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Client Alert

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Are Pharma Speaker Programs Facing an Existential Crisis?

Exploring the Implications of HHS-OIG's Special Fraud Alert and Groundbreaking Novartis CIA Requirements on Compliance Program Policies and Controls that Govern Speaker Programs

A Special Fraud Alert issued by the U.S. Dept. of Health and Human Services, Office of Inspector General (OIG or the Office) on November 16, 2020, advises pharmaceutical and medical device companies to use caution in conducting speaker programs. The Special Fraud Alert, which is the first released by OIG in more than six years, cautions manufacturers and health care professionals (HCPs) regarding speaker program activities. In the Alert, OIG categorizes speaker programs as "inherently risky" and expresses skepticism about their educational value, especially when such programs are conducted under circumstances that are less conducive to learning. OIG offers a non-exhaustive list of characteristics that pose higher risks for a speaker program arrangement to violate the federal health care program anti-kickback statute ("AKS"). This Fraud Alert is the latest in a line of OIG warning signals to industry regarding speaker program activities.

We analyze this new Fraud Alert, discuss how recent enforcement activity foreshadowed OIG's positions, and provide insights for life sciences companies assessing the compliance implications of their speaker programs going forward.

OIG'S SPECIAL FRAUD ALERT LISTS "SUSPECT CHARACTERISTICS" OF MANUFACTURER SPEAKER PROGRAMS

The Special Fraud Alert sets forth a list of speaker program characteristics that OIG perceives as raising elevated AKS risk. The AKS, in relevant part, makes it unlawful to pay or receive any remuneration for the purpose of inducing the purchase, use, prescription or referral of a product or service paid for in whole or in part by a federal healthcare

program.[1] The list builds upon allegations made as part of cases that OIG and the Department of Justice (DOJ) have investigated in recent years. OIG's list of suspect or high-risk attributes is intended to be illustrative, not exhaustive, as follows:[2]

- Little or no substantive information is presented;
- Alcohol is available or a meal exceeding modest value is provided to the attendees of the program (the concern is heightened when the alcohol is free);
- The program is held at a venue that is not conducive to the exchange of educational information (e.g., restaurants or entertainment or sports venues);
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive changes in relevant information;
- There has been a significant period of time with no new medical or scientific information nor a new FDA- approved or cleared indication for the product;
- HCPs attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic);
- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others, or family members of the speaker or HCP attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information;
- The company's sales or marketing business units influence the selection of speakers or the company selects HCP speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (e.g., a return on investment analysis is considered in identifying participants); and/or
- The company pays HCP speakers more than fair market value for the speaking service or pays compensation that takes into account the volume or value of past business generated or potential future business generated by the HCPs.

Clearly, the mere presence or absence of any of the above factors is not determinative of whether a particular arrangement would violate the AKS.[3] Importantly, however, OIG views these risks in light of recent studies analyzing industry payments to physicians, showing that physicians who receive industry payments are significantly more likely to prescribe or purchase from a manufacturer that paid them for services.[4] Accordingly, OIG argues that many speaker programs are unnecessary and not commercially reasonable because the information typically conveyed at them is available through other means that do not require manufacturers to make payments to physicians. OIG concludes by saying that it has significant concerns about companies offering payment in connection with speaker programs, and takes aim at in-person programs specifically:

> "While companies may have decreased in-person speaker program-related remuneration to HCPs during the pandemic, risks remain whenever payments are offered or made to HCPs who generate Federal health care program business for the company. The risks associated with speaker programs will become more pronounced if companies resume in-person speaker programs or increase speaker program-related remuneration to HCPs. Companies should assess the need for in-person programs

given the risks associated with offering or paying related remuneration and consider alternative less-risky means for conveying information to HCPs."[5]

Consistent with these concerns, if the requisite intent is present, then both the company and the HCP speakers/attendees may be subject to criminal, civil, and administrative enforcement actions.[6] Thus, the Special Fraud Alert certainly signals an intent for federal enforcement agencies to increase scrutiny of speaker program activities, especially those that share some or all of the above risk factors.

