rebates and discounts to promote the sale of Myfortic to pharmacies and that it had an obligation to ensure that its rebate and discount relationships with pharmacies relating to Myfortic complied with the AKS. *See supra* at ¶¶ 50-54.

130. Nonetheless, in pursuit of the profits associated with higher Myfortic sales, Novartis chose to disregard its duty to comply with the AKS. Indeed, to reap the growth in Myfortic sales produced by the kickbacks, Novartis not only ignored its compliance obligations, but also violated its own compliance policies and requirements.

131. One example of Novartis's intentional circumvention of its own policies and requirements involved the company's efforts in 2011 to use rebates to induce the on-site pharmacies that Walgreen's operated in transplant centers and Walgreen's mail-order division to "convert" patients already taking CellCept or generic CellCept to Myfortic.

132. Specifically, in 2011, Novartis's transplant division was under serious pressure to meet its Myfortic sales target, which required Myfortic sales to grow by more than 25% above the 2010 level.

133. To meet that target, the transplant division created a plan "to accelerate growth" in Myfortic sales. A key aspect of that plan called for Novartis to "[l]everage" its relationship with pharmacies to "convert" transplant patients already on a competitor drug to Myfortic. More specifically, Novartis focused on offering inducements to two pharmacies with access to large transplant patient populations – Twenty-Ten (*see supra* at ¶¶ 110-122) and the on-site and mail-order divisions of Walgreen's – to drive growth in Myfortic sales.

134. As the operations director at Novartis's transplant division explained in an e-mail, the transplant division's objective in its negotiations with Walgreen's was to induce Walgreen's to "[f]acilitate conversion" of patients already taking CellCept or generic CellCept to

Myfortic.

135. Walgreen's, in turn, understood what Novartis expected in exchange. For example, as a Novartis executive responsible for pharmacy accounts explained in a February 25, 2011 e-mail to the top two executives in the transplant division, the vice president and the operations director, and other Novartis executives, Walgreen's planned to discuss the subject of conversion "in detail" at an upcoming presentation on its "capabilities."

136. However, Walgreen's also made clear to Novartis that, while the pharamcy was willing to explain its "conversion" capabilities orally, it "cannot put this in writing."

137. Novartis executives understood Walgreen's message clearly. For example, in May 2011, and in advance of a meeting between Novartis's senior management and senior executives at Walgreen's, the operations director at Novartis's transplant division (and a recipient of the February 25, 2011 e-mail) advised a Novartis vice president who would be attending the Walgreen's meeting to avoid using the word "conversion" because Walgreen's "was not comfortable with" that term.

138. Under its own E&C Policies, Novartis executives and employees "are required to speak up and raise [a] concern" whenever they "have a question or concern about whether a current or proposed activity is proper." Here, the fact that Walgreen's wanted to explore a deal with Novartis based on the pharmacy's "conversion" capabilities, while refusing to "put this in writing," raised an obvious compliance concern. Indeed, according to one of the top executives at Novartis, the company's compliance policies required an employee to report this situation, *i.e.*, when a pharmacy approached Novartis to discuss its "capabilities" to convert patients to a Novartis drug. Such a report, moreover, would have required Novartis to undertake an investigation and, potentially, to report the situation to HHS-OIG as a "Reportable Event" under the Novartis CIA. *See* Novartis CIA ¶¶ III.E, H.

139. The executives at Novartis's transplant division, however, chose to ignore the requirements of the company's own policies. To conceal this compliance problem, none of these executives reported any concern about keeping discussions of Walgreen's "conversion" capabilities from being "put [] in writing." Instead, they pushed ahead and approved a proposed deal under which Walgreen's would receive financial incentives from Novartis in exchange for facilitating the conversion of transplant patients to Myfortic from CellCept or generic CellCept.

140. While the Novartis transplant executives' clear disregard of company policies in their negotiations with Walgreen's was based on their specific goal of accelerating Myfortic growth to meet the sales target in 2011, this conduct was emblematic of a general philosophy at Novartis of putting sales and profits before compliance. Indeed, as set forth above, Novartis knowingly implemented a Myfortic strategy that was premised, in key part, on using kickbacks, under the guise of "performance" rebates and discounts, to induce pharmacies to purchase or to recommend Myfortic in plain violation of the AKS. *See supra* at ¶¶ 123-129.

V. Novartis's Myfortic Kickback Scheme Caused Tens of Thousands of False Claims to Be Submitted to Medicare and Medicaid and the Payment of Tens of Millions of Dollars of Reimbursements to Pharmacies Receiving Kickbacks

141. As Novartis and the pharmacies profited from their kickback scheme through, respectively, escalating levels of Myfortic sales and ongoing flows of kickback payments, Medicare and Medicaid were made to bear the financial cost of this corrupt scheme. All of the pharmacies receiving kickbacks from Novartis submitted Myfortic claims to Medicare and Medicaid. Further, in seeking Medicare and Medicaid reimbursement, neither these pharmacies nor Novartis disclosed their *quid pro quo* arrangements. The Myfortic kickback scheme, in short, resulted in the submission of tens of thousands of false Medicare and Medicaid claims.

142. Those false claims, in turn, caused Medicare and Medicaid to disburse tens of millions of dollars in reimbursements that should not have been paid. Specifically, Novartis data

shows that the total amount of Myfortic sales by pharmacies receiving kickbacks was well in excess of $100 million; and, according to a "payer mix" analysis that Novartis received in 2011, reimbursements by Medicare and Medicaid accounted for 47% of the total Myfortic sales through those pharmacies and their peers. Thus, Novartis has, through its kickback scheme, knowingly caused tens of millions of dollars in losses to those federal healthcare programs.

THE EXJADE KICKBACK SCHEME

I. Overview

143. As with the Myfortic scheme, the crux of the Exjade kickback scheme involved Novartis using incentives to induce a specialty pharmacy, BioScrip, to set aside its independent clinical judgment and, instead, carry out marketing activities for Novartis. Here, rather than having the pharmacy direct its marketing efforts at physicians (as was the case for Myfortic), Novartis schemed to have BioScrip recommend refills directly to Exjade patients.

144. In order to achieve its sales goals for Exjade, Novartis knew it had to increase the refill rate and, thus, "maximize the life time value of each [Exjade] patient" for the company. Starting in early 2007, Novartis was particularly focused on this objective because its market research had shown that a significant percentage of physicians and patients were opting to discontinue Exjade therapy due to the drug's frequent side effects. To increase the refill rate and thus maximize its Exjade sales, Novartis used a bundle of kickbacks – in the form of patient referrals Novartis directed to BioScrip (as detailed below, *see infra* at ¶¶ 162-167, Novartis dictated the number of new patients referred to BioScrip to fill their Exjade orders) and rebates Novartis paid to BioScrip – to induce BioScrip to initiate and continue a program, from February 2007 to May 2012, that was designed to get Exjade patients to order more refills.

145. Specifically, in February 2007, Novartis leveraged its control over BioScrip's access to Exjade patient referrals to induce BioScrip to initiate an intensive effort to call Exjade

patients to recommend refills and to get patients who stopped ordering Exjade to "restart." *See infra* at ¶¶ 177-185. Then, starting in late 2007, Novartis's Exjade marketing team implemented a system – called "Paying for Performance" – that tied the volume of patient referrals from Novartis and kickback payments Novartis paid to BioScrip in the guise of rebates to the pharmacy's delivering higher refill rates and more Exjade shipments for Novartis. In exchange for more patient referrals and higher "rebates" from Novartis, BioScrip assigned employees to call Exjade patients and – under the guise of offering "clinical counseling" or "education" – encourage them to order more refills.

