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What Comes Next? Against the Backdrop of the Yates Memo, Novartis Announces a \$390M Healthcare Settlement

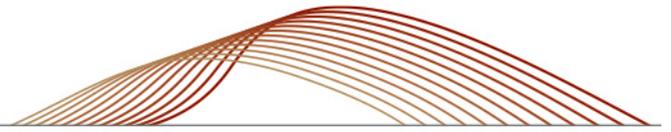
By [Gary F. Giampetruzzi](#), [Terra L. Reynolds](#) & [Mor Wetzler](#)

During an analyst call on October 27, 2015, Novartis AG's CEO Joe Jimenez announced that its U.S. affiliate, Novartis Pharmaceuticals Corporation ("Novartis" or the "Company") reached a settlement in principle under which it will pay \$390 million to the U.S. Department of Justice ("DOJ") and certain states to resolve civil claims that the company induced specialty pharmacies to boost prescriptions for Novartis drugs by paying kickbacks in the form of rebates.¹ The claims against Novartis stemmed from a whistleblower lawsuit brought by a former Novartis employee in which the DOJ and multiple states intervened in January 2014.² The DOJ had twice amended its complaint, and was seeking up to \$3.35 billion in damages and fines.³ In a rarity for large, multinational pharmaceutical companies in the U.S. health care enforcement context, Novartis had been scheduled to proceed to trial on November 2, 2015 in federal court in the Southern District of New York.⁴ This settlement, if consummated, serves as yet another reminder of the continued enforcement focus—civil as well as criminal—on the pharmaceutical industry in the United States, and sends the clear warning that both pharmacies and pharmaceutical benefits managers ("PBMs") are squarely in the enforcement crosshairs.

The Government's Case Against Novartis

This would not be the first foray into the world of U.S. healthcare enforcement for Novartis. On September 30, 2010, the Company entered into an agreement with the DOJ under which it agreed to pay \$422.5 million to resolve criminal and civil liability stemming from its off-label promotion of certain drugs and payment of kickbacks to healthcare professionals.⁵ At the time, Novartis also signed a five-year Corporate Integrity Agreement ("CIA") with the Department of Health and Human Services Office of Inspector General ("HHS-OIG") under which it agreed to implement additional compliance-related measures, including additional auditing, training, education, reporting, and disclosures.⁶

In April 2013, the DOJ intervened in a *qui tam* lawsuit and filed a civil false claims complaint in *United States, ex rel., et al. v. Novartis Pharmaceuticals Corporation*, 11 CV 8196 (S.D.N.Y.), resulting in the matter at hand.⁷ At the time, Preet Bharara, U.S. Attorney for the Southern District of New York, characterized Novartis as "a repeat offender, having settled healthcare fraud charges based on kickbacks less than three years ago."⁸

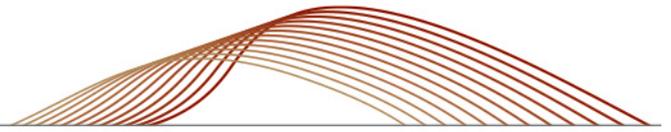


In its initial complaint, the DOJ alleged that Novartis gave “kickbacks, in the form of rebates and discounts, to 20 or more pharmacies in exchange for their switching transplant patients from competitor drugs to N[ovartis’] drug, Myfortic,” a treatment to prevent organ rejection by transplant recipients, causing Medicare and Medicaid to issue “tens of millions of dollars in reimbursements based on false, kickback-tainted claims.”⁹ The DOJ subsequently twice amended its complaint against Novartis to include a separate product, Exjade, a medicine used for reducing excess iron in patients who undergo blood transfusions, and some of the specialty pharmacies with which Novartis had partnered.¹⁰ The government claims that Novartis referred patients and paid kickbacks, in the form of rebates, to specialty pharmacies in an effort to get those pharmacies to recommend the drugs to patients and thereby increase sales of those drugs.¹¹

With respect to Myfortic, Novartis allegedly provided rebates to pharmacies that it determined were able to “grow the [Myfortic] business” by switching patients to Myfortic, and it then offered incentives to those pharmacies that “commit[ed] to convert patients to Myfortic.”¹² Prior to launching Exjade, Novartis established an exclusive distribution system, called EPASS, which would process and fulfill nearly all prescriptions, including three pharmacies and a data vendor that would process incoming prescriptions and allocate the patients among the three EPASS pharmacies.¹³ Six pharmacies sought membership in EPASS, and Novartis selected the three pharmacies, including BioScrip and Accredo, based on factors including the “key” criterion of the number of Medicare and Medicaid patients served by those pharmacies.¹⁴

