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# Enforcement in Life Sciences Series

## Key Cases in 2020 Reflect Emerging DOJ Focus for Pharmaceutical and Medical Device Makers

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### About the Enforcement in Life Sciences Series

Recent settlements between the U.S. Department of Justice (DOJ) and a range of FDA-regulated drug and medical device manufacturers provide a snapshot of the DOJ's enforcement focus.[1] These settlements involve new DOJ theories of liability or new ways of evaluating long-standing industry practices, and may be harbingers of future DOJ enforcement activity. In this six-part series of client alerts, we take an in-depth look at the facts and legal theories in each case or set of cases, discuss what makes each novel, and consider the compliance implications for each. You can find copies of all the client alerts in the series here.

### DOJ Introduces Novel Theories of Liability and Requires Unprecedented Controls in Speaker Program Settlement

In August 2020, Novartis Pharmaceuticals Corporation entered into a $678 million civil settlement agreement with the DOJ to resolve allegations that, as an inducement to prescribe Novartis drugs, the company paid health care practitioners (HCPs) who served as speakers at, or simply attended, Novartis speaker events and other events. As noted in our August 24, 2020, client alert "Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs," the DOJ has developed a skilled approach to investigating speaker programs, and such programs remain among the highest-risk marketing practices in the life sciences industry. Beyond the headline-grabbing civil fines and penalties, the *Novartis* settlement is notable because it includes an extensive corporate integrity agreement (CIA) with the Office of the Inspector General of the Department of Health and Human Services (HHS-OIG).

Unlike many civil settlement agreements, in which settling companies deny liability,[2] the settlement required Novartis to admit responsibility for a lengthy list of acts of

[1] The series will examine the following topics: (i) speaker programs; (ii) off-label and promotional enforcement; (iii) relationships with tech vendors; (iv) FDA interactions during agency inspections; (v) joint promotional programs with physician-customers; and (vi) the first Sunshine Act reporting settlement. This series will not address several novel legal theories that have been introduced in recent opioid settlements, as we believe those theories are unique to the opioid space and not broadly applicable to drug and device makers generally.

[2] In recent years, the U.S. Attorney's Office for the Southern District of New York (which settled the *Novartis* matter), has required that defendants admit certain conduct in connection with civil settlement agreements; this practice is less widespread in other U.S. Attorney's Offices.

misconduct, including novel types of conduct not generally relied upon by the DOJ in prior speaker program enforcement actions. For example, Novartis admitted:

1. sales representatives were encouraged to spend their full speaker program budgets and evaluated on whether they did so in annual reviews;
2. the meal associated with the programs constituted kickbacks for those attendees who attended multiple programs and did not have a professional need to receive the presented information multiple times; and
3. the company conducted a return-on-investment (ROI) analysis for its speaker program attendees.

The DOJ's focus on the money a company spends on attendees, rather than exclusively on the money it spends on speakers, reflects a shift that bears watching. We first saw spending on program attendees emerge as a theory of liability in the 2018 *Abiomed* settlement, where the DOJ's theory of liability was that a company's spending too much money on attendees potentially impaired their medical decision-making. While the DOJ has not asserted that expenditures on attendee meals are kickbacks *per se*, it does seem to believe that tracking the ROI of attendee expenditures may demonstrate that a company believes the money spent on attendee meals, rather than the educational content of the program, is a driver of increased prescribing.

In addition to featuring these more novel areas of focus, the *Novartis* settlement included allegations of wrongdoing similar to those in prior speaker program settlements (*e.g.*, using venues not conducive to educational exchange, presenting programs with little or no educational content, and selecting speakers based on past or likely future prescribing). The DOJ also alleged that company communications suggested that sales representatives should consider using the telephone rather than email when discussing compliance concerns.

Finally, the Novartis CIA imposes novel compliance controls by permitting only two types of speaker programs: (i) external speaker programs, which are conducted by HCPs who are not Novartis employees, and which may only be virtual; and (ii) internal speaker programs, which must be conducted by Novartis employee HCPs, and which may be held live at any time. Further, Novartis' external speaker programs may occur only for 18 months following FDA approval of a product or indication, with recordings continuing to be made available after that time. This limit on the window of time for hosting speaker programs is new, and is worth focus, as many companies have traditionally hosted speaker programs for years following a product's release.

The CIA also imposes stringent limits on the remuneration paid to external HCPs for speaking engagements, setting a cap of $100,000 in total remuneration across all external speakers for each newly approved government-reimbursed product or indication, with no more than $10,000 paid to any single speaker. Thus, speaker fees can only exceed $100,000 if multiple product indications are approved at various points in time or if the product is not government-reimbursed. These limits are much lower than many companies' current benchmarks for speaker program payments.

### Compliance Implications

Underscoring the government's suspicion of speaker programs, the HHS-OIG issued a Special Fraud Alert on speaker programs on November 16, 2020, which highlighted the Anti-Kickback Statute risks of conducting such programs and raised questions regarding common speaker program practices.[3]

The Special Fraud Alert makes clear that HHS-OIG views paying a physician to promote a company's product via a speaker program, particularly when the speaker has prescribed the company's product or can do so in the future, as inherently high-risk. The office categorizes the practice of providing meals and other things of value to prescribing attendees the same way. Given the increasing government scrutiny of such programs, we offer a four-part compliance framework that might be useful to companies when evaluating their programs:

- First, a robust and consistent needs assessment process to evaluate the legitimate business need for speaker programs is an important foundation for making many speaker program decisions. Accordingly, companies should evaluate the rigor of their needs assessment process, including whether the process meaningfully considers the need for speaker programs for each particular product at the particular proposed point in time, including the number and frequency of programs based on product approvals, label expansions or other relevant clinical data.
- Second, companies should ensure that their planned speaker programs are tailored to the legitimate business purpose identified through the needs assessment process. This could include limits on the number and type of programs overall and the number of programs a single attendee can attend, as well as strictly limiting or prohibiting field involvement in the selection of speakers.

[3] See our August 24, 2020, client alert "Novartis' $678 Million Settlement Sets Guideposts for Life Sciences Industry Speaker Programs."

- Third, companies should evaluate and update as necessary the controls in place regarding venues, speaker compensation, meal cost limits and other safeguards to ensure meals and venues are incidental to the educational content and not the primary draw for the attendees.
- Finally, companies should consider using data-driven monitoring and auditing programs — including but not limited to analysis of information generated for Sunshine Act reporting purposes — to ensure strict compliance with program limits.

Companies conducting ROI assessments of speaker programs should carefully consider the need for the analysis and who receives it, and ensure that it severs any link between the provision of remuneration and prescriptions for both program speakers and attendees. Also, companies should review their incentive compensation and performance review metrics to ensure neither incentivizes employees to meet targets or quotas that involve efforts that do not meet a clear and timely educational need.