Annals of Health Law

Volume 23
Issue 1 *Winter 2014*

Article 3

2014

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## I. INTRODUCTION

Continuing medical education (CME) helps healthcare professionals in the United States keep their knowledge and skill sets up to date so they can provide the best possible care, improve patient outcomes, and protect patient safety through presentations and discussions on specific treatments and developments in medicine.[1] In its current state, however, it does not achieve this goal.[2] The Institute of Medicine (IOM) has accused pharmaceutical and medical device companies of financing CME delivery, influencing it solely to increase their market shares.[3]

Because of growing criticism of the influence of pharmaceutical and medical device manufacturers on CME, the industry has cut back its support to accredited CME providers in recent years. For example, Pfizer and GlaxoSmithKline, two of the largest drug manufacturers in the world, announced in 2008 and 2009, respectively, that they would no longer provide money to for-profit CME providers.[4] The trend of diminishing commercial support has continued: 2012 marked the sixth consecutive year of declining financial support for CME. Industry contributions in 2012 decreased 10.3% from 2011.[5] This accounted for approximately 27% of

* J.D., American University Washington College of Law, 2013; B.A., Washington University in St. Louis, 2010.

1. INST. OF MED., SUMMARY: REDESIGNING CONTINUING EDUCATION IN THE HEALTH PROFESSIONS 3 (Nancy Adler & Susanne Stoiber eds., 2009).

2. Id.

3. Id. at 4.

4. See Ed Silverman, Pfizer Ending Support for CME by Third Parties (July 2, 2008, 11:05AM), http://www.pharmalot.com/2008/07/pfizer-ending-support-for-cme-by-third-parties/; Press Release, GlaxoSmithKline, GSK Limits Medical Education Funding to Independent Programs with Highest Impact on Patient Care (Sept. 21, 2009), http://us.gsk.com/html/media-news/pressreleases/2009/2009_us_pressrelease_10062.htm.

5. ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., ACCME ANNUAL REPORT-2012 10 (2013), available at http://www.accme.org/sites/default/files/630_2012_Annual_Report_20130724_2.pdf; see also Ed Silverman, Commercial Support for CME Dives, Again (July 30, 2012, 9:09:AM), http://www.pharmalot.com/2012/07/commercial-support-for-cme-dives-again/ (noting that CME income fell 1.1% in 2011 from 2010, and the number of

CME providers' total income, opposed to over 50% in 2007.[6] Institutions provided 82% of CME without commercial support.[7] The drop in commercial support is not necessarily attributable only to industry restraint. Many factors have influenced the decline, including a weak national economy, a slowing pharmaceutical pipeline, more rigorous Accreditation Council for Continuing Medical Education (ACCME) guidelines, and a general growing criticism of industry-funded CME.[8] ACCME is the body responsible for accrediting institutions offering CME, developing criteria for evaluation of CME, and reviewing developments in CME's support of quality healthcare.[9] Despite the existence of ACCME Standards for Commercial Support, which set forth restrictions on how industry can provide funding to CME providers, they do not go far enough in minimizing industry influence on CME programs.[10]

While the recent decrease in industry support for CME results in decreased conflicts of interest, it has not eliminated industry influence over CME delivery. While the federal Department of Health and Human Services (HHS) has traditionally left the regulation of CME activity to the ACCME, ACCME has been lax in enforcing its own accreditation standards.[11] As a result, the Centers for Medicare and Medicaid Services

providers dropped to 687 from a peak of 736 in 2007). Interestingly, commercial support for CME provided by medical schools has not decreased as sharply, though several medical schools have begun to adopt policies that shy away from industry funding. See Natasha Singer & Duff Wilson, Debate Over Industry Role in Educating Doctors, N.Y. TIMES, June 23, 2010, at B1. The University of Michigan, for example, decided in 2010 that it would no longer accept money from drug and device manufacturers to fund CME activities. Id.

6. See ACCME ANNUAL REPORT-2012, supra note 5, at 10.

7. Id. at 35.

8. Kevin B. O'Reilly, As CME Funding Shifts from Industry, Others Foot the Bill, AMERICAN MEDICAL NEWS (Sept. 12, 2011), http://www.amednews.com/article/20110912/profession/309129948/2/.

9. Accreditation Council for Continuing Med. Educ., About Us, http://www.accme.org/about-us (last visited Nov. 16, 2013).

10. See ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., THE ACCREDITATION REQUIREMENTS OF THE ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME), 1 (2012) [hereinafter ACCME STANDARDS FOR COMMERCIAL SUPPORT], available at http://www.accme.org/sites/default/files/626_Accreditation_Requirements_Document_20120924.pdf; see, e.g., INST. OF MED., supra note 1; Marc A. Rodwin, Drug Advertising, Continuing Medical Education, and Physician Prescribing: A Historical Review and Reform Proposal, 38 J. L. MED. & ETHICS 807, 811 (2010).

