



United States
Attorney's Office
Southern District of New York

PRESS RELEASE

Acting Manhattan U.S. Attorney Announces \$678 Million Settlement Of Fraud Lawsuit Against Novartis Pharmaceuticals For Operating Sham Speaker Programs Through Which It Paid Over \$100 Million To Doctors To Unlawfully Induce Them To Prescribe Novartis Drugs

Wednesday, July 1, 2020

For Immediate Release

U.S. Attorney's Office, Southern District
of New York

Novartis Admits to Certain Conduct Alleged in the Lawsuit and Agrees to Strict Limitations on Its Ability to Conduct Future Speaker Programs

Audrey Strauss, the Acting United States Attorney for the Southern District of New York, William F. Sweeney Jr., Assistant Director-in-Charge of the New York Office of the Federal Bureau of Investigation ("FBI"), Gregory E. Demske, Chief Counsel to the Inspector General of

the United States Department of Health and Human Services, Office of the Inspector General (“HHS-OIG”), Scott J. Lampert, Special Agent in Charge of HHS-OIG’s New York Regional Office, Leigh-Alistair Barzey, Special Agent in Charge of the Northeast Field Office of the U.S. Department of Defense - Office of Inspector General’s Defense Criminal Investigative Service (“DCIS”), and Christopher Algieri, Special Agent in Charge the Department of Veterans Affairs, Office of Inspector General, Northeast Field Office (“VA OIG”), announced today that the United States has settled a civil fraud lawsuit against NOVARTIS PHARMACEUTICALS CORPORATION (“NOVARTIS”), part of Swiss drug manufacturer Novartis International AG, alleging that NOVARTIS violated the federal False Claims Act and Anti-Kickback Statute by providing doctors with cash payments, recreational outings, lavish meals, and expensive alcohol to induce them to prescribe NOVARTIS cardiovascular and diabetes drugs reimbursed by federal healthcare programs. Specifically, the Government alleged that NOVARTIS organized tens of thousands of sham educational events at high-end restaurants and other venues, paid exorbitant speaker fees to doctors who gave no meaningful presentations, and provided expensive meals and alcohol to doctor attendees and their guests. When those doctors then prescribed NOVARTIS’s cardiovascular and diabetes drugs, federal healthcare programs paid hundreds of millions of dollars in reimbursements for these tainted prescriptions. As part of the settlement, approved today by U.S. District Judge Paul G. Gardephe, NOVARTIS will pay the United States and various States a total of \$678 million. NOVARTIS also made extensive factual admissions in the settlement and agreed to strict limitations on any future speaker programs, including reductions to the amount it may spend on such programs.

Acting U.S. Attorney Audrey Strauss said: “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 increases 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.”

FBI Assistant Director-in-Charge said: “Not only did Novartis incentivize doctors to host these speaking events, reps bribed the doctors to write more prescriptions of the company’s drugs to give Novartis an advantage over competitors within their field. Greed replaced the responsibility the public expects from those who practice medicine, not to mention the potential for an erosion of trust in the pharmaceutical industry as a whole. This conduct was reprehensible and dishonest. Patients and consumers deserve better, and our office will continue to pursue any similar allegations of this kind.”

HHS-OIG Chief Counsel Gregory Demske said: “OIG will continue to work closely with the Department of Justice to investigate and pursue kickbacks regardless of the form they take. 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.”

HHS-OIG Special Agent in Charge Scott J. Lampert said: “The various kickback schemes employed by Novartis threatened the impartiality of medical decision-making and the financial integrity of Medicare and Medicaid. Greed must never play a part in patient care. Along with our law enforcement partners, HHS-OIG will continue to hold pharmaceutical companies accountable when they step over the line to maximize their market share at the expense of taxpayer-funded federal health care programs.”

DCIS Special Agent in Charge Leigh-Alistair Barzey said: “Protecting the integrity of TRICARE, the healthcare system for military members and their dependents, is a top priority for the DCIS. When pharmaceutical corporations offer kickbacks and engage in other fraudulent activity to induce medical professionals to prescribe their products, they undermine the integrity of TRICARE and other healthcare plans. The settlement agreement announced today is the result of a joint effort and demonstrates the DCIS’s ongoing commitment to work with its law enforcement partners and the U.S. Attorney’s Office, to investigate and prosecute companies that seek to profit by engaging in schemes such as those identified in this case.”

VA-OIG Special Agent in Charge Christopher Algieri said: “Kickback schemes undermine our federal healthcare programs, including healthcare benefits administered by the U.S. Department of Veterans Affairs. We will continue to work collaboratively with our law enforcement partners and the U.S. Attorney’s Office to protect the quality of veterans’ healthcare and integrity of VA’s programs.”

In its Complaint in this lawsuit, the Government alleged that between 2002 and 2011 (the “Relevant Period”), NOVARTIS hosted tens of thousands of speaker programs and related events under the guise of providing educational content, when in fact the events served as nothing more than a means to provide bribes to doctors. NOVARTIS paid physicians honoraria, purportedly as compensation for delivering a lecture regarding a NOVARTIS medication, but, as NOVARTIS knew, many of these programs were nothing more than social events held at expensive restaurants, with little or no discussion about the NOVARTIS drugs. Indeed, some of the so-called speaker events never even took place; the speaker was simply paid a fee in order to induce the speaker to prescribe NOVARTIS drugs.