146. Novartis and BioScrip promoted this effort as a nurse-led program that focused on patients and resulted in better clinical outcomes. In fact, however, Novartis and BioScrip understood that BioScrip's program of calling Exjade patients regarding refills was not designed for the patients' benefit. Instead, as Novartis records show, the objective of the program was to increase sales by obtaining more refill orders and, thus, enable Novartis to achieve its "National Exjade Sale Target [$]." As a former BioScrip supervisor has explained under oath, Novartis's system of "tying rebates and patient referrals to the number of refill shipments caused [BioScrip] to be focused exclusively on the number of orders and refill rates, rather than on patient care."

147. Further, as Novartis and BioScrip were aware, the calls from BioScrip did not provide Exjade patients with unbiased clinical information; instead, and unbeknownst to the patients, those calls emphasized the benefits of getting refills and downplayed the significance of Exjade's side effects. For example, from 2007 to late 2010, BioScrip employees were directed to follow a set of talking points for discussing Exjade with patients. Those talking points – which Novartis had reviewed and approved – indicated that "Exjade therapy can cause some discomfort initially, but it usually resolves over time." But those talking points nowhere disclosed the fact that, as the FDA-approved package insert indicated, Exjade treatment had been

linked to a lengthy list of severe side effects, including "acute renal failure [that was] fatal in some patients and requiring dialysis in others," "fatal GI hemorrhages," and "non-fatal upper GI irritation, ulceration and hemorrhage."

148. Similarly, Novartis and BioScrip were aware that nearly all the BioScrip employees assigned to "counsel" Exjade patients lacked the clinical knowledge or patient information to provide appropriate counseling to patients regarding Exjade. For example, as former BioScrip employees have acknowledged, they were directed to tell Exjade patients who were experiencing side effects to keep on ordering refills and "manage" the side effects, even though they did not have formal training on Exjade's side effects or how to manage such side effects. Further, even when BioScrip sought information from Novartis in late 2009 regarding whether Exjade was still appropriate for patients with myelodysplastic syndrome ("MDS"), a key group of Exjade patients, Novartis failed to alert BioScrip that Novartis itself had proposed a contra-indication for Exjade for a large segment of MDS patients, *i.e.*, "high-risk" MDS patients.

149. The Exjade kickback scheme, in short, enabled Novartis to have BioScrip perform marketing tasks to increase Exjade sales behind the façade of patient-oriented clinical activities run by an independent healthcare provider. This scheme was highly profitable for Novartis. For example, according to an October 2007 study prepared for Novartis marketing executives, by comparison to the other pharmacies dispensing Exjade, BioScrip generated a $2,000 "net benefit" for Novartis on a per-patient basis. Similarly, when Novartis marketing executives performed a return-on-investment ("ROI") analysis in 2011 to assess the effectiveness of the rebates paid to BioScrip, they determined that Novartis was realizing a 7.8:1 ROI from BioScrip. In other words, for each dollar in kickback paid to BioScrip under the guise of rebates, Novartis obtained $7.80 in return in terms of additional Exjade sales. Indeed, during the course of this kickback scheme, Novartis obtained hundreds of millions of dollars in Exjade

sales through BioScrip, including, as relevant here, tens of millions of dollars in sales that were covered by either Medicare or Medicaid reimbursements.

150. BioScrip likewise reaped significant benefits from its participation in the Exjade kickback scheme. Each quarter, BioScrip earned hundreds of thousands of dollars in kickbacks from Novartis, in the guise of rebates, and dispensing fees in connection with Exjade sales, a significant percentage of which was covered by Medicare and Medicaid reimbursements.

II. Exjade's Indicated Use and Its Safety Profile

151. In November 2005, FDA approved Exjade for use in treating "chronic iron overload due to blood transfusions ... in patients 2 years of age and older." Repeated blood transfusions can lead to a build-up of iron in the body; and excess iron can cause damage to organs such as the liver or the pancreas. Exjade, an iron-chelation drug, helps remove iron from a patient's body.

152. Novartis obtained FDA approval for Exjade under an accelerated process established pursuant to 21 C.F.R. § 314.510. Due to Exjade's accelerated approval by the FDA, Novartis was required to conduct several post-approval studies regarding Exjade's efficacy and side effects. In addition, FDA regulations required Novartis to submit all Exjade promotional materials to FDA for review at least 30 days before their use. *See* 21 C.F.R. § 314.550.

153. Patients can receive blood transfusions in connection with a variety of health problems. Thus, Exjade has been prescribed for patients with a number of underlying conditions, the most common conditions being beta-thalassemia (a blood disorder that affects red blood cells), sickle cell disease (a blood disorder that causes red blood cells to assume a sickle shape), and myelodysplastic syndrome (or "MDS," which encompasses a collection of bone marrow disorders that affect the production of the myeleoid type of blood cells).

154. Novartis, in turn, classified the market for Exjade as comprising four types of

patients: (1) patients with beta-thalassemia, (2) patients with sickle cell disease, (3) MDS patients, and (4) patients with "other anemias" that required blood transfusions.

155. According to pre-approval clinical studies for Exjade, the most frequent adverse events reported during the pre-approval studies included vomiting, nausea, abdominal pain, and an increase in serum creatinine (a clinical measure of kidney function). Thus, the original, November 2005 Exjade package insert (commonly referred to the "Exjade label") provided warnings about potential effects on the kidneys and liver, and recommended that monthly tests be conducted on the functioning of those organs, along with monthly serum ferritin tests (a clinical measure of a patient's blood iron level).

156. However, after patients began to use Exjade outside of the clinical study setting, Exjade's safety profile worsened significantly in terms of both the frequency and severity of reported adverse reactions. For instance, according to internal Novartis records, Novartis recognized by early 2007 that the adverse events associated with Exjade "are higher in the real world than reported in clinical trials."

157. In addition, post-approval safety studies showed that the adverse reactions associated with Exjade use also were more severe. These findings led to the addition of numerous warnings to the Exjade label, including:

- In late 2006, the Exjade label was updated to indicate that kidney failures and cytopenias (a reduction in production of certain blood cells) had been reported.
- In April 2007, the Exjade label was updated to report that some patients with kidney failure and cytopenias had died.
- In January 2008, a clinical recommendation was added to the Exjade label, emphasizing to prescribers that prescribing Exjade to patients to remove iron should be based on the anticipated "clinical benefit and risks of Exjade therapy." In addition, the updated Exjade label also included a warning about liver failures.

- In October 2008, two more warnings were added to the Exjade label — one regarding gastrointestinal ulcerations and bleeding, and the other regarding Exjade's toxicity at higher doses for patients with lower blood iron levels.

158. In January 2010, the safety concerns culminated in the requirement that the Exjade label feature a "Black Box warning."[5] As Novartis records show, the January 2010 label change resulted from an extensive analysis of Exjade safety data mandated by FDA. Specifically, in April 2009, FDA asked Novartis to analyze reports of patients who died while taking Exjade, as well as the risks and benefits of Exjade to MDS patients.

159. Novartis, in turn, submitted two responses to FDA's questions. First, in July 2009, Novartis responded to FDA and recommended that Exjade be contra-indicated for certain MDS patients. Then, in September 2009, Novartis reported that, according to an analysis of the more than 1,800 deaths of Exjade patients reported in an adverse event database, more than 1,000 of these patients were classified as having MDS.