11. See, e.g., Senate Special Committee on Aging Committee Hearing, INFOTECH NEWS (July 30, 2009) [hereinafter Nissen Testimony], http://it.tmcnet.com/news/2009/07/30/4301036.htm (recounting Steven Nissen, MD, Chairman, Department of Cardiovascular Medicine, Cleveland Clinic's testimony to the Senate's Special Committee on Aging, including that the ACCME's enforcement is "largely ineffective," as the organization seems "uninterested or incapable of enforcing" its own policies); Nissen Puts Stake Through ACCME's Heart at Senate Hearing on Industry-Funded CME, PHARMA MARKETING

(CMS) recently promulgated rules under the Physician Payments Sunshine Act that require full disclosure of any industry payments to physicians through CME activities.[12] However, the regulations exempt indirect payments made by industry players to accredited CME providers from the reporting requirements, creating a means for industry to avoid disclosure of payments made.[13] This has reignited the debate about Industry influence over CME delivery.

This article highlights the various flaws in the way CME is conducted, financed, regulated, and evaluated. Part II discusses the regulatory framework for CME activities, including the accreditation process and the history of the roles of the FDA and the HHS Office of Inspector General's (OIG's) roles in ensuring independence and reliability in CME content. Part III focuses on the various shortcomings of the current regulatory schemes that seek to protect against undue industry influence in CME activity. Finally, Part IV provides recommendations for improving the CME programming framework to ensure accountability and independence for CME providers.

## II. HISTORY AND SHORTCOMINGS OF THE CURRENT CME REGULATION REGIME

While HHS has largely left CME regulation to ACCME, a regulatory framework does exist - made up of various federal laws, regulations, and industry codes. The federal government has a hand in preventing off-label marketing that occurs during CME activities, though courts have largely restricted it from directly regulating CME content because of First Amendment concerns.[14] Instead, the ACCME's accreditation standards and its Standards for Commercial Support are the primary means of regulation for CME activities.[15] The ACCME enforces its guidelines through the threat of revoking a CME provider's accreditation.[16] Other voluntary guidelines, such as the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers and the Pharmaceutical Research

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BLOG (July 30, 2009), http://pharmamkting.blogspot.com/2009/07/nissen-puts-stake-through-accmes-heart.html.

12. Physician Payments Sunshine Act, 42 U.S.C.A. § 1320a-7h(a)(1)(A) (West, WestlawNext through P.L 113-31).

13. See 42 C.F.R. § 403.904(g)(1) (West, WestlawNext through Dec. 26, 2013; 78 Fed Reg 78,691); see also Larry Husten, No Sunshine for Continuing Medical Education, FORBES (Feb. 1, 2013), http://www.forbes.com/sites/larryhusten/2013/02/01/no-sunshine-for-continuing-medical-education/.

14. See, e.g., Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

15. See ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, at 1.

16. See id.

Manufacturers Association (PhRMA) Code, also play a role in creating an environment that limits industry bias in CME.[17] Because these other guidelines are only voluntary, however, their effectiveness is limited. Finally, while the federal government is restricted from regulating CME content beyond off-label promotion, it can require full disclosure of industry payments to physicians through the Physician Payments Sunshine Act (PPSA). This legislation, too, is limited in curbing industry influence, as the final regulations do not require disclosure of industry payments to accredited CME providers. This section defines CME and explains the various forms of industry bias before discussing each of these sources of CME regulation and its effectiveness in curbing industry bias in CME activities.

### A. What is CME?

Graduating from medical school and completing residency mark the first steps in a physician's career-long commitment to education.[18] Physicians obtain this continued education through CME programs. CME consists of presentations and discussions on specific treatments and developments in medicine and helps physicians and other medical professionals obtain information and insights that can improve patient care.[19] CME is required by most state licensing authorities in order for physicians to maintain their medical license.[20] Hospitals and other institutions may impose additional CME requirements on physicians who practice at their facilities.[21]

Many CME programs are either partially or fully subsidized by pharmaceutical and medical device manufacturers whose products are often related to the topic of the CME program.[22] Therefore, CME can provide an effective forum through which industry sponsors market their products and increase prescriptions for their products. Drug companies' interests,

17. See generally PHARM. RESEARCH & MFRS. OF AM., CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS 1, 6 (2009) [hereinafter PHRMA CODE], available at http://www.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008-1.pdf.

18. Medical Research and Education: Higher Learning or Higher Earning?: Hearing before the S. Special Comm. on Aging, 111th Cong. 1 (July 29, 2009) (statement of Lewis Morris, Chief Counsel to the Inspector Gen., Dep't of Health & Human Servs.) [hereinafter Morris Testimony], available at https://oig.hhs.gov/testimony/docs/2009/07292009_oig_testimony.pdf.

19. See AM. MED. ASS'N, THE PHYSICIAN'S RECOGNITION AWARD AND CREDIT SYSTEM 2 (2010), available at http://www.ama-assn.org/resources/doc/cme/pra-booklet.pdf.

20. See generally AM. MED. ASS'N, STATE MEDICAL LICENSURE REQUIREMENTS AND STATISTICS 53-56 (2010), available at http://www.ama-assn.org/ama1/pub/upload/mm/40/table16.pdf.

