Overview
On November 16, the Health and Human Services (HHS) Office of Inspector General (OIG) issued a Special Fraud Alert highlighting the fraud and abuse risks associated with payments to physicians related to speaker programs sponsored by pharmaceutical and medical device companies. Company-sponsored speaker programs are a common tool used by pharmaceutical and device companies to educate physicians about their products. They generally entail a physician or other health care professional (HCP) giving a speech or presentation – the content of which may be either company-generated or, if generated by the speaker herself, approved by the company – about a drug or medical device of the company and then taking questions from program attendees. Companies commonly pay the speaker an honorarium and provide free meals and education to attendees. Companies have traditionally utilized speaker programs because HCPs, when considering which drug or device to prescribe their patients, are notoriously skeptical of promotional information from sales representatives from pharmaceutical and medical device companies, who typically lack the medical background possessed by HCPs. Sponsored speaker programs link those skeptical HCP customers with an HCP colleague whom they can trust and who believes in the drug’s or device’s value.

Despite the pharmaceutical and device companies’ longstanding use of speaker programs to educate HCPs about their products, OIG appears to take a different view of company-sponsored speaker programs, expressing doubt as to whether those programs have any educational value at all. To this end, OIG illustrates its view by warning that sponsored speaker programs carry “inherent fraud and abuse risks,” and opines that “at least one purpose of remuneration associated with speaker programs is often to induce or reward referrals.” These fraud and abuse risks are, in OIG’s view, rooted in the “remuneration” – which can be as de minimis as free food and drink – that pharmaceutical and medical device companies provide to convince physicians to speak or to attend as audience members.

The Anti-Kickback Statute’s Application to Company-Sponsored Speaker Programs
The Anti-Kickback Statute (AKS) is designed to ensure that physicians and other health care practitioners act in the best interests of their patients, and not in their own financial self-interest. The statute makes it a felony to knowingly and willfully offer, pay, solicit, or receive remuneration with the purpose of inducing or rewarding prescriptions or referrals for items or services reimbursable by a federal health care program. This prohibition is founded upon the idea that such remuneration could improperly influence the HCP’s referral or treatment decisions to the detriment of patients. As the Special Fraud Alert describes it, “[t]his remuneration to HCPs may skew their clinical decision making in favor of their own and the company’s financial interests, rather than the patient’s best interests.”

The AKS has potentially broad application because the AKS is frequently interpreted to define “remuneration” to include, as a practical matter, anything of value. And, at least according to some courts and OIG, the AKS prohibits paying such remuneration if “at least one purpose” was to induce prescriptions or referrals; it does not need to be the only purpose. This stands in stark contrast, for example, with the PhRMA Code for industry-physician interactions and the AdvaMed Code of Ethics, both of which permit modest meals conducive to informational exchange.
A December 4, 2020 District of Massachusetts opinion in United States v. Regeneron Pharmaceuticals, Inc. provides a recent example of just how broad the AKS’s definition of remuneration can be. A simplified version of the allegations in Regeneron is that the company allegedly made charitable contributions to a foundation that would provide copay assistance to patients who received the company’s drug. Readers may see how – aside from whether the alleged conduct is lawful or unlawful – this could arguably constitute remuneration to the patients. But the Regeneron opinion went even further, concluding that the promise of foundation-covered copays also arguably benefited prescribing HCPs. The opinion reasoned that the foundation-covered copays could have remunerated HCPs by “saving physicians’ time that might be spent on explaining copays and assessing patients’ financial hardship, removing the financial risk to physicians if they prescribed a drug that patients could not [cover the copay amount owed to the provider], appeasing staff and patients, and generating increased business due to satisfied patients.” A broad interpretation of remuneration like the one in Regeneron is potentially limitless and would implicate many sponsored-speaker programs.

