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life sciences

CLIENT ALERT

# Prescriptions and Persuasion: Analyzing the Purpose, Risks, and Vulnerabilities of Speaker Programs

"OIG has significant concerns about companies offering or paying remuneration (and HCPs soliciting or receiving remuneration) in connection with Speaker Programs." - Office of Inspector General, Health and Human Services, Special Fraud Alert: Speaker Programs, November 16, 2020.<sup>1</sup>

Speaker Programs have received a fair share of scrutiny in recent years. Enforcement actions regarding allegations of the life sciences industry hosting "sham" Speaker Programs<sup>2</sup>, the OIG's Special Fraud Alert on Speaker Programs<sup>3</sup>, and updated PhRMA Code guidance on managing Speaker Programs<sup>4</sup> have all been significant topics for an industry that has utilized these programs as part of its marketing strategies for decades.

In this article, we will take stock of the current state of Speaker Programs and aim to pose some thoughtful questions on what companies should think about when structuring their speaker bureaus to mitigate the inherent risk.

## Why do companies have Speaker Programs?

Speaker Programs are promotional events that traditionally have formed part of a marketing mix designed to increase share of voice. These company-arranged and managed events provide the opportunity for a practicing Healthcare Professional (often a thought leader or clinical investigator of the company's product) to present company-approved information about the product to other healthcare professionals.

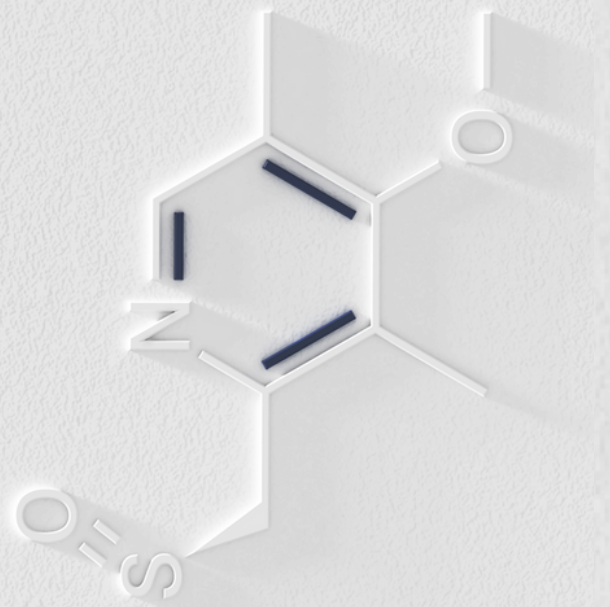
The primary objective of Speaker Programs is/ should be to create awareness about a company's product in line with the approved label, and to supplement/ augment other promotional activities, such as field sales-led promotional detailing, commercial exhibiting opportunities, etc.

In addition, Speaker Programs have, over time, become an increasingly significant vehicle to securing "time on the calendar" with healthcare professionals who have limitations on access to sales representatives through their hospital or medical practice's policies on rep visits.<sup>5</sup>

Furthermore, peer-to-peer communications have frequently been seen as an effective tool to supplement the typical sales rep promotional efforts with "legitimized" communication provided by a respected peer healthcare professional.

## Why do Speaker Programs carry legal risks?

Speaker Programs often involve engaging a healthcare professional as a speaker, for a fee, to be trained on the content of the program and then to deliver the presentation to other healthcare professionals.



Speaker Programs are viewed as promotional activities by enforcement agencies and the communications of paid Speakers at these events are attributed to the company. This structure raises a number of risks related to appropriate communication regarding company products:

- > **Off-Label Promotion:** Pharmaceutical companies are generally only allowed to promote their products for approved uses as specified by regulatory authorities. Companies must ensure that Speaker Programs adhere to these limitations and that content presented by paid Speakers does not promote products beyond their approved indications or encourage off-label use.
- > **Fair Balance:** Under U.S. law and other regulations globally, promotion must be truthful, not misleading, and be communicated with a fair balance of benefits and risks. Speaker Program presentation content and associated communications by the speaker must comply with these expectations.
- > **Adverse Event Reporting:** Regulatory bodies require pharmaceutical manufacturers to report any adverse events associated with a pharmaceutical or medical device product. Adverse events or other product quality issues may come up during Speaker Programs and need to be handled appropriately.