21. Id. at 1.

22. See ACCME ANNUAL REPORT-2012, supra note 5, at 10.

however, do not necessarily align with physicians' interests in providing the best possible care for their patients, as such companies have stockholders and therefore aim to maximize profits and increase market share.[23]

### B. Commercial Bias in CME

Because CME providers depend financially on pharmaceutical and medical device companies, the potential for bias and conflicts of interest is great. In particular, there is a risk that companies will use CME as a means to inappropriately influence health professionals to increase their market shares.[24] Generally, two major forms of commercial bias in the CME context: (1) commercial content bias, where the content or format of a CME activity is designed to promote a specific product of one of the commercial sponsor; and (2) commercial topic bias, where the prevalence of topics becomes skewed toward topics that are commercially supported.[25]

Content bias can take place in a variety of ways. For example, a drug company might provide slides for a particular speaker at a CME activity to ensure that the speaker discusses their drug, or a drug company might plant an audience member to ask a particular question about their drug. The most blatant form of content bias occurs when a CME program funded by a drug company presents information about a drug that unfairly compares it to other drugs by making claims that a specific drug is the best treatment.[26] Drug companies also realize they can profit from merely urging physicians to prescribe a particular class of drugs in which their product exists.[27]

A well-known example of content bias in CME occurred in the 2000s when AstraZeneca's used CMEs to promote off-label uses for its anti-psychotic drug Seroquel, a drug approved to treat schizophrenia and bipolar disorder in adult patients.[28] Federal prosecutors alleged that AstraZeneca had targeted its illegal marketing towards doctors who do not typically treat schizophrenia or bipolar disorder, such as primary care physicians,

23. INST. OF MED., supra note 1.

24. See id. at 71.

25. ACCREDITATION COUNCIL FOR CONTINUING MED. EDUC., STATEMENT FROM THE ACCREDITATION COUNCIL FOR CONTINUING MEDICAL EDUCATION (ACCME) TO THE INSTITUTE OF MEDICINE COMMITTEE ON CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 11 (2008), available at http://accme.org/sites/default/files/null/151305e9-cb64-4bac-8539-fe010b640527_uploaddocument.pdf.

26. See HOWARD BRODY, HOOKED: ETHICS, THE MEDICAL PROFESSION AND THE PHARMACEUTICAL INDUSTRY 206 (2007).

27. See id. at 207.

28. Press Release, Dep't of Justice, Pharmaceutical Giant AstraZeneca to Pay $520 Million for Off-label Drug Marketing (Apr. 27, 2010), available at http://www.justice.gov/opa/pr/2010/April/10-civ-487.html.

pediatricians, and geriatricians.[29] AstraZeneca allegedly unduly influenced speakers participating in company-sponsored CME by providing them with content to use during presentations.[30] In response to these allegations that it engaged in a widespread scheme to illegally promote off-label uses for Seroquel, the company settled for $520 million.[31]

Topic bias, on the other hand, occurs when CME covers topics that have the most commercial (i.e., industry) support, rather than topics that fill gaps in medical education geared toward achieving better patient outcomes.[32] CME providers develop programming that attracts funding from drug and device companies - programming that involves treatments using the drug and device companies' products.[33] Topic bias is detrimental to patient care because it results in physicians learning about treatments that involve use of specific drugs or medical devices rather than treatments that achieve the best outcomes.[34] As this article explains below, most CME regulation aims to limit content and topic bias,[35] thereby ensuring that CME programming does not serve as a platform for drug and device companies to engage in off-label promotion.

### C. *History of the FDA's Regulation of CME*

In the 1980s, drug and device companies began increasing their funding for CME seminars and they routinely paid physicians' expenses for registration, travel, and lodging for CME programming.[36] Recognizing the dangers of too much industry influence on CME, the FDA considered stepping in to regulate CME in the early-1990s.[37] In response, the American Medical Association (AMA) and the Pharmaceutical Research Manufacturers Association (PhRMA) issued voluntary guidelines prohibiting such funding in an effort to prevent stricter federal oversight.[38] Nonetheless, in 1992 the FDA issued a draft policy indicating that although drug company-controlled CME programs could not recommend off-label

29. Id.
30. Id.
31. Id.
32. See INST. OF MED., supra note 1.
33. See id.
34. See id.
35. See, e.g., Accreditation Council for Continuing Med. Educ., Standards for Commercial Support: Standards to Ensure Independence in CME Activities, http://www.accme.org/printpdf/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support (last visited Nov. 26, 2013).
36. See Rodwin, supra note 10, at 810.
37. See id.
38. See id.

uses, the CME, independent of industry influence, could recommend off-label uses.[39] This 1992 draft still allowed commercial funders, such as drug and device companies, to recommend speakers for individual events.[40] CME providers and faculty were required to disclose their financial relationships with commercial funders, and faculty that discussed off-label drug uses had to state that the FDA had not approved the uses.[41]

