FDA Med Conference Study Raises Pharma Enforcement Risks

By **Jaime Jones, Brenna Jenny and Coleen Klasmeier** (August 5, 2021)


Jaime Jones


Brenna Jenny


Coleen Klasmeier

The U.S. Food and Drug Administration recently announced a new study on pharmaceutical companies' interactions with health care providers at exhibit booths during medical conferences.[1]

According to the relevant Federal Register notice, the study is designed to "provide insights to inform the advisory comments that [the FDA's Office of Prescription Drug Promotion, or OPDP,] provides to pharmaceutical companies that voluntarily seek FDA review" of exhibit booth materials.[2]

The study can also be expected to generate insights that may be used by the U.S. Department of Justice to pursue companies for potential instances of off-label promotion or making statements about safety or efficacy that could be characterized as false or misleading.

With the study launching nearly immediately — FDA representatives will be polling health care provider participants at unannounced medical conferences held during the time period of August 2021 through August 2022[3] — and particularly in light of the pandemic-necessitated lull in attendance at such conferences, drug companies should be refreshing training and other compliance efforts designed to ensure that company representatives align their communications to approved messages and to reflect fair balance.

The OPDP study "focuses on understanding the landscape of health care provider directed promotion of prescription drugs at medical conferences in general and, more specifically, how elements of pharmaceutical booths in medical conference exhibit halls impact health care provider attendees' perceptions of the drugs that are promoted at those booths."[4]

To do so, the OPDP will conduct a two-part study. First, researchers will ask conference attendees who are prescribers a line of questions designed to reveal how pharmaceutical companies "communicate about prescription drugs from the perspective of medical conference/exhibit hall attendees."[5]

The FDA's notice underscores how important it is that "the information provided by exhibitors to health care providers regarding the risks and efficacy of prescription medications not be false or misleading."[6] Accordingly, questions will probe the disclosures and disclaimers given to prescribers and any publications or references accompanying the presentation of information.

The second part of the study involves showing those same prescribers a video simulating an interaction between a pharmaceutical company representative at a medical conference and a prescriber.

Half of the study participants will view a video in which a disclaimer about data limitations is present, and the rest will view a video without the disclaimer. Half of the videos will involve a company representative with a business background and the other half will feature someone with a medical background.

Study participants will then be asked questions designed to show how the presence of a data limitation disclaimer and the background of the booth representative influence prescribers' perceptions of the promoted products.

The FDA disclosed the criteria the researchers will use to choose the conferences where prescriber attendees will be asked to participate. Twelve conferences, taking place between August 2021 and August 2022, that focus on therapeutic areas with the following attributes will be selected:

- "High number of currently promoted branded medications;
- high volume of prescriptions written;
- large patient population; and
- high amount of new drug development and promotional spending."[7]

Conferences must also take place within the U.S., have attendance of 5,000 or more individuals and focus on prescribers and clinicians, not insurers. The OPDP will seek to enroll conference attendees into the survey study, which will take place online, within seven days of their conference attendance.

By soliciting health care provider impressions of their recent interactions with pharmaceutical company representatives, the OPDP's study may do more than simply inform the review of written booth materials.

The study shines a spotlight on an area of industry engagement with prescribers that has long interested government enforcers — the myriad unscripted and undocumented conversations between pharmaceutical company representatives and prescribers. The government often lacks access to the content of these communications, particularly when they occur at medical conferences.

Where such information is available, usually related to in-office sales calls and in the form of call notes, physician verbatim data, other contemporaneous documentation or even some cases recordings, it has provided much fodder to fuel government investigations of alleged promotional misconduct.

Moreover, the study will likely generate insights relevant to the DOJ's modern take on its old off-label promotion enforcement wave — a focus on false or misleading statements — which has been necessitated by increasing judicial recognition of protections under the First Amendment for truthful, nonmisleading commercial speech.

Indeed, over recent years various DOJ officials have committed to bringing enforcement actions premised on such statements, explaining that they would be looking to "determine

whether a company's marketing was truthful or was instead false or misleading," and that this question is "just as relevant to on label marketing as … to off label marketing."[8] A number of settlements over the past few years reflect the DOJ pursuing allegedly false or misleading statements that minimized risks, overstated efficacy or otherwise misled prescribers about a particular drug.[9]

The information the OPDP intends to capture in this new study will be of great interest to the DOJ in future actions focused on supposedly false and misleading statements. But there is a real risk that such information, generated from prescribers' overall subjective recollections and potentially incorrect impressions of manufacturer speech, may lead the government down enforcement rabbit holes.

In all events, it is clearly more important than ever that pharmaceutical companies redouble their training of representatives attending medical conferences to ensure that they are prepared consistently to convey company-approved, accurate product messaging, including risk information and limitations on statements about safety and efficacy.

Where possible, companies should conduct compliance surveillance of interactions at booths and should consider ensuring that prescribers are provided with written materials reflecting the approved and fair balanced product information. Written confirmation of these messages may be important in ensuring prescribers can accurately recall the interactions if asked.

Jaime L.M. Jones, Brenna E. Jenny and Coleen Klasmeier are partners at Sidley Austin LLP.

[1] 86 Fed. Reg. 37,160 (July 14, 2021).

[2] Id. at 37,161.

[3] Id. at 37,162.

[4] Id. at 37,161.

[5] Id. at 37,162.

[6] Id. at 37,161.

[7] Id. at 37,162.

[8] DOJ, Press Release, Deputy Assistant Attorney General James M. Burnham Delivers Remarks to the 2018 Food and Drug Law Institute Conference (Dec. 13, 2018).

[9] See, e.g., DOJ, Press Release, Pharmaceutical Company Targeting Elderly Victims Admits to Paying Kickbacks, Resolves Related False Claims Act Violations (Sept. 26, 2019).