

## Outside Counsel

## Expert Analysis

# Continuing Medical Education: Criminal Risks in Sponsorship

Just as the legal profession requires Continuing Legal Education (CLE) for all practitioners, the medical field similarly requires physicians to update and enhance their skills through participation in Continuing Medical Education (CME). Yet whereas it is difficult to conceive of a situation in which legal professionals could face criminal charges arising out of their participation in CLE, the situation is vastly different in the medical field, and the difference arises from the extent to which pharmaceutical and medical device manufacturers sponsor CME as part of their marketing efforts. In fact, recent testimony before the United States Senate underscores the significant degree of skepticism within federal law enforcement towards corporate-sponsored CME, the government's view that CME is often a thinly veiled effort to market products and funnel money to doctors, and the considerable risk that criminal exposure can result.

### Public Hearing

On July 29, 2009, the Senate Special Committee on Aging conducted a public hearing revealingly titled "Medical Research and Education: Higher Learning or Higher Earning?"<sup>1</sup> The hearing included testimony and the submission of written statements from, among others, the organization that oversees most CME accreditation in the United States, the pharmaceutical company Merck, trade associations representing both the medical device industry and the drug industry, and various physicians and academics who are either critical of or supportive towards industry funding of CME. Perhaps most notable at the hearing, however, was the testimony and written submission of Lewis Morris, who is Chief Counsel to the Inspector General of the United States Department of Health and Human Services (HHS-OIG) and thus is intimately involved in and familiar with the enforcement of criminal statutes in health care-related cases.<sup>2</sup>

The testimony and written statement that Mr. Morris presented to the Senate Special Committee on behalf of HHS-OIG consisted essentially of three parts. First, the HHS-OIG testimony addressed

By  
**Robert M.  
Radick**



background issues such as the extent of drug and device-manufacturer sponsorship of CME and the effect that such sponsorship has on CME content. Second, the HHS-OIG testimony described certain federal criminal laws that are "implicated by industry sponsorship of CME" and discussed criminal prosecutions that have arisen in the CME context. Third, the HHS-OIG testimony suggested various methods of ensuring CME's integrity and protecting it from commercial bias. Given the revealing nature of the HHS-OIG testimony—and in particular, the light it sheds on the aggressive approach of federal law enforcement towards corporate-sponsored CME—the testimony warrants careful review.

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### Sponsorship and Oversight

At the outset, the HHS-OIG testimony described what the government evidently believes to be the troubling interplay between CME and drug and device manufacturers. As the testimony indicates, while some physicians pay for their own CME, the more typical scenario is one in which drug and device manufacturers sponsor and subsidize the costs of CME presentations in order to promote their products, maximize market share and increase shareholder return. According to one report cited in the testimony, in 2007 alone the pharmaceutical industry paid more than \$1 billion to sponsor CME activities conducted in the United States. Another report cited in the testimony suggests the significant benefits of such sponsorship, noting that each dollar

that pharmaceutical companies spent on physician events and meetings, including CME, generates \$3.56 in increased revenue.

The danger of this extensive corporate sponsorship of CME, the testimony suggests, is the impact it has on CME content. In fact, the HHS-OIG testimony reflects the government's view that, through influence that can be "overt or subtle," the involvement of drug and device companies in CME tends to result in CME content that is strongly biased towards the sponsor's products, complements the sponsor's marketing strategies, and "almost exclusively covers topics related to commercial products, instead of broader discussions of patient care."

The testimony further opines that by allowing CME providers to offer programs that are funded directly by drug and device manufacturers, and by failing to review CME content in advance of its presentation, the Accreditation Council for Continuing Medical Education, which is the principal CME accrediting organization in the United States, does not act as a meaningful check on the introduction of commercial bias into CME. Thus, while certain of the testimony offered during the Senate hearing identified benefits that can result from industry sponsorship of CME,<sup>3</sup> the government's position appears simple: drug and device-company sponsorship of CME produces biased content that puts corporate profits ahead of patient health.

### Criminal Exposure

Given the decidedly critical view of HHS-OIG towards corporate sponsorship of CME, it is not surprising, then, that the HHS-OIG testimony next described the government's view that criminal prosecutions can have a salutary effect on industry influence. Indeed, in what may have been intended as a warning to the industry, the HHS-OIG testimony describes two criminal statutes that can be used and, in some instances, have been used to prosecute pharmaceutical companies, device manufacturers and even physicians for their alleged abuse of CME.

The first of the two criminal statutes cited by HHS-OIG as relevant to curbing bias in CME are the provisions of the Federal Food, Drug and Cosmetic Act (FDCA)<sup>4</sup> that generally prohibit drugs and devices from being introduced into interstate commerce unless first approved by the Food and Drug Administration (FDA). Under the FDCA, the marketing of products for uses that the FDA has not already reviewed and approved—a practice commonly referred to in the industry as "off-label marketing"—constitutes a misdemeanor criminal

ROBERT M. RADICK is a principal of Morvillo, Abramowitz, Grand, Iason, Anello & Bohrer. He was formerly the chief of Health Care Fraud Prosecutions in the U.S. Attorney's Office for the Eastern District of New York. In that position, he supervised the latter stages of the 'United States v. Gleason' case, discussed in this article.

offense, and off-label marketing can also rise to the level of a felony if undertaken with an intent to defraud or mislead.<sup>5</sup> Thus, while physicians are free to prescribe drugs and devices for indications not approved by the FDA,<sup>6</sup> pharmaceutical and device manufacturers risk significant criminal exposure under the FDCA for promoting such off-label use.