### 1. 1997 CME Guidance

In 1997, the FDA published its final guidance document relating to the commercial support of CME that was less stringent than the 1992 guidance: the Final Guidance on Industry-Supported Scientific and Educational Activities (CME Guidance).[42] The CME Guidance contained a list of twelve factors that industry and CME providers could use to help keep CME activities independent of industry influence.[43] The FDA stated that it would not prosecute CME providers that discussed off-label uses for failing to meet one of its criteria for independence.[44]

The 1997 guidance made it clear that the FDA did not intend to regulate industry-supported CME programs that are independent of the influence of the supporting company.[45] Rather, the FDA published the guidance document to provide a list of factors on which companies and CME providers can rely, to ensure that their activities are free from the supporting manufacturer's influence.[46]

### 2. Washington Legal Foundation Cases

In 1997, the Washington Legal Foundation (WLF) challenged the CME guidance alleging that it unconstitutionally restricted commercial speech. The WLF sought to enjoin the FDA from enforcing or relying on its policies restricting manufacturer off-label promotion of drugs and devices

39. Draft Policy Statement on Industry-Supported Scientific and Educational Activities, 57 Fed. Reg. 56,412 (Nov. 27, 1992).

40. Id.

41. Id.

42. 62 Fed. Reg. 64,074 (Dec. 3 1997).

43. Id. at 64,097-99 (indicating that some of the factors included control of content and selection of presenters and moderators; disclosures; the focus of the program; the audience selection; the opportunities for discussion; provider involvement in sales or marketing; complaints, etc.).

44. See Rodwin, supra note 10, at 810-11.

45. 62 Fed. Reg. at 64,076.

46. Id.

through its involvement in CME seminars and symposia.[47] Applying the test from *Central Hudson Gas & Electric Corp. v. Public Service Comm'n* of New York,[48] the court found that the guidance documents violated the First Amendment because they were not the least burdensome method of restriction on commercial speech.[49] The court pointed out that full, complete, and unambiguous disclosure by the manufacturer would advance the FDA's interest while placing a smaller burden on manufacturers.[50] The court thus granted summary judgment and issued a permanent injunction barring the FDA from continuing to enforce its off-label marketing policies based on the guidance documents.[51]

Under the injunction, a manufacturer was still required to disclose its interest in the subject drug or device if it "sponsors or provides financial support" for the CME program in which unapproved uses are referenced. The manufacturer was also still required to disclose that the FDA had not approved the referenced use. The court's order, however, enjoined the FDA from prohibiting manufacturers from suggesting content or speakers in connection with a CME program as long as the manufacturer met two conditions: (1) the manufacturer made the two disclosures, and (2) the program was administered by an "independent program provider."[52]

The FDA ultimately took the position that the CME guidance did not independently authorize it to prohibit or sanction speech.[53] Because the FDA claimed that the guidance document was not binding on the agency, the Court of Appeals for the District of Columbia later vacated the

47. Wash. Legal Found. v. Friedman (WLF I), 13 F. Supp. 2d 51, 54 (D.D.C. 1998) amended by 36 F. Supp. 2d 16 (D.D.C. 1999) appeal dismissed, judgment vacated in part sub nom. Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000) and amended by 36 F. Supp. 2d 418 (D.D.C. 1999) and appeal dismissed, judgment vacated in part sub nom. Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).

48. 447 U.S. 557, 563 (1980) (finding that a law or regulation restricts free speech in a commercial setting will violate the First Amendment by considering the following factors: (1) whether the speech at issue concerns lawful activity and is not misleading; (2) whether the asserted government interest is substantial; (3) whether the regulation directly advances the governmental interest asserted; and (4) whether it is not more extensive than is necessary to serve that interest).

49. WLF I at 73.

50. Id. (noting that full disclosure is less restrictive on speech while also dealing more precisely with the FDA's concerns).

51. Id. at 74.

52. Id. at 74-75 (defining "independent program provider" as one that has (i) has no common ownership or other corporate affiliation with the manufacturer, engages in the business of creating and producing CME seminars, and (ii) is accredited by a national accrediting organization pertinent to the topic of the seminars).

53. Wash. Legal Found. v. Henney (WLF II), 202 F.3d 331, 335 (D.C. Cir. 2000).

injunction.[54] The FDA then issued a notice regarding the WLF II case, stating that it would continue to use the CME guidance in its enforcement but that a manufacturer may raise the First Amendment defense if the FDA brought an enforcement action.[55] After the WLF moved to reaffirm the prior injunction, the district court expressed disapproval of the FDA's notice, describing it as a "farce" and suggesting that its policy of inviting constitutional challenges does not solve any constitutional issues.[56] Nonetheless, the court did not reaffirm the prior injunction.[57]

### D. Current Federal Approach: FDA and OIG Enforcement of Off-Label Promotion, False Claims Act, and Anti-Kickback Statute Violations