According to the DOJ, under a “Paying for Performance” system implemented by Novartis in 2007, in exchange for more patient referrals and higher rebates from Novartis, the pharmacies implemented a “clinical counseling” and “education” program to encourage patients to order more refills.¹⁵ Novartis records show that the objective of these nurse-led programs was “to increase sales by obtaining more refill orders and, thus, enable Novartis to achieve its National Exjade Sale Target.”¹⁶ Also as part of the EPASS program, Novartis kept “Exjade Scorecards” measuring “adherence scores,” or how long patients ordered refills.¹⁷ Novartis’ adherence scores measured refills regardless of whether a patient’s doctor had stopped the patient’s therapy.¹⁸ Pharmacies with high adherence scores (refill rates) received higher per-shipment rebates and more patient referrals.¹⁹ In 2008, Novartis offered additional “performance rebates” based on the number of Exjade orders that the pharmacies shipped to patients each quarter.²⁰

The DOJ’s complaint also focused on the all-important factor of potential patient harm. The DOJ alleges that, in an effort to improve adherence scores, including on the monthly scorecards, the pharmacies’ counseling and education programs did not inform patients of the products’ serious, life-threatening side effects, such as kidney failure and gastrointestinal hemorrhage. Moreover, the DOJ alleges that Novartis knew the pharmacies were pressuring patients to order refills and giving patients “biased information that emphasized the benefits of getting refills while understating the severity of the side effects.”²¹ For example, Novartis purportedly approved BioScrip’s Exjade talking points, which indicated regarding side effects that Exjade could “cause some discomfort initially,” but that such discomfort “usually resolves over time.”²² The talking points did not include that, as the FDA-approved package insert indicated, Exjade treatment had been linked to a “lengthy list of severe side effects” including kidney failure, which was fatal in some patients, and GI ulceration and hemorrhage.²³ Novartis also allegedly withheld warnings added to the Exjade label, including the January 2010 “blackbox warning” from BioScrip, even when BioScrip explicitly asked about this safety information.²⁴ The DOJ contends that Novartis knew the pharmacy personnel calling patients “lacked the requisite clinical guidance and training or the relevant patient health information” to offer advice regarding the



side effects,²⁵ and the patient information system used by BioScrip did not track data needed for BioScrip's Exjade team to advise patients about continued use of the product.²⁶

Two of the pharmacies (BioScrip and Accredo) at the heart of the DOJ's case against Novartis had already entered into civil settlements with the states and the DOJ, likely making the Novartis defense more challenging. BioScrip settled in January 2014 for \$15 million, while Accredo settled in May 2015 for \$60 million.²⁷ These pharmacies' settlements included extensive factual admissions elaborating on the DOJ's allegations against Novartis.²⁸ The DOJ alleged that the arrangements described above caused pharmacies to submit false claims to federal healthcare programs (Medicare and Medicaid) that were tainted by kickbacks, "causing the programs to pay tens of millions of dollars in reimbursements that should not have been paid."²⁹ The DOJ's complaint asserted that Novartis engaged in some of the foregoing conduct when the Company had "additional compliance obligations" under the CIA it entered in September 2010.³⁰

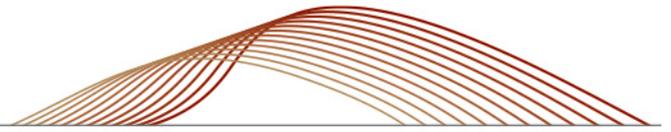
Five Key Takeaways from the Prospective Settlement

Novartis' prospective settlement was reached against the backdrop of more than six years of concentrated enforcement activity by the DOJ against pharmaceutical companies. In May 2009, the DOJ and the Department of Health and Human Services (HHS) created the Health Care Fraud Prevention and Enforcement Action Team (HEAT) dedicated to fighting health care fraud.³¹ A review of DOJ enforcement activity between January 2009 and September 2015 reveals that during those years, the DOJ entered into settlements with pharmaceutical companies under which those companies agreed to pay, in aggregate, more than approximately \$9.5 billion to resolve civil cases and approximately \$5.3 billion in criminal fines and forfeiture orders to resolve criminal cases relating to kickback and off-label allegations and more than approximately \$1 billion to resolve civil cases involving drug pricing and drug safety. In announcing yet another pharmaceutical settlement with Warner Chilcott on October 29, 2015, which followed the announcement of the Novartis settlement by just two days, Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Justice Department's Civil Division stated that the DOJ "is committed to . . . ensuring that financial arrangements in the healthcare marketplace comply with the law. The Department will continue to hold companies and responsible individuals accountable when they use improper incentives . . . to promote their products."³²