160. Finally, in January 2010, the "Black Box" warning was added to the revised Exjade label, highlighting the fact that "Exjade may cause" kidney failure, liver failure, and gastrointestinal hemorrhage, and that "[i]n some reported cases these reactions were fatal." The revised label also specified that Exjade was contraindicated for patients with "high-risk MDS," *i.e.*, MDS patients who are sicker than other MDS patients. In that regard, internal Novartis records show that Novartis knew that more than 40% of MDS patients using Exjade in late 2009 had high-risk MDS and, thus, were "inappropriate patients" for Exjade.

III. Novartis's Distribution and Marketing Strategies for Exjade

A. Within the EPASS Distribution Network It Created, Novartis Controlled the Volume of Exjade Patient Referrals to BioScrip and the Other EPASS Pharmacies

[5] The "Black Box warning" is the strongest warning for a prescription drug that the FDA can require. Pursuant to FDA regulations, the warning must be in bold print and presented in a format that makes the information visually accessible. *See* 21 C.F.R. §§ 201.57(c)–(d).

161. Prior to launching the drug, Novartis decided to establish an exclusive distribution system for Exjade that would be responsible for processing and fulfilling close to all of the Exjade prescriptions. This system, which Novartis called the EPASS ("Exjade Patient Assistance and Support Services") network, was designed to include three pharmacies that were responsible for dispensing Exjade, and a data vendor that, among other things, processed incoming Exjade prescriptions and allocated the patients among the three EPASS pharmacies.

162. BioScrip applied to participate in the EPASS network in August 2005, and was selected by Novartis in late 2005 as one of the three EPASS pharmacies. BioScrip and Novartis entered into a contract in November 2005 concerning their relationship and BioScrip's role in the EPASS network (the "2005 BioScrip Exjade Contract").

163. Under that initial contract, BioScrip was principally responsible for sending Exjade shipments to patients, contacting Exjade patients to determine whether they wanted to order refills, and confirming that the shipments had been received. Novartis and BioScrip understood that BioScrip needed to obtain an Exjade patient's consent before shipping a refill even if a doctor's prescription authorized such a refill.

164. The 2005 BioScrip Exjade Contract also provided for BioScrip to assist Novartis with enrolling patients in education programs that Novartis planned to establish, including one called "Simple Steps."[6] In addition, BioScrip agreed to submit to Novartis, through the EPASS hub, detailed information regarding Exjade patients' course of therapy, including the medical conditions for which the patients were receiving Exjade, the patients' dosage, whether patients ordered refills, and whether physicians discontinued therapy.

165. In return for these services, the 2005 BioScrip Exjade Contract entitled

BioScrip to receive a per-shipment rebate of $13 from Novartis. But, as Novartis understood, beyond the rebates, just having access to patient referrals as a member of the EPASS network was very valuable to BioScrip: getting more Exjade patients translated to higher sales, larger Medicare and Medicaid reimbursements, higher dispensing fees, and more rebates from Novartis.

166. Exjade subscriptions (with limited exceptions) had to be issued on an "EPASS enrollment form" and submitted to the EPASS data vendor. Because the great majority of Exjade prescriptions were funneled through EPASS, Novartis had the ability to allocate thousands of new patient referrals among the EPASS pharmacies. More specifically, Novartis had unfettered control over how the EPASS data vendor allocated approximately half of all new patients whose insurers and doctors did not specify a choice of pharmacy (the "undesignated patients"). In this regard, the 2005 BioScrip Exjade Contract did not contain any provision that conditioned BioScrip's access to patient referrals or its participation in EPASS to any performance threshold, such as BioScrip's refill or shipment level.

B. Novartis Focused on Maximizing Refills As a Means To Achieve Its Sales Targets and Profit Objectives for Exjade

167. For Novartis, maximizing the number of refills for each patient was essential to meeting its sales targets and profit objectives for Exjade. This was because, as Novartis recognized, the population of potential Exjade patients was "very small," comprising only "about 15 out of [every] 100,000 people." Thus, even before the drug was launched, one of the Exjade marketing team's imperatives was to "maximize[e] the life time value of each patient" to Novartis.

168. By early 2007, increasing the refill rate per patient became even more important

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[6] As internal Novartis e-mails show, Novartis was unable to obtain FDA approval for a large number of "patient education" materials to be used as part of Simple Steps. Thus, Novartis abandoned the program in mid-2007, before it had been meaningfully implemented.

for Novartis because fewer than expected Exjade patients were ordering refills. As the Exjade marketing team understood, two of the main causes for the falling refill rate among Exjade patients were (i) the frequency of side effects experienced by Exjade patients, and (ii) changes in the composition of patients starting Exjade therapy.

169. In terms of Exjade's side effects, the Exjade marketing team understood that the side effects were both more frequent and more severe than the pre-approval clinical studies had indicated and, further, were leading a significant percentage of prescribers and patients to decide against ordering refills. For example, according to a marketing study Novartis received in early 2007, only "53% of physicians believe [Exjade's] potential side effects can be effectively managed without discontinuation." Moreover, the data submitted by the EPASS pharmacies also showed the Exjade marketing team that side effects were a major cause for patients to stop ordering Exjade.

170. Further, by early 2007, Novartis also knew that the composition of Exjade patients was shifting to fewer patients who received transfusions on a regular basis and a higher percentage of "intermittent" patients (*i.e.*, patients who had blood transfusions intermittently) with "lower iron overload" levels.[7] As the head of the Exjade marketing team acknowledged in a February 2007 e-mail, the intermittent patients were more likely to stop getting Exjade refills "after several months" because they would "have almost normalized iron values."

171. For Novartis's Exjade marketing team, the prospect of fewer refills per patient represented a "key issue" to its ability to achieve the Exjade sales target for 2007. Thus, by

[7] As Novartis records show, a significant number of the patients who started using Exjade in late 2005 and 2006 had switched from Desferal, another iron-chelation drug that must be administered through daily injections. This meant that Desferal patients typically had high iron levels and required chronic blood tranfusions. By 2007, fewer patients were switching to Exjade from Desferal. Thus, Novartis focused on expanding the patient population for Exjade by targeting patients who had lower blood iron levels and/or required less frequent transfusions.

March 2007, the marketing team identified "improve[ing] refill rates" among Exjade patients and "generat[ing] 're-starts'" (*i.e.*, getting patients who stopped ordering Exjade refills to resume ordering) as one of its top three priorities.

172. Indeed, improving refill rates among Exjade patients, which Novartis called "adherence," was the "top strategic imperative" for the Exjade marketing team in late 2007 and 2008. Further, as Novartis records show, getting Exjade patients to order more refills continued to be a key marketing objective for Novartis from 2009 to 2012.

IV. Starting in February 2007, Novartis Leveraged Its Control Over Patient Referrals to Make BioScrip Recommend Refills Directly to Exjade Patients

173. As noted above, the Exjade marketing team saw the falling refill rate as a "key risk" to its being able to achieve Novartis's Exjade sales target for 2007. Indeed, by early 2007, senior executives at Novartis were concerned about an emerging "performance gap" between the "actual" level of Exjade sales and the "budget[ed]" sales target for Exjade. For example, for the month of January 2007, Novartis only obtained $12.57 million in net sales for Exjade, well short of its budget "goal of $15.6 [million]."