NOVARTIS' JUNE 2020 SETTLEMENT AND CORPORATE INTEGRITY AGREEMENT FORESHADOWED OIG'S POSITION AND OFFER ADDITIONAL INSIGHTS INTO OIG'S VIEWS ON SPEAKER PROGRAMS

As OIG points out in the Special Fraud Alert, the Office has consistently identified speaker programs as an area of potential risk under the AKS. In its 2003 Compliance Program Guidance for Pharmaceutical Manufacturers, OIG specifically identified direct payments made by pharmaceutical manufacturers to physicians pursuant to speaking arrangements as an area of potential risk.[7] Since then, OIG has reiterated its concerns in subsequent publications and through regular enforcement activity related to such programs.[8]

Although there are numerous examples of enforcement related to speaker programs, most recently, Novartis entered into a $642 million settlement that resulted in tight guardrails placed around the company's speaker programs pursuant to a Corporate Integrity Agreement (CIA) entered into with OIG.[9] The settlement itself resulted from allegations that Novartis hosted tens of thousands of speaker programs that were more social events than educational, with some never having even taken place. Prosecutors also alleged that speakers for the programs were chosen based on prescription volume and that decisions about the program were traceable to top management at the company's North American headquarters in New Jersey.

Although only binding on Novartis, the CIA is instructive as to what OIG views as key compliance measures regarding speaker programs. As a general matter, OIG views CIA provisions as a reflection of what they believe to be compliance best practices. Specifically, with respect to external speaker programs (i.e., programs where an HCP not employed by Novartis is the speaker), Novartis may only compensate HCPs under the following circumstances:

- The program must be conducted in a virtual format, meaning that the external speaker is remote (e.g., at his/her practice, home or other location not requiring travel) and not in the same location as any audience member;[10]
- The program may only occur within the first 18 months following FDA approval of a new product or a new indication for an existing product;[11] and
- No more than a maximum of $100,000 in total remuneration is paid to all external speakers, with no individual speaker being paid more than a maximum of $10,000 for speaker services for a product or indication.[12]

In addition to the onerous and groundbreaking requirements described above, Novartis also is required to take each of the following steps with respect to its external speaker programs:

- Identify a business need for external speaker programs;[13]
- Select speakers based on objective standardized criteria without any involvement by field sales representatives;[14]
- Pay speakers according to a centrally managed, pre-established rate structure that is based on an independent fair-market analysis;[15]

- Establish centralized systems to track all remuneration and expenses (including speaker fees, travel, and other expenses) paid to each external speaker and the total remuneration paid in connection with all external speaker programs;[16]
- Require all external speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Novartis approved materials and requirements that external speakers may not directly or indirectly promote the product for off-label uses);[17] and
- Not organize or facilitate a group gathering of HCPs outside of an individual HCP's institution or office setting for purposes of participating in or viewing any external speaker program.[18]

Further, the CIA also places restrictions on Novartis' internal speaker program activities (i.e., programs where a Novartis employee is the speaker) by requiring the company to:

- Identify a business need for internal speaker programs;[19]
- Maintain records relating to all internal speaker programs, including records of the attendees at such programs;[20]
- Hold such programs in a venue other than a restaurant. Alcohol may not be provided or available for purchase;[21]
- Train all Novartis employees who are internal speakers on their compliance obligations;[22] and
- Certify compliance and identify policy violations and ensure appropriate follow-up activity to address such violations.[23]

Importantly, the restrictions imposed on Novartis under the CIA go far beyond simply cleaning up allegedly unlawful activity. First, it is notable that the recent Novartis settlement resolved allegations of activities that occurred ten to fifteen years ago and even earlier; recent activities and practices were not at issue. Second, OIG Chief Counsel, Greg Demske, acknowledged the CIA as making "fundamental changes to [Novartis'] speaker program practices" including no longer paying for "inherently-risky-in-person programs."[24] Demske further cited the "widely- recognized compliance risks associated with paid speaker programs" sending a warning signal that paradigmatic change was imminent.[25] In retrospect, these Novartis CIA provisions appear to have been OIG's first shot across the bow to industry regarding speaker program activities, especially in-person programs.

NOW WHAT? WHAT SHOULD COMPLIANCE AND LEGAL DEPARTMENTS CONSIDER IN RESPONSE TO THESE RECENT DEVELOPMENTS

A close reading of OIG's list of "suspect" activities raises significant concerns for manufacturers because some of the risk areas contradict activities that are generally condoned by the PhRMA and AdvaMed Codes. For example, OIG seems to indicate that restaurants may no longer be a proper venue for speaker program activities, contradicting industry codes and decades of industry practice.[26] This is the first time that OIG has taken a position that contradicts these industry codes, which had been shared with OIG prior to release without the agency raising any objections. In addition, OIG indicates that the mere availability of alcohol at a program creates a risk, and an even higher risk if a manufacturer pays for it (rather than having attendees purchase drinks with their own money). OIG previewed both of these restrictions with the Novartis CIA, which, as noted, flatly prohibits both restaurants and alcohol from any speaker programs.

