PG Bulletin
September 17, 2020

DOJ's $678 Million Novartis Settlement for False Claims Act and Anti-Kickback Statute Violations—Changing Big Pharma's Expectations for Compliance Programs

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On July 1, 2020, amidst the chaos of the global COVID-19 pandemic, the Acting United States Attorney for the Southern District of New York, Audrey Strauss, announced that the United States settled a civil fraud lawsuit against Novartis Pharmaceuticals Corporation.

According to the Department of Justice's (DOJ's) press release, the settlement agreement requires Novartis to pay a total of $678,000,000. As part of the settlement details, $591,442,008.92 will be paid to the United States as damages under the False Claims Act, 31 U.S.C. § 3729, $38,406,717.42 will be paid to the United States as proceeds of violations of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), and $48,151,273.66 will be paid to various states' Medicaid Programs. The settlement also requires Novartis to amend its business practice arrangements by entering into a five-year Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG).

Novartis entered into two settlement agreements on June 29, 2020 and June 30, 2020, respectively. The June 29, 2020 Stipulation and Order of Settlement and Dismissal (Stipulation) entered between the government and Novartis addresses allegations for sham speaker fees. The June 30, 2020 Settlement Agreement (Settlement) between the government and Novartis addresses illegal co-pay allegations. The $678,000,000 settlement includes the total amount for both these allegations.

Illegal Co-Pays and False Claims Act Violations

The June 30 Settlement involves the prescription drugs Gilenya, and Affinitor. The U.S. Food and Drug Administration (FDA) approved Gilenya for treatment of Multiple Sclerosis and Affinitor for treatment of advanced Renal Cell Carcinoma. The FDA subsequently approved Affinitor for a new use for treatment for Progressive Neuroendocrine Tumors of Pancreatic Origin (PNET).

In the Settlement, the government alleged, among other things, that Novartis caused false claims to be submitted to the Medicare program for payment of the drugs, and used various foundations with Patient Assistance Programs (PAPs) as "conduits to pay kickbacks to Medicare patients." PAPs provide financial assistance or free prescription drugs to low income individuals. The OIG has issued multiple advisory opinions and

guidance regarding PAPs that describe the government's general concerns with pharmaceutical manufacturers who sponsor the targeted use of funds for specific drugs. When patients receive drugs through Medicare's prescription drug program (Part D), they are often required to participate in cost-sharing initiatives that take the form of co-payments, deductibles, or coinsurance, collectively referred to as "co-pays." Under the Anti-Kickback Statute, a health care provider's payment of any remuneration, including co-pays, could be suspect because it can induce patients to use a particular service, treatment, or drug that they would not use in the absence of such remuneration. By paying these co-pays, Novartis allegedly caused the submission of false claims to the government's Medicare program.

The government accused Novartis of funding various foundations' PAPs that would pay Medicare beneficiaries' co-pays when they were prescribed a Novartis-brand drug for the purpose of inducing them to use Novartis' drugs for treatment. According to the Settlement, with respect to Gilenya, Novartis allegedly donated funds to a foundation to coincide with a time period when 364 individuals who were already receiving free drugs through one of Novartis' free drug programs would subsequently become eligible for Medicare and need assistance with Gilenya's co-pays.

With respect to Affinitor, the government said that Novartis knew that the drug was only approved by the FDA for second-line treatment purposes, which generally means that drugs like Affinitor are only intended to be used when certain first-line treatment drugs were not effective for treatment. The government said that Novartis conditioned its donation of funds to another foundation upon the requirement that the foundation modify its eligibility criteria for the use of such funds to ensure that it could not be used on any first-line treatments. Amending the eligibility criteria guaranteed that a substantial portion of the co-pays could only be used to subsidize second-line treatment drugs like Affinitor. Further, after Affinitor was approved by the FDA for treatment of PNET, Novartis purportedly asked a different foundation to open up an Affinitor co-pay assistance fund for treatment of PNET, even though Novartis knew that the FDA had approved a competing drug to treat PNET. The foundation subsequently launched a PNET fund to exclusively pay for patients who used Affinitor. Under the terms of that fund, patients who sought assistance with co-pays for the competitor drug would not qualify for any co-pay assistance. Novartis must now pay a total of $51,250,000 to the government to settle these claims.

Speaker Fees and Anti-Kickback Violations

The concurrent settlement for speaker fees involves unlawful promotional practices by Novartis' Cardiovascular Division. The initial complaint was brought to the government in January 2011 by a qui tam whistleblower, Oswald Bilotta, a former Novartis sales representative. The complaint alleged, among other things, that Novartis illegally induced physicians to write prescriptions for three blood pressure drugs—Lotrel, Valturna, and Starlix—through a wide array of kickback and unlawful marketing

schemes. The government intervened and filed an amended complaint in 2013. The allegations cover a nine-year period from January 1, 2002 through November 21, 2011.

