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.