A November 12, 2020 Eastern District of Pennsylvania decision United States ex rel. Gohil v. Sanofi features a clearer allegation of remuneration and provides a more common example of how speaker programs typically implicate the AKS. There, a pharmaceutical company maintained a “speakers bureau” of physicians who would give speeches about one of the company’s drugs. Those physician-speakers were paid an honorarium at approximately market rate. In order to prepare the physician-speakers, the company would hold quarterly one to two-day seminars providing updated data. These seminars, however, were held in places like Las Vegas, Key West, and upscale Cayman Island resorts. All expenses were paid by the company, which also provided an honorarium for training. In denying the company defendant’s summary judgment motion, Gohil concluded that a whistleblower sufficiently alleged, and presented sufficient factual dispute, that the company-sponsored speaker training programs induced false claims. The court reasoned that even though the speaker training programs were not explicitly dependent on prescriptions, there was enough evidence to establish a genuine question regarding whether the programs – which included all-expenses paid trips to desirable locations and other valuable entertainment and social activities – violated the AKS. Gohil concluded that there was a genuine question whether those programs were intended, at least in part, to induce HCPs to prescribe the drug at issue because of their influence on the speakers rather than the audience. The court did not, however, analyze in detail the circumstances under which speaker programs could wrongfully induce HCPs in the audience to prescribe the drug at issue.

It is easy to see why speaker programs might trigger AKS scrutiny. Companies offer remuneration in the form of food, drinks, education, and sometimes entertainment for the purpose of connecting HCPs for a discussion that companies hope will induce referrals or orders for one or more company products as a result of scientific exchange and education. Moreover, combining the honorarium paid to the speaker with the fact that no company would select a speaker who does not use its products creates the logical inference that the company is paying the speaker, at least in part, as a reward for using its products. However, a zero-tolerance policy toward speaker programs could punish or chill legitimate scientific exchange among physicians, and discourage companies from disseminating truthful clinical data regarding their products to HCPs.

One way in which Congress has attempted to manage this risk is through disclosures. For example, pharmaceutical and device companies are required to report all speaker honoraria and related payments under the Sunshine Act of 2010. Those disclosures are published on the website of the Centers for Medicare & Medicaid Services. Indeed, OIG summarized the 2017, 2018, and 2019 speaker compensation data on page 1 of its Special Fraud Alert. However, the increased transparency since the Sunshine Act has not led to any palpable drop in OIG’s and DOJ’s AKS enforcement efforts.

OIG’s Prior Pronouncements on Speaker Programs

As the Special Fraud Alert explains, the issuance of guidance on the AKS risk associated with speaker programs does not break new ground for OIG. In the 2003 OIG Compliance Program Guidance for Manufacturers, OIG identified industry compensation of HCPs in connection with marketing or sales activities, including speaking, as an area of potential risk under the AKS. OIG highlighted that engaging in entertainment, recreation, travel, meals, or other benefits in connection with informational or marketing presentations may potentially Implicate the AKS. In 2010 the OIG issued A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, recommending that physicians ensure that any consulting compensation not be based on the ability to prescribe a company’s products.

This clear prior guidance regarding the AKS risks posed by speaker programs then begs two related questions: What does the new Special Fraud Alert add to the discussion? And, will the new Special Fraud Alert signal a new wave in AKS enforcement priorities? Only time will tell in some measure for both questions. But we need not look back beyond the March 26, 2013 OIG Special Fraud Alert on Physician-Owned Entities for an example of a OIG fraud alert that led to widespread and sustained enforcement activity across the country.

What Makes This Special Fraud Alert Different
While past OIG guidance identified potential risks associated with speaker programs, the November 2020 Special Fraud Alert is different. In contrast to the previous statements that some amorphous group of speaker programs might entail risk, the Special Fraud Alert takes a harsher stance: speaker programs are presumptively suspect and will be expected to justify their existence. This is consistent with the choice to issue guidance as a “Special Fraud Alert,” which implies to industry readers that OIG believes there is a substantial enough level of noncompliant behavior to justify such an alert. The presumptive suspicion of speaker programs combined with the Special Fraud Alert status provide reason to believe that staying within industry-accepted practices may not be sufficient to avoid risk.