In a world of continued commercial growth and increased focus on compliance risks outside of the United States, the Novartis settlement and underlying allegations serve as a reminder of the need to remain vigilant on the domestic front. In doing so, companies throughout the pharmaceutical industry should consider the following key takeaways from the Settlement:

Takeaway 1 – Pharmacies and Pharmacy Benefit Managers Are in Focus

Novartis' prospective settlement reflects the DOJ's more recent focus on the relationships that pharmaceutical companies have with pharmacies and pharmacy benefit managers (PBMs). For example, on February 11, 2015, a pharmaceutical manufacturer entered into a settlement with the DOJ under which it agreed to pay \$7.9 million to resolve claims that it paid kickbacks, in the form of price concessions on certain drugs, to a PBM, in exchange for the PBM maintaining a separate drug's "sole and exclusive" status on certain formularies maintained by the pharmacy benefit manager and through other marketing activities related to those formularies.³³ In announcing the settlement, Acting Assistant Attorney General Joyce R. Branda of the DOJ Civil Division stated, "We will continue to pursue pharmaceutical companies that pay kickbacks to pharmacy benefit managers. . . . Hidden financial agreements between drug manufacturers and pharmacy benefit managers can improperly



influence which drugs are available to patients and the price paid for drugs.”³⁴ The DOJ is not alone in its focus. In addition to having its agents serve as a critical member of investigative teams examining pharmaceutical companies, the HHS-OIG has further focused on the relationships between pharmaceutical companies and pharmacies by addressing “Direct to Consumer” (DTC) marketing programs at least three times in 2014 in its workplan, report, and special announcement bulletin, and issuing Advisory Opinions in 2014 and 2015 that touched upon the relationships between pharmaceutical companies and pharmacies.³⁵

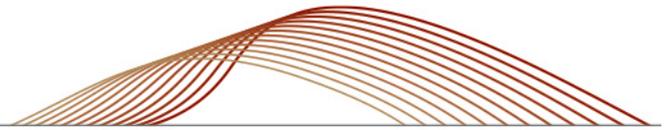
Takeaway 2 – SDNY Is Gaining Prominence in Healthcare Enforcement

The prospective settlement between Novartis and the DOJ also reflects the increased role of the United States Attorney’s Office for the Southern District of New York in the DOJ’s enforcement efforts against pharmaceutical companies. While the United States Attorney’s Offices for the District of Massachusetts and the Eastern District of Pennsylvania have traditionally led much of the DOJ’s enforcement efforts against pharmaceutical companies, on March 31, 2010, Preet Bharara, the United States Attorney for the Southern District of New York, announced the formation of the Civil Frauds Unit to “combat large-scale and sophisticated financial frauds, including . . . pharmaceutical fraud.”³⁶ U.S. Attorney Bharara explained that more than two dozen civil and criminal prosecutors would be tasked to investigate and prosecute financial fraud.³⁷ Three years later, U.S. Attorney Bharara announced the DOJ’s intervention in two *qui tam* lawsuits and filing of two civil lawsuits against Novartis in the Southern District of New York, and now this widely renowned office has brought home this \$390M resolution.

Takeaway 3 – Be Careful What You Say, Even After a Resolution Has Been Announced

Novartis’ announcement of the prospective settlement followed years of litigation in the Southern District of New York, and came only a week before the company was scheduled to proceed to trial. In press reports regarding the prospective settlement with the DOJ, Novartis CEO Joe Jimenez was quoted as stating, “We’re not admitting liability, it’s something we just believe we want to put behind us and that’s why we’ve reached an agreement and settlement in principle.”³⁸ Reports further quoted Jimenez as describing the rebates Novartis provided to its specialty pharmacies as being “quite common”—designed to incentivize specialty pharmacies to ensure that patients completed a course of medicine.³⁹ “We continue to maintain that specialty pharmacies must continue to play a role in ensuring patient adherence,” he said. “How that’s going to play out as to whether we change our behavior or not remains to be seen.”⁴⁰