At the same time, OIG's statement in the Special Fraud Alert that "the presence or absence of any such factors is not determinative of whether a particular arrangement would violate the anti-kickback statute" suggests that, in at least some situations, the suspect activities would not be expressly prohibited if adequate safeguards are in place.[27] There have been particularly egregious allegations and cases involving speaker programs in the past (as described at the beginning

of OIG's Alert), and OIG's concerns should be viewed and digested within that broader context. For example, high-end or lavish restaurants (like those at issue in some past cases/settlements) would create an increased/substantial risk. But what are the risks of holding in-person speaker programs at modest restaurants with appropriate spaces for informational/educational sessions, especially if a company can explain why in-person programs are effective ways to deliver educational content? Thus, the Special Fraud Alert offers a lack of clear directives. In light of the lack of clarity, manufacturers are under pressure to consider how to respond. We offer the following options for consideration.

a. *Look to the Novartis CIA and OIG Special Fraud Alert as new standards against which to compare a company's speaker program activities and compliance controls*

The Novartis CIA and OIG Special Fraud Alert offer guidance to manufacturers seeking to reduce the risk of their speaker programs. For example, manufacturers can start to reduce risk by moving their programs online and relying more heavily on employees as speakers. These recent developments also suggest that it may be prudent for manufacturers to review the Novartis CIA restrictions and points from the Fraud Alert and be prepared to explain/support aspects of their speakers' bureaus that depart from those documents. It is becoming clear that OIG and other enforcement authorities will be more likely to question aspects of speaker program activities that include components noted in the Fraud Alert or that depart from the Novartis CIA requirements (including, for example, holding programs in restaurants where alcohol is served). Manufacturers should be prepared to support and defend aspects of their programs that deviate from those documents.

Although there remains ambiguity as to whether these recent developments pose an existential threat to speaker programs as we know them, what is clearer is that a manufacturer's overall compliance infrastructure around speaker programs is now more critical than ever to help reduce scrutiny and risk going forward. OIG acknowledged that it intentionally issued the Alert during a pandemic emergency that is curtailing many in-person activities.[28] Thus, the timing of the Alert is likely a purposeful signal to manufacturers that it may be time to develop new infrastructure around their speaker programs. At a minimum, manufacturers should consider, among other things: (1) adopting thoughtful and diligent annual needs assessments (regarding the number of speakers and programs needed over a particular time period); (2) instituting centrally managed, pre-established rate structures based on independent fair- market analysis, as well as tracking all expenses on a per-speaker and aggregated level, and clearly documenting presenter activities; (3) ensuring that the same attendees do not attend multiple programs on the same issue; (4) avoiding undue influence by sales and marketing personnel on speaker selection; and (5) conducting regular audits to ensure compliance and fulfillment of a legitimate business need. These and other compliance controls will be even more important going forward than they have been in the past. There is also now a reduced margin for error in effectively implementing these controls.

b. *Strictly Adhere to the PhRMA and AdvaMed Codes*

Although OIG may be questioning aspects of the PhRMA and AdvaMed codes (as currently written), these codes continue to provide helpful guidance to manufacturers that seek to operate compliant speaker programs. Adherence to industry codes does not provide express protection from the AKS, but it goes a long way toward defending allegations of illicit activity.

In any event, even if a manufacturer decides to focus exclusively on the PhRMA/AdvaMed Codes as the baseline for legitimate speaker program guidelines and rules, recent developments suggest that it is critical that the compliance controls and infrastructure around those rules be operating effectively. For manufacturers that had compliance concerns about their speaker programs prior to the pandemic, now is the time to act. We anticipate that in-person activity will become increasingly possible in 2021 and OIG has sent a clear signal to industry that it will be watching.

Accordingly, manufacturers would be wise to use the temporary pause in in-person speaker programs as an opportunity to recalibrate around compliance.

c. Seek Clarity from OIG

In its Fraud Alert, OIG is suggesting that activities conducted consistent with industry standard nonetheless could be subject to enforcement scrutiny. As the prime example, the Fraud Alert suggests that there could be additional scrutiny if a manufacturer holds in-person programs in restaurant settings where alcohol would be available, even if the activities are completely appropriate and legitimate (and conducted in accordance with industry standard). The fact that such legitimate activities now could be more likely to subject a company to enforcement scrutiny, whistleblower allegations, and DOJ investigation should give manufacturers cause for concern for many reasons (e.g., cost and disruption of responding to a Civil Investigative Demand or whistleblower complaint, even if a company ultimately prevails).