In the CME context, as the HHS-OIG testimony makes clear, drug and device companies risk criminal prosecution under the FDCA when they attempt to use CME as a means of disguising what in fact are covert off-label marketing campaigns. As an example of such a prosecution, the HHS-OIG testimony described the 2004 resolution of a Department of Justice investigation into Warner-Lambert's illegal marketing of the drug Neurontin. Although Neurontin had been approved by the FDA solely to supplement other medications used to treat seizures in epilepsy patients, the government alleged that Warner-Lambert engaged in a wide-ranging campaign to illegally promote Neurontin for a variety of off-label uses, and the company's marketing campaign was alleged to have included purportedly independent medical education events for which Warner-Lambert in fact directed the topic, speakers, content and participants.<sup>7</sup> Warner-Lambert ultimately resolved the Department of Justice's investigation into its marketing of Neurontin through a guilty plea to two felony counts of violating of the FDCA, the payment of a \$240 million criminal fine, the payment of \$190 million in civil damages, and its entry into a Corporate Integrity Agreement with HHS-OIG.<sup>8</sup>

A second off-label prosecution cited in the HHS-OIG testimony demonstrates that the misuse of CME can result in criminal charges against not just drug and device companies, but individual physicians as well. In April 2006, a grand jury sitting in the Eastern District of New York charged a psychiatrist named Peter Gleason with multiple criminal counts arising from instances in which, as a result of having been paid tens of thousands of dollars by the pharmaceutical company Orphan Medical Inc. (Orphan), Mr. Gleason illegally promoted Orphan's narcolepsy drug Xyrem for off-label uses.<sup>9</sup> (The author of this article supervised the latter stages of this matter while chief of Health Care Fraud Prosecutions in the U.S. Attorney's Office for the Eastern District of New York.)

According to the charging instruments in the case, Orphan engaged in a scheme to expand its limited market for Xyrem by paying Mr. Gleason to promote the drug off-label at medical education events conducted across the country. Notwithstanding pretrial motion practice in which Mr. Gleason argued that his promotional efforts on behalf of Orphan were protected under the First Amendment, Mr. Gleason ultimately pled guilty to a misdemeanor misbranding count,<sup>10</sup> and Orphan pled guilty to felony misbranding and agreed to pay civil and criminal penalties totaling \$20 million.<sup>11</sup>

In addition to identifying illegal off-label marketing as a crime that can result from industry involvement in CME, the HHS-OIG testimony indicated that the abuse of CME can result in significant criminal exposure under the federal antikickback statute as well.<sup>12</sup> In essence, the antikickback statute makes it a felony to knowingly and willfully offer, pay, solicit or receive anything of value as an inducement or reward for the purchase of goods and services covered by government health care programs.

In a simple example, offering a doctor or medical

professional cash in order to cause the prescribing of a particular drug or the use of a specific device would constitute a violation of the antikickback statute if the drug or device were reimbursable under federal programs. Similarly, a doctor or medical professional would likewise commit a felony violation of the antikickback statute if he or she knowingly and willfully accepted cash that was intended to influence his or her prescribing.

In the context of CME, as the HHS-OIG testimony notes, the item of value illegally provided or offered to a medical professional to reward or induce prescriptions would not likely be as obvious as a direct cash payment, but instead could include appointment to a position as a faculty member at CME programs, which itself would likely generate significant speaker's fees. Indeed, although there does not appear to have been a reported case in which a doctor was prosecuted for accepting kickback payments in the guise of speaker's fees for CME, the HHS-OIG testimony suggests that the government is more than willing to apply the antikickback statute to prosecute such disguised payments.

### Potential Reforms

After describing the potential for criminal prosecutions arising out of industry misuse of CME, the HHS-OIG testimony lastly addressed various proposals for reform. In this regard, the HHS-OIG testimony reflects the agency's view that the "surest way to eliminate commercial bias in CME is to eliminate industry sponsorship by funders who have a significant financial interest in physicians' clinical decisions." In other words, given the risk that CME will be "co-opted as a marketing tool" and that federal laws will be violated as a result, the position reflected in the HHS-OIG testimony is that CME should be sponsored solely by sources that have no financial interest in a medical provider's decisions, and that commercial entities such as drug and device manufacturers should be permitted to deliver promotional messages to physicians not through CME, but solely through advertising and marketing instead.