The press reports of the remarks made by Novartis CEO Joe Jimenez in announcing the resolution may have caused the Company more issues. How those remarks were received by the government is unclear, and how they could be used in the future, such as in increasingly common follow-on civil litigation cannot be known at this time. Following the press reports, though, Novartis issued a “clarification” press release regarding the announcement of the settlement in principle.⁴¹ The Company referred to media coverage that “did not accurately reflect our position and the seriousness of the Company’s commitment to working with the government to ensure our behaviors and interactions with specialty pharmacies meet the highest ethical standards.”⁴² The Company emphasized that it will make detailed admissions of fact concerning the Government’s allegations, and that the company did not intend to suggest that it is “not addressing the Government’s concerns or the particular issues on which the litigation focused.”⁴³



Takeaway 4 – Novartis’ Exposure Under the CIA

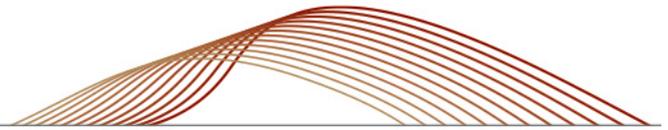
Novartis’ announcement of its prospective settlement with the DOJ comes just barely five years after its last settlement with the Department on September 30, 2010, when the company signed a five-year Corporate Integrity Agreement (CIA).⁴⁴ Under the fairly standard terms of the CIA, Novartis could be excluded from federal health care programs, including Medicare and Medicaid, for material breaches of the agreement and subject to monetary penalties for less significant breaches.⁴⁵ As the final terms of the settlement have not been announced, the impact of Novartis’ prospective settlement with the DOJ on its liability under the CIA is unclear. However, according to Novartis’ SEC Form 6-K, filed on October 27, 2015, “[f]inalization of the settlement is contingent upon the negotiation and execution of mutually acceptable written agreements with the United States Department of Justice, the Office of Inspector General of the US Department of Health & Human Services (including corporate integrity obligations), the states and the relator.”⁴⁶ As such, it appears that the two sides are working through this issue.

Takeaway 5 – The Yates Memorandum, Warner Chilcott, and Individual Corporate Wrongdoers

The announcement of the prospective Novartis settlement rests against the backdrop of the DOJ’s September 9, 2015 Yates Memorandum, which set forth policies on how the Department should investigate and prosecute individual corporate wrongdoers in the context of corporate investigations.⁴⁷ The DOJ recently demonstrated its commitment to hold both companies and individual corporate wrongdoers accountable. On October 29, 2015, the U.S. Attorney’s Office for the District of Massachusetts announced the indictment of a former Warner Chilcott president with conspiring to pay kickbacks to physicians to induce them to prescribe the company’s drugs.⁴⁸ That same day, the DOJ announced Warner Chilcott’s agreement to pay \$125 million to resolve its criminal and civil liability arising from the company’s illegal marketing of certain drugs.⁴⁹ In announcing the indictment and Warner Chilcott settlement, U.S. Attorney Carmen Ortiz stated, “Today’s enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud.”⁵⁰

For a company under government investigation and seeking cooperation credit, the Yates Memorandum states that the company “must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the D[OJ] all facts relating to that misconduct.”⁵¹ Company counsel should therefore work to ensure that the relevant parties (company counsel and the government) have a mutual understanding around what that means and how that bears on the nature and scope of the internal investigation. In the *qui tam* and civil complaint underlying the Novartis case, there were several allegations of improper and arguably criminal conduct regarding individuals at the Company. It of course remains to be seen whether the prosecutors here, as was just the case with the former Warner Chilcott executive, will seek to hold any individuals criminally responsible, and again demonstrate that the Yates Memorandum is more than another policy statement.

