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Emerging Trends: Off-Label Use and Health Care Fraud Investigations

In a stunning move that has roiled the health care industry, prosecutors from the Department of Justice recently arrested and indicted the first-ever physician charged with illegally promoting the off-label use of a prescription drug. More recently, the Department of Justice and other law enforcement agencies have strongly indicated that they plan to actively investigate and pursue other physicians who may have received kickbacks from medical device companies in exchange for using their products. This is a notable break from prosecutors' usual focus on corporations and other business organizations.

Here, Daniel R. Margolis, a white collar criminal defense attorney and a former federal prosecutor in New York, and Edgar D. Bueno, a health care attorney and former Senior Counsel for the Office of Inspector General for the Department of Health and Human Services, discuss the new challenges facing physicians, practice groups and the health care industry in general under this new enforcement focus.

Q. Doctors are rarely charged for participating in kickback and off-label promotion schemes. Do the recent arrest of Dr. Gleason and pronouncements by government officials point to a new trend in prosecution?

Margolis: While it remains to be seen whether these developments signal a new trend, we think that the arrest of Maryland psychiatrist Dr. Peter Gleason and subsequent assertions by the DOJ and other federal regulators send a clear message that the federal government is willing to actively pursue individual physicians who participate in illegal kickback and drug promotion schemes.

Traditionally, the DOJ has prosecuted pharmaceutical and medical device manufacturers, rather than physicians. In fact, over the past several years, pharmaceutical and medical device companies have paid literally billions of dollars to resolve government investigations into allegations they broke federal laws prohibiting kickbacks and the promotion of drugs and medical devices for uses not approved by the U.S. Food and Drug Administration, which is known as off-label promotion.

As U.S. Attorney Christopher Christie of New Jersey recently said, now that they've "dealt with the supply issue," they will deal with the "demand issue," i.e., individual doctors. A spokesman for Christie's office confirmed that his office has ongoing investigations into individual physicians. Christie's statements were recently echoed by Lewis Morris, Chief Counsel in the Office of the Inspector General of the Department of Health and Human Services, who said the department is actively looking at those soliciting kickbacks.

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Bueno: The Office of Inspector General, on the other hand, does have some history in pursuing individual physicians and group practices for accepting bribes and kickbacks. In doing so, they have threatened physicians with hefty administrative fines and exclusion from participation in federal health care programs which means they could no longer receive reimbursement from Medicare and Medicaid. Interestingly, in investigating these cases, the OIG has had to rely on employees and sales representatives from the pharmaceutical and device companies to supply evidence against those physicians. I think this new focus by DOJ will only embolden the OIG to increase its own enforcement in this area.

Q. What's the basic legal framework involved here?

Margolis: Federal law prohibits drug and medical device manufacturers from directly promoting their products for off-label use. At the same time, physicians are allowed to prescribe federally-approved drugs for any use, even if they are not so indicated on the drug's label. They are also allowed to lecture about those uses and publish research papers on them. They can even accept money from non-industry-related organizations to speak at medical education seminars where off-label uses are discussed.

Q. Why would a doctor prescribe a drug for off-label use?

Bueno: Medical science is exactly that—a science that continually evolves. Physicians, who desperately want to help a patient that doesn't respond to drugs approved by the FDA, will sometimes prescribe other drugs that, while not approved for that particular ailment, have proven effective.

Margolis: It's understandable that physicians want to help their patients. But the DOJ is concerned that Big Pharma is conspiring to promote their drugs for off-label uses by enlisting physicians to speak or publish on their behalf. Disseminating information about off-label uses of a drug could open enormous and lucrative new markets for the drug's manufacturer.

Q. What's being alleged in the case against Dr. Gleason?

Margolis: The government alleges that he accepted fees and expenses to speak at hundreds of industry lectures and continuing medical education events, and received payments for office visits to individual doctors to talk about off-label uses of the narcolepsy drug Xyrem. In 2005 alone, he accepted approximately \$100,000 in fees and expenses from Xyrem's manufacturer. The government alleges that these programs were "thinly disguised promotional events" rather than educational seminars. In a press statement following his indictment, one FBI agent went so far as to liken Dr. Gleason to a "carnival snake oil salesman."

Q. What is Dr. Gleason's defense in this case?

Margolis: He has submitted a motion to dismiss the case arguing, among other things, that prohibiting him from talking about off-label drug uses violates his free speech rights under the First Amendment. This defense has been met with some success in the courts when offered on behalf of pharmaceutical companies and medical device manufacturers, but has never been tried in the defense of an individual physician.

What may be difficult for the government in this case and others against doctors is the issue of intent. In off-label drug promotion prosecutions, the government must prove that the defendant intended to promote the off-label use of the drug or medical device. Physicians could argue that they only

intended to conduct research on off-label uses and publish the results so that other physicians could make educated judgments about the drugs they prescribe to their patients. Similarly, in anti-kickback prosecutions, doctors could argue that they accepted payments from drug and medical device companies as reimbursement for their time, but they did not intend that the payments would have any impact on their prescribing habits or device usage, which is required under the statute.

Q. Who needs to be concerned about this?

Margolis: What concerns doctors most about Dr. Gleason's case is that they fear it will chill their ability to speak freely about prescription drugs at industry conferences and educational events, which could also stifle their ability to help patients. Until now, they felt no legal liability for doing so.

Penalties against physicians convicted of anti-kickback violations or off-label promotion offenses could include significant jail time, large fines and loss of research funding. On top of that, doctors found guilty of health care fraud cannot seek reimbursement from any federal or state health care program for medical services they perform.

Bueno: This new trend in investigations and prosecution should also concern physician groups, hospitals, research facilities and any individual or health care entity that receives funding from the drug or device industry or employs physicians who do so. As prosecutions increase, physicians may find that it is simply too risky to accept funding or other gratuities. In fact, there have been several large academic medical centers that now prohibit their staff physicians from receiving anything of value from vendors, including items such as coffee mugs, pens and notepads. While such measures may seem a bit extreme, it is not surprising given the government's focus in this area.

Margolis: Another potential ramification is that physicians may grow wary of accepting funding from drug and medical device companies for their participation in the companies' marketing activities. This may fundamentally alter key marketing practices currently employed throughout the drug and medical device industry.

Q. What steps can the health care industry take to comply with anti-kick-back and off-label promotion rules?

Bueno: There are so many rules and regulations, especially in the area of off-label, that almost anyone can get tripped up, or worse, get ensnared in an investigation. I believe it is important to have an effective compliance program that has a strong training and education component so staff and employees are well informed of the rules. Also, health care companies should carefully monitor the interactions and financial dealings between physicians on staff and industry representatives. Some of the areas of inquiry that the government has focused on recently have been: medical directorships, education and research grants, free samples, speaking engagements, speaker training programs, royalty arrangements and deep discounts on products. Finally, if an arrangement or an offer appears questionable or raises potential conflicts of interest, seek an opinion from outside counsel experienced in this area.

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“Emerging Trends” is a monthly feature produced by Pillsbury Winthrop Shaw Pittman, highlighting key legal issues impacting businesses today. To schedule an interview with any of our lawyers or to receive a copy of “Emerging Trends” on a regular basis, please contact Sandi Sonnenfeld at 212.858.1741 or at sandi.sonnenfeld@pillsburylaw.com.