

Client Alert

April 2013

Government Alleges that Company's Speaker Programs are Illegal Kickbacks

Last Friday, the US Attorney for the Southern District of New York filed a [lawsuit](#) against Novartis Pharmaceuticals Corporation ("Novartis") alleging that the company defrauded federal healthcare programs by paying illegal kickbacks to over 25,000 healthcare professionals ("HCPs") via illegitimate speaker programs. It is notable that the lawsuit was brought by federal prosecutors in the Southern District of New York, an aggressive US Attorney's office not previously known for its prosecution of health care fraud.

The government alleges that from January 2002 through at least November 2011, Novartis used promotional speaker programs to pay kickbacks both to speakers and program attendees. The programs concerned the Novartis drugs Lotrel, Valtorna, and Starlix, as well as other Novartis drugs.

The complaint contains a variety of allegations that, according to the government, demonstrate that the programs were not bona fide speaker engagements but rather were ruses for funneling illegal kickbacks to HCPs. If true, the alleged conduct far exceeds the bounds of reasonable speaker programs outlined in the PhRMA Code. These allegations include:

Inadequate or Non-Existent Informational Exchange

- Speakers skipped slides in the deck that Novartis provided to the speaker or did not show the slides at all.
- Programs took place at venues that were not conducive to informational exchange (e.g., sports bars, fishing trips).
- Speakers and attendees mainly socialized at events, with little to no discussion of the drug product at issue.

Extravagant Meals

- Although Novartis' compliance policies established a monetary cap for providing "modest meals" to HCPs at speaker programs, sales representatives could evade this limit through use of an "unmet minimum." The unmet minimum was equal to the difference between a restaurant's minimum spend for an event and the per person charge for the event.
- This practice, among others, enabled Novartis to spend lavishly on food and alcohol, well beyond its established "modest meal" standards.
- In an extreme example, a meal at Nobu in Dallas cost \$3,250 per person.

Sales Representative Involvement

- Novartis' sales representatives had a quarterly budget for speaker programs, which they were pressured to spend.
- Sales representatives selected the speaker, the program topic, the date of the program, and the program venue.
- Many of the speakers that the sales representatives chose were family practice doctors and internists, rather than specialists in the appropriate fields of medicine.
- Sales representative compensation was based in part on the number of prescriptions written by doctors on representative's call lists, creating an incentive to use speaker programs as a vehicle to pay kickbacks to doctors.

Repeat Speakers and Attendees

- There was no limit on the number of speaker programs a doctor could attend or how often a doctor could attend the same program, and sales representatives were able to select repeatedly the same doctors on their call lists to be attendees at speaker programs on exactly the same topics.
- Often, speaker programs were attended by the same groups of HCPs who were friends with one another as well as with the speaker. "The doctors knew that if they did not attend each other's events the programs could not take place and none of them would continue to get paid by Novartis." Complaint ¶ 114.

Violation of Internal Company Policies

- Novartis' policy required at least three HCP attendees per speaker program, and HCPs from the speaker's own medical practice did not count toward the minimum attendance. Many speaker programs, however, went forward with less than three HCPs in attendance, and many programs had no one in attendance other than members of the speaker's own practice.
- Novartis falsified documents to make it appear that programs were legitimate, with an appropriate number of attendees, when they were not.

Improper Compensation

- Some speakers were paid for programs that did not even occur.
- Speakers were paid an average of between \$750 and \$1,500 per program, "with some speakers earning as much as \$3000 per program." Complaint ¶ 57.

The Complaint further alleges that Novartis' compliance policies were inadequate to prevent speaker program fraud and abuse. Alleged deficiencies include:

- Failure to require that a restaurant have a private room, or a quiet atmosphere, so as to be an acceptable speaker program venue.
- Failure to implement checks on whether sales representatives truthfully reported speaker program attendees.
- Failure to require attendee signatures.

- No controls to prevent sales representatives from hosting programs in which the same doctors repeatedly spoke to the same attendees on the same topic.
- Inadequate compliance monitoring for speaker programs.

According to the complaint, many instances of speaker program abuse were reported to Novartis' compliance department, but responsible employees were not adequately sanctioned.

As a result of the above misconduct, the government alleges that HCPs wrote prescriptions for Novartis drugs that they otherwise would not have written, resulting in the submission of many thousands of false claims to federal healthcare programs. According to the complaint, Novartis conducted internal analyses showing that the speaker programs had a high return on investment. The complaint cites examples where doctors began writing more prescriptions for the drugs at issue when they were paid speaker honoraria, and their prescribing habits dwindled or even disappeared once the doctors stopped receiving honoraria.

Based on these alleged violations of the Anti-Kickback Statute and False Claims Act, the government seeks treble damages, civil penalties, and restitution.

How We Can Help

Hunton & Williams LLP's Food and Drug Practice has extensive experience developing and advising on comprehensive drug and device marketing compliance programs, including appropriate interactions between industry and HCPs. Our lawyers have helped clients prepare internal policies governing appropriate product promotion through industry-sponsored speaker programs, with a focus on complying with the federal Food, Drug, and Cosmetic Act, the federal Anti-Kickback Statute and similar state statutes, the False Claims Act, and industry codes like the PhRMA Code. If you need assistance with developing, revising, or implementing your organization's compliance practices, or have questions regarding any facet of state and federal fraud, abuse, and disclosure laws, please contact us.

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