Speaker Program Limits Are Specific To Novartis Settlement

By **Meena Datta, Whitney Nebolisa and Beth Hardcastle** (August 17, 2020)

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Much has been written about the recent settlement between Novartis Pharmaceuticals Corp. and the U.S. Department of Justice that resolves allegations of misconduct relating to in-person speaker programs held by the company from 2002 to 2011.

In particular, the novel and detailed speaker program restrictions set forth in the associated corporate integrity agreement between Novartis and the U.S. Department of Health and Human Services Office of Inspector General has garnered a great deal of discussion and interest within the pharmaceutical industry, specifically with respect to so-called virtual speaker programs.

The fundamental question many legal and compliance professionals are asking is whether the onerous speaker program restrictions in the Novartis corporate integrity agreement signal a heightened expectation by the OIG and DOJ with respect to compliance controls around speaker programs more generally.

It would be premature to view the restrictions in the Novartis corporate integrity agreement as the new normal for pharmaceutical speaker programs more generally. In particular, recent corporate integrity agreements, including those related to settlements addressing speaker programs, lack the specific restrictions set forth in the Novartis corporate integrity agreement.

Moreover, the underlying allegations relating to speaker program misconduct at issue in the Novartis case are similar in kind than alleged misconduct at issue in other cases. This, in turn, could suggest that the Novartis corporate integrity agreement may be better understood to be tailored to the specific circumstances and allegations of misconduct at issue in the Novartis case and not an evolution in the OIG's thinking about speaker programs more generally.

Nevertheless, it is always useful to examine corporate integrity agreements to understand their requirements and evaluate whether there are controls that may be useful for effective compliance design and implementation.

To that end, this article analyzes the remote learning and other speaker program restrictions in the Novartis corporate integrity agreement and provides context for the relative significance of the Novartis corporate integrity agreement restrictions for pharmaceutical manufacturer speaker programs more generally.

DOJ's Sustained Focus on Speaker Programs

As a threshold matter, the DOJ's attention on speaker programs is not new. Settlements within the pharmaceutical industry over the last 20 years have resolved various allegations related to speaker program misconduct that violated the Anti-Kickback Statute and other laws.

In the last four years, we have seen two other speaker program-specific settlements come out of the U.S. Attorney's Office for the Southern District of New York, the same office involved in the Novartis settlement. Like the Novartis settlement, the prior Southern District of New York speaker program cases contained allegations that the speaker programs sponsored by those companies lacked a legitimate purpose or were mere shams.

In general, corporate integrity agreements associated with speaker program settlements require affected manufacturers to create controls around speaker programs, such as ensuring that speakers complete compliance trainings, creating a centralized tracking system, and regular monitoring of speaker programs. But, the controls described in corporate integrity agreements are typically programmatic, and do not dictate the "where, when, and how" of the manufacturer's speaker programs.

Novartis Corporate Integrity Agreement — Speaker Program Restrictions

Why is the Novartis speaker program corporate integrity agreement so notable? It contains the following novel and restrictive measures.

First, as a threshold matter, speaker programs can no longer take place at restaurant venues, and alcohol may not be served or be available for purchase at these events. This is more restrictive than the prior corporate integrity agreements in which the underlying conduct related to speaker programs, and more specific and restrictive than widely accepted standards and practices, such as those set forth in the PhRMA Code on Interactions with Healthcare Professionals.

Second, the corporate integrity agreement specifies particularly onerous requirements for external speaker programs. Under the corporate integrity agreement, external speaker programs are defined as those which involve a healthcare professional speaker who is not a company employee. For these programs, events can be held only virtually, meaning that "the External Speakers shall be remote and shall not be in the same location as any audience member."

Sales representatives are not to be involved in the selection of external speakers, including the provision of nominations or recommendations. Moreover, programs led by external speakers must be completed within 18 months of U.S. Food and Drug Administration approval of a new product or indication. These programs are also subject to a total $100,000 cap on remuneration for each new product or indication, with each nonemployee speaker allowed a maximum of $10,000 payment for each new product or indication.

These requirements do not carry over to internal speaker programs. Internal speaker programs are programs in which the speaker is a company employee who is also a health care professional. For instance, there is no requirement in the corporate integrity agreement that an internal speaker be in a separate location from the audience. Likewise, there is no limitation on programming based on the timing of a product's life cycle.

The specific reasons driving these differences are not articulated in the corporate integrity agreement or settlement, but the restrictions, in some cases, can be tied to the underlying alleged conduct. Namely, it could be the case that the sharp compliance controls drawn around external speaker programs were focused on the misconduct at issue in the Novartis settlement.

For example, according to the government's allegations, sales representatives' nominations or recommendations regarding speakers were always approved by Novartis as long as the physician had a valid license and was not suspended or disbarred. The novel requirement that sales representatives cannot nominate or recommend speakers may stem from this alleged conduct.

In addition, the restrictions may reflect a conservative posture agreed upon by the parties. In any case, the effect is clear, namely, to highly restrict external speaker programs. This targets the obvious concern that external speakers are in a position to write prescriptions and recommend products, and therefore may be improperly motivated to recommend or prescribe to obtain additional speaking opportunities, and associated honoraria, in the absence of appropriate controls.

It is also worth noting that the Novartis speaker program corporate integrity agreement contains other novel restrictions, such as employee bonus restrictions. It is also notable that Novartis was under a corporate integrity agreement for a different matter at the time that the speaker program corporate integrity agreement was negotiated.

It is not atypical for the OIG to impose particularly onerous corporate integrity agreement requirements on companies that have engaged in multiple instances of misconduct over time. These observations could suggest that the OIG may have been focused on conduct-specific compliance controls in its negotiation of the Novartis corporate integrity agreement in light of their prior offenses rather than sending a broader message to the industry regarding speaker program guardrails.

Ultimately, the reasons for the heightened speaker program restrictions in the Novartis corporate integrity agreement are unclear as the misconduct at issue is similar in kind to alleged misconduct at issue in other cases. But to the extent any corporate integrity agreement contains new restrictions, it is often useful to consider such restrictions as reflective of the OIG's thinking with respect to the compliance controls needed in that particular case.

Any such new restrictions, however, may or may not reflect the OIG's thinking on broader compliance controls for the industry more generally. Compliance and legal departments should consider monitoring marketplace trends in speaker program implementation to understand whether virtual approaches to speaker programs remain commonplace following the COVID-19 crisis. They should also remain apprised of DOJ, OIG and other enforcement or legal developments with respect to such programming.

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