OIG’s Special Fraud Alert labs multiple attacks at speaker programs. OIG notes that it is “skeptical about the educational value of [sponsored speaker] programs,” remuneration as minor as “free food and drink” is “often” intended for the prohibited purpose of inducing or rewarding referrals; and that OIG has “significant concerns” about the role of remuneration in sponsored speaker programs. And it offers no practical model or example for how a company could offer speaker programs without running afoul of the AKS. The conclusion of the Special Fraud Alert warns that sponsored speaker programs even when accompanied by minimal free food and drink will carry increased risk of criminal, civil, and administrative enforcement from now on.

Industry members will face difficult questions when seeking to resume speaker programs, and OIG’s Special Fraud Alert does not provide any easy answers. We recommend a few considerations for risk-averse industry members who seek to resume speaker programs while minimizing exposure.

First, industry can review the characteristics of speaker programs that make OIG suspicious and attempt to avoid those characteristics. The Special Fraud Alert presents a list of such characteristics.

- Alcohol or a meal exceeding modest value (the concern is heightened when the alcohol is free).
- Programs held at a location un conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues).
- Large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information.
- Program held on a product despite a significant period of time passing since any new medical or scientific information or a new indication for the product.
- HCP attendees who previously spoke or attended programs on the same or substantially the same topics.
- Attendees include friends, family, employees of the same medical practice or facility as the speaker, or others who do not have a legitimate business reason to attend the program.
- Sales or marketing business units influence the selection of speakers or speakers/attendees are selected based on past or expected revenue related to the company’s products (e.g., a return on investment analysis is considered in identifying participants).
- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account past or future business generated by the HCPs.

Though presumably aimed at providing guidance to companies in their administration of speaker programs, many of these “suspect” characteristics raise more questions than answers, and neglect to take into consideration the realities of how and under what circumstances HCPs are inclined to participate in legitimate scientific discussions. For example, what constitutes a meal of “modest value”? Moreover, OIG appears to condemn programs without any meaningful regard as to whether the content presented or discussed rests on truthful and reliable clinical and scientific information.

Finally, OIG includes a caveat to maintain flexibility should it deem other characteristics similarly “suspect” in the future: the list above was illustrative, not exhaustive, and not determinative of whether an arrangement would be suspect under the AKS as a result. Avoiding the pitfalls flagged by OIG therefore reduces risk, but it does not eliminate it.

Problems with the Special Fraud Alert

Based on the Special Fraud Alert’s aggressive stance and the lack of certainty provided to industry, as well as its detachment from the realities of HCP education and decision-making, we think a number of observations with the Special Fraud Alert are worth noting.

Most importantly, the Special Fraud Alert misunderstands the realities of modern dissemination of truthful, non-misleading information about a drug or device including data, physician practices, and off-label information about the benefits of that drug or device for patients. Of course, lavishing food, vacations, and entertainment on speakers and speaker prospects under the guise of “training,” as alleged in Gohil, clearly presents kickback problems. However, when it comes to program attendees, which is the primary focus of the Special Fraud Alert, there is no disputing that HCPs are busy, and presenting this information from one HCP to another in a forum that allows for back-and-forth between professionals and the exchange of clinical experience has educational benefits. Moreover, it is a stretch to conclude that HCPs in the audience are going to prescribe that drug or device because they received a modest meal, a few cocktails and a half-hour talk.

HCPs are licensed professionals subject to a code of ethics whose discretion to act in the best interests of their patients is protected by statute. We can and should trust them to ingest information with a critical eye, and to evaluate the drug or
device’s utility accordingly. Presuming the opposite is simply inconsistent with reality.