As a result of the WLF cases, the FDA has little room to regulate CME activities directly. However, industry support for CME may implicate several federal laws in specific circumstances. One example is the FDA and OIG's regulation of off-label marketing. Under the Food, Drug, and Cosmetic Act (FDCA), a drug or device manufacturer may not introduce a new drug, biologic, or device into interstate commerce without having obtained approval from the FDA for the product's label.[58] When its label contains information that has not been approved by the FDA pursuant to the drug's new drug application (NDA) or supplemental NDA, a new drug's label is illegally false or misleading.[59] Further, while physicians may prescribe drugs or devices for unapproved, or "off-label" use, the FDCA prohibits any company from marketing such products for any off-label use.[60]

Realizing the opportunities to increase drug sales through physicians prescribing drugs for off-label uses, drug companies seek to promote their drugs for off-label uses in any legal (and illegal) way possible. Drug companies often fund CME activities specifically because they can effectively promote off-label uses for their products under the regulatory protections enjoyed by accredited CME, as its content is scientifically

54. Id. at 337.

55. Decision in Wash. Legal Foundation v. Henney, 65 Fed. Reg. 14,286 (Mar. 16, 2000).

56. Wash. Legal Found. v. Henney, 128 F.Supp.2d 11, 15 (D.D.C. 2000).

57. Id. at 16.

58. 21 U.S.C.A. § 355(a)-(b) (West, WestlawNext through P.L. 113-31).

59. Id.; see also § 331(a) (providing that introducing a misbranded drug into interstate commerce is a "prohibited act"); § 334(a)(1) (providing that prohibited drugs introduced into interstate commerce are subject to seizure by the FDA).

60. See § 352(a).

supported and peer-reviewed. Thus, the FDA cannot directly regulate CME content unless it has sufficient evidence that the drug company's role in the CME program amounted to off-label promotion.

Another law that is implicated when a drug company promotes off-label uses for a drug during a CME event is the Federal False Claims Act (FCA).[61] The FCA provides that anyone who knowingly presents or causes to present a false or fraudulent claim for payment or reimbursement for medical items or services, or makes or causes to be made a false record or statement material to an obligation to pay the government is liable for a civil monetary penalty plus treble damages, which can be hundreds of millions of dollars.[62] The FCA is implicated when a pharmaceutical manufacturer engages in a scheme to promote off-label uses for its drugs and the illegal marketing campaign results in the submission of claims for payment from federal healthcare programs.[63] Conspiring to submit false claims, such as a CME provider knowingly collaborating in the promotion of an off-label use, could also lead to a cause of action under the FCA.

CME programs funded by drug or device manufacturers may also implicate the Federal Anti-Kickback Statute.[64] The Anti-Kickback Statute prohibits payments to induce the referral of beneficiaries of federal healthcare programs.[65] It targets any person or entity that knowingly and willfully solicits or receives any remuneration or offers or pays any remuneration related to furnishing or obtaining items or services paid by a federal healthcare program.[66] In the CME context, the Anti-Kickback Statute is implicated when a pharmaceutical manufacturer directs a CME provider to pay a physician to speak at a CME event in exchange for the physician prescribing more of the drug company's products.

While these laws are expansive and largely effective in deterring or punishing illegal kickbacks and off-label marketing,[67] they were not developed to limit industry influence on CME activity specifically. As

61. See 31 U.S.C.A. § 3729 (West, WestlawNext through P.L. 113-31).

62. Id.; see also Katie Thomas & Michael S. Schmidt, Glaxo Agrees to Pay $3 Billion in Fraud Settlement, N.Y. TIMES (July 2, 2012), http://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html?pagewanted=all.

63. See § 3729(g).

64. See 42 U.S.C.A. § 1320a-7b(b) (West, WestlawNext through P.L. 113-31).

65. See id.

66. Id.

67. Notably, illegal kickback and off-label marketing are still widespread practices, as evidenced by the many settlements drug companies enter into with the federal government. See, e.g., Katie Thomas, Johnson & Johnson Unit Settles State Cases Over Risperdal, N.Y. TIMES (Aug. 30, 2012), http://www.nytimes.com/2012/08/31/business/johnson-johnson-unit-settles-state-cases-over-risperdal.html; Glaxo Agrees to Pay $3 Billion in Fraud Settlement, supra note 62.

demonstrated by the WLF line of cases, courts tend to disfavor federal enforcement of laws in contexts that inhibit commercial speech in the medical fields.[68] Thus, the Anti-Kickback Statute, the FDCA, and the FCA are largely ineffective in regulating commercial bias in CME.

### E. The OIG Guidelines

In 2003, the OIG issued proposed guidelines that restricted pharmaceutical and medical device funding of CME activities.[69] After the AMA, PhRMA, and more than twenty-five medical societies requested that OIG drop the restrictions on CME funding, the OIG, in its 2003 final guidelines, conceded.[70] As the OIG stated in its final guidance, "support for educational activities sponsored and organized by medical professional organizations raise little risk of fraud or abuse."[71] Still, OIG explained that commercial sponsors risk prosecution when they control CME content.[72] The guidelines recommend that drug and device companies separate marketing activities from grant making activities.[73] These guidelines, however, still leave much of the enforcement and compliance monitoring up to the ACCME and their Standards for Commercial Support.

