UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,	:	11 Civ. 8196 (CM) (JCF)
Plaintiff-Intervenor,	:	**STIPULATION AND ORDER OF SETTLEMENT AND DISMISSAL**
v.	:	
NOVARTIS PHARMACEUTICALS CORP. *et al.*,	:	
Defendants.	:	

WHEREAS, this Stipulation and Order of Settlement and Dismissal (the "Stipulation") is entered into by and among (*i*) plaintiff the United States (the "United States" or the "Government"), by its attorney Preet Bharara, United States Attorney for the Southern District of New York, (*ii*) the *qui tam* relator David Kester ("Relator"); and (*iii*) defendant Novartis Pharmaceuticals Corporation ("Novartis," and together with the Government and Relator, the "Settling Parties"), through their respective authorized representatives;

WHEREAS, in November 2011, Relator filed a sealed *qui tam* action (the "Action") in the United States District Court for the Southern District of New York (the "Court") pursuant to 31 U.S.C. § 3730(b), the *qui tam* provision of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (the "FCA"), alleging, *inter alia*, that defendant Novartis violated the FCA and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), in connection with distributing the iron chelation drug Exjade through the Exjade Patient Assistance and Support Services ("EPASS") network and distributing the immunosuppressant drug Myfortic through certain specialty pharmacies;

WHEREAS, on April 23, 2013, the United States intervened in the Action against Novartis based on Novartis's alleged participation in the kickback scheme involving Myfortic;

WHEREAS, on October 30, 2013, the United States intervened in the Action against Novartis based on Novartis's alleged participation in the kickback scheme involving Exjade, and

in or about January 2014, eleven states (the "Litigating States") also intervened in this case against Novartis;

WHEREAS, the Government alleges that Novartis violated the FCA and the AKS as follows: (a) from in or about February 2007 to in or about May 2012, Novartis (i) gave patient referrals, discounts, and rebates to Accredo Health Group, Inc. ("Accredo"), BioScrip, Inc. ("BioScrip"), and U.S. Bioservices Corporation ("US Bioservices") to induce these pharmacies to recommend to patients that they order Exjade refills and (ii) thereby caused Accredo, Bioscrip, and US Bioservices to submit false claims to Medicare and Medicaid for reimbursement for Exjade; and (b) from in or about June 2004 to in or about December 2013, Novartis (i) gave discounts and/or rebates to specialty pharmacies (including Transcript Pharmacy, Bryant's Pharmacy and Healthcare Center, Kilgore's Medical Pharmacy, Baylor Health Care System, and Twenty-Ten Pharmacy) in return for their agreement to recommend to physicians to prescribe Myfortic instead of the competitor drug CellCept or generic versions of CellCept and (ii) thereby caused these pharmacies to submit false claims to Medicare and Medicaid for reimbursement for Myfortic. The conduct described in this recital paragraph is the "Covered Conduct" for purposes of this Stipulation;

WHEREAS, the Government has entered into settlement agreements with Bioscrip and Accredo in connection with their involvement in the alleged Exjade kickback scheme pursuant to which BioScrip and Accredo made admissions and agreed to pay the Government $11,685,705.43 and $45,060,598.87, respectively; and the Litigating States have entered into settlement agreements with Bioscrip and Accredo for the same conduct for $3,314,294.57 and $14,939,401.03, respectively; and

WHEREAS, to avoid the delay, uncertainty, and expense of further litigation, the United States, the Relator, and Novartis have reached a full and final mutually agreeable resolution of

these claims;

NOW, THEREFORE, IT IS HEREBY ORDERED that:

1. Novartis consents to this Court's exercise of personal jurisdiction over Novartis.

2. a. Novartis admits, acknowledges, and accepts responsibility for the following facts relating to the Exjade claims:

Introduction:

In 2005, Novartis obtained approval from the FDA to distribute Exjade, an iron chelation drug. Novartis decided to have Exjade distributed through a closed network of three specialty pharmacies. Toward the end of 2006, Novartis determined that fewer patients were ordering prescription refills than expected, which, among other things, was impacting Novartis's ability to meet its Exjade sales forecast. Novartis also determined that the refill rate of one of the pharmacies lagged behind the refill rates of the other two pharmacies. In February 2007, Novartis indicated to that pharmacy that, if the pharmacy did not improve its performance, Novartis would terminate its relationship with that pharmacy or reduce the number of patients to be assigned to that pharmacy. In response, the pharmacy told Novartis that it would put in place a program through which its personnel, including nurses, would reach out to Exjade patients to encourage them to order their prescribed refills. Later in 2007, Novartis pushed the other two pharmacies to put in place similar programs, which the pharmacies did. In 2008, Novartis took further steps to incentivize all three pharmacies distributing Exjade to increase prescription refill levels, which included allocating a larger share of patients to the pharmacy with the highest "adherence" metric (as measured based on the number of refills) and paying additional rebates to the pharmacies for meeting quarterly shipment goals based on Novartis's sales targets. These arrangements remained in place until in or about March 2012.

