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**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| UNITED STATES OF AMERICA, | : | 11 Civ. 8196 (CM) |
| Plaintiff, | : | **COMPLAINT-IN-INTERVENTION OF THE UNITED STATES OF AMERICA** |
| v. | : | |
| NOVARTIS PHARMACEUTICALS CORPORATION, | : | |
| Defendant. | : | |

The United States of America, 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") 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 a Novartis-orchestrated kickback scheme. Under this scheme, Novartis paid kickbacks to pharmacies in exchange for the pharmacies switching transplant patients to the Novartis drug Myfortic, or continuing to

recommend and dispense Myfortic instead of cheaper, generic competitor drugs. As part of the scheme, Novartis also has knowingly caused the pharmacies to submit false claims 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. *See* 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994).

3. Although Novartis knew that the AKS prohibited it from giving kickbacks to pharmacies to promote Myfortic, it disregarded that prohibition, choosing instead to put sales growth and profits before its duty to comply with federal law. Specifically, from 2005 until the present, 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 from Novartis, 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. *See infra* at ¶¶ 47-48, 55-62. 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 ¶ 99. 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 kickback scheme. *See infra* at ¶ 84.

4. Moreover, 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 ¶¶ 50, 76-77. 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 ¶¶ 45-46, 53, 87. 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 ¶¶ 110-121.

5. For Novartis, the Myfortic kickback scheme has been 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 ¶¶ 52-56. 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]."

6. Transplant patients and the public fisc, on the other hand, have borne the cost of the Myfortic kickback scheme orchestrated by Novartis. 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 have paid tens of millions of dollars to pharmacies for Myfortic based on false claims that were never entitled to federal reimbursement. *See infra* at ¶¶ 122-123.

## JURISDICTION AND VENUE

7. 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.

8. This Court may exercise personal jurisdiction over Novartis 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 transacts business in this District and, in furtherance of its fraudulent kickback scheme, caused to be submitted or conspired to submit false claims in this District.

## THE PARTIES

9. 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.

10. 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).

## THE APPLICABLE STATUTES

11. 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.

12. 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).

13. 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.*

14. 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);
>
> (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

material to a false or fraudulent claim, *id.* § 3729(a)(1)(B); or

(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]

"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]

15. 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

16. ***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 was enacted as part of the

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[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 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,

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. HHS, through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "sponsors") authorized to sell Part D insurance coverage. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts.

17. 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 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.

18. ***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.

19. The Medicaid programs in all states reimburse for prescription drugs. Under the

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47103 (1999), the FCA civil penalties are $5,500 to $11,000 for violations, such as those alleged

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.

20. Further, the States require certifications by pharmacists as a condition of providing Medicaid reimbursement for the prescriptions they write. In New York, for example, the Medicaid program requires a pharmacy to certify, *inter alia*, that it "agree[s] to abide by all applicable Federal and State laws as well as the rules and regulations of other New York State agencies particular to the type of program covered by this enrollment application."

## MYFORTIC'S REIMBURSEMENT STATUS AND COMPETITIVE POSITION

21. 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.

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here, occurring on or after September 29, 1999.

22. 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.

23. 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.

24. 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.[3] 42 U.S.C. § 1396r-8(k)(6).

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

25. 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.

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

### I. Novartis's Awareness of Medicare and Medicaid Coverage for Myfortic Sales by Pharmacies

26. 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.

27. 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."

28. 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.

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

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.

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

30. 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.

31. 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.

32. 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).

33. 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."

34. 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

35. 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).

36. 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.

37. 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).

38. 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).

39. 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 ORCHESTRATED BY NOVARTIS

### I. The Basic Structure of the Myfortic Kickback Scheme

40. 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.

41. 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.

42. 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.

43. 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.

44. 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.

45. 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.

46. 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.

47. 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.

48. 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.

49. 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]."

50. 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

51. 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.

52. 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."

53. 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.

54. 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."

55. 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."

56. 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.

57. 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.

58. 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]."

59. 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.

60. 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.

61. 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.

62. 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**

63. 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]."

64. 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.

65. 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."

66. 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."

67. 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.

68. 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.

69. 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.

70. 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.

71. 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

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

73. 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.

74. 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."

75. 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.

76. 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.

77. 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."

78. 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.

79. 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.

80. 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**

81. 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.

82. 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)."

83. 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.

84. 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.

85. 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.

86. 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.

87. 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.

88. 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.

89. 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**

90. 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.

91. 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.

92. 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.

93. 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.

94. 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."

95. 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."

96. 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."

97. 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.

98. 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.

99. 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.

100. 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.

101. 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.

102. 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

103. 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.

104. 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."

105. 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 ¶¶ 51-55, 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.

106. 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.

107. 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."

108. 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.

109. 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

110. 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 ¶¶ 26-39.

111. 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.

112. 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.

113. 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.

114. 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 ¶¶ 90-112) and the on-site and mail-order divisions of Walgreen's – to drive growth in Myfortic sales.

115. 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.

116. 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."

117. 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."

118. 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.

119. 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.

120. 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.

121. 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 ¶¶ 103-109.

## 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

122. 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.

123. 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.

## 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))

124. The United States incorporates by reference paragraphs 1 through 123 above as if fully set forth in this paragraph.

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

126. 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 federal anti-kickback statute, 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.

127. 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).

128. 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))**

129. The United States incorporates by reference paragraphs 1 through 123 above as if fully set forth in this paragraph.

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

131. 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 federal anti-kickback statute, 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.

132. 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 federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b). 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.

133. 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).

134. 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))

135. The United States incorporates by reference paragraphs 1 through 123 above as if fully set forth in this paragraph.

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

137. 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 federal anti-kickback statute, 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.

138. 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).

139. 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

140. The United States incorporates by reference paragraphs 1 through 123 above as if fully set forth herein.

141. 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 federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

142. 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.

143. 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.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor and against Novartis 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)), for treble the United States' damages, in an amount to be determined at trial, plus an $11,000 penalty for each false claim submitted in violation of the FCA;

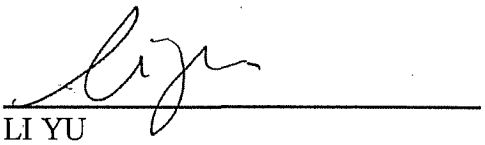
(b) On the First, Second, and Third Claims for relief, an award of costs pursuant to 31 U.S.C. § 3729(a)(3);

(c) On the Fourth Claim for relief (Unjust Enrichment), for the damages sustained and amounts by which Novartis retained illegally obtained monies, plus interest, costs, and expenses; and

(f) for such further relief as is proper.

Dated: New York, New York
April 19, 2013

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

By: 

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