The underestimation of HCPs’ ability to absorb scientific exchange in the face of an evening of food and drink at a comfortable venue leads the Special Fraud Alert to mistake the purpose behind the provision of de minimis remuneration like a modest meal. The Special Fraud Alert concludes that based on the use of online sponsored speaker programs during the COVID-19 pandemic, there is no need for return to in-person programs involving remuneration not provided for online programs. In particular, the Special Fraud Alert focuses on the ability of HCPs to “access the same or similar information provided in a speaker program using various online resources” and various publicly available third-party resources. The implication of this section and the conclusion is that if online webinars and third-party resources are sufficient to educate HCPs during the pandemic, then companies would only resume in-person sponsored speaker programs if they intended those programs as a vehicle for kickbacks.

The Special Fraud Alert’s position ignores something parents around the country have learned in the past nine months: in-person group programs are more effective than online, passive learning. Group programs involve dialogues both with speakers and with other HCPs regarding best practices, common pitfalls, and diverse experiences. In-person attendance is isolating and prone to distraction. An online attendee checks their email, feeds the dog, and checks the score of the Washington Nationals game, all the while remaining “present.” An in-person attendee has fewer distractions and the pressure of other peers to be polite and pay attention. Attendance is not the same as retention, and there is good reason to believe that in-person speaker programs aid retention.

Because in-person programs involve more attendee time and attention, they require remuneration not provided for online talks. HCPs are busy people. Playing a webinar in the background while completing paperwork is not the same thing as attending an hour-long presentation. In our experience, many HCPs attend sponsored speaker programs during meal breaks, the one time they have a sufficient block of free time. It is unrealistic to expect HCPs to do that without being provided a modest meal. And the provision of modest food and drink in a comfortable setting can also be conducive to informal discussions among HCPs, which has educational benefit in and of itself. Moreover, as mentioned earlier, the risk of the HCP changing their prescribing decisions based on the modest meal is minimal, and at worst based on a jaundiced view of the integrity of HCPs.

The Special Fraud Alert laments that HCPs who receive such remuneration are more likely to prescribe or order a company’s products than those who do not. But just because “remuneration” is necessary to entice HCPs to attend an educational event and HCPs educated about a drug or device are more likely to use that drug or device does not mean that remuneration is intended to induce that use.

For now, however, the OIG appears to disagree.

Moving Forward

Until FDA or HHS – OIG lacks express authority to establish regulations or policy – engages in a meaningful notice and comment rulemaking regarding the pros and cons of speaker programs, or until Congress intervenes, it appears that OIG and industry will continue to talk past one another. Many companies believe in good faith that speaker programs are an effective way to educate their physician-customers about products that can help patients, and thereby drive sales. OIG’s current position, however, is that while it does “not intend[] to discourage meaningful HCP training and education” events, it reads the AKS to prohibit company-sponsored speaker programs involving even de minimis “remuneration.” Because the ultimate purpose of traditional in-person speaker programs is to educate HCPs about their products, the Special Fraud Alert suggests that those traditional programs are now categorically subject to potential enforcement; this leaves companies in a difficult position.

Companies should consult in-house counsel before sponsoring speaker programs involving food, drink, or other remuneration even if such a program was commonplace less than a year ago. We expect to see increased use of OIG’s advisory opinion process, which OIG advertised at the end of the Special Fraud Alert. As OIG notes, the lawfulness of speaker program arrangements under the AKS depends on the facts, circumstances, and intent of the parties. It is much safer to present those facts, circumstances, and intent in the context of seeking a prospective advisory opinion than defending against a retrospective enforcement action. Although the advisory opinion process typically requires outside counsel and significant resources, risk-averse companies have no other avenue for certainty for the time being.

Moreover, now that HHS has put the industry on notice, companies practicing business as usual when it comes to speaker programs, after having considered this Special Fraud Alert, could be viewed as having acted with the requisite intent under the AKS. And potential relators and their counsel are more likely to point to the Special Fraud Alert to support allegations of AKS-based false claims, even where speaker programs occurred prior to the Special Fraud Alert’s issuance.

There will likely be many companies that continue doing business as usual including sponsored speaker programs. While there is no way to predict the future, OIG’s Special Fraud Alert gives the agency maximum flexibility to pursue criminal, civil, and administrative enforcement actions in response. Companies should therefore proceed with caution if possible.