In addition to the communication risks inherent in Speaker Programs, these events carry risks due to the fees, expenses, and other non-monetary value that is provided to the Speaker and attendees. Speaker Programs often take place at an off-site location (usually a restaurant) where all attendees receive a free meal. Speaker Programs may also take place in an office or hospital setting, or increasingly may take place virtually where a Speaker presents to different sites that log-in to participate in the presentation. Often a meal is still provided to all attendees that participate.

- > **Anti-Kickback Statutes:** In many countries, including the United States, pharmaceutical companies must comply with “anti-kickback”/ “anti-bribery” statutes. These laws prohibit the exchange of anything of value, such as remuneration or incentives, in exchange for referrals or the promotion of specific products. Speaker Programs must ensure that they do not violate these laws and that payments made to Speakers are for legitimate educational services and not inducements for prescribing or promoting certain medications. Furthermore, Speaker Programs that are alleged to be “sham” events, where little or no information is provided, could also be viewed as kickbacks in the form of a nice meal/ entertainment provided to the attendees with no legitimate educational/ promotional purpose.
- > **Fair Market Value:** Regulatory agencies expect that payments made to healthcare professionals for participating in Speaker Programs reflect fair market value for the services provided. Overcompensation could be viewed as a means to improperly influence prescriptions and other healthcare decisions. It is essential to ensure your company uses a consistent methodology for paying Speakers in a way that does not vary based on, for example, company-favoritism.
- > **Transparency and Disclosure:** Many regulatory bodies require the disclosure of financial relationships between pharmaceutical companies and healthcare professionals. Disclosure obligations aim to mitigate potential conflicts of interest through transparency and promote ethical practices. Companies may be required to report Speaker Program-related payments and other transfers of value (such as the value of the dinner provided to attendees) under relevant transparency laws.



## What are some examples of Speaker Program enforcement?

In announcing the July 2020 settlement with Novartis, acting U.S. Attorney Audrey Strauss underscored the recent scrutiny on Speaker Programs as alleged vehicles for kickbacks.

“For more than a decade, Novartis spent hundreds of millions of dollars on so-called Speaker Programs, including speaking fees, exorbitant meals, and top-shelf alcohol that were nothing more than bribes to get doctors across the country to prescribe Novartis’ drugs. Giving these cash payments and other lavish goodies interferes with the duty of doctors to choose the best treatment for their patients and increases drug costs for everyone. This Office will continue to be vigilant in cracking down on kickbacks, however they may be dressed up, throughout the pharmaceutical industry.”

Novartis has not been the only manufacturer to settle for alleged healthcare compliance-related violations related to Speaker Programs. Below is a small sample of the many Speaker Program-focused settlements over the past decade:

> **GlaxoSmithKline (GSK)**<sup>6</sup>: In 2012, GSK reached a \$3 billion settlement with the U.S. Department of Justice. The settlement included allegations that the company used improper marketing practices, including Speaker Programs, to promote various drugs, such as Advair and Paxil. GSK was accused of providing incentives to Healthcare Professionals to encourage them to prescribe their medications.

- > **Salix Pharmaceuticals**<sup>7</sup>: In 2016, Salix settled for \$54 million to resolve allegations related to holding sham speaker programs. Specifically, the government focused on the company frequently holding programs at “swanky restaurants to get doctors to push its products.” Salix also allegedly held pre-recorded events where a Salix employee was supposed to use a laptop to play a pre-recorded video of a doctor delivering a slide presentation, and then call the paid Speaker, who was to be available to answer any questions by telephone. The video allegedly was often not played or “intentionally played in a manner so it could be ignored.”
- > **Insys Therapeutics**<sup>8</sup>: Insys Therapeutics, a pharmaceutical company primarily focused on pain management medications, faced legal troubles regarding its Speaker Programs. In 2019, the company reached a settlement with the U.S. Department of Justice (DOJ) for \$225 million. The settlement was related to allegations that Insys used its Speaker Programs to incentivize doctors to prescribe its highly addictive opioid painkiller, Subsys, for off-label uses. Further, the government alleged Insys’ programs “mere pretexts for paying thousands of dollars in sham Speaker fees to prescribers for the purpose of inducing them to prescribe Subsys.”
- > **Biogen**<sup>9</sup>: One of the allegations resulting in the \$900 million settlement Biogen agreed to in 2022 was that the company’s Marketing team hired a “greatly exaggerated” number of HCPs to be paid speakers for mature products, with evidence that some Speakers were hired because they were deemed “at risk” of switching to competitor products.

## How do (or should) companies manage Speaker Program risk?

It's worth noting that Speaker Programs themselves are not inherently problematic. They can serve as a legitimate tool to create awareness and provide education for healthcare professionals, learning from their peers about new medications and treatment options. However, when companies use these programs as a means to incentivize inappropriate prescribing practices through payments or meals, or to promote off-label uses, Speaker Programs can raise legal and ethical concerns.

So, how best to manage?

- > Challenge marketing regarding Speaker Program plans, for example:
  - > What is the educational gap the Company believes Speaker Programs will fill?
  - > Is the proposed Speaker Bureau for a mature product, and if so, why is further peer-to-peer education needed?
  - > Did the company solicit feedback from Speaker Program attendees and did the Company review this feedback in developing their future plans?
  - > Has the Company analyzed its recent Speaker Bureaus to determine the size and scope of a new bureau – were there a lot of previously trained speakers that weren't utilized?
  - > How has the Company determined the number of speakers to engage and train?
  - > Does the number of Speaker Programs planned reflect an audience of appropriate attendees that could prescribe or utilize Company products for on-label uses?
  - > Why are particular types of programs being considered? For example, are live programs where managing Speaker travel, unexpected cancellations, minimum restaurant room fees, etc. truly necessary?
- > Challenge the organization to consider other ways to increase share of voice – the fourth industrial revolution has come and gone and the role of digital communication is an expectation in the market. There are new operational challenges (and legal risk) to increasing your digital presence, but companies shouldn't be solely tied to traditional modes of communication – especially expensive ones like Speaker Bureaus.
- > Consider the role of virtual Speaker Programs, or pre-recorded programs that can be watched by Healthcare Professionals at their convenience. The COVID-19 pandemic demonstrated that these types of programs are not only possible but may be preferred by busy healthcare professionals that have experienced in managing clinical responsibilities with independent learning.
- > Consider the role of meals at a Speaker Program. While providing a modest lunch or dinner to practicing clinicians as part of a legitimate program can serve an important logistical purpose, the meal should not be the main purpose of the event.
- > Consider the Company's stance on alcohol – based on consistent messaging from enforcement agencies, it is likely in the company's best interest to not serve alcohol and have clear policies on expectations for attendees purchasing their own alcohol.
- > When you develop new Speaker Program policies, training, processes, etc., test them – very often legal and compliance teams are surprised by how a seemingly well-controlled activity doesn't stand up to their expectations once they are out in the field to monitor an event.





It's important to note that regulatory concerns and requirements may vary between countries and jurisdictions. Furthermore, a company's own business, from therapeutic area to customer base, may drive the level of risk related to holding Speaker Programs. Pharmaceutical companies should consult with legal and compliance professionals to ensure adherence with applicable laws and regulations specific to their operating regions. Epsilon Life Sciences is uniquely positioned to help assess your compliance controls related to Speaker Programs. Not only have we assisted with numerous companies in developing a successful control framework, we have also worked closely with companies that have had their Speaker Programs processes questioned and investigated by the government and other adversarial parties.

#### Sources:

- <sup>1</sup> <https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf>
- <sup>2</sup> <https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-678-million-settlement-fraud-lawsuit-against#:~:text=Prescribe%20Novartis%20Drugs-,Acting%20Manhattan%20U.S.%20Attorney%20Announces%20%24678%20Million%20Settleme nt%20Of%20Fraud,Them%20To%20Prescribe%20Novartis%20Drugs>
- <sup>3</sup> <https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf>
- <sup>4</sup> <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf>
- <sup>5</sup> Crossing the threshold: More than half of physicians restrict access to sales reps. Sep 3, 2015. Fierce Pharma
- <sup>6</sup> <https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>
- <sup>7</sup> <https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-54-million-settlement-against-salix-pharmaceuticals>
- <sup>8</sup> <https://www.justice.gov/opa/press-release/file/1063051/download> at p. 13-14
- <sup>9</sup> <https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments>; quotes from third amended complaint <https://www.statnews.com/wp-content/uploads/2022/07/THIRD-AMENDED-COMPLAINT-biogen-bawduniak.pdf>



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