The allegations in the Stipulation include Novartis' violation of the False Claims Act and the Anti-Kickback Statute by paying doctors remuneration to prescribe various cardiovascular drugs through the mechanism of speaker program honoraria and related misconduct. Specifically, the government alleged that Novartis paid remuneration in the form of "cash, meals, alcohol, hotels, travel, entertainment, and honoraria fees" to health care practitioners who spoke at or attended Novartis speaker events, roundtables, speaker training meetings, or lunch-in-learns to induce them to prescribe multiple cardiovascular drugs including Lotrel, Valturna, Starlix.

Novartis admitted and accepted responsibility for much of its conduct. In particular, and according to the Stipulation, during the nine-year period, Novartis had an ethics and compliance policy that required compliance with the Anti-Kickback Statute and outlined the basic tenets of the statute, including prohibitions against any remuneration to induce the recommendation of any item or services reimbursed under Medicare or Medicaid. The Stipulation also states that Novartis signed a PhRMA Code in 2002, an industry-wide marketing code governing the pharmaceutical industry's relationships with health care practitioners. Novartis' internal compliance policies were allegedly adopted in response to this Code and specifically provide that meals should only be provided to doctors in connection with "[i]nformational presentations and discussions" that "provide scientific or educational value," and that are "modest," "occur[red] in a venue and manner conducive to informational communication," and are provided "on [no] more than an occasional basis." However, Novartis admitted in the Stipulation that some of its business practices were inconsistent with its own policies.

Novartis admitted that it used sales information to target high-prescribing doctors to become paid speakers at events to induce them to continue to prescribe more of Novartis' prescription drugs. In one instance, over the course of the nine-year period, Novartis paid a physician over $320,000 in honorarium who wrote more than 8,000 prescriptions for the drugs covered under the federal health care programs.

Additionally, Novartis' sales representatives arranged thousands of dinners without any real agenda or purpose. Most of the dinners occurred at some of the country's most expensive restaurants and steakhouses and other venues, like wineries and golf resorts, which Novartis admitted were not conducive to having any meaningful medical discussions. In addition, Novartis' internal compliance policies set a $125 per person limit for food and alcohol, but more than 12,000 dinners and speaker events held throughout the relevant period exceeded those limits. On one occasion, Novartis spent $680 per person for a dinner at Danton's Gulf Coast Seafood Restaurant in Houston, TX. Moreover, Novartis held many speaker events where sales representatives did not require the speakers who received the honorarium to speak at all, or allowed speakers to click through presentation slides in "a matter of minutes," and also paid some doctors honoraria for speaker events that allegedly never occurred. Furthermore, Novartis'

employees falsified records to make it appear that the amount of money that was spent on doctors through the honoraria and speaker programs was less than what was actually spent.

The Stipulation, and the five-year CIA, are particularly significant because Novartis entered into an earlier settlement agreement (2010 Settlement) and associated CIA in 2010 (2010 CIA) as a result of similar allegations. These included claims that Novartis promoted the sale and use of Trileptal, a drug approved by the FDA for seizures, for uses that were not approved by the FDA (i.e., off-label uses) and were not medically accepted indications for which the federal and state Medicaid programs provided coverage. In the 2010 Settlement, the government also claimed that Novartis provided illegal remuneration through speaker programs, advisory boards, and gifts, including entertainment, travel, and meals, to health care professionals to induce them to promote and prescribe other hypertension treatment drugs (e.g., Diovan, Zelnorm and Sandostatin), not included as part of the 2020 Settlement Agreement. Novartis agreed to pay a $237,500,000 settlement amount in compromise of the 2010 disputed claims.

Amended Corporate Integrity Agreement

As part of the Stipulation for speaker fees, HHS-OIG further extended Novartis' 2010 CIA. The amended CIA makes significant changes to Novartis' speaker programs. Any programs that engage a non-Novartis employee as a speaker or presenter on behalf of Novartis must be held virtually, and the external speaker cannot be in the same location as any audience member. Additionally, the events cannot occur in restaurant venues, and alcohol cannot be served or available for purchase at the events. The timeline for holding an external speaker event is limited to 18 months. This timeline prohibits Novartis from engaging speakers and paying any honoraria for events that occur any later than 18 months from the time a new drug is approved by the FDA and reimbursed by federal health care programs, or the FDA approves a new indication for use of a previously approved drug. Lastly, the total cap on Novartis' honoraria per speaker for each product and its indication is a maximum of $100,000, excluding travel and accommodation expenses.

The amended provisions in the CIA suggest that HHS-OIG may begin to implement stricter measures to mitigate any perceived risks of fraud and abuse. The Novartis Stipulation and amended CIA should also prompt compliance officers, executive leadership, and operational managers to take a closer look at their compliance programs to ensure that accurate staffing levels are maintained throughout the compliance period and that regular field audits are conducted for all speaker programs. Lastly, compliance officers should promote and encourage transparent communications so that compliance issues/concerns are raised promptly and addressed quickly. For example, in the Stipulation, the government noted that Novartis' chief compliance officer verbally discouraged employees from documenting events in writing during training presentations. As such, any communications discouraging full written disclosure may be scrutinized by government investigators and construed as complicit actions in a fraud

investigation. These steps could collectively improve a compliance program's effectiveness and help to abate fraud and abuse.