Detailed Admissions:

A. In November 2005, Novartis sought and obtained accelerated approval from the FDA to market Exjade for the treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. FDA's regulations regarding accelerated approval required Novartis to conduct certain clinical trials to assess the long-term clinical benefits and risks of Exjade and to submit all Exjade promotional materials to FDA for review.

B. Novartis marketed Exjade for use by a small patient population with chronic iron overload due to blood transfusions. These patients had received blood transfusions in connection with several types of serious underlying conditions, including myelodysplastic syndromes ("MDS"), beta thalassemia, and adult and pediatric sickle cell disease ("SCD"). Novartis also expected that both private insurance and government

healthcare programs, such as Medicaid and Medicare, would cover a portion of the costs of Exjade.

C. In late 2005, Novartis created a closed distribution network for Exjade called EPASS ("Exjade Patient Assistance and Support Services") that included three specialty pharmacies – Accredo, BioScrip and US Bioservices (the "EPASS SPs"). Novartis selected those pharmacies through a competitive bidding process based on their previous experiences providing specialty pharmacy services, such as refill reminders, drug administration instruction and insurance reimbursement assistance. Specifically, in November and December 2005, Novartis signed contracts with BioScrip, Accredo, and US Bioservices pursuant to which those specialty pharmacies would dispense Exjade and provide related services.

D. EPASS was administered by the LASH Group ("LASH"), a third-party vendor under contract with Novartis. Doctors who prescribed Exjade submitted a patient registration form and the prescription to LASH for fulfillment. Those prescriptions were distributed among the three EPASS pharmacies.

E. Within the EPASS network, certain of the prescriptions were directed to a particular pharmacy based on insurance requirements or physician preference. The remaining prescriptions received by EPASS were not designated for a particular pharmacy by insurers or physicians. The distribution of the prescriptions for those patients (the "undesignated patients") among the three EPASS pharmacies was made at the direction of Novartis, which initially allocated the undesignated patients among the three SPs evenly in a round-robin fashion. During the 2006 to 2012 period, undesignated patients accounted for up to approximately 50% of all Exjade prescriptions submitted to EPASS.

F. Novartis knew that Exjade patient referrals had economic value to the EPASS SPs. Specifically, Novartis was aware that more Exjade patient referrals led to more dispensing fees, and, typically, additional rebates for the EPASS SPs and higher sales revenues.

G. During all relevant times, nearly all of the Exjade prescriptions dispensed to patients by the EPASS SPs were shipped by mail. For refills, the EPASS SP called patients (or their caregivers) to obtain consent and, if the patients agreed to order the refills, dispensed refill shipments of Exjade. While a physician had prescribed such a refill, the EPASS SPs required patient consent before they could ship a refill to an Exjade patient.

H. Pursuant to their contracts with Novartis, the EPASS SPs collected data on the reasons that patients stopped ordering Exjade refills and provided such data to LASH on a regular basis.

I. In 2005 and 2006, Novartis submitted Exjade promotional materials to FDA for review. FDA stated that these promotional materials should not

imply that Exjade had been shown to be effective for preventing multi-organ damage. The FDA also stated that these promotional materials should indicate that further studies were being performed to determine whether taking Exjade provided long-term benefits and/or presented long-term risks.

J. From at least 2006, Novartis maintained an ethics and compliance policy (the "E&C Policy") that applied to all its employees and associates. That policy stated that Novartis was required to comply with the federal Anti-Kickback Statute ("AKS"). The E&C Policy also stated that the AKS "makes it a criminal offense to, among other things, knowingly and willfully offer ... any 'remuneration' in exchange for, or to induce the ... recommendation of, any item or service for which payment may be made under Medicare [or] Medicaid."

K. By 2007, the discontinuation data that the EPASS SPs submitted to LASH showed that physicians' choices to discontinue Exjade therapy and the side effects of Exjade therapy were common reasons reported by Exjade patients for stopping their ordering of refills.