174. By February 2007, the Exjade marketing team was particularly concerned about the refill level at BioScrip, which – while "higher than [Novartis's] original 2006 forecast" – was below the refill levels at the other two EPASS pharmacies. According to a February 2007 Novartis financial analysis, the difference in refill levels translated into millions of dollars in Exjade sales for Novartis.

175. To obtain more refill orders through BioScrip, the Exjade marketing team decided to leverage Novartis's control over patient referrals to make BioScrip recommend refills to Exjade patients. More specifically, in late February 2007, Novartis advised BioScrip that, because it generated lower levels of refills as compared to the other two EPASS pharmacies,

BioScrip had been placed under a "performance improvement plan" (the "PIP").

176. As Novartis executives explained to BioScrip at a February 2007 meeting at Novartis's offices in New Hanover, New Jersey, the PIP was a 45-day period – from late February to early April – during which BioScrip had to increase the refill level among its Exjade patients and convince as many of the Exjade patients who had stopped ordering refills to resume ordering. In addition, as part of the PIP, Novartis also made BioScrip provide weekly updates about the numbers of Exjade refill orders that it obtained and the number of patients that BioScrip was able to "restart" on Exjade.

177. Although neither the 2005 BioScrip Exjade Contract and nor any of its amendments required BioScrip to maintain any refill level, Novartis knew that it could impose the PIP on BioScrip because it controlled access to Exjade patient referrals, which were valuable to BioScrip. Specifically, Novartis informed BioScrip that unless it complied with the PIP and achieved certain "success measures," such as raising its refill levels, Novartis would cut off the flow of undesignated patient referrals to BioScrip or remove BioScrip from the EPASS network.

178. In response to the threat of losing access to Exjade patient referrals, BioScrip initiated an intensive effort to obtain more refill orders from its Exjade patients and to convince patients who had stopped ordering Exjade refills to resume ordering. Specifically, a group of employees in BioScrip's specialty pharmacy unit – including a newly-hired licensed practical nurse ("LPN"), two or three medical assistants, and several customer service representatives ("CSRs") – were assigned to call Exjade patients to encourage them to order refills and to call patients who had stopped ordering Exjade refills to encourage them to resume ordering.

179. However, when BioScrip employees recommended Exjade refills to patients during those calls, their recommendations were not based on assessments of whether refills were clinically appropriate. Instead, BioScrip employees were directed to encourage patients to order

Exjade refills or resume ordering without regard to whether the patients were experiencing potentially significant side effects or had achieved their therapeutic goals.

180. For example, according to the newly-hired LPN who made calls during this period, she was assigned to call Exjade patients "immediately upon starting work at BioScrip." She was not "given training on Exjade or its side effects" and "did not know [which] side effects were typical or unusual." Nonetheless, when she reached Exjade patients over the phone, she was directed to "emphasize to patients the importance of staying on Exjade" and "counsel patients to manage any side effects they had."

181. By April 2007, BioScrip's intensive efforts to recommend refills had resulted in a significant increase in the refill level among its Exjade patients, and BioScrip employees had convinced 139 patients to resume ordering Exjade. Further, BioScrip also promised Novartis that it would continue assigning one or more nurses to call Exjade patients "to keep[] these patients on drug therapy." Based on those results and BioScrip's pledge to maintain its focus on recommending Exjade refills to patients, the Exjade marketing team at Novartis decided that BioScrip had passed the PIP and would continue to receive undesignated patient referrals.

182. Nonetheless, Novartis continued to monitor closely BioScrip's efforts in recommending refills to Exjade patients and the level of refill orders at BioScrip. Specifically, starting from July 2007, the Exjade marketing team held monthly teleconference calls (and some in-person meetings) with BioScrip to discuss its refill rates as shown in the monthly "Exjade Scorecard" — a spreadsheet created by Novartis to compare the Exjade refill rates at BioScrip and the other two EPASS pharmacies.

183. To avoid the risk of losing access to Exjade patient referrals, BioScrip continued its efforts to call patients and encourage them to order Exjade refills or restart on Exjade, and, starting in mid-2007, formalized the staffing and procedures for these calls.

BioScrip created a team that was supposed to work exclusively on Exjade (the "Exjade Team"), consisting of the LPN hired in early 2007, two or three medical assistants, and several CSRs (for a few months in mid-2007, BioScrip assigned a second LPN to the Exjade Team; otherwise, there was only one LPN on the Exjade Team from 2007 to 2012). BioScrip also created a protocol, which it named "ScripCare" (also referred to as "BioScripCare" in BioScrip's records) that provided the Exjade Team with a basic timeline for calling Exjade patients to encourage them to order refills and certain scripts for how to discuss Exjade therapy with new patients.

184. Novartis, in turn, advised BioScrip on the creation of ScripCare program, including how BioScrip employees should discuss Exjade's potential side effects with patients and which members of the Exjade Team should make the calls. For example, the Exjade marketing team at Novartis reviewed and approved the scripts for BioScrip's Exjade Team to use in discussing side effects with new Exjade patients, which indicated that Exjade therapy could "cause some discomfort initially," but that such discomfort "usually resolves over time."

V. From Fall 2007 to May 2012, Novartis Induced BioScrip to Keep Promoting Exjade Refills to Patients in Exchange for More Patient Referrals and Higher Rebates

185. By fall 2007, Novartis saw that it was reaping significant financial gains from the Exjade refill promotion program at BioScrip. For example, according to an analysis provided to the Exjade marketing team on October 11, 2007, comparing BioScrip with the other two EPASS pharmacies, BioScrip was generating – "for every patient" – "$1.5k more" in Exjade sales for Novartis. That, combined with the fact that Novartis was paying lower rebates to BioScrip as compared to the other two EPASS pharmacies, meant that Novartis received a "net benefit … of $2k" from each "patient at BioScrip." In November 2007, another comparative study showed that, for Novartis, "an Exjade patient [at] BioScrip is worth $800-$2,800 more than a patient serviced by another [pharmacy]."

186. Recognizing the economic benefit of having BioScrip call Exjade patients to recommend refills, Novartis realized that it needed to offer BioScrip additional incentives to ensure that it would continue devoting efforts to the ScripCare program. Thus, in October 2007, executives from Novartis's Exjade marketing team and managed market team began discussing with BioScrip different ways that Novartis could "reward" BioScrip for its high refill levels.

187. During those discussions, Novartis told BioScrip that, in exchange for maintaining the highest refill rate within EPASS, BioScrip could be given all or a disproportionately large share of the undesignated patient referrals. In addition, Novartis discussed the potential for paying BioScrip kickbacks in the guise of higher rebates, including rebates tied to its refill rate or the number of its refill shipments.

188. Novartis also used those discussions to ensure that BioScrip tailored its promotional efforts to Novartis's Exjade marketing strategies by disclosing key aspects of its Exjade marketing goals and tactics to BioScrip. For example, at an October 11, 2007 meeting at BioScrip's offices in Columbus, Ohio, Novartis gave BioScrip the internal Novartis sales goal for Exjade and the key Exjade marketing tactics that Novartis had developed. Then, at a January 15, 2008 meeting at Novartis's offices in Florham, New Jersey, Novartis went further and gave BioScrip a version of Novartis's 2008 Exjade marketing plan.

