

Blog Post

Novartis' Simultaneous Settlements Break Records

July 20, 2020

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Novartis Pharmaceuticals Corporation (Novartis) has started July with significant settlements, putting two different fraud and abuse matters behind them. In what has been identified as the largest settlement of an Anti-Kickback Statute lawsuit brought by a whistleblower pursuant to the False Claims Act's (FCA) *qui tam* provision, Novartis, a pharmaceutical company based in East Hanover, New Jersey, has agreed to pay \$678 million to settle a lawsuit alleging that it made improper payments to physicians through sham physician education programs to encourage them to prescribe its medications from 2002-2011. In a separate but simultaneous settlement, Novartis paid \$51.25 million to settle claims that it improperly paid patients' co-pays through charitable patient assistance programs (PAPs).

Alleged Physician Kickback Scheme

According to a July 1 press release from the Department of Justice (DOJ), Novartis resolved a lawsuit originally filed by a whistleblower in 2011 in the Southern District of New York, *U.S. ex rel. Biolatta v. Novartis*, in which the federal government ultimately intervened and litigated. The lawsuit alleged that Novartis paid kickbacks to physicians through tens of thousands of sham speaker programs with alleged educational content to induce the physicians to prescribe ten different medications

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that Novartis sold for the treatment of diabetes and cardiovascular conditions. Novartis paid physicians honoraria to purportedly compensate them for delivering lectures regarding those Novartis medications. The federal government asserted that many of these speaker programs were merely social events at expensive restaurants devoid of substantive content, if they occurred at all. Novartis allegedly targeted high-volume prescribers to be paid “speakers” and then pressured them to prescribe more Novartis medications to their patients.

Audrey Strauss, Acting U.S. Attorney for the Southern District of New York, described these inducement activities as “nothing more than bribes” and emphasized their impact on healthcare decision-making and costs:

For more than a decade, Novartis spent hundreds of millions of dollars on so-called speaker programs, including speaking fees, exorbitant meals, and top-shelf alcohol that were nothing more than bribes to get doctors across the country to prescribe Novartis’s drugs. Giving these cash payments and other lavish goodies interferes with the duty of doctors to choose the best treatment for their patients and increase drug costs for everyone. This office will continue to be vigilant in cracking down on kickbacks, however they may be dressed up, throughout the pharmaceutical industry.

To resolve these kickback allegations, Novartis agreed to pay \$591,442,008 back to Federal healthcare programs and to pay \$48,151,273 to settle state Medicaid claims. Novartis also agreed to forfeit an additional \$38.4 million pursuant to the Civil Asset Forfeiture Statute. The whistleblower’s attorney stated that Novartis’ \$678 million settlement of this lawsuit is the largest payment ever to settle allegations of Anti-Kickback Statute violations brought by a whistleblower.

Although the amount of the recovery to be awarded to the whistleblower is yet to be determined, the *qui tam* statute permits him to recover between 15% and 25% of the settlement's proceeds. 31 U.S.C. § 3730(d). In a recent interview with NBC News, the whistleblower said that he initially became concerned about fraud because the speaker programs often addressed Novartis medications that were older and well-known, obviating the need for educational events. He alleged that when he brought his concerns about fraud to a manager at Novartis, he was told, "I'm sure we could find something on you." As part of the government's investigation, the whistleblower reportedly secretly recorded himself giving cash payments to two physicians and receiving verbal confirmation from four other doctors that they had received remuneration from him previously. The whistleblower's attorney indicated that his client could receive as much as \$75 million from the settlement.

Alleged Patient Co-Pay Scheme

In a separate yet simultaneous settlement, Novartis agreed to pay an additional \$51.25 million to settle claims that it allegedly paid patients' co-pays for Novartis' medications through contributions to PAPS from 2010-2013. According to U.S. Attorney for the District of Massachusetts Andrew E. Lelling, Novartis settled claims that it "coordinated with three co-pay foundations to funnel money through the foundations to patients taking Novartis' own drugs." Specifically, the government accused Novartis of using the foundations as "captive" PAPs to specifically pay the co-pays for patients taking two of its medications: Gilenya, which is used to treat relapsing multiple sclerosis, and Afinitor, which is used to treat advanced renal cell carcinoma. U.S. Attorney Lelling underscored the severity of the allegations, "As a result [of the alleged co-pay scheme], the [sic] Novartis' conduct was not 'charitable,' but rather functioned as a kickback scheme that undermined the structure of the Medicare program and illegally subsidized the high

costs of Novartis's drugs at the expense of American taxpayers."

Corporate Integrity Agreements

At the time of the conduct that gave rise to the above-referenced settlements, Novartis was operating under a five-year CIA with the Office of Inspector General of the Department of Health and Human Services (OIG) that was signed in September 29, 2010. That CIA was extended by another five years and amended to include additional obligations on November 19, 2015 when Novartis entered into another settlement with the government. Not surprisingly, as part of these simultaneous settlements, Novartis has agreed to execute a third five-year CIA with the OIG. The CIA Novartis executed on June 30, 2020 supersedes the original CIA and contains very company-specific obligations.

Gregory E. Demske, Chief Counsel to the OIG, explained that pursuant to the CIA, Novartis has agreed, among other things, to limit its paid physician speaker programs to a solely virtual format:

To address Novartis's conduct and the widely-recognized compliance risks associated with paid speaker programs, the CIA requires Novartis to make fundamental changes to its speaker program practices. Under the CIA, Novartis must significantly reduce the number of programs and the number of paid physicians, and can no longer pay for inherently-risky in-person programs.

Specifically, Novartis can have future physician education programs only within the first 18 months after the subject medication's FDA approval, and Novartis' payments to physicians for presenting at such programs are capped at \$10,000 per physician, with a total cap of \$100,000 for each medication or indication.

According to the CIA, Novartis must also implement policies and procedures to support its independence from any patient assistance programs to which it contributes. The CIA requires that Novartis establish an Independent Charitable Co-Pay Foundation (ICCF) Executive Committee to handle essentially all aspects of its contributions to independent charity PAPs. That Committee must operate separately and independently from Novartis' commercial operations, such as its sales and marketing units, and it must establish criteria for donations to PAPs "to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Novartis to patients and does not impermissibly influence patients' drug choices."

Novartis' CEO, Vas Narasimhan, issued a statement in which he emphasized the drug company's changes in management and current compliance culture:

Today's settlements are consistent with Novartis' commitment to resolve and learn from legacy compliance matters. We are a different company today – with new leadership, a stronger culture, and a more comprehensive commitment to ethics embedded at the heart of our company. . . . With these agreements we mark an important milestone on our journey to build trust with society as we continue reimagining medicine to improve and extend lives all around the world.

Novartis' experience demonstrates that entering into a CIA is not the last stage of compliance but only the beginning. Compliance issues can arise even in companies that have already been thoroughly investigated, and companies must continue to be vigilant and respond appropriately to reports of compliance concerns.

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