L. In April 2007, Novartis updated the warnings section of the Exjade package insert to add warnings concerning renal failures and cytopenias. In December 2007, Novartis further updated the warnings and post-marketing experience sections of the Exjade package insert to add information concerning hepatic failures.

M. By January 2007, Exjade sales in the United States were below Novartis's internal budgeted sales target due to, among other reasons, lower than anticipated refill rates. One Novartis internal analysis stated, among other things, that, by continuing to allocate the same number of undesignated patients to BioScrip as to Accredo, Novartis would lose $3,200 in sales per Exjade patient or over $2.7 million in Exjade sales per year.

N. At a February 7, 2007 meeting, Novartis managers told BioScrip executives that the level of refill rates and other adherence metrics for BioScrip's Exjade patients were below the levels achieved by Accredo and US Bioservices. Novartis told BioScrip that it was willing to give BioScrip an opportunity to try to improve its performance. Novartis also indicated to BioScrip that, if BioScrip did not improve its performance, Novartis would terminate its Exjade distribution relationship with BioScrip or reduce the number of undesignated patient assigned to BioScrip.

O. At a February 15, 2007 meeting at Novartis's office in New Jersey, BioScrip executives presented BioScrip's improvement plan to Novartis, which involved implementing "tactics to show improved compliance and persistency rates within 45 days". As part of this plan, BioScrip informed Novartis that BioScrip would initiate a patient recovery program to encourage patients who had stopped ordering Exjade refills to resume

ordering. BioScrip also told Novartis that it would assign employees to discuss the "importance of continuation of therapy" with Exjade patients. More specifically, according to its presentation, BioScrip told Novartis that BioScrip would tell patients that they "should [] continue taking Exjade" because "undetected or untreated excess iron kills after inflicting injury to a variety of body organs."

P. In April 2007, Novartis was aware that BioScrip's action plan had led to more than 100 patients restarting the filling of their Exjade prescriptions and had increased the overall refill rate among Exjade patients at BioScrip. On April 12, 2007, Novartis managers notified BioScrip that it would be allowed to remain in EPASS and continue receiving undesignated Exjade patients.

Q. In or about June 2007, Novartis began issuing monthly "Exjade Scorecards" to the EPASS SPs that measured, among other things, the pharmacies' patient "adherence" scores. Novartis calculated the adherence score in the Exjade Scorecards based on how long Exjade patients continued to order refills after their initial prescription. In calculating that score, which was used to compare all three EPASS SPs, Novartis excluded patients who were deceased, but did not exclude patients who had been directed to stop therapy by their physicians or who had stopped therapy due to side effects.

R. By the summer of 2007, Novartis's Exjade Scorecards showed that the refill rates among BioScrip's Exjade patients, as reflected in the adherence score, was significantly higher than at Accredo and at US Bioservices. Novartis's internal analysis attributed the higher score at BioScrip to its use of nurses to call Exjade patients. Specifically, at a July 2007 meeting, BioScrip showed Novartis "case studies" of how nurses at BioScrip conducted "interventions" with Exjade patients. In one case study, the BioScrip nurse advised an adult SCD patient that "by not taking Exjade daily, she may experience more frequent relapses," which "may be more serious and less easily resolved," and advised the patient about "the long term effects of iron overload and how important Exjade compliance was to her long term health." In another case study, BioScrip told an MDS patient's spouse that taking "5-10 mins per day to devote to Exjade therapy would have a significant impact on [the patient's] long term health."

S. BioScrip and Novartis managers concluded that nurses were more proficient than pharmacists at developing relationships with Exjade patients and encouraging patients to stay on prescribed Exjade therapy by discussing the consequences of iron overload and how patients could manage side effects. Further, by August 2007, Novartis's internal analysis showed that the difference in refill rates meant that Exjade net sales were between $800 to $2,800 higher for a patient assigned to BioScrip as compared to a patient assigned to Accredo or US Bioservices.

T. Starting in August 2007, Novartis indicated to US Bioservices and then Accredo that Novartis was dissatisfied with their performance in terms of their adherence scores in the Exjade Scorecards. To increase these adherence scores, Novartis pushed US Bioservices and Accredo to implement adherence improvement plans that involved assigning nurses to call patients and encourage them to stay on Exjade prescriptions. Novartis also told US Bioservices and Accredo that, if those pharmacies did not increase their adherence scores, Novartis would reduce the number of undesignated patients allocated to those pharmacies.