189. Those discussions, which continued throughout 2008, eventually led Novartis to offer three types of kickbacks to cement BioScrip's commitment to promoting Exjade refills. Most immediately, Novartis raised BioScrip's per-shipment rebate for Exjade by more than 50%, *i.e.*, from $13 to $20, starting in January 2008. As Novartis and BioScrip both understood, this was to reward BioScrip for its high refill rates in late 2007 and to ensure that BioScrip continued to call Exjade patients to recommend refills. Further, in late 2008, Novartis again increased BioScrip's per-shipment rebate by 50%, from $20 to $30, starting on January 1, 2009.

190. In terms of patient referrals, Novartis informed BioScrip in November 2008 that, starting in January 2009 and continuing for six months, BioScrip would receive 60% of the undesignated referrals (vs. just 20% each for the other two EPASS pharmacies) due to its high refill rate as shown in the Exjade Scorecard for September 2008. This was part of Novartis's tactic of pitting the three EPASS pharmacies against each other based on their performance – in terms of how long their Exjade patients continued to order refills – as reported in the Exjade Scorecards, and then rewarding the pharmacy with the best refill performance with the most patient referrals. As deposition testimony shows, BioScrip agreed to the implementation of this scheme. Under this scheme, BioScrip was again rewarded for continuing to have a high refill rate relative to the two other EPASS pharmacies in early 2009 — for the second half of 2009, BioScrip was given 40% of the undesignated patient referrals.

191. Third, in 2008, Novartis also began offering BioScrip kickbacks under the guise of "performance rebates" based on the number of Exjade orders that BioScrip shipped to patients each quarter. Specifically, under the two-tier structure agreed to by Novartis and BioScrip, Novartis paid BioScrip $7 per Exjade shipment if BioScrip's quarterly Exjade shipments exceeded the "tier 1" threshold, and $14 per shipment if the quarterly shipments exceeded the "tier 2" threshold. As explained in marketing presentations that Novartis sent to BioScrip, Novartis set those shipment thresholds based on its "National Exjade Sales Target ($)."

192. For the Exjade marketing team at Novartis, the tactic of pitting the EPASS pharmacies against each other to compete for patient referrals, together with the Exjade performance rebate, formed the "Paying for Performance" strategy for Exjade. As Novartis marketing plans show, the Exjade marketing team not only conceived of this effort to use BioScrip and other pharmacies to promote Exjade, but also allocated part of the Exjade marketing budget to pay for some of the kickbacks offered to BioScrip in the guise of rebates.

193. This bundle of kickback incentives was sufficient to induce BioScrip to keep promoting Exjade refills in support of Novartis's marketing goals. For example, in a February 2009 strategy presentation, a BioScrip account management executive summarized what Novartis had conveyed regarding its marketing goals and tactics for Exjade, and then declared that the "BioScrip Strategic Plan [for Exjade] is to mirror and support Novartis priorities." Specifically, the Exjade Team at BioScrip continued to call patients and – under the guise of offering education about Exjade therapy, reminders, and clinical counseling – encourage the patients to order Exjade refills or to "restart" on Exjade.

194. These recommendations to patients to order refills or to restart Exjade therapy, however, were not based on independent clinical assessments of whether a refill or restarting Exjade therapy was needed or clinically appropriate. As a former Exjade Team member acknowledged, meeting Exjade shipment goals in order to "make Novartis happy," instead of patient care, was BioScrip's top priority.

195. Thus, Exjade Team members were directed to try to get refill orders irrespective of whether such refills were needed. For example, a former CSR on the Exjade Team was told to "try to get [patients] to refill their prescription" even "if a patient already had more than a months' supply of Exjade on hand."

196. Further, even if some members of the Exjade Team had attempted to make individualized clinical assessments or to offer appropriate counseling, most of them did not have sufficient training or the requisite patient health data to do so.

197. In June 2010, Novartis sought to further align BioScrip's refill promotion efforts with Novartis's Exjade marketing goals by revising how BioScrip earned performance rebates on Exjade shipments. As Novartis records show, this rebate structure was designed to "incentivize [BioScrip] to maximize[e] length on therapy" by recommending refills to Exjade

patients during the period when, according to EPASS data, they were mostly likely to discontinue therapy. Specifically, under the new arrangement, BioScrip received higher rebates if it shipped Exjade to a patient between his or her fourth and ninth months of therapy.

198. The revised rebate scheme again proved an effective inducement. For example, in 2011, Novartis compared the average number of shipments per patient dispensed by BioScrip against the average for another pharmacy that did not promote Exjade refills through purported patient education and counseling. That comparison showed that, during the first six months of therapy, BioScrip shipped 9.3 more days of Exjade than the other pharmacy. This, as Novartis recognized, translated to a 7.8 ROI, *i.e.*, return on investment, from its payments to BioScrip.

VI. Novartis Knew That Its Promotion of BioScrip's Exjade Program as Patient-Focused and Clinically Beneficial Was Belied by BioScrip's Exclusive Focus on Refill Orders and the Program's Clinical Deficiencies

A. Novartis and BioScrip Promoted BioScrip's Exjade Program as Patient-Focused and Clinically Beneficial

199. Another prong of Novartis's Exjade marketing efforts was to promote alleged benefits of the EPASS system – especially the purported clinical education and counseling offered by BioScrip and the other EPASS pharmacies – to both physicians and patients.

200. Thus, the Exjade sales representatives at Novartis were trained to tell physicians that the "#1 goal" for BioScrip and the other EPASS pharmacies was to "focus on patient and compliance." More specifically, the Exjade sales representatives were instructed to say that BioScrip and its peers offered "patient education by RNs [registered nurses] & pharmacists" as well as "counsel[ing] around side effects [of Exjade]," and that those programs not only "improve [Exjade] patient care," but also "lead to better patient outcomes."

201. To echo Novartis's marketing pitch, BioScrip also developed and distributed marketing materials to promote its Exjade program. For example, according to a 2009 BioScrip

marketing brochure, BioScrip's program for Exjade (referred to as the "Iron Overload care" program in the brochure) "is patient centric, disease focused and therapy conscious." The BioScrip brochure further claimed that this program "provides consistent assessment, education, and intervention resulting in improved patient healthcare delivery."

202. Further, through the calls that BioScrip made to patients as they began Exjade therapy, Novartis and BioScrip also promoted the clinical services purportedly offered by BioScrip directly to these new Exjade patients. When members of the Exjade Team called new patients, they were directed to tell the patients that BioScrip was assigning a nurse to call the patients to share information "about your new [Exjade] therapy, your disease and how to best manage taking your Exjade." In addition, the Exjade Team members also encouraged the patients to call BioScrip "to discuss symptoms you are experiencing or if you are concerned about a side effect." More specifically, the patients were told that the purpose of the calls was "to provide you with the best possible care while taking [] Exjade."

B. Novartis Knew That BioScrip's Exjade Program Was Designed to Generate Refills, Rather Than to Focus on Patient Care or Clinical Benefits

203. Contrary to how it promoted the Exjade program at BioScrip, Novartis knew that BioScrip's program paid little heed to patient care and was even less equipped to deliver clinical benefits for Exjade patients.

204. Instead, as Novartis knew, BioScrip designed the program to generate Exjade refill orders so as "to make Novartis [] happy." Specifically, under the guise of having its "nurse-led team" offer patient education, reminders, and clinical counseling, BioScrip was promoting Exjade refills by pressuring patients to order refills and by giving patients biased information that emphasized the benefits of getting refills while understating the severity of the side effects. Further, even if some members of the Exjade Team at BioScrip had wished to give

patients independent clinical advice, they – as Novartis was aware – lacked the requisite clinical guidance and training or the relevant patient health information to offer such advice.