### F. *The ACCME's Standards for Commercial Support*

In addition to compliance with the federal laws described above and voluntary compliance with the OIG guidance, CME providers must comply with the ACCME accreditation guidelines and Standards for Commercial Support. While the FDA and OIG largely defer to the ACCME – a non-governmental fee-funded group – for compliance monitoring, the ACCME standards fall short of minimizing commercial influence on CME activity. For example, the ACCME Standards for Commercial Support allow providers to show potential and current funders their draft program and receive suggestions from industry sponsors.[74] The standards only prohibit an industry sponsor from requiring a CME provider to accept advice or services concerning teachers, authors, participants, or other education

68. See, e.g., WLF II.

69. Draft OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 67 Fed. Reg. 62,057 (Oct. 3, 2002).

70. Rodwin, supra note 10, at 811; see OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003).

71. 68 Fed. Reg. at 23,738.

72. Id.

73. Id.

74. See Rodwin, supra note 10, at 811.

matters, including content, as conditions of contributing funds or services.[75] This section summarizes the ACCME standards with which CME providers must comply to obtain accreditation, develop a CME topic, and solicit funds from industry sponsors. It also highlights the deficiencies in the ACCME's standards and enforcement processes.

1. Obtaining Accreditation

For a CME provider to be able to give CME credits to physicians, the provider must first obtain ACCME "accreditation."[76] The ACCME accreditation standards contain provisions to ensure that CME is independent, based on valid content, and contributes to health care improvement for patients.[77] The ACCME accredits hundreds of CME providers, most of which are physician membership organizations, publishing/education companies, medical schools, and healthcare delivery systems.[78] One of the primary requirements for eligibility is that the organization applying for accreditation not be a "commercial interest," defined as any entity producing, marketing, reselling, or distributing healthcare goods or services consumed by, or used on, patients.[79] This policy seeks to ensure that organizations developing CME stay district from entities with commercial interests in healthcare goods or services.[80] A CME provider also cannot advocate for a commercial interest, have a parent company that advocates for a commercial interest, or have a sister company that advocates for a commercial interest or is a commercial interest.[81] If an

75. See ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, para. 3.2.

76. See PHRMA CODE, supra note 17, at 6. Pharmaceutical and device manufacturers need not obtain accreditation to sponsor their own programs as part of so-called "non-CME" or "informational presentations." Id. At these events, a drug company through a speaker has free rein to say whatever it wants – subject to the restrictions in the PhRMA Code, which is a voluntary code, and in the FDCA, Anti-Kickback Statute, and FCA. Id. While these financial interactions between industry and physicians present issues of reliability and bias for information presented to physicians, an in depth discussion of non-accredited CME activities is beyond the scope of this paper. Id.

77. ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10.

78. BERNARD LO & MARILYN J. FIELD, CONFLICTS OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 140 (2009) (noting that ACCME had 740 accredited CME providers in 2008).

79. See Accreditation Council for Continuing Med. Educ., Definition of a Commercial Interest, http://www.accme.org/printpdf/requirements/accreditation-requirements-cme-providers/policies-and-definitions/definition-commercial-interest (last visited Nov. 26, 2013).

80. Accreditation Council for Continuing Med. Educ., Determining Your Eligibility, http://www.accme.org/printpdf/cme-providers/first-time-applicant/determining-your-eligibility (last visited Nov. 26, 2013).

81. Accreditation Council for Continuing Med. Educ., See How Can I Determine if My Organization is a Commercial Interest?, http://accme.org/printpdf/ask-accme/how-can-i-

applicant is unsure whether it is an ACCME-defined commercial interest, it can request a corporate structure review from the ACCME for a $4,000 fee.[82]

If the applicant is eligible to apply for accreditation, it must then verify through a document review process that it is capable of complying with ACCME Standards for Commercial Support.[83] The ACCME makes an initial accreditation decision based upon the organization's demonstration of its ability to maintain a compliance program to root out conflicts of interest and to prevent control or influence of CME content by industry sponsors.[84] Receiving initial accreditation results in a two-year provisional accreditation term, after which the organization can obtain either a four- or six-year term of accreditation.[85]

### 2. Developing and Obtaining Approval for a Topic

Before planning a specific CME program, a CME provider must first develop a topic – a process that can be ripe for undue influence and bias from industry. Interestingly, the ACCME Standards for Commercial Support do not prohibit CME providers from asking pharmaceutical or device companies about topics or speakers. The industry sponsor may not, however, require the provider to accept advice or services concerning teachers, authors, participants, or content as conditions of contributing funds or services.[86] The ACCME Standards for Commercial Support require that the provider make independent decisions about how it uses this advice from commercial entities and prohibits the commercial supporter from controlling the content or speakers in any way.[87]

### 3. Obtaining Commercial Support for CME Activities

After obtaining approval to hand out CME credit for a given CME activity, a provider can solicit drug and device companies for commercial support. The ACCME Standards for Commercial Support define

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determine-if-my-organization-commercial-interest (last visited Nov. 26, 2013).