U. At a meeting in December 2007, US Bioservices managers told Novartis that US Bioservices had initiated a nurse program in which nurses were provided with scripts for discussing Exjade therapy with patients over the phone and encouraging them to refill their prescriptions. A presentation shared with Novartis at that meeting included a sample discussion between a US Bioservices nurse and the parent of a pediatric SCD patient in which the nurse stated that "it is important for [the child] to take his Exjade every day. Exjade is used to remove excess iron from the blood. A lot of iron in the blood can cause [the child] to not grow as tall as he could and when he grows up, the iron in his blood could prevent him from having kids."

V. In January 2008, Accredo also provided Novartis with the call template that the nurse at Accredo would follow in making calls to Exjade patients. That call template directed the nurse at Accredo to tell patients that compliance with Exjade therapy regimen is extremely important and that, if untreated, iron overload could result in arthritis, liver or heart problems, high blood sugar, persistent abdominal pain, severe fatigue, and skin discoloration. With regard to adverse reactions, Accredo's 2008 Exjade call template directed the nurse to ask what side effects, if any, the patient was experiencing, but did not specifically direct the nurse to discuss the risks of renal impairment or hepatic impairment.

W. In the first half of 2008, Novartis managers told Accredo that Accredo's performance on the adherence metric in the Exjade Scorecards was below Novartis's expectations. Novartis also indicated that, if Accredo's adherence score did not improve, it could receive fewer undesignated patients.

X. In 2008 and 2009, Novartis implemented an incentive program for the EPASS SPs that included two components. First, Novartis offered additional rebates, which were called "Paying for Performance" within Novartis, to the pharmacies if they met quarterly shipment goals that Novartis had set based on its Exjade sales targets. Second, beginning in January 2009, Novartis implemented a system for allocating undesignated patients among the EPASS SPs based on the adherence scores in the Exjade Scorecards. Specifically, Novartis would allocate a higher percentage of undesignated patients to the EPASS SP with the top adherence score in the Exjade Scorecards and allocate fewer undesignated

patients to the other two pharmacies. Novartis was aware that the EPASS SPs undertook efforts to increase the number of prescribed Exjade refills that their patients ordered.

Y. Specifically, from January 2009 to March 2012, Novartis directed LASH to allocate the undesignated patients to the EPASS SPs based on the adherence scores in the Exjade Scorecards. For example, in the first half of 2009, BioScrip received 60% of all undesignated patients because it had the highest adherence score in late 2008, while Accredo and US Bioservices each received 20% of such patients. Similarly, after Accredo obtained the highest adherence score in 2010, it received 60% or more of all undesignated patients in 2011, and BioScrip and US Bioservices each received 20% or less of such patients. Novartis was aware that, upon receiving these undesignated patients, the EPASS SPs as a general practice dispensed Exjade to the patients. Novartis was aware that (i) these patients included Medicare and Medicaid beneficiaries, (ii) the EPASS SPs as a general practice billed Medicare and Medicaid for the Exjade dispensed to such beneficiaries, (iii) the EPASS SPs billed and received millions of dollars in reimbursements from Medicare and Medicaid and (iv) Novartis obtained at least $20 million in net proceeds for the Exjade dispensed to these beneficiaries.

Z. In January 2010, a "black box warning" was added to the Exjade package insert to provide additional warning concerning the risk of renal impairment, hepatic impairment, and gastrointestinal hemorrhage. Novartis sent a letter to all physicians who prescribe Exjade to notify them of the label change. In addition, members of Novartis's clinical team advised and trained the SPs on the black box warning. Novartis did not, however, request that the EPASS SPs revise their call scripts to require their nurses to discuss the risks of renal impairment, hepatic impairment, or gastrointestinal hemorrhage with Exjade patients.

AA. Between 2008 and March 2012, Novartis and the EPASS SPs executed a series of amendments to their EPASS contracts. Neither the original agreements from 2005 nor any of the amendments specified the basis for determining the volume of undesignated patients that the pharmacies would receive.

BB. In or about March 2012, Novartis notified the EPASS SPs that, starting in April 2012, Novartis would stop basing the number of undesignated patients allocated to those pharmacies on the adherence score in the Exjade Scorecards. In April 2012, Accredo stopped assigning nurses to call Exjade patients to discuss their Exjade therapy.

b. Novartis admits, acknowledges, and accepts responsibility for the following facts relating to the Myfortic claims:

A. In 2004, the FDA approved Myfortic, a Novartis-manufactured immunosuppressant, to prevent organ rejection in kidney transplant patients. Myfortic's competitor drug was CellCept, another brand name drug that was marketed by Roche, and, beginning in 2009, generic versions of CellCept.