205. First, as Novartis and BioScrip both understood, Novartis judged BioScrip's Exjade program according to whether the program helped Novartis achieve its sales and marketing goals for Exjade.

206. For example, in determining how to allocate patient referrals among BioScrip and the other EPASS pharmacies under its "paying for performance" strategy, Novartis measured "performance" exclusively in terms of how long BioScrip and the other pharmacies got their Exjade patients to continue to order refills. Tellingly, while Novartis euphemistically called this measure in the Exjade Scorecard the "adherence score," Novartis and BioScrip both understood that this measure was not based on whether Exjade patients were adhering to their doctors' orders. Specifically, as a Novartis marketing executive explained, there would be "a drop in the adherence [score]" for BioScrip if some "patient[s] stopped receiving Exjade shipments because their doctors had stopped their therapy."

207. Likewise, as BioScrip's e-mails show, Novartis explained that the shipment goals for determining whether BioScrip would earn performance rebates in 2008 and 2009 were based on Novartis's "national brand [*i.e.*, marketing] goals" for Exjade – more specifically, the "National Exjade Sales Target ($)."

208. BioScrip, in turn, understood that "to keep Novartis happy" meant making Exjade shipment goals, instead of caring for patients, the "top priority" for its Exjade Team. As a former Exjade Team supervisor explained under oath, Novartis's "system of tying rebates and patient referrals to the numbers of refill shipments caused [BioScrip] to be focused exclusively on the number of orders and refills, rather than on patient care." Thus, BioScrip not only pushed patients who already had too much Exjade on hand to order more refills, *see supra* at ¶ 196, it

also continued to ship Exjade to physicians' offices even though patients were not picking up the shipments and the doctors' offices "would become overstocked with Exjade."

209. Tellingly, there is no reference anywhere in Novartis's or BioScrip's sales or marketing materials or the talking points given to the Exjade Team at BioScrip to the fact that Novartis was offering BioScrip a bundle of incentives tied to whether the pharmacy was meeting shipment goals based on Novartis's "Exjade sales target."

210. Further, Novartis knew that the purported patient "education" and "counseling" offered by BioScrip involved biased advice that emphasized the benefits of getting refills while understating the severity of Exjade's side effects. As a Novartis clinical executive admitted at his deposition, when a pharmacy spoke with a patient about a drug's side effects, it is "not at all" clinically appropriate to "only discuss the less serious side effects and not to refer to the more severe potential side effects;" instead, the pharmacy "should go over the severe [side effects]" and make them "more of a priority."

211. In practice, however, Novartis had BioScrip promote Exjade refills by focusing on the less serious side effects while ignoring the more serious ones. Specifically, as noted above, *see supra* at ¶ 185, BioScrip created a set of talking points for its Exjade Team to use in discussing Exjade therapy with patients. With regard to side effects, the talking points indicated that Exjade could "cause some discomfort initially," but that such discomfort "usually resolves over time." In January 2008, BioScrip reviewed those talking points with Novartis, and Novartis approved them. From then until November 2010, BioScrip required the Exjade Team to follow the talking points approved by Novartis when they discussed Exjade and its side effects with patients starting Exjade therapy. As a former medical assistant on the Exjade Team explained, if patients reported "side effects [] such as diarrhea or vomiting," they were told "that they should continue taking Exjade and wait for the side effects to pass."

212. However, as noted above, *see supra* at ¶¶ 152-161, numerous warnings – including the January 2010 "Blackbox Warning" – were added to the Exjade label between 2008 and 2010. Those warnings highlighted that Exjade was associated with severe gastrointestinal ("GI") side effects, including serious GI ulcerations and potentially fatal GI hemorrhages, that did not resolve over time. In addition, the warnings also discussed other severe side effects, such as renal and hepatic impairments, that could be fatal.

213. In addition, as e-mails and deposition testimony show, Novartis also withheld from BioScrip negative safety information regarding the use of Exjade among high-risk MDS patients. In July 2009, as discussed above, *see supra* at ¶ 160, Novartis submitted a proposal to FDA to change the Exjade label to add a contra-indication for high-risk MDS patients. Further, by late September 2009, Novartis knew that more than 40% of the MDS patients taking Exjade were "inappropriate MDS patients," *i.e.*, high-risk MDS patients.

214. However, Novartis not only did not alert BioScrip to these safety issues directly, but also failed to share the relevant safety information after BioScrip specifically requested the information. On September 28, 2009, and after noticing a public alert indicating that the FDA was investigating adverse events, including deaths, among MDS patients taking Exjade, a BioScrip executive contacted her point of contact at Novartis for clinical issues to discuss safety issues for MDS patients using Exjade.

215. Rather than sharing the safety information being discussed within Novartis, the clinical executive at Novartis instead advised BioScrip that, with regard to MDS patients using Exjade, "there [was] no plan for a label change and patients should not discontinue taking Exjade." Further, while that clinical executive promised to "update [BioScrip] as additional information becomes available," he admitted in deposition that he did not provide any update to BioScrip regarding the "sizeable number" of "inappropriate patients who were taking Exjade."

216. Finally, Novartis also was aware that BioScrip did not provide its Exjade Team with access to the types of patient health data essential for advising an Exjade patient regarding whether to continue taking the drug. As a Novartis executive admitted at her deposition, to offer such advice, a healthcare professional needed to know, at a minimum, an Exjade patient's "serum creatinine level" and "up-to-date serum ferritin level."[8] However, as Novartis was aware, the patient information system that BioScrip used for its Exjade program did not track either type of data for most of the Exjade patients at BioScrip.

VII. Novartis and BioScrip Failed to Include Core Elements of Their Relationship in Their Exjade Rebate Contracts

217. Novartis not only chose to hide the truth about BioScrip's Exjade program from its promotion of that program, it also did not include two key aspects of its kickback relationship with BioScrip in the rebate contracts they maintained.

218. First, neither the original 2005 BioScrip Exjade Contract nor the new contract that Novartis signed with BioScrip in June 2010 (the "2010 BioScrip Exjade Contract") referred to their shared understanding that, to keep receiving undesignated patient referrals, BioScrip had to satisfy Novartis's expectation regarding refills levels.

219. As discussed above, the Exjade kickback scheme began as a result of Novartis's imposing a PIP on BioScrip in early 2007 and conditioning BioScrip's continued access to patient referrals on its achieving a refill level that satisfied Novartis. *See supra* at ¶¶ 177-178.

220. In April 2011, after BioScrip's refill levels had dipped temporarily, Novartis again invoked this unwritten understanding to impose a "Corrective Action" plan on BioScrip and cut off the flow of undesignated patient referrals to BioScrip until it demonstrated

[8] More specifically, the serum creatinine level indicates whether Exjade was affecting the patient's renal function, as renal impairment is a serious side effect for Exjade patients; and the

"improvement" in its refill levels and got a sufficient number of patients who stopped ordering Exjade to "restart."

221. BioScrip responded by intensifying its focus on promoting Exjade refills to patients and launching an aggressive campaign to "intervene[e]" to restart patients on Exjade. Nonetheless, Novartis kept BioScrip from getting undesignated patient referrals for three full months. According to a May 2011 Novartis e-mail, this was intended to give BioScrip a clear "warning" on the consequence of not satisfying Novartis's expectation regarding refills levels.