82. Determining Your Eligibility, supra note 80.

83. Accreditation Council for Continuing Med. Educ., Initial Accreditation Process http://www.accme.org/printpdf/cme-providers/first-time-applicant/initial-accreditation-process (last visited Nov. 26, 2013).

84. Accreditation Council for Continuing Med. Educ., How the ACCME Makes Decisions, http://www.accme.org/printpdf/cme-providers/first-time-applicant/how-accme-makes-decisions (last visited Nov. 26, 2013).

85. Id.

86. ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, at 3.

87. Id.

"commercial support" as financial or "in-kind contributions given by a commercial interest that are used to pay all or part of the costs of a CME activity."[88] Examples include meals, speaker honoraria, travel expenses, or a meeting space.[89] When a provider decides to solicit funds from drug and device manufacturers, it must first inform the ACCME of its intent to do so by listing potential commercial supporters on a sponsorship application.[90] When completing grant requests, the provider must also demand that any payments be made directly to the provider, as opposed to any speakers or vendors.[91] Once the provider approves a request, the manufacturer generally responds with a Letter of Agreement (LOA), which the provider submits to the ACCME prior to the date of the CME program.[92]

The CME provider must make all decisions regarding the disposition and disbursement of commercial support. The industry sponsor cannot require the provider to accept advice or services concerning teachers (speakers), authors, participants, or content as a condition of contributing funds. The parties, including the CME provider, must include in a signed written agreement the terms, conditions, and purposes for the commercial support.[93] The CME provider must be able to produce accurate documentation showing the receipt and expenditure of the commercial support.[94]

Further, the CME provider must be able to show that everyone who is in a position to control the content of an education activity has disclosed all relevant financial relationships with any commercial interest to the CME provider.[95] CME providers must have a formal process to identify and resolve any conflicts of interest.[96] These ACCME standards aimed at resolving conflicts of interest target those in a position to control CME content. For example, the ACCME requires CME providers to give a

88. Id. at 13.

89. See id. at 4.

90. See id. at 11.

91. Id. at 4.

92. See ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, at 4, 13. A LOA is a written agreement specifying the terms, conditions, and purposes of the commercial support awarded by a commercial entity to a provider. Id. All commercial support requires a LOA with the signatures of the director of the CME provider and the supporting company. Id.

93. See id. at 4.

94. Id.

95. Id. at 13 (defining "relevant financial relationships" as financial relationships in any amount occurring within the previous twelve months that create a conflict of interest). An individual who refuses to disclose any relevant financial relationship is disqualified from being a planning committee member, teacher, or author of CME and cannot have any control over the presentation or evaluation of the CME program. Id. at 3.

96. Id.

balanced view of therapeutic options and encourages the use of generic names of therapies, rather than promoting the proprietary names.

4. Problems with ACCME Standards for Commercial Support

The availability of industry funding affects the types of CME programs being offered. If alignment with industry interests determines CME content, areas that lack industry support, some of which may be better for patient health outcomes, generally receive less funding. A drug company generally only funds CME programming that involves discussion of a drug or class of drugs related to one of the company's products, even though such drugs may not yield better health outcomes as other potential topics of CME programming.[97] Thus, reducing the amount of funding from commercial interests would likely change the nature of CME content, focused on better patient health outcomes than those having to do with specific drugs and devices.

The ACCME guidelines are largely ineffective at limiting bias as result of influential industry interests at the topic selection and funding solicitation stages. Standard 3.2 of the ACCME Standards for Commercial Support provides that an industry funder cannot require a CME provider to accept advice or services concerning teachers, authors, participants, or content of programming as conditions of contributing funds or services.[98] However, this provision does not expressly prohibit drug and device companies from offering advice, CME providers from soliciting suggestions, or CME providers from voluntarily following suggestions from commercial supporters.[99]

Consider a hypothetical situation in which a Pharm Inc. manufactures the drug Cholesteran, which is FDA approved for lowering cholesterol in adults. A CME provider approaches Pharm Inc. for topic ideas for an upcoming CME activity. Pharm Inc. suggests that treatments for childhood obesity would be a novel and informative topic and informs the CME provider that studies have proven that Cholesteran is effective in lowering cholesterol levels in obese children with high cholesterol. The CME provider thanks Pharm Inc. for its input and ultimately decides to plan a CME activity about treatments for childhood obesity. Pharm Inc. does not provide any input as to the content of the CME activities or presentations. Following the decision to focus on childhood obesity treatments, the CME

97. See INST. OF MED., supra note 1, at 74.

98. See ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, at 3.

99. See id.; Rodwin, supra note 10, at 811 (finding in the author's interviews with CME providers that these practices are in fact common).

provider asks Pharm Inc., along with several other drug manufacturers, to fund the CME event. Knowing that the CME program concerns a topic for which one of the company's drugs is an effective treatment, Pharm Inc. gladly funds the program. It does not, however, plan any CME content. Under the ACCME Standards for Commercial Support, this interaction is acceptable.[100] At the topic selection phase, the CME provider approached Pharm Inc., and Pharm Inc. provided its thoughts without requiring the CME provider to pursue the topic it suggested. At the CME planning phases, the CME provider approached Pharm Inc. about funding and Pharm Inc. provided funding knowing that Cholesteran, or at least Cholesteran's class of drugs, would likely be mentioned without requiring the CME provider to mention such information.