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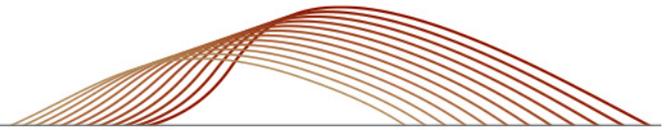
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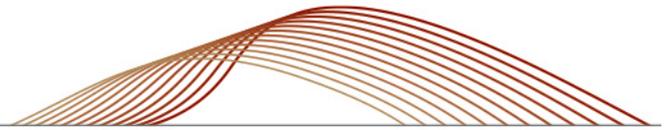
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- ¹ Denise Roland and John Letzing, "Novartis Profit Hurt by U.S. Settlement: Swiss drug company settled claims that it used rebates to get specialty pharmacies to increase prescriptions," *The Wall Street Journal*, October 27, 2015, available at <http://www.wsj.com/articles/novartis-profit-hurt-by-u-s-settlement-1445928106>.
 - ² *United States, ex rel. Kester, et al. v. Novartis Pharmaceuticals Corporation*, 11 CV 8196 (S.D.N.Y.), Dkt. No. 15 ("DOJ Complaint"); Dkt. No. 253 ("Kester Third Amended Complaint").
 - ³ *Id.*, Dkt. No. 472. The DOJ sought up to \$1.52 billion in damages, which represents triple the amount of money that Medicare and Medicaid paid for the drugs as a result of kickbacks between 2004 and 2013, as well as up to \$1.83 billion in fines—or \$5,500 to \$11,000 for each of more than 166,000 allegedly false claims that were submitted for reimbursement to the healthcare programs.
 - ⁴ *Id.*, Dkt. No. 491.
 - ⁵ "Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-label Promotion and Kickback Allegations," September 30, 2010, available at <http://www.justice.gov/opa/pr/novartis-pharmaceuticals-corp-pay-more-420-million-resolve-label-promotion-and-kickback>.
 - ⁶ "Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation," September 30, 2015, available at http://www.pharma.us.novartis.com/assets/pdf/n_int_056605.pdf.
 - ⁷ That same month, the DOJ also intervened in a separate *qui tam* lawsuit against Novartis in which the DOJ alleges that Novartis paid kickbacks, in the form of speaker fees for programs that were often nothing more than mere social occasions and lavish meals, to doctors as a means of inducing them to prescribe Novartis drugs that were reimbursed by federal health care programs. *United States ex rel. Bilotta v. Novartis Pharmaceuticals Corporation et al.*, 11-CV-0071 (S.D.N.Y.). The case is currently pending with fact and expert discovery due to close in 2016. *Id.*, Dkt. No. 131.
 - ⁸ "Manhattan U.S. Attorney Files Healthcare Fraud Lawsuit Against Novartis Pharmaceuticals Corp. For Orchestrating a Multi-Million Dollar Prescription Drug Kickback Scheme," April 23, 2013, available at <http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-files-healthcare-fraud-lawsuit-against-novartis-pharmaceuticals>.
 - ⁹ "Manhattan U.S. Attorney Files Healthcare Fraud Lawsuit Against Novartis Pharmaceuticals Corp. For Orchestrating A Multi-Million Dollar Prescription Drug Kickback Scheme," April 23, 2013, available at <http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-files-healthcare-fraud-lawsuit-against-novartis-pharmaceuticals>. 11 CV 8196, DOJ Complaint.
 - ¹⁰ See 11 CV 8196 (S.D.N.Y.), Dkt. Nos. 62 (DOJ First Amended Complaint adding BioScrip as defendant), 231 ("DOJ Second Amended Complaint"), and 420 (intervening in the Kester Third Amended Complaint as to Accredo).
 - ¹¹ *Id.*
 - ¹² DOJ Second Amended Complaint ¶¶ 142, 144.
 - ¹³ DOJ Second Amended Complaint ¶ 241.
 - ¹⁴ Kester Third Amended Complaint ¶ 109; DOJ Second Amended Complaint ¶ 124.
 - ¹⁵ DOJ Second Amended Complaint ¶ 221. See also Kester Third Amended Complaint ¶ 121.
 - ¹⁶ DOJ Second Amended Complaint ¶ 226 (internal quotations omitted).
 - ¹⁷ DOJ Second Amended Complaint ¶ 262.
 - ¹⁸ DOJ Second Amended Complaint ¶ 286.
 - ¹⁹ DOJ Second Amended Complaint ¶ 269-70.
 - ²⁰ DOJ Second Amended Complaint ¶ 271.

