Lessons From Novartis' $678M Speaker Program Settlement

By **John Bentivoglio, Avia Dunn and Elizabeth Berry** (August 5, 2020, 6:31 PM EDT)

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Novartis Pharmaceuticals Corporation recently agreed to pay $678 million to settle False Claims Act litigation with the U.S. Department of Justice involving one of the most common industry marketing tactics: physician-led speaker programs. The settlement is the largest ever focused on speaker programs.

Beyond the headline-grabbing civil fines and penalties, the settlement includes an extensive corporate integrity agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services that places onerous restrictions on Novartis' use of speaker programs going forward.

Companies conducting similar programs should carefully review the Novartis corporate integrity agreement to benchmark their programs and determine whether additional controls are advisable given the high-risk nature of speaker programs and other sales and marketing activities addressed in the agreement.

Settlement Follows Years of Litigation

Following the filing of the initial qui tam complaint by a Novartis sales representative in 2011, the DOJ intervened approximately two-and-a-half years later in August 2013. Over the course of nearly a decade, the parties engaged in protracted motions practice that culminated in a May 2019 trial date, which was subsequently adjourned.

Novartis ultimately agreed to pay a total of $678 million — with $629.8 million in fines, penalties and forfeiture to the U.S. and $48.1 million to various states — to resolve allegations that Novartis paid health care practitioners, who spoke at or attended Novartis speaker events, roundtables, speaker training meetings or lunch-n-learns to induce them to prescribe Novartis drugs in violation of the Anti-Kickback Statute and FCA.

Although the covered conduct spanned from 2002 to 2011 and involved programs promoting 10 separate Novartis drugs, the DOJ acknowledged that approximately 90% of the events at issue took place prior to 2009. As is typical for civil FCA settlements with the U.S. Attorney's Office for the Southern District of New York, Novartis was required to admit and accept responsibility for certain conduct.

Although the scope of covered conduct included typical areas of DOJ focus in speaker program-related settlements (e.g., number and type of program attendees, nature of venues, falsification of program records), the DOJ expanded the scope of known problematic conduct to place an emphasis on areas that have yet to be fully explored through litigation or settlements.

Budgeting

The DOJ placed a strong emphasis on speaker program budgets, explaining that sales representatives were encouraged to spend their full promotional budget and that their ability to spend the allotted budget was factored into their overall sales performance in annual reviews. Although a violation of company policy should not equate to a violation of the AKS, the settlement included admissions that sales representatives violated company compliance policies by spending more than the allotted per person budget.

Return on Investment

Companies frequently conduct return on investment on attendees. Typically, the DOJ takes issue with return on investment conducted on a speaker's past or future prescriptions. Here, however, the DOJ focused on Novartis' calculation of return on investment based on new prescriptions written by doctor attendees. It is unclear whether DOJ's concern stems only from the fact that numerous prescribers repeatedly attended programs in a short period of time, or if attendee return on investment could be a focus of future investigations.

Compliance Program

The DOJ alleged that Novartis failed to implement a fully effective compliance program, in part, by monitoring only a small number of speaker programs and providing sales representatives advance notice of the upcoming program audit. The settlement agreement did not provide details on how many audits would have been appropriate, nor whether the advance notice undermined the effectiveness of the audits.

Complaints

The DOJ also took issue with the purported lack of adequate compliance resources and dilatory attention provided to complaints, observing that Novartis had a backlog of potential AKS violations that went unaddressed. These admissions underscore the need to ensure that all compliance concerns are investigated and promptly resolved.

Bonuses

The settlement includes a general admission that Novartis incentivized sales personnel with bonuses tied to growth in local market share. Although neither the settlement nor the corporate integrity agreement prohibits such a compensation structure or provides guidance about what the government considers acceptable, use of incentive compensation as a driver of behavior is a consistent area of DOJ focus.

The Corporate Integrity Agreement

As part of the settlement, Novartis[1] and the HHS OIG entered into a corporate integrity agreement to "address Novartis' conduct and the widely-recognized compliance risks associated with paid speaker programs."[2] The corporate integrity agreement sets forth extensive and novel compliance obligations spanning an unprecedented 109 pages with five appendices — perhaps the longest corporate integrity agreement ever.