Nonetheless, at the same time the HHS-OIG testimony argued for a complete end to industry sponsorship of CME, the testimony also noted that this approach may not be immediately obtainable because "CME providers would need to identify alternative sources of funds to maintain the availability of CME." As a result, the HHS-OIG testimony offered three suggestions that, in the agency's view, would permit for continued industry funding of CME while simultaneously controlling industry's ability to influence the messages that physicians receive. In particular, the testimony recommended: (1) the separation of the CME grant-making functions within drug and device companies from those segments of the companies that focus on sales and marketing; (2) the establishment of "objective criteria" for making grants to a CME provider for particular CME programs; and (3) the elimination of industry control over the speakers used or content presented at CME, so as to prevent off-label marketing and the use of CME as a means of delivering illegal kickback payments to medical professionals.

### Conclusion

Measures that restrict drug and device company sponsorship of medical education would shift CME

costs onto physicians themselves, and as the HHS-OIG testimony realistically concludes, "whether the medical profession and health care industry are willing to embrace these measures remains to be seen." What is clear, however, is the scope of the government's concerns regarding commercial sponsorship of CME, and the serious risk that those who run afoul of those concerns will be prosecuted as a result.

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1. A Webcast of the hearing and copies of witness testimony are available at [http://www.aging.senate.gov/hearing\\_detail.cfm?id=316410&](http://www.aging.senate.gov/hearing_detail.cfm?id=316410&).

2. See "Medical Research and Education: Higher Learning or Higher Earning? Hearing Before the Senate Special Committee on Aging," 111th Cong. (2009) (written statement of Lewis Morris, Chief Counsel, Office of Inspector General, Department of Health and Human Services) (hereinafter, HHS-OIG Testimony), <http://www.aging.senate.gov/events/hr2141m.pdf> (last visited Oct. 6, 2009).

3. "Medical Research and Education: Higher Learning or Higher Earning?" at 3 (written statement and testimony of Thomas Stossel, MD), <http://www.aging.senate.gov/events/hr214ts.pdf> (last visited Oct. 6, 2009).

4. 21 U.S.C. §§301-399a.

5. Off-label marketing is criminalized under statutes that relate specifically to the "misbranding" of drugs and devices. See 21 U.S.C. §333(a)(1) (misdemeanor misbranding offense); 21 U.S.C. §333(a)(2) (felony misbranding offense). Pursuant to the FDCA, drugs and devices are considered "misbranded" if their labeling does not contain adequate directions for or warnings against their use. Courts have held that when a drug or device manufacturer promotes an item for an unapproved use, the labeling on that item is inadequate and the item is thus to be considered misbranded. See, e.g., *United States v. Caronia*, 576 F. Supp.2d 385, 389 n.2 (EDNY 2008).

6. See *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

7. See Information at 8-11, *United States v. Warner-Lambert Company LLC*, Crim. No. 04-10150 (D. Mass. May 13, 2004), <http://f11.findlaw.com/news.findlaw.com/wsj/docs/pfizer/usw151304cinf.pdf> (last visited Oct. 6, 2009).

8. See Plea Agreement at 4, *United States v. Warner-Lambert Company LLC*, Crim. No. 04-10150 (D. Mass. Sept. 2, 2009), <http://f11.findlaw.com/news.findlaw.com/wsj/docs/pfizer/usw151304plea.pdf> (last visited Oct. 6, 2009). Subsequent to the July 29, 2009, hearing before the Senate Special Committee on Aging, the Department of Justice also filed felony misbranding charges against Pharmacia & Upjohn Company (a subsidiary of Pfizer) based in part on Pfizer's alleged use of CME to promote the drug Bextra for unapproved uses. See Information at 17, *United States v. Pharmacia & Upjohn Company Inc.*, (D. Mass. Sept. 2, 2009), <http://www.usdoj.gov/usao/ma/Press%20Office%20-%20Press%20Release%20Files/Pfizer/Information.pdf> (last visited Oct. 6, 2009). On Sept. 15, 2009, Pharmacia & Upjohn pled guilty to the charge, and agreed upon civil and criminal penalties in the case totaling \$2.3 billion.

9. Indictment, *United States v. Peter Gleason*, Cr. No. 06-229 (EDNY April 5, 2007) (on file with author).

10. Mr. Gleason withdrew his motion in connection with the guilty plea, but Alfred Caronia, a co-defendant and former sales representative of Orphan who was also charged in the case, continued to advance the constitutional arguments. Those arguments were ultimately rejected by the court, see *United States v. Caronia*, 576 F.Supp.2d 385 (EDNY 2008), and following a jury trial, Mr. Caronia was convicted of a misdemeanor conspiracy to misbrand.

11. Indictment, *United States v. Orphan Medical Inc.*, Cr. No. 07-531 (EDNY July 13, 2007) (on file with author); Press Release, U.S. Attorney's Office for the Eastern District of New York, "Jazz Pharmaceuticals Inc. Agrees to Pay \$20 Million to Resolve Criminal and Civil Allegations in 'Off-Label' Marketing Investigation" (July 13, 2007), <http://www.usdoj.gov/usao/nye/pr/2007/2007jul13a.html> (last visited Oct. 6, 2009).

12. 42 U.S.C. §1320a-7b(b).