B. Novartis offered discounts and market share rebates to certain SPs that dispensed Myfortic. The written agreements between Novartis and those specialty pharmacies specified the market share thresholds necessary for the pharmacies to earn rebates on Myfortic sales. Those agreements did not refer to any action that the pharmacies contemplated taking to increase Myfortic's market share.

C. At various times, including while negotiating Myfortic discounts and rebates, Novartis personnel and certain specialty pharmacies discussed specific steps the pharmacies could take to increase Myfortic's market share and potentially earn a higher rebate.

D. In late 2010, Novartis and Kilgore's Medical Pharmacy in Columbia, Missouri discussed amending Kilgore's Myfortic rebate contract. In late 2010 and continuing into early 2011, Novartis's personnel also had discussions with Kilgore's staff about Kilgore's contacting physicians regarding a potential interaction between Cellcept (or generic CellCept) and proton pump inhibitors ("PPIs"). In 2011, and after Novartis and Kilgore's executed an amended Myfortic rebate contract, Kilgore's contacted physicians about the potential interaction and suggested that they prescribe Myfortic to certain patients who were taking CellCept/generic CellCept and a PPI.

E. In July 2011, after the owner of Transcript Pharmacy in Flowood, Mississippi, contacted Novartis to request a Myfortic rebate contract, an account manager at Novartis met with Transcript's owner. Transcript's owner offered to contact transplant physicians to inform them about the interaction between CellCept (or generic CellCept) and PPIs, and to suggest that physicians prescribe Myfortic to those patients. Subsequently, in August 2011, Novartis and Transcript executed a Myfortic rebate agreement.

3. Novartis agrees to make the following payments: (i) a payment of $286,870,245.98 (the "Settlement Amount"), plus interest, which shall be compounded annually at the following rates: (a) a rate of 2% (two percent) accruing from September 2, 2015, to the date this Stipulation is signed by the Settling Parties, and (b) a rate of 0.5% (one-half percent) accruing from the day after the date this Stipulation is signed by the Settling Parties to the date of

payment; and (ii) a payment of $20 million (the "Forfeiture Amount") as money subject to forfeiture under 18 U.S.C. § 981(a)(1)(C).

a. No later than fourteen (14) business days after the latter of the entry by the Court of (i) this Stipulation and (ii) the Forfeiture Order (as defined below in Paragraph 12(d)), Novartis shall pay the Settlement Amount and all interest accrued thereon pursuant to written wire instructions to be provided by the United States.

b. No later than ten (10) days after the Effective Date, Novartis shall pay the Forfeiture Amount pursuant to written wire instructions to be provided by the United States.

4. Subject to the exceptions in Paragraph 7 below (concerning excluded claims), conditioned upon Novartis's full and timely payment of the Settlement Amount, including interest, pursuant to paragraph 3.a, the United States, on behalf of itself, its officers, agencies and departments, releases Novartis and its current and former officers, directors, employees, assigns, attorneys, agents and corporate parents and subsidiaries from any civil or administrative monetary claim the United States has under the FCA, the Civil Monetary Penalties Laws (42 U.S.C. § 1320a-7a), the Program Fraud Civil Remedies Act (31 U.S.C. §§ 3801-3812), and the common law or equitable theories of fraud, unjust enrichment and payment by mistake for the Covered Conduct.

5. Subject to the exceptions in Paragraph 7 below (concerning excluded claims), conditioned upon Novartis's full and timely payment of the Forfeiture Amount, and the entry of the Forfeiture Order by the Court, the United States, on behalf of itself, its officers, agencies and departments, releases any claim the United States has under 18 U.S.C. § 981(a)(1) for the Covered Conduct.

6. In consideration of the obligations of Novartis in this Stipulation and the Addendum to the Corporate Integrity Agreement entered into between the Office of Inspector General,

Department of Health and Human Services ("OIG-HHS") and Novartis, conditioned upon Novartis' full payment of the Settlement Amount plus interest to the United States pursuant to paragraph 3.a, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Novartis under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Novartis from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7, below.

7. Notwithstanding the releases given in Paragraphs 4, 5, and 6 of this Stipulation, or any other term of this Stipulation, the following claims of the United States are specifically reserved and are not released by this Stipulation:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as expressly stated in this Stipulation, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct; and

e. Any liability based on obligations created by this Stipulation.

8. Novartis waives and shall not assert any defenses it may have to any federal criminal prosecution or federal administrative action relating to the Covered Conduct that may

be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Stipulation bars a remedy sought in such federal criminal prosecution or federal administrative action.