Although the agreement incorporates virtually all provisions in recent sales and marketing corporate integrity agreements, it also requires "fundamental changes to [Novartis'] speaker program"[3] by restricting the company's ability to engage in such programs. These types of limitations are rarely included in corporate integrity agreements, and emphasize not only the seriousness of the underlying conduct, but the fact that HHS OIG and Novartis have entered into three compliance agreements since 2010.[4]

Novel Speaker Program Restrictions

Perhaps most notably, the corporate integrity agreement imposes strict limits and extensive obligations on Novartis' speaker program. The corporate integrity agreement distinguishes between internal speaker programs (employee health care practitioners) and external speaker programs (non-Novartis employee health care practitioners).

In contrast to traditional speaker programs, Novartis may no longer host speaker programs in restaurant venues or provide alcohol. Moreover, external speaker programs must be conducted in a virtual format, and Novartis may not organize a gathering outside of an individual health care practitioners's institution or office.

Although many companies host speaker programs for years following product release to ensure health care practitioners are well-educated on the product, Novartis' external speaker programs may occur only within 18 months of a newly approved government reimbursed product or indication, although recordings of the virtual programs may be made available during and following the 18-month period. It appears that internal speaker programs may be conducted live.

The corporate integrity agreement also limits the remuneration that can be allocated to a newly approved government reimbursed product or indication: $100,000 in total remuneration across all external speakers and no more than $10,000 to any given speaker.

New Accountability Provisions for Corporate Integrity Agreement Compliance

The FCA agreement incorporates the corporate integrity agreement's external speaker program limitations and provides a separate enforcement mechanism for violations. Under the corporate integrity agreement, a senior Novartis executive must certify to the HHS OIG that, to the best of his or her knowledge, Novartis complied with the requirements relating to external speaker programs.

The certification must include a description of any failures to comply and the associated corrective action. Should HHS OIG determine that Novartis or the certifying official failed to comply with the corporate integrity agreement restrictions, the FCA settlement provides that HHS OIG may refer the alleged violation to the U.S. Attorney's Office for the Southern District of New York to seek injunctive relief against the company and monetary penalties against the certifying official.

Provisions of Note in the Corporate Integrity Agreement

Board Obligations

Generally, corporate integrity agreements impose on boards of directors review and oversight responsibility for matters related to compliance with federal health care programs and FDA requirements. It likewise is not unusual for HHS OIG to require a board to hire an external expert when the parent company is located outside of the U.S. and the corporate integrity agreements imposes board obligations on the U.S. operating or holding company.

In this instance, the board also is required to hire an independent expert to review the effectiveness of the company's compliance program and provide written recommendations for the board to consider as part of its review and oversight responsibilities.

Training

HHS OIG has long required companies entering into corporate integrity agreements to implement mandatory training. Historically, corporate integrity agreements generally required a minimum number of hours of training.

However, HHS OIG appears to have heeded recommendations we outlined in an earlier **Law360 guest article** and permitted Novartis to develop an appropriate training plan, without hour mandates. The corporate integrity agreement requires Novartis to develop a written training plan to ensure the occurrence of at least annual corporate integrity agreement and compliance training. Moreover, Novartis must ensure that board members receive training regarding their corporate governance and compliance review and oversight responsibilities.

Monitoring, Auditing and Oversight

Under the terms of the corporate integrity agreement, Novartis is required to establish monitoring programs for promotional activities and nonpromotional activities. Although monitoring programs are common in sales and marketing corporate integrity agreements, Novartis' corporate integrity agreement includes unique provisions related to speaker selection and ensuring external programs

are restricted to a virtual format.

Although the amount of required audits of promotional activities varies by corporate integrity agreement, the Novartis agreement includes new guideposts for audits of comparable activities: audits of four external speaker programs for each newly approved government reimbursed product or indication; 60 full-day ride-alongs with sales representatives per reporting period; and a records review for five government reimbursed products per reporting period to assess sales activities in the field.

Novartis also is required to conduct audits of at least 60 consultant engagements with health care practitioners and at least 30 medical education grants per reporting period.

Reviews by Independent Review Organizations

Although Novartis is required to engage an independent review organization, nothing in the review procedures affects Novartis' "liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including" the AKS. In effect, this provision seems to preclude Novartis from arguing that compliance with the independent reviews creates a defense, even though the company presumably could still argue that its reasonable reliance on independent reviews negates an intent to violate the law.

Novartis also cannot make any claim of privilege, including work product privilege, relating to information related to the independent review organization engagement. While this is not the first corporate integrity agreement to contain such a provision, it is relatively unique. Historically, HHS OIG has imposed such a provision on entities that previously received an advisory opinion, or that entered into an amendment to the underlying corporate integrity agreement. This suggests that HHS OIG may include the provision when it has reservations regarding previous representations made by the company.