The Government’s complaint further alleged that NOVARTIS sales representatives, on the instruction of their managers, selected high-volume prescribers to serve as the paid “speakers” at these events with the intent to induce them to write more – or keep writing many – NOVARTIS prescriptions. The sales representatives then pressured the speakers to increase their prescriptions of NOVARTIS drugs, and often dropped doctors from the program if they failed to

do so. Further, the Government alleged that this widespread kickback scheme was the result of decisions made by top management at NOVARTIS's North American headquarters in New Jersey.

As part of the settlement, NOVARTIS admitted and accepted responsibility for certain conduct alleged by the Government including the following:

- Some NOVARTIS sales representatives intended the honoraria paid to doctors to be an inducement to these doctors to prescribe more NOVARTIS drugs.
- NOVARTIS paid many high-prescribing doctors tens or hundreds of thousands of dollars in honoraria.
- In thousands of instances, NOVARTIS paid for the same group of doctors, often colleagues or friends, to have dinners together repeatedly. Doctors in these groups would sometimes rotate being the speaker and receiving the honorarium payment.
- NOVARTIS sales representatives hosted programs at some of the most expensive restaurants in the United States, intending to induce the doctors in attendance to continue to write NOVARTIS prescriptions. These restaurants included some of the most high-end restaurants in the country, such as Masa, Daniel, Gramercy Tavern, Il Mulino, Babbo, Peter Luger, Le Bernardin, and Eleven Madison Park in New York City; Charlie Palmer's in Washington, D.C.; Morton's Steakhouse and the Four Seasons in Chicago; Joe's Stone Crab in Miami; Abacus, Nobu, and the Four Seasons in Dallas; Gary Danko in San Francisco; Patina and Matsuhisa in Los Angeles; Grill 225 in South Carolina; and Commander's Palace in New Orleans.
- Throughout the Relevant Period, more than 12,000 speaker programs and roundtables had meal spends that were considerably in excess of the \$125 per person limit set by NOVARTIS's compliance policies.
- For example, in 2008, at a speaker program held at Ruth's Chris Steakhouse in Pikesville, Maryland, NOVARTIS held an event with only one doctor in the audience for the speaker's presentation, at which it spent \$448 per person on food and alcohol, in addition to the \$1,000 honorarium payment provided to the speaker.
- During the Relevant Period, some NOVARTIS sales representatives conducted programs at venues where the focus was on entertainment, including fishing trips, sporting events, wine tastings, and hibachi tables. NOVARTIS conducted hundreds of events at wineries and golf clubs.
- Sales representatives also conducted events at Hooters.
- At many of NOVARTIS's speaker programs, the sales representative hosting the event did not require the speaker, who was being paid an honorarium, to deliver a presentation at all, or allowed the speaker to click through the power point presentation in a matter of minutes. In those instances, the majority of the time was spent socializing and enjoying dinner.

- NOVARTIS in a number of instances paid doctors honoraria for purportedly speaking at events that never took place.
- On Long Island, at least one NOVARTIS sales representative organized fraudulent speaker programs by arranging for a restaurant to create fake receipts to make it appear that a dinner had taken place, and then using the budgeted funds to purchase gift cards that were distributed to high-prescribing doctors. Doctors were then also paid honoraria for “speaking” at these sham events.
- NOVARTIS’s compliance training materials suggested that emails advocating illegal kickbacks were improper in part because they “reflect[] ignorance of the import of written communications, and put[] the Company at risk.” NOVARTIS’s Chief Compliance Officer also stated in training presentations: “If you don’t have to write it, don’t. Consider using the phone.”

Under the settlement, NOVARTIS will pay a total of \$678,000,000, of which (i) \$591,442,008.92 will be paid to the United States as False Claims Act damages, (ii) \$38,406,717.42 will be forfeited to the United States as proceeds of violations of the Anti-Kickback Statute; and (iii) \$48,151,273.66 will be paid to various States.

The settlement also requires NOVARTIS to reform its business practices. Contemporaneously with this settlement, NOVARTIS has entered into a corporate integrity agreement (“CIA”) with HHS-OIG that will significantly curtail the company’s ability to conduct speaker programs going forward, and will dramatically reduce the amount of money that NOVARTIS may spend on such programs. Under the five-year CIA, NOVARTIS speaker programs are only permitted under limited circumstances and must be conducted in a virtual format such as a webinar. The CIA also requires multi-faceted monitoring of NOVARTIS’s operations and obligates company executives and Board members to certify compliance annually with the terms of the CIA. The strict limitations on speaker programs imposed by the CIA are also incorporated into the settlement. The settlement provides procedures for the Government to raise violations of these requirements with the district court.

This matter was initially brought to the Government’s attention by a whistleblower who filed a complaint pursuant to the False Claims Act.

Ms. Strauss praised the investigative work of the FBI, HHS-OIG, and DCIS. She also thanked the Commercial Litigation Branch of the U.S. Department of Justice’s Civil Division in Washington, D.C., and the Office of Counsel to the Inspector General of HHS for their critical assistance in this case.

The case is being handled by the Office’s Civil Frauds Unit. Assistant U.S. Attorneys Jeannette Vargas, Pierre Armand, Mónica Folch, Jacob Lillywhite, Jennifer Jude, and Jacob Bergman are in charge of the case, and Assistant U.S. Attorney Alex Wilson of the Money Laundering and Transnational Criminal Enterprises Unit is responsible for the forfeiture aspects of the case.

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