9. Novartis fully and finally releases the United States, and its agencies, officers, employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Novartis has asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. Novartis releases the Relator, and his heirs, attorneys, agents, successors, and assigns, from any claims related to the Relator's allegations in this Action.

11. The Relator, for himself and his heirs, successors, attorneys, agents, and assigns, releases Novartis, and all of its current and former officers, directors, employees, assigns, attorneys, agents, and corporate parents and subsidiaries, from any and all manner of claims, proceedings, liens, and causes of action of any kind or description that the Relator has against Novartis related to the Relator's allegations in this Action, including but not limited to all claims related to Exjade, Myfortic, TOBI, TOBI Podhaler, Tasigna and Gleevec. Provided, however, that, neither the Relator's release in this paragraph nor any other term of this Stipulation affects in any manner any claim of the United States against Novartis or any other person or entity except to the extent that such claim is expressly released by the United States in Paragraphs 4, 5 or 6 above. Further provided that nothing in this Stipulation releases or shall be deemed to release Relator's claims for his reasonable expenses and attorneys' fees and costs from Novartis pursuant to 31 U.S.C. § 3730(d) and analogous provisions in state law. Relator and Novartis

have separately resolved the foregoing claims for reasonable expenses and attorney's fees and costs, and have reached a separate agreement under which those claims are released. Pursuant to 31 U.S.C. § 3730(b)(1), the United States consents to Relator's settlement and dismissal of the Action.

12. Novartis agrees as follows:

a. Novartis agrees that the Forfeiture Amount represents a substitute *res* for $20 million in net proceeds obtained by Novartis as a result of the conduct described in the facts set forth in paragraph 2 (the "Admissions") of this Stipulation, and that the Forfeiture Amount is subject to civil forfeiture to the United States. Novartis further agrees that this Stipulation shall be attached and incorporated into a civil forfeiture complaint that will be filed against the Forfeiture Amount in the United States District Court for the Southern District of New York. Novartis releases any and all claims it may have to such funds.

b. Novartis expressly waives all constitutional and statutory challenges in any manner to any forfeiture carried out in accordance with this Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. Novartis also waives service of the civil forfeiture complaint and consents to *in rem* jurisdiction as to the Forfeiture Amount. Novartis further agrees to the entry of a Final Order of Forfeiture against the Forfeiture Amount.

c. Upon approval of this Stipulation, Novartis shall release any and all claims it may have to the Forfeiture Amount and execute such documents necessary to accomplish forfeiture of the funds. Novartis agrees that it will not file a claim with any Court or otherwise contest the civil forfeiture of the Forfeiture Amount and will not assist a third party in asserting any claim to the Forfeiture Amount. Novartis certifies that the funds used to pay the Forfeiture Amount are not the subject of any lien, security agreement, or other encumbrance. Transferring encumbered funds or failing to pass clean title to these funds in any way will be considered a breach of this Stipulation.

d. Novartis and the United States understand that the Stipulation and forfeiture of the Forfeiture Amount ("Forfeiture Order") must be approved by the United States District Court. If the Court declines to approve this Stipulation or the Forfeiture Order for any reason, the United States and Novartis are released from any obligation imposed upon them by this Stipulation, this Stipulation shall be null and void, and the United States shall not premise any action against Novartis upon any admissions or acknowledgments contained herein, including the Admissions.

e. Novartis agrees that the Forfeiture Amount shall be treated as a penalty paid to the United States government for tax purposes. Novartis agrees that it will not claim, assert, or apply for a tax deduction or tax credit with regard to any federal, state, local or foreign tax for the Forfeiture Amount.

13. Nothing in paragraph 12 (regarding the Forfeiture Amount) or any other provision of this Stipulation constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

14. The Relator shall not object to this Stipulation and agrees and confirms, pursuant to 31 U.S.C. § 3730(c)(2)(B), that the terms of this Stipulation are fair, adequate, and reasonable under all the circumstances. Relator further agrees to waive and release any claim he may have asserted to any portion of the Forfeiture Amount.