Executive and Employee Recoupment

Some, but not all, corporate integrity agreements impose a requirement that the company implement a financial recoupment program. In addition to the increasingly common executive financial recoupment program triggered upon a determination of significant misconduct, the Novartis corporate integrity agreement includes a second recoupment provision of newer vintage, designed for Novartis associates.

This provision requires Novartis associates to comply with all applicable laws and Novartis policies in order to earn incentive payments. Upon a finding of a material violation, however, incentive grants to associates are rescinded, and any grant already provided must be repaid.

Other Provisions of Note

Novartis recently entered into a separate settlement with the U.S. Attorney's Office for the District of Massachusetts relating to the company's relationships with independent charitable foundations, or ICFs.[5] As is typical for such settlements, the corporate integrity agreement provides guardrails for the going-forward relationship between the company and any ICF and requires Novartis to establish a group independent from the commercial organization to govern its relationship with ICFs.

The corporate integrity agreement also includes requirements related to Novartis' relationships with specialty pharmacies, an apparent hold over from the 2015 addendum. In part, Novartis may not direct, encourage or otherwise offer any financial remuneration to a pharmacy to switch patients to the company's government reimbursed products.

Implications for Other Life Sciences Companies

The Novartis settlement addresses what is arguably the highest risk marketing practice in the life sciences industry: paying health care practitioners, who often prescribe the company's products, to promote those products to other physicians. The DOJ has become adept at investigating such conduct and combining in-depth analyses of speakers and program attendees with documents and testimony that examine the commercial motivations behind the number, content, faculty and

audience of programs.

What specific activities should companies review? Here are some suggestions based on the Novartis settlement and corporate integrity agreement.

Needs Assessments

Companies are increasingly conducting a needs assessment to refine their marketing budgets. This process should be rigorous, well-documented and undergo compliance review to ensure the number of speaker programs conducted is based solely on the need to educate health care practitioners on new products, new indications or other developments requiring updated information on the company's products.

Attendee Credentials

Companies should consider imposing strict limits on the types of health care practitioners and practitioner staff that can attend programs, with a focus on the types of attendees who need the information for a particular product. A one-size-fits-all policy may not provide the tailored inquiry suggested by the settlement papers.

Attendee Frequency

Companies should consider imposing strict limits on the number of how many programs and over what time period within a given geographic area a health care practitioners or a member of a practioner's staff can attend the same or similar programs. In addition to providing written guidelines, companies should consider utilizing automated systems that prevent health care practitioners and/or practitioner staff from registering for the same or similar event during a specified time period.

Field-based Involvement

Companies should consider clearly delineating the role of sales representatives and others who receive incentive compensation based on territory or regional sales or market share targets in selecting speakers and program attendees. Companies should also ensure headquarter-based review of speakers and attendees to ensure compliance with speaker program policies.

Monitoring and Auditing

Companies should consider implementing robust monitoring and auditing programs that look at both individual programs and programs in the aggregate to ensure compliance with speaker and attendee limits.

It is also worth noting that lawyers and compliance professionals should be careful about how they communicate compliance policies to company personnel. It is entirely appropriate to advise personnel to move communications to phone or video communications if that is needed to discuss complicated issues and convey nuance, options and strategies to conduct activities in a compliant manner.

But advising people to avoid putting things in writing — without indicating a legitimate need to do so — can raise prosecutorial eyebrows given the possibility the guidance will be misinterpreted as giving the OK to improper conduct as long that conduct is not documented.

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[1] Novartis Corporation, the U.S. corporate arm of Novartis AG, entered into the CIA. For ease of

reading, Novartis Corporation also is referred to as "Novartis."

[2] "Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians," U.S. Department of Justice, July 1, 2020, https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.

[3] "Acting Manhattan U.S. Attorney Announces $678 Million Settlement of Fraud Lawsuits Against Novartis Pharmaceuticals Corporation For Operating Sham Speaker Programs Though Which It Paid Over $100 Million to Doctors to Unlawfully Induce Them to Prescribe No," U.S. Attorney's Office for the Southern District of New York, July 1, 2020, https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against.

[4] The 2020 CIA superseded and replaced the parties' previous CIA, originally signed in 2010 and extended and modified in 2015.

[5] "Novartis Agrees to Pay Over $51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations," U.S. Attorney's Office for the District of Massachusetts, July 1, 2020, https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay.