

Life Sciences

Considerations for Rebooting Speaker Programs Post-Pandemic

It's well known that educational speaker programs have presented numerous compliance risks in the pharmaceutical and medical device industry over the past decade, as evidenced by multiple Corporate Integrity Agreements, settlements, and even prosecutions that hinge on conduct associated with speaker programs. Companies have sought to avoid the spotlight by mitigating the inherent risks through targeted controls in order to keep these programs in play rather than discontinue them altogether. Meanwhile, the Office of Inspector General (OIG) has subtly, and not-so-subtly, conveyed its skepticism of speaker programs pure educational value in recent years. The OIG withheld formal guidance on the topic until last month, when it solidified a position on speaker programs through the issuance of a Special Fraud Alert (SFA).ⁱ

"Speaker programs have been a critical tool in the marketing tool belt to connect with healthcare professionals, especially as access to in-office details have continued to decline over the last decade," Saul B. Helman MD said.

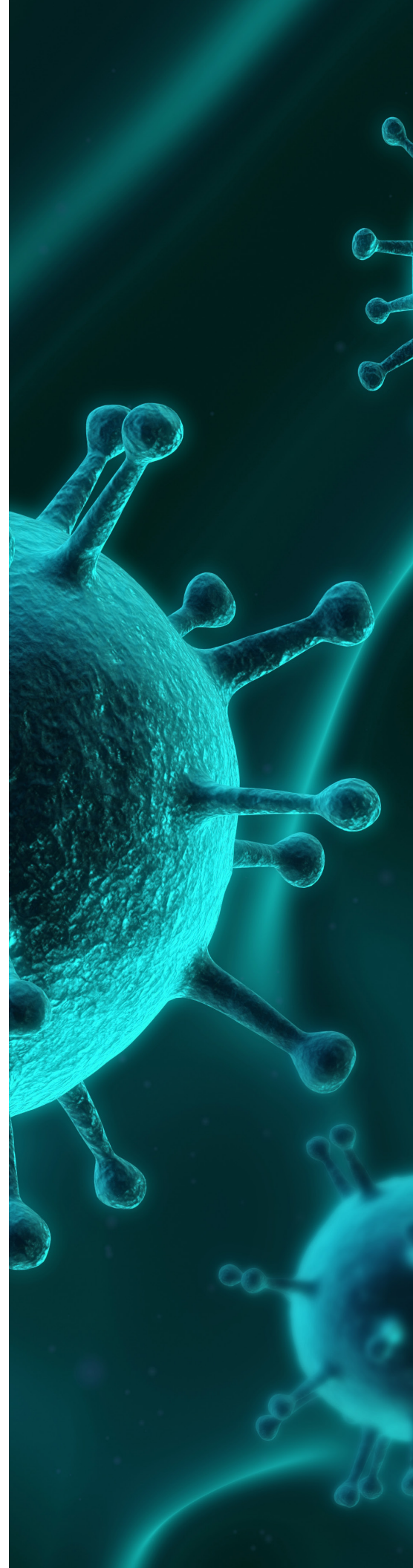
What Are the Palpable Impacts of Special Fraud Alerts?

The OIG issues SFAs to identify practices in the healthcare industry that are particularly vulnerable to abuse.ⁱⁱ SFAs serve two purposes: 1) They notify the industry that the OIG has become aware of certain abusive practices to which the office plans to pursue, prosecute, or bring administrative action as appropriate; and 2) They serve as a powerful instructive tool by giving industry compliance leaders the opportunity to proactively evaluate risks associated with designated practices and either adjust compliance controls, or reevaluate business operations knowing that scrutiny of those practices by enforcement authorities is intense.

If history is a teacher, publication of the November 2020 SFA suggests that further intensified scrutiny of speaker programs is imminent, and more restrictive regulations may not be far behind. For example, an SFA was issued in 2013 to call attention to potential violations of the Anti-Kickback Statute (AKS) around physician-owned entities.ⁱⁱⁱ In 2014, the Department of Justice sued Reliance Medical Systems over an alleged kickback scheme involving physician-owned distributors (PODs).^{iv} Scrutiny around this compliance risk continued into 2018 with the OIG's investigation into 12 physician-owned entities that purchased spinal devices from PODs.^v

Impetus for Special Fraud Alerts on Speaker Programs

In the past, the OIG and DOJ have resolved criminal and civil cases where companies allegedly violated the AKS through remuneration to healthcare professionals in the form of payments for speaker programs which, through a variety of colorful scenarios, ultimately gave rise to fraud impacting US federal healthcare programs.^{vi} The November 2020 SFA collects characteristics of fraudulent or "sham" programs reflected in recent cases and uses the combined power of these scenarios as a basis for questioning their overall educational value, and fundamentally advancing a strong position against restaurant-based speaker programs. While this is the first time the OIG has ever proffered a direct opinion on the practice of in writing, speaker programs, this SFA is simply a summary of key cases directly tied to inappropriate speaker program activity.



The OIG suggests that the intent of speaker programs has increasingly included efforts to induce prescriptions through unjust remuneration¹ payments. Over the past decade, programs that have been held accountable for inducing prescriptions through unjust remuneration payments have:

- Selected high-prescribing healthcare providers (HCPs) as speakers.
- Only paid speakers after meeting designated sales targets.
- Held programs at recreational venues.
- Invited audience members who have no use for the educational information.

Examples in the Industry:

- GlaxoSmithKline: In 2012, GlaxoSmithKline (GSK) pled guilty to a civil False Claims Act (FCA) lawsuit for paying kickbacks to HCPs with the intent to induce additional prescriptions for their psychological drugs.^{vii} Several features of GSK's speaker programs call into question the event's educational value:
 - Remuneration in the form of sponsored gifts, expensive meals, recreational activities, and speaker appearances (e.g., comedians)
 - **Events held in the form of sponsored lunch and dinner programs, hunting trips, spa treatments, lavish weekend conferences, trips to luxurious resorts in places such as Jamaica, Bermuda, Puerto Rico and Hawaii^{viii}**
 - Attendees often included top-prescribing HCPs^{ix}
 - Attendees included individuals with no legitimate interest in the topic (e.g., spouses and administrative staff)
 - Attendees frequented programs on the same topic in a short period of time
 - Speakers were paid substantial honoraria

- Novartis: In 2013, the Department of Justice (DOJ) filed a second civil FCA lawsuit against Novartis Pharmaceuticals Corp. for violating the FCA and AKS.^x Novartis' speaker programs exhibited patterns that called into question their educational value:
 - **Payments to HCPs for speaker programs that did not occur at all or had few or no attendees**
 - Events held in the form of lavish dinners, fishing trips, and meals at Hooters restaurants
 - **Educational presentations were often not given or partially shown**
 - HCPs who participated spent little or no time discussing the drug at issue
 - Attendees frequented programs on the same topic in a short period of time
 - Speakers were paid substantial honoraria

- Salix Pharmaceuticals: In 2016, Salix Pharmaceuticals entered a civil fraud lawsuit with the FBI for violating the AKS and FCA by using speaker programs as a mechanism to pay kickbacks and induce additional prescriptions of their gastroenterology products.^{xi} Several features of Salix's speaker programs called into question the event's educational value:
 - **Events held at high-end restaurants and included the serving of alcohol**
 - Speakers were paid substantial honoraria
 - HCPs who participated spent little or no time discussing the product at issue
 - Attendees frequented programs on the same topic in a short period of time
 - **Attendees were often from the same practice or otherwise knew each other**
 - Attendees included top-prescribing HCPs or were viewed as potential high-prescribers
 - Attendees included individuals with no legitimate interest in the topic (e.g., spouses and administrative staff)
 - **Educational presentations were often not given, partially shown, or intentionally presented in a manner so it could be ignored**
 - **Speakers and attendees showed a significant increase in prescribing habits following the event**

A key takeaway from the OIG's SFA is a list of suspect characteristics that often point toward illegitimate educational events:

How to Spot a Faulty Speaker Program

1. Alcohol or meals that exceed modest fees are provided, especially when alcohol is free of charge
2. Program with no substantive information present
3. Venue is not conducive to education
4. Company sponsors programs on the same topic, especially when information has not changed recently
5. Significant time period of no new changes in medical literature on the topic
6. HCPs attend speaker programs on the same topic
7. Attendees have no legitimate business reason for being there
8. Sales or marketing of product influence selection of the speaker
9. Speakers are paid more than what fair market value deems appropriate

1. Remuneration paid purposefully with the intent to induce referrals or services that are covered by Federal Health Care programs is a violation of the AKS. Such a violation, which simultaneously triggers the FCA, holds all parties responsible. Doctors prescribing higher amounts based on remuneration, as well as the company providing remuneration, could potentially face fines, prison time, and exclusion from Federal Care Programs.

Considerations for Speaker Programs in the Wake of COVID-19

Though the number of speaker programs has significantly decreased as a result of COVID-19, with some companies restaurant-based continuing to hold live programs where permitted by local law and/or ordinance, the industry and regulators expect these programs to return with the development of treatments and vaccines. When they do, the SFA states that the OIG will be paying special attention to company conduct of speaker programs.

There are several ways to stay on top of this curve.

1. Build in diversity in the marketing mix to include other channels for product awareness campaigns, leveraging digital, virtual, and electronic channels.
2. Diversify the field force with definitive roles and responsibilities that are clear to HCPs.
3. Differentiate clearly what is promotional, what is educational, what is medical/clinical, and what is access.
4. Further redesign speaker programs in context of purpose, content, delivery (external or internal).
5. Companies should consider providing alternative resources to HCPs such as online medical literature, detailed product package inserts, and educational conferences held by third parties.
6. In addition to alternative resources, creating a compliance culture driven by intent may help reduce AKS violations with speaker programs. Violations of the AKS are predicated on evidence of intentional disregard for compliance with its regulations. Ensuring values-based compliance controls will proactively protect companies, HCPs, and patients in the long-run.

Considerations for the Future

This is the first time that the OIG has explicitly expressed concern around speaker programs in an official written policy position. It has become a significant red flag for abuse within the industry and the OIG's skepticism on the issue has solidified to the point they are taking a more forward-leaning position on enforcement to discourage the practice altogether. Based on the history of regulation and settlements following SFAs, we can expect more oversight and stricter prosecution if a company or HCP engages in illegal kickbacks under the guise of education. Moving forward, consider the following when it comes to your organization:

- Is your organization preemptively assessing its speaker program practices and other fee-for-service arrangements? (Some companies have begun seeking proactive, independent audits of its speaker program practices.)
- What additional controls are plausible for your company's specific business operations?
- Are there alternative promotional practices to leverage to decrease reliance on speaker program activity?
- Is your organization actively monitoring its programs?
- If the government asks compliance officers to describe actions they took in 2020 regarding speaker program activity, will it be obvious that they read and understood the SFA and considered it actionable guidance?



Speaker programs are the nidus of compliance risk—an event with the objective of creating awareness of the product, designed as an educational program with a promotional purpose, paying a healthcare professional and feeding others, with the potential for optics that do not shed positive light on the industry.

– Saul B. Helman, MD

Endnotes

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