In the final sentence of the Special Fraud Alert, OIG invites manufacturers and HCPs to seek further guidance on specific arrangements by submitting an Advisory Opinion to OIG. By submitting an Advisory Opinion request, a manufacturer may confirm the compliance status of its speaker programs. Given the uncertainty arising out of the new Special Fraud Alert guidance, manufacturers may seek greater clarity by seeking an Advisory Opinion to have more security around any changes to their speaker program operations. Note that a favorable Advisory Opinion would also help to insulate a manufacturer against potential whistleblower allegations, as well.

CONCLUSION

OIG's Special Fraud Alert sends a clear signal to pharmaceutical and medical device manufacturers that speaker programs will receive heightened scrutiny going forward. The Alert follows in the wake of recent enforcement activity and statements by OIG indicating the same. That the Alert is concurrent with the COVID-19 pandemic is intentional and should not be ignored. Manufacturers would be wise to re-assess the compliance status of their speaker programs and should consider seeking further guidance and clarity from OIG, including through the Advisory Opinion process.

King & Spalding regularly counsels pharmaceutical and medical device manufacturers on a range of health care compliance issues, including speaker program business rules and compliance controls. We also regularly work with OIG and DOJ in the context of investigations and enforcement actions, and have substantial experience utilizing the OIG Advisory Opinion process to seek guidance and clarity from OIG. We are happy to help manufacturers further consider the implications of these recent developments for their speaker programs and determine next steps and meaningful risk mitigation strategies.

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[1] *See* 42 U.S.C. § 1320a-7b
[2] Id. at 5-6.
[3] Id. at 5.
[4] Id. at 3.
[5] Id. at 7.
[6] Id.
[7] *See* U.S. Dept. of Health and Human Svcs., Office of Inspector General, Compliance Program Guidance for Pharmaceutical Manufacturers (April 2003) at 21 *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf
[8] *See, e.g.*, U.S. Dept. of Health and Human Svcs., Office of Inspector General, A Roadmap for Physicians: Avoiding Medicare and Medicaid Fraud and Abuse at 22 *available at* https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf (current as of November 17, 2020); *see also* U.S. Dept. of Justice, Press Release, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations (September 26, 2019) *available at* https://www.justice.gov/opa/pr/pharmaceutical-company-targeting-elderly-victims-admits-paying-kickbacks-resolves-related#:~:text=Avanir%20has%20also%20agreed%20to,which%20is%20not%20an%20approved; *See also* U.S. Attorney's Office, S.D.N.Y., Manhattan U.S. Attorney Announces $54 Million Settlement Against Salix Pharmaceuticals for Using "Speaker Programs" as Mechanism to Pay Illegal Kickbacks to Doctors to Induce Them to Prescribe Salix Products (June 9, 2016) *available at* https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-54-million-settlement-against-salix-pharmaceuticals
[9] *See* U.S. Dept. of Justice, Press Release, Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020) available at https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians ($591 million was attributable to Novartis' speaker programs).
[10] Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis Corporation (June 30, 2020) at 13 *available at* https://oig.hhs.gov/fraud/cia/agreements/Novartis_Corporation_06302020.pdf.
[11] Id.
[12] Id. at 14 (note that payments for travel and travel related expenses do not count towards this limit).
[13] Id. at 28.
[14] Id. at 28.
[15] Id. at 28.
[16] Id. at 29.
[17] Id. at 29.
[18] Id. at 29.
[19] Id. at 30.
[20] Id. at 30.
[21] Id. at 30.
[22] Id. at 30.
[23] Id. at 30.

[24] See U.S. Dept. of Justice, Press Release, Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020) available at https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians ($591 million was attributable to Novartis' speaker programs).
[25] Id.
[26] See, e.g., PhRMA Code of Interactions with Health Care Professionals at 19 available at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf (suggesting that a private room at a restaurant is a proper venue for a speaker program).
[27] U.S. Dept. of Health and Human Svcs., Office of Inspector General, Special Fraud Alert: Speaker Programs at 5 (November 16, 2020) available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.
[28] Id. at 6.