222. As e-mails show, that "warning" was not lost on BioScrip. Its intensive effort to recommend refills and to get patients who stopped ordering Exjade to "restart" continued through 2011, resulting in BioScrip again having the highest refill rate among the EPASS pharmacies in late 2011. That, in turn, led Novartis to allocate 60% of the undesignated patient referrals to BioScrip starting in January 2012.

223. Second, the 2005 and 2010 BioScrip Exjade Contracts also failed to disclose anything regarding the competition for patient referrals among the EPASS pharmacies that Novartis implemented starting in late 2008, even though this was an integral part of Novartis's relationship with BioScrip.

224. As discussed above, *see supra* at ¶¶ 187-194, this competition for patient referrals represented half of the bundle of incentives offered to BioScrip (performance rebates being the other half of the bundle) pursuant to Novartis's "paying for performance" strategy. As a former Novartis vice president responsible for Exjade contracting acknowledged in deposition, Novartis saw both the competition for patient referrals and the performance rebates as "part of an overall evolution of the EPASS system." Further, as emails show, BioScrip likewise viewed the

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serum ferritin level is relevant to assessing whether the patient continues to require therapy or has achieved his or her therapeutic goals.

ability to get "an increased allocation of [undesignated] patients" based on higher refill levels as a basic aspect of its relationship with Novartis.

225. In drafting its contracts with BioScrip, however, Novartis chose to act as if there was no such understanding with BioScrip, as neither the 2005 nor the 2010 BioScrip Exjade Contract contained any disclosure about half of the bundle of incentives Novartis was offering to BioScrip — the ability to get more Exjade patient referrals by getting more refill orders and thus raising its refill rate in the Exjade Scorecard.

VIII. The Exjade Kickback Scheme Caused the Submission of Thousands of False Claims to Medicare and Medicaid

226. As Novartis and BioScrip profited from their Exjade kickback scheme through, respectively, higher sales and the higher fees and rebates associated with additional patient referrals, Medicare and Medicaid were made to bear the financial cost of this corrupt scheme.

227. Throughout the Exjade kickback scheme, *i.e.*, from February 2007 to May 2012, BioScrip submitted claims to Medicare Part D and Medicaid seeking reimbursement for the Exjade shipments it dispensed. These Medicare and Medicaid claims were false and ineligible for reimbursement because each claim had been tainted by kickbacks.

228. Further, in seeking Medicare and Medicaid reimbursement, BioScrip did not disclose its kickback relationship with Novartis or the fact that its Exjade claims resulted from a scheme that violates the AKS, a statute that BioScrip was required to, and promised to, comply in its contracts with Part D sponsors and its Medicaid enrollment forms. In addition, neither Novartis nor BioScrip disclosed to Medicare or Medicaid that BioScrip was promoting Exjade refills in exchange for kickbacks from Novartis in the form of patient referrals and rebates.

229. As Medicare Part D data shows, Medicare Part D plans made reimbursements to BioScrip for more than 37,900 Exjade claims submitted during the course of the Exjade kickback

scheme. In total, Medicare Part D plans paid out tens of millions of dollars in reimbursements for these kickback-tainted false claims, over 70% of which represented the federal government's contributions to the Medicare Part D plans.

230. Medicaid claims data shows that the Medicaid state agencies similarly issued reimbursements to BioScrip for tens of thousands of Exjade claims submitted during the course of the Exjade kickback scheme. For example, between February 2007 and May 2012, New York Medicaid alone reimbursed BioScrip on over 4,800 claims relating to Exjade. In total, the Medicaid state agencies also paid out tens of millions of dollars in reimbursements for the kickback-tainted false claims submitted in connection with the Exjade kickback scheme.

231. In short, by orchestrating the Exjade kickback scheme, Novartis and BioScrip caused the submissions of tens of thousands of false claims to Medicare and Medicaid. The scheme, in turn, caused federal healthcare programs to pay out tens of millions of dollars based on the kickback-tainted false Exjade claims.

FIRST CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729 (a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

232. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

233. The United States seeks relief against Novartis under Section 3729(a)(1) of the FCA, 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A) .

234. As a result of its offering and paying kickbacks to induce pharmacies to purchase, order, or recommend the purchasing or ordering of Myfortic, in violation of the AKS, 42 U.S.C. § 1320a-7b(b), Novartis caused the pharmacies to present claims for reimbursement to Medicare and Medicaid that were false or fraudulent.

235. Accordingly, Novartis knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

236. By reason of the false or fraudulent claims that Novartis knowingly caused the pharmacies to present to Medicare and Medicaid, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements
(31 U.S.C. § 3729(a)(2)(2000) and, as amended, 31 U.S.C. § (a)(1)(B)(Supp. 2009))

237. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

238. The United States seeks relief against Novartis under Section 3729(a)(2) of the FCA, 31 U.S.C. § 3729(a)(2) and, as amended, 31 U.S.C. § 3729(a)(1)(B) (Supp. 2009).

239. As a result of its offering and paying kickbacks to induce pharmacies to purchase, order, or recommend the purchasing or ordering of Myfortic, in violation of the AKS, 42 U.S.C. § 1320a-7b(b), Novartis caused the pharmacies to make false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid.

240. More specifically, the pharmacies falsely certified, stated, and/or represented that the reimbursements they sought for Myfortic they dispensed were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. The pharmacies' false certifications, statements, or representations caused Medicare and Medicaid to pay out sums that would not have been paid if those programs had been made aware of the falsity of the pharmacies' certifications, statements, or representations.

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

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

THIRD CLAIM

Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729 (a)(3)(1986) and, as amended, 31 U.S.C. § 3729 (a)(1)(C))

242. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

243. The United States seeks relief against Novartis under Section 3729(a)(3) of the FCA, 31 U.S.C. § 3729(a)(3) (1986), and, as amended, 31 U.S.C. § 3729 (a)(1)(C).

244. As set forth above, Novartis conspired with numerous pharmacies to offer and pay kickbacks in exchange for, or to induce, the pharmacies to purchase, order, or recommend Myfortic in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2), thereby causing the pharmacies to submit false and fraudulent claims to Medicare and Medicaid seeking reimbursement for Myfortic dispensed in connection with the kickback scheme.

245. Accordingly, Novartis conspired to defraud the United States by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3) (1986), and conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729 (a)(1)(C) (2009).

246. By reason of the false or fraudulent claims Novartis and the pharmacies conspired to get allowed or paid or by reasons of their conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount

to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

FOURTH CLAIM

Unjust Enrichment

247. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.

248. As set forth above, the United States issued Medicare and Medicaid reimbursements to pharmacies based on false or fraudulent claims for Myfortic, which the pharmacies dispensed as result of kickbacks offered or paid by Novartis and in violation of federal laws and regulations, including but not limited to the AKS, 42 U.S.C. § 1320a-7b(b).

249. The circumstances of Novartis's receipt of monies based on pharmacies' dispensing Myfortic as a result of kickbacks offered or paid by Novartis are such that, in equity and in good conscience, Novartis should not retain such monies, the amount of which is to be determined at trial.

250. By reason of Novartis's unjust enrichment, the United States is entitled to disgorgement of all monies that Novartis earned as a result of its Myfortic kickback scheme and/or imposition of a constructive trust in favor of the United States on those monies.

