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New Pharma FCA Settlement Shows Need for Speaker Program Compliance

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On January 24, 2025, the Justice Department announced a large settlement with a life sciences company (Biohaven Pharmaceutical Holding Company Ltd. or Biohaven) that had recently been purchased by Pfizer, Inc. The settlement was sizable and just one in a string of settlements scrutinizing life sciences speaker programs over the last decade. Yet life sciences companies educating health care providers on the clinical benefits of products is still valuable for all—for the life sciences company, the health care provider, and the providers' patients—so the critical question is where the line is drawn between government-compliant educational events and non-compliant ones.

This article seeks to draw that line by (1) analyzing the specific conduct in the recent settlement that the Justice Department contends crossed a compliance line, (2) explaining how life sciences companies and health care providers can install compliance checks to spot potentially non-compliant programs, and (3) emphasizing how critical it is for those acquiring life sciences companies to vet the to-be-acquired company's speaking programs and other physician arrangements.

How Biohaven Crossed a Compliance Line

Speaker programs, when legitimate and properly documented, are fantastic opportunities to foster meaningful discussions of medical devices, drugs, technologies, and other products. But, for decades, wrongdoers sought to mask kickbacks through speaker programs in what came to be known in Department of Health and Human Services Office of Inspector General (OIG) fraud alerts as "sham" speaker programs. These shams often include allegations of speakers getting paid to speak to empty rooms or to sales representatives only. Stories of egregious shams abound from years back and have been a focus of enforcement efforts, including Corporate Integrity Agreements placing guardrails on speaker programs from organizations operating these sham speaker programs.

Yet legitimate educational programs continue to serve an important purpose in health care, and life sciences companies have been careful in more recent years to monitor educational programs to ensure legitimacy and to properly document the educational purpose in order to rebut against later allegations of fraud. Some companies, however, still take risks on speaker programs that draw government attention, highlighting that sham speaker programs are still happening despite the industry shift.

The Biohaven settlement shows an example of the type of conduct that leads to enforcement issues. According to the settlement agreement and the Justice Department's press release announcing the settlement, the company began by identifying high-prescribing physicians of a particular migraine medication and selected only those high-

prescribing physicians to become speakers on the medicine. Furthermore, the company was alleged to have offered repeat programs on the same topic, resulting in no additional educational value. Finally, the company was alleged to have had speakers present on the drug not to health care providers but to the prescribers' spouses and other family members, along with colleagues from the speakers' own medical practices.

In sum, the drug company's speaker program had several indications that it was not being conducted with the purpose of educating providers. Repeated content, a lack of genuinely interested consumers of the educational content, and inviting speakers based on prescribing behavior all signaled to the Justice Department that this speaker program was not seeking to obtain legitimate educational value but instead was designed to channel illegal kickbacks.

Compliance Checks Can Spot Issues and Keep You on the Right Side

In the life sciences industry, companies must have effective compliance programs to identify and eliminate potentially non-compliant speaker events. Educating sales staff on the Anti-Kickback Statute, False Claims Act, and past enforcement in the space is necessary but not sufficient. Life sciences companies must also require documentation on the purpose of the educational event, including the educational gaps that the program is meeting, as well as who is speaking, why the speakers are qualified and chosen, who the audience is, where the event is taking place, and why that location is an appropriate venue for the program. To help mitigate risk, life sciences companies encourage those reports to be checked by compliance professionals to determine whether the event is of legitimate educational value to the health care professionals set to attend the program.

Health care providers also must take steps to vet the activities in which their personnel participate. While most speaker-program enforcement actions are against life sciences companies rather than health care providers, the Anti-Kickback Statute is a two-way statute, allowing enforcement against both the payer and recipient of the kickback. The Justice Department has brought action against physicians (often referred to as key opinion leaders) who receive payments for sham speaker programs in the past and could do so in the future as well. Accordingly, health care provider organizations should monitor payment their physicians receive, whether the program has legitimate educational value, and that the payment they receive for identified services is consistent with fair market value.

The M&A Angle of the Pfizer Settlement

The Justice Department's press release states that Pfizer acquired Biohaven and that the speaker program existed until Pfizer acquired the company. In other words, Pfizer discovered the speaker program and ended it. A qui tam, however, was filed by a former sales representative of Biohaven before Pfizer's acquisition. It is unclear whether the Justice Department went overt before or after the acquisition, but it is clear that the settlement was not in the context of a self-disclosure, as sometimes occurs when non-compliant conduct is discovered during diligence.

This settlement is important to those organizations contemplating mergers and acquisitions in the life sciences and health care industries because it shows how liability can be acquired. Here, Pfizer put a stop to the conduct but Biohaven—now a subsidiary of Pfizer—still retained liability. For those conducting diligence as part of mergers and acquisitions, mechanisms for handling potentially non-compliant conduct that can mitigate risk for the acquiring party should be fully vetted by deal counsel.

In closing, the Pfizer settlement shows the Justice Department and whistleblowers are continuing to scrutinize speaker programs that lack a legitimate educational purpose and are not presented to appropriate audiences. Life sciences companies and health care providers must give serious thought to their compliance programs and document the educational programs they offer to demonstrably show that these programs (and any compensation

for such) are addressing educational gaps relevant to the health care provider attendees, are consistent with fair market value, and are not just pass-throughs for kickbacks.

