Settlement Renews Focus on Speaker Program Compliance; Complaint Highlights Additional Compliance Considerations

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The U.S. Department of Justice (DOJ) announced in January 2025 that Pfizer Inc. (Pfizer) agreed to pay $59.7 million on behalf of its subsidiary Biohaven Pharmaceutical Holding Company Ltd. (Biohaven) to resolve allegations related to violations of the Anti-Kickback Statute and False Claims Act. The settlement was reached in connection with company-sponsored speaker programs, which have long been the subject of government scrutiny, enforcement actions, and whistleblower complaints. The complaint, filed by a whistleblower, also contained allegations, which, while not covered by the settlement agreement, serve as reminders that there are additional activities and interactions to evaluate for legal and compliance risks in connection with the commercialization of products.

Alleged Improper Kickbacks

By way of a *qui tam* or whistleblower complaint, a former Biohaven sales representative alleged that Biohaven provided improper remuneration to health care providers (HCPs) to induce prescribing practices of the company's migraine medication Nurtec ODT (Nurtec) through improper speaker program arrangements. The settlement resolves allegations of activity from March 1, 2020 through September 30, 2022, which Biohaven denies. Pfizer terminated the Nurtec speaker programs upon its acquisition of Biohaven in October 2022.

Some of the alleged improper activity occurred following several notable government settlements related to speaker programs, which were followed by a Department of Health and Human Services Office of the Inspector General (HHS-OIG) Special Fraud Alert in November 2020. The Special Fraud Alert raised skepticism of speaker programs due to their fraud and abuse risks (and was followed by corresponding *PhRMA Code on Interactions with Health Care Professionals* updates). According to the complaint, the types of suspect characteristics of speaker programs listed in the Special Fraud Alert were a "blueprint" for Biohaven's speaker programs.

Throughout the alleged violative period, which was during the height of the COVID-19 pandemic and beyond, Biohaven allegedly provided improper remuneration to HCPs to induce them to prescribe Nurtec through some of its speaker programs (it was alleged in the complaint that the company ran more than 1,200 speaker programs during part of 2020). Biohaven allegedly selected certain providers to present and/or attend speaker programs, offering honoraria to speakers for speaker programs – tens of thousands of dollars (and sometimes more than a hundred thousand dollars). The programs were allegedly held virtually, in HCPs' offices, or at offsite venues, including high-end restaurants where expensive meals and drinks were provided to attendees. Some programs were allegedly attended by individuals with no educational need to attend such programs, including repeat attendees who attended multiple programs on the same topic, and friends, family members, and staff from the speakers' own practices.

Additional Allegations

In addition to the alleged conduct mentioned above that was subject to the settlement agreement, the complaint further alleged additional misconduct related to Biohaven's Nurtec sales and marketing practices (not all specifically covered by the settlement agreement), including but not limited to, the following allegations:

1. *Inaccurate Payment Reports.* Biohaven allegedly underreported speaker payment data to the Centers for Medicare & Medicaid Services (CMS) Open Payments system in an alleged attempt to hide some payments made to speakers.

2. *Improper Lunch and Learns*. Biohaven allegedly encouraged its sales professionals to host multiple "lunch and learns," but according to the complaint, due to COVID-19 restrictions, it was difficult to hold compliant lunch programs that had an educational component. In some cases, sales representatives allegedly focused on providing food, sometimes in the form of a food/ice cream truck paid for by Biohaven and available to providers' offices, including staff and patients, and did not attempt to provide an educational or "learn" portion of the lunch and learn for providers. Photographs of food trucks at Nurtec events were included in the complaint.

3. *Electronic Health Record (EHR) Software Cost Assistance.* Biohaven allegedly gave providers EHR software cost assistance in violation of the Anti-Kickback Statute because the assistance relieved providers' financial obligations.

4. *Improper Provision of Copay Cards.* Biohaven allegedly provided prescribers with insurance coverage information that attached a copay card coupon for Medicare and Medicaid patients, fraudulently leading patients to believe they could use them.

5. *Misleading Marketing Tactics.* At some speaker programs, Nurtec sales representatives allegedly steered some speakers "off script" to elicit illegal off-label discussions about Nurtec. It was also alleged that a District Manager encouraged sales representatives to make an off-label claim about the efficacy of the product. Additionally, Nurtec sales representatives allegedly were also provided with a sales aid for use on sales calls that impermissibly compared Nurtec directly to competitors because there were no head-to-head studies that could be the basis of such comparisons.

Although the additional allegations listed above were not specifically mentioned as part of the conduct covered by the settlement agreement (which focused on alleged speaker program kickbacks), they serve as reminders that other activities and interactions related to the commercialization of a product, in addition to speaker programs, warrant careful consideration and scrutiny for potential legal and compliance risk.

Conclusion

Overall, the settlement highlights the government's stated commitment to investigate and hold accountable those who violate laws meant to protect the integrity of the medical profession and the pharmaceutical sector. As the DOJ stated in a press release announcing the settlement, it is committed to using "every tool at its disposal to prevent pharmaceutical manufacturers from undermining the objectivity of treatment decisions by health care providers." The settlement also underscores the role of due diligence, including thorough compliance risk assessments of potentially high-risk activities (during and after a corporate acquisition). Finally, the settlement reinforces the collaboration with compliance and legal to understand and advise on risks related to speaker programs and other commercialization activities, particularly in the busy period after a product is first approved.

Porzio's team of Life Sciences attorneys can provide legal and compliance assistance to companies, including related to the development and commercialization of their products, navigating and evaluating speaker programs, and other activities and interactions.