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- ²¹ DOJ Second Amended Complaint ¶¶ 284, 290.
- ²² DOJ Second Amended Complaint ¶ 291. If patients reported “side effects [] such as diarrhea or vomiting,” they were told “that they should continue taking Exjade and wait for the side effects to pass.” *Id.*
- ²³ DOJ Second Amended Complaint ¶¶ 227, 291.
- ²⁴ DOJ Second Amended Complaint ¶¶ 292-95.
- ²⁵ DOJ Second Amended Complaint ¶ 284.
- ²⁶ DOJ Second Amended Complaint ¶ 296.
- ²⁷ See 11 CV 8196 (S.D.N.Y.), Dkt. No. 41 (BioScrip Stipulation and Order of Settlement and Dismissal; DOJ press release available at: <http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-simultaneously-files-additional-healthcare-fraud-claims-against>) (“BioScrip Settlement”); Dkt. No. 418 (Accredo Stipulation and Order of Settlement and Dismissal; DOJ press release available at: <http://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-60-million-civil-fraud-settlement-accredo-health-group>) (“Accredo Settlement”). Both pharmacies were defendants in the relator’s original complaint. Around the time of the Accredo Settlement, the DOJ intervened in the Kester Third Amended Complaint as to Novartis regarding allegations involving Accredo. See Dkt. No. 420. Claims against a third pharmacy, CVS Caremark, were dismissed by agreement of the parties on October 6, 2015. Dkt. Nos. 502-03.
- ²⁸ See 11 CV 8196 (S.D.N.Y.) Dkt. No. 41; Dkt. No. 418.
- ²⁹ DOJ Second Amended Complaint ¶ 1.
- ³⁰ DOJ Second Amended Complaint ¶¶ 135-39. These requirements included ensuring that Novartis’ “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.” DOJ Second Amended Complaint ¶ 137.
- ³¹ “HEAT: A Year of Tackling Health Care Fraud,” August 27, 2010, available at <http://www.justice.gov/opa/blog/heat-year-tackling-health-care-fraud>.
- ³² “Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations,” October 29, 2015, available at <http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>.
- ³³ “AstraZeneca to Pay \$7.9 Million to Resolve Kickback Allegations,” available at <http://www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations>.
- ³⁴ *Id.*
- ³⁵ See <http://oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf> at 31 (OIG “will identify the safeguards that pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D.”); <http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf> at 22 (Controls put in place by manufacturers and their third party vendors “may not reliably prevent coupons from being processed for drugs paid for by Part D.”); http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf at 3 (The “offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law.”). See also HHS OIG Ad. Op. 14-05, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2014/AdvOpn14-05.pdf> at 1 (OIG would not impose administrative sanctions on a pharmaceutical manufacturer related to its “direct-to-patient product sales program that allows eligible patients to purchase one of the manufacturer’s brand-name products for a fixed cash price from an online retail pharmacy vendor outside of any applicable prescription drug insurance benefit.”); HHS OIG Ad. Op. 15-11, available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-11.pdf> at 7. OIG would not impose administrative sanctions on pharmaceutical manufacturers related to their bridge program under which patients, including Medicare Part D beneficiaries, receive a temporary free supply of a drug through a specialty pharmacy while awaiting coverage determinations from respective health insurers, in part because the patient “cannot obtain future prescription refills from the Pharmacy. Further, because the Pharmacy’s dispensing is limited to certain client programs, it is unlikely that the Arrangement would induce the patient to obtain other federally reimbursable drugs from the Pharmacy.”).
- ³⁶ United States Attorney, Southern District of New York, “United States Attorney Preet Bharara Announces Formation of Civil Frauds Unit,” March 31, 2010, available at <http://www.justice.gov/archive/usao/nys/pressreleases/March10/civilfraudsunitpr.pdf>.
- ³⁷ *Id.*
- ³⁸ See, e.g., D. Roland and J. Letzing, “Novartis Profit Hurt by U.S. Settlement,” *Wall Street Journal*, Oct. 27, 2015, available at <http://www.wsj.com/articles/novartis-profit-hurt-by-u-s-settlement-1445928106>.



³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ Press release available at <http://www.us.novartis.com/info/newsroom/news-description.jsp?id=137235>.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ “Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-label Promotion and Kickback Allegations,” September 30, 2010, available at <http://www.justice.gov/opa/pr/novartis-pharmaceuticals-corp-pay-more-420-million-resolve-label-promotion-and-kickback>.

⁴⁵ “Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis Pharmaceuticals Corporation,” September 30, 2015 at 52-57, available at http://www.pharma.us.novartis.com/assets/pdf/n_int_056605.pdf.

⁴⁶ Novartis AG. Report of Foreign Private Issuer (Form 6-K) (Oct. 27, 2015), Exh. 99.2 Interim Financial Report, at 48, available at <http://www.sec.gov/Archives/edgar/data/1114448/000137036815000084/0001370368-15-000084-index.htm>.

⁴⁷ Yates Memorandum available at <http://www.justice.gov/dag/file/769036/download>.

⁴⁸ “Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations,” October 29, 2015, available at <http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ Yates Memorandum at 3.