15. The Settlement Amount and Forfeiture Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary, or any federal or state payer, related to the Covered Conduct; and Novartis agrees not to resubmit to any Medicare carrier or intermediary or any federal or state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

16. Novartis shall be in default of this Stipulation if it fails to pay the Settlement

Amount and/or the Forfeiture Amount as set forth in Paragraph 3. The United States will provide written notice of any default, to be sent by e-mail and first-class mail to the counsel for Novartis identified in Paragraph 25. In the event of default, the entire remaining unpaid balance shall be immediately due and payable by Novartis, and interest shall accrue at the rate of 12% per annum compounded daily on the remaining unpaid principal balance, beginning seven (7) business days after delivery of the notice of default. If the remaining unpaid balance, with all accrued interest, is not paid in full within seven (7) business days following delivery of the notice of default, Novartis shall agree to entry of a consent judgment in favor of the United States against Novartis in the amount of the unpaid balance (including interest), and the United States, at its option, may (a) rescind this Stipulation and such consent judgment and assert claims against Novartis for the Covered Conduct; (b) seek specific performance of the Stipulation; (c) offset the remaining unpaid balance (including interest) from any amounts due and owing Novartis at the time of default by any department, agency, or agent of the United States; or (d) exercise any other rights granted by law, or under the terms of this Stipulation, or recognizable at common law or in equity. Novartis shall not contest any offset imposed or any collection action undertaken by the United States pursuant to this paragraph, either administratively or in any Federal or State court. In addition, Novartis shall pay the United States all reasonable costs of collection and enforcement under this paragraph, including attorneys' fees and expenses. In the event that the United States opts to rescind this Stipulation, Novartis shall not plead, argue, or otherwise raise any defense under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that relate to the Covered Conduct.

17. Notwithstanding any provision herein, if the United States District Court declines to approve this Stipulation or the Forfeiture Order, this Stipulation shall be deemed rescinded and

vacated and (i) in the event payment of the Forfeiture Amount was made by Novartis pursuant to Paragraph 3.b, the United States shall direct the Forfeiture Amount to be returned to Novartis; (ii) the United States shall have the right to reinstate the Complaint; and (iii) upon reinstatement of this action, the Parties shall have the right to complete all fact and expert discovery remaining as of September 2, 2015.

18. Novartis agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Novartis, its present or former officers, employees, and agents in connection with:

(1) the matters covered by this Stipulation;

(2) the United States' civil investigation of the Covered Conduct;

(3) the investigation, defense, and corrective actions undertaken by Novartis in response to the United States' civil investigation of the Covered Conduct (including attorney's fees);

(4) the negotiation and performance of this Stipulation;

(5) the payments Novartis makes to the United States pursuant to this Stipulation and any payments that Novartis may make to Relator, including costs and attorneys' fees; and

(6) the negotiation of, and obligations undertaken pursuant to any integrity agreement relating to the Covered Conduct with OIG-HHS to (i) retain an independent review organization to perform annual reviews required by any such integrity agreement, and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees

Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in this Paragraph (*i.e.*, Paragraph 18(a)(6)) that may apply to the obligations undertaken pursuant to any such integrity agreement affects the status of costs that are not allowable based on any other authority applicable to Novartis.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Novartis, and Novartis shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Novartis or any of its agencies or departments to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Novartis further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Novartis or any of its agencies or departments, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Novartis agrees that the United States, at a minimum, shall be entitled to recoup from Novartis any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment. The United States reserves its rights to disagree with any calculations submitted by Novartis or any of its rights to audit, examine, or re-examine Novartis's books and records to determine that

no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph, and to disagree with any calculations submitted by Novartis or any of its agencies or departments concerning any Unallowable Costs included in payments previously sought by Novartis, or the effect of any such Unallowable Costs on the amount of such payments.

19. Except as expressly provided to the contrary in this Stipulation, this Stipulation is intended to be for the benefit of the Settling Parties only. The Settling Parties do not release any claims against any other person or entity.

20. Novartis agrees that it waives and shall not seek payment of any of the health care billings covered by this Stipulation from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims submitted in connection with the Covered Conduct.

21. This Stipulation is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Stipulation is the United States District Court for the Southern District of New York. For purposes of construing this Stipulation, it shall be deemed to have been drafted by the Settling Parties, and shall not, therefore, be construed against any Settling Party for that reason in any subsequent dispute.

22. Each of the Settling Parties shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Stipulation; provided, however, that nothing in this Stipulation releases or shall be deemed to release Relator's claims for his reasonable expenses and attorneys' fees and costs from Novartis pursuant to 31 U.S.C. § 3730(d) and analogous provisions in state law. Relator and Novartis have separately resolved the foregoing claims for reasonable expenses and attorneys' fees and costs, and have reached a separate agreement under which those claims are released.

23. The undersigned counsel and other signatories represent and warrant that they are

fully authorized to execute this Stipulation on behalf of the persons and entities indicated below.