FIFTH CLAIM

Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729 (a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A))

251. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

252. The United States seeks relief against Novartis and BioScrip under Section 3729(a)(1) of the FCA, 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

253. In furtherance of the Exjade kickback scheme, Novartis offered and gave kickbacks to induce BioScrip to recommend the purchasing or ordering of Exjade, in violation of the AKS, 42 U.S.C. § 1320a-7b(b), and caused BioScrip to present claims for reimbursement to Medicare and Medicaid that were false or fraudulent.

254. In furtherance of the Exjade kickback scheme, BioScrip accepted kickbacks from Novartis in exchange for recommending the purchasing or ordering of Exjade, in violation of the AKS, and presented claims for reimbursement to Medicare and Medicaid that were false or fraudulent. Accordingly, Novartis caused BioScrip to knowingly present false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

255. By reason of the false or fraudulent claims presented to Medicare and Medicaid in connection with the Exjade kickback scheme orchestrated by Novartis and BioScrip, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SIXTH CLAIM

Violations of the False Claims Act: Use of False Statements
(31 U.S.C. § 3729(a)(2)(2000) and, as amended, 31 U.S.C. § (a)(1)(B)(Supp. 2009))

256. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

257. The United States seeks relief against Novartis and BioScrip under Section 3729(a)(2) of the FCA, 31 U.S.C. § 3729(a)(2) and, as amended, 31 U.S.C. § 3729(a)(1)(B) (Supp. 2009).

258. In furtherance of the Exjade kickback scheme, Novartis offered and gave kickbacks to induce BioScrip to recommend the purchasing or ordering of Exjade, in violation of

the AKS, 42 U.S.C. § 1320a-7b(b), and caused BioScrip to make false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid.

259. In furtherance of the Exjade kickback scheme, BioScrip accepted kickbacks from Novartis in exchange for recommending the purchasing or ordering of Exjade, in violation of the AKS, and made false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid. More specifically, BioScrip certified, stated, and/or represented that the reimbursements it sought for Exjade shipments were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. These false certifications, statements, or representations, in turn, caused Medicare and Medicaid to pay out sums that would not have been paid if those programs had been made aware of the falsity of such certifications, statements, or representations. Accordingly, Novartis knowingly caused BioScrip to use false records or statements materials to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

260. By reason of these false records or statements used in connection with the Exjade kickback scheme orchestrated by Novartis and BioScrip, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SEVENTH CLAIM

Violations of the False Claims Act: Conspiring to Violate the False Claims Act (31 U.S.C. § 3729 (a)(3)(1986) and, as amended, 31 U.S.C. § 3729 (a)(1)(C))

261. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth in this paragraph.

262. The United States seeks relief against Novartis and BioScrip under Section 3729(a)(3) of the FCA, 31 U.S.C. § 3729(a)(3) (1986), and, as amended, 31 U.S.C.

§ 3729 (a)(1)(C).

263. As set forth above, Novartis and BioScrip conspired to orchestrate a kickback scheme in which Novartis offered and paid, and BioScrip accepted, kickbacks in exchange for recommending Exjade refills in violation of the AKS, 42 U.S.C. § 1320a-7b(b)(2), thereby causing BioScrip to submit false and fraudulent claims to Medicare and Medicaid seeking reimbursement for Exjade dispensed in connection with the kickback scheme.

264. Accordingly, Novartis and BioScrip conspired to defraud the United States by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3) (1986), and conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729 (a)(1)(C) (2009).

265. By reason of the false or fraudulent claims Novartis and BioScrip conspired to get allowed or paid or by reasons of their conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

EIGHTH CLAIM

Unjust Enrichment

266. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.

267. As set forth above, the United States issued Medicare and Medicaid reimbursements to BioScrip based on false or fraudulent claims for Exjade, which BioScrip dispensed as result of kickbacks offered or paid by Novartis and in violation of federal laws and regulations, including but not limited to the AKS, 42 U.S.C. § 1320a-7b(b).

268. The circumstances of Novartis's and BioScrip's receipt of monies based on BioScrip's dispensing Exjade as a result of kickbacks offered or paid by Novartis are such that,

in equity and in good conscience, Novartis and BioScrip should not retain such monies, the amount of which is to be determined at trial.

269. By reason of Novartis's and BioScrip's unjust enrichment, the United States is entitled to disgorgement of all monies that Novartis and BioScrip earned as a result of the Exjade kickback scheme and/or imposition of a constructive trust in favor of the United States on such monies.

NINTH CLAIM

PAYMENT BY MISTAKE OF FACT

270. The United States incorporates by reference paragraphs 1 through 232 above as if fully set forth herein.

271. The United States seeks relief against BioScrip to recover the Medicare and Medicaid reimbursements obtained by BioScrip for Exjade shipments that were made as a result of mistaken understandings of fact. Medicare and Medicaid made payments to BioScrip for Exjade shipments under the erroneous belief that BioScrip was entitled to such payments. Specifically, in making such payments, the United States reasonably relied upon and assumed that BioScrip, in submitting claims to Medicare and Medicaid, had complied with applicable Medicare and Medicaid rules and regulations, including the AKS, 42 U.S.C. § 1320a-7b(b), and that the claims were for expenditures allowable under the relevant rules and regulations. This erroneous belief was material to the United States' decision to pay these claims.

272. Under such circumstances, the United States' payment of federal funds under the Medicare and Medicaid programs was by mistake and was not authorized. BioScrip, accordingly, is liable to account for and repay such funds, the amount of which is to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

(a) On the First, Second, and Third Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1), 3729(a)(2), and 3729(a)(3), and, as amended, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B), and 3729(a)(1)(C)), a judgment against Novartis for treble the United States' damages resulting from the Myfortic kickback scheme, in an amount to be determined at trial, plus an $11,000 penalty for each false claim submitted in violation of the FCA;

(b) On the Fourth Claim for relief (Unjust Enrichment), a judgment against Novartis for the damages sustained and/or amounts by which Novartis was unjustly enriched by the Myfortic kickback scheme, plus interest, costs, and expenses;

(c) On the Fifth, Sixth, and Seventh Claims for relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1), 3729(a)(2), and 3729(a)(3), and, as amended, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B), and 3729(a)(1)(C)), a judgment against Novartis and BioScrip holding them jointly and severally liable for treble the United States' damages resulting from the Exjade kickback scheme, in an amount to be determined at trial, plus an $11,000 penalty for each false claim submitted in violation of the FCA;

(d) On the Eighth Claim for relief (Unjust Enrichment), a judgment against Novartis and BioScrip holding them jointly and severally liable for the damages sustained and/or amounts by which they were unjustly enriched by the Exjade kickback scheme, plus interest, costs, and expenses;

(e) On the Ninth Claim for relief (Payment by Mistake of Fact), a judgment

against BioScrip for the damages sustained and/or amounts by which BioScrip retained illegally obtained monies in connection with the Exjade kickback scheme, plus interest, costs, and expenses;

(f) An award of costs incurred by the United States against Novartis and BioScrip pursuant to 31 U.S.C. § 3729(a)(3); and

(g) such further relief as is proper.

Dated: New York, New York
January 6, 2013

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

By: 

LI YU
REBECCA C. MARTIN
ELLEN M. LONDON
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, N.Y. 10007
Telephone: (212) 637-2734/2714/2737
Fax: (212) 637-2686
Email: li.yu@usdoj.gov
rebecca.martin@usdoj.gov
ellen.london@usdoj.gov
Attorneys for the United States