

The Nucleus: Life Sciences Regulation and Enforcement Updates

May 6, 2025

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

Avia M. Dunn

Partner / Washington, D.C.
202.371.7174
avia.dunn@skadden.com

Maya P. Florence

Partner / Boston
617.573.4805
maya.florence@skadden.com

Richmond Blake

Associate / Washington, D.C.
202.371.7086
richmond.blake@skadden.com

This memorandum is provided by Skadden, Arps, Slate, Meagher & Flom LLP and its affiliates for educational and informational purposes only and is not intended and should not be construed as legal advice. This memorandum is considered advertising under applicable state laws.

One Manhattan West
New York, NY 10001
212.735.3000

500 Boylston St.
Boston, MA 02116
617.573.4800

1440 New York Ave., NW
Washington, DC 20005
202.371.7000

Speaker Program Settlement Highlights Compliance Risks for Life Sciences Companies

On April 29, 2025, the U.S. Attorney's Office for the Southern District of New York (SDNY) announced a \$202 million civil False Claims Act (FCA) settlement with Gilead based on allegations that the company's speaker program violated the Anti-Kickback Statute.¹ While the headline is attention-grabbing, the resolution pertains to historical conduct predating the November 2020 Special Fraud Alert from the U.S. Department of Health and Human Services' Office of Inspector General (HHS-OIG) on speaker programs and bears strong similarities to a number of other speaker program-based settlements over the past five years.

This is the second settlement involving similar allegations since the Trump administration took office. As such, the settlement is perhaps more notable insofar as it serves to remind life sciences companies of the types of speaker program compliance analyses manufacturers may wish to consider performing, and more generally of the importance of maintaining rigorous controls around speaker program activities.

Summary of Resolution

Gilead agreed to pay \$202 million to resolve a nearly decade-old *qui tam* case initially filed by a physician relator who treated patients diagnosed with HIV/AIDS. As is typical for civil FCA settlements with the SDNY, Gilead was required to admit and accept responsibility for certain conduct. According to the settlement papers, between 2011 and 2017 the company paid 548 healthcare providers more than \$23.7 million in the form of honoraria, meals and travel expenses, which the SDNY alleged was intended to induce recipients to prescribe various HIV drugs sold by Gilead. Specifically, the government questioned the educational value of these speaker programs, citing issues such as frequency and type of attendees, cost and location of the venue, amount of alcohol served and the level of commercial influence on speaker selection. Sales personnel also reportedly circumvented per person meal limits by including the cost of food and beverages in charges identified as room fees. Regarding the speakers themselves, the settlement papers state that speakers were nominated by sales personnel, sometimes based on the fact that they were either already high prescribers or had the potential to be; highlight the distance certain speakers traveled to speak at programs at desirable destinations, including in response to speakers' requests to be booked for a program in a particular city; and describe a group of speakers who repeatedly attended each other's programs (along with other attendees).

¹ "U.S. Attorney Announces \$202 Million Settlement With Gilead Sciences For Using Speaker Programs To Pay Kickbacks To Doctors To Induce Them To Prescribe Gilead's Drugs." U.S. Attorney's Office for the Southern District of New York, April 29, 2025.

Speaker Program Settlement Highlights

Compliance Risks for Life Sciences Companies

Takeaways

As noted above, while the SDNY's press release may garner attention, in evaluating the settlement it is important to note that the time period at issue predates the HHS-OIG Special Fraud Alert regarding speaker programs, as well as a number of other speaker program-based FCA settlements alleging conduct of the type addressed in the Special Fraud Alert. At the same time, it is clear that the SDNY's allegations are based upon a review of aggregated speaker program data across years. The settlement therefore serves as a helpful reminder that the government will collect and analyze speaker program-related data to identify trends, and expects companies to do the same and respond accordingly when potentially problematic trends are observed.

Companies that wish to mitigate speaker program-related risk and get ahead of potential whistleblowers should consider implementing, or reinvigorating, in-house reviews of the types of markers that the government often considers in speaker program cases. These include the frequency and types of attendees, venues, per-person event costs, speakers traveling significant distances to participate in events and aggregate honorarium payments made to high prescribers. Specific compliance practices to consider may include:

- Ensuring a noncommercial, headquarters-based review of speakers and attendees to confirm compliance with speaker program policies.
- Clearly delineating the role of sales personnel (or others compensated based upon sales) in selecting speakers and program attendees.
- Implementing and adhering to restrictions on program attendees (both health care practitioners and staff) to ensure attendees have an identifiable need for program content.
- Imposing restrictions on repeat attendance at the same or similar programs.
- Conducting routine speaker compliance training to ensure they are aware of and comply with company expectations.
- Performing unannounced live monitoring of speaker programs, as well as randomized audits of speaker program documentation (contracts, attendee sheets, etc.).
- Consistently imposing discipline for speaker program-related compliance violations, and publicizing such discipline, where appropriate, to deter future missteps.