24. This Stipulation may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Stipulation. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Stipulation.

25. Any notice pursuant to this Stipulation shall be in writing and shall, unless expressly provided otherwise herein, be delivered by express courier and by e-mail transmission, followed by postage-prepaid mail, to the following representatives:

TO THE UNITED STATES:

Li Yu
Rebecca C. Martin
David J. Kennedy
Jeffrey K. Powell
Peter M. Aronoff
Assistant United States Attorneys
Southern District of New York
86 Chambers Street, 3rd Floor
New York, NY 10007
E-mail: Li.Yu@usdoj.gov
Rebecca.Martin@usdoj.gov
Jeffrey.Powell@usdoj.gov
David.Kennedy@usdoj.gov
Peter.Aronoff@usdoj.gov

TO THE RELATOR:

Shelley Slade, Esq.
Vogel, Slade & Goldstein, LLP
1718 Connecticut Ave., N.W., 7th Floor
Washington, D.C. 20009
E-mail: SSlade@vsg-law.com

Arun Subramanian, Esq.
Susman Godfrey LLP
560 Lexington Ave, 15th Fl.
New York, NY 10022
E-mail: asubramanian@SusmanGodfrey.com
TO NOVARTIS:

Evan R. Chesler, Esq.
Rachel G. Skaistis, Esq.
Benjamin Gruenstein, Esq.
Cravath, Swaine, & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019
Email: echesler@cravath.com
rskaistis@cravath.com
bgruenstein@cravath.com

26. The effective date of this Stipulation is the date upon which this Stipulation is entered by the Court (the "Effective Date").

27. This stipulation does not resolve the relator's claim under 31 U.S.C. § 3730(d) for a percentage of the Settlement Amount, and the relator and the United States will request upon the filing of this Stipulation that the Court retain jurisdiction over such claim unless and until resolved through settlement or judgment.

28. Novartis, having truthfully admitted the facts set forth in Paragraph 2 (the "Admissions"), agrees that it shall not take any action or make any public statements contradicting or denying, directly or indirectly, the Admissions or its other representations or agreements in this Stipulation. Consistent with this provision, Novartis may raise defenses and/or assert affirmative claims and defenses in any proceedings brought by private and/or public parties as long as doing so does not contradict the Admissions or such representations or agreements.

29. This Stipulation constitutes the complete agreement between the Settling Parties.

This Stipulation may not be amended except by written consent of the Settling Parties.

For the United States:

Dated: November 18, 2015

PREET BHARARA
United States Attorney

By: _____
LI YU
REBECCA C. MARTIN
DAVID J. KENNEDY
JEFFREY K. POWELL
PETER M. ARONOFF
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007

Dated: November ___, 2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

By: _____
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of the Inspector General

For Novartis:

Dated: November 18, 2015

CRAVATH, SWAINE, & MOORE LLP

By: _____
EVAN R. CHESLER, ESQ.
RACHEL G. SKAISTIS, ESQ.
BENJAMIN GRUENSTEIN, ESQ.
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019

NOVARTIS PHARMACEUTICALS CORPORATION

By: _____
CHRISTI SHAW
President

29. This Stipulation constitutes the complete agreement between the Settling Parties. This Stipulation may not be amended except by written consent of the Settling Parties.

For the United States:

Dated: November ___, 2015

PREET BHARARA
United States Attorney

By: _____
LI YU
REBECCA C. MARTIN
DAVID J. KENNEDY
JEFFREY K. POWELL
PETER M. ARONOFF
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, New York 10007

Dated: November 18th, 2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES

By: Robert K. DeConti
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of the Inspector General

For Novartis:

Dated: November ___, 2015

CRAVATH, SWAINE, & MOORE LLP

By: _____
EVAN R. CHESLER, ESQ.
RACHEL G. SKAISTIS, ESQ.
BENJAMIN GRUENSTEIN, ESQ.
Worldwide Plaza
825 Eighth Avenue
New York, New York 10019

NOVARTIS PHARMACEUTICALS CORPORATION

By: _____
CHRISTI SHAW
President

For the Relator:

Dated: November 18, 2015

VOGEL, SLADE & GOLDSTEIN, LLP

By: Shelley R. Slade
SHELLEY R. SLADE, ESQ.

SUSMAN GODFREY LLP

By: _____
ARUN SUBRAMANIAN, ESQ.

David Kester
DAVID KESTER

SO ORDERED:

HON. COLLEEN MCMAHON
UNITED STATES DISTRICT JUDGE

Dated: 11/20/2015