Even though Pharm Inc. did not require the CME provider to do anything, the company influenced the CME provider by providing input and financial support. The CME provider planned the CME event about treatments for childhood obesity knowing that Pharm Inc. would likely fund the program. This exemplifies how CME programs cover topics that support drug and device-based treatments without explicit direction from drug and device companies. Moreover, the CME provider is more likely to include information about its commercial supporters' products, including Pharm Inc.'s Cholesteran, knowing that Pharm Inc. otherwise might not support the CME provider's next CME activity. CME providers, whether not-for-profit medical organizations or for-profit commercial companies, depend on the funding they receive from industry for their continued success. CME providers instead seek to develop long-term relationships with commercial supporters.[101]

Conflicts of interest are particularly problematic at the topic selection and funding solicitation stages with medical education and communications companies (MECCs). MECCs are for-profit companies that advertise their programming to the drug industry to obtain commercial support.[102] Drug and device companies often hire MECCs to organize meetings, find speakers for conferences or lectures, and develop enduring materials.[103] Often located in close proximity to the headquarters of major pharmaceutical and device companies, MECCs solicit funds from the pharmaceutical industry to put on various educational activities.[104] As Steven E. Nissen, M.D., Chairman of the Department of Cardiovascular

100. See ACCME STANDARDS FOR COMMERCIAL SUPPORT, supra note 10, at 3.
101. See id.
102. BRODY, supra note 26, at 209.
103. INST. OF MED., supra note 1, at 67.
104. See Nissen Testimony, supra note 11.

Medicine at Cleveland Clinic, stated in his testimony before the Senate Committee on Aging in 2009, MECCs provide a "veneer of independence" that hide the promotional nature of CME programming.[105] The brochures often state that the program was funded through an unrestricted educational grant from the sponsoring company, even though the MECCs often select speakers and topics that they know will please the companies funding their activities.[106] In fact, Pfizer and GlaxoSmithKline ceased their funding of CME programming organized by for-profit MECCs to avoid the appearance of impropriety due to suspect relationships that had developed between MECCs and industry.[107]

Despite the fact that the ACCME has updated its accreditation requirements and standards for commercial support several times over the past decade, the organization has not enforced the standards.[108] Data shows that CME providers have breached the ACCME standards. In 2007, the ACCME found that one in four of its accredited CME providers was openly breaching ACCME guidelines.[109] The ACCME's role in restricting commercial bias is limited. It does not preapprove CME content and routinely does not monitor CME programs.[110] Oversight is largely after the fact; it occurs once ACCME learns of a complaint concerning a noncompliant CME activity.[111] Furthermore, the ACCME's safeguards cannot detect when a drug company plants an individual in the audience at a CME event to ask a particular question about a drug, to ensure that the discussion includes that drug.[112] Moreover, the ACCME's primary enforcement tool is revocation of a CME provider's accreditation, which may occur for until significantly after the noncompliance.[113] To monitor bias in CME, the ACCME requires providers to survey participants about commercial bias at the conclusion of events.[114] Participants, however, may not be in the best position to detect the bias.

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105. Id.

106. Id.

107. See Janice Hopkins Tanne, Pfizer Stops Funding Medical Education Run by For-Profit Companies, 337 BMJ 73 (2008). It is important to note that MECCs can be significant resources; for example, they can supply well-trained staff who provide high quality CME programming. See INST. OF MED., supra note 1, at 72.

108. See, e.g., Nissen Testimony, supra note 11.

109. BRODY, supra note 26, at 319-20.

110. Morris Testimony, supra note 18.

111. Id.

112. INST. OF MED., supra note 1, at 72.

113. See id.; see also Morris Testimony, supra note 18 (noting that in one case up to nine years elapsed between identification of noncompliance with ACCME standards and revocation of a CME provider's accreditation).

114. INST. OF MED., supra note 1, at 72.

To resolve the issues with relying on volunteer participant reporting, the Association of American Medical Colleges (AAMC) recommended that it and other interest groups collaborate with the ACCME to create a process through which CME offerings would be externally evaluated for compliance with applicable guidelines.[115] However, until such voluntary processes are widely implemented, the ACCME's ability to minimize commercial bias is limited. For these reasons, in its 2007 investigation of industry influence on CME activities, the Senate Finance Committee found that ACCME standards were inadequate.[116] The Senate committee cited the ways in which the standards enable CME providers to accommodate suggestions and input from drug companies while claiming independence because the drug companies are not requiring them to do anything.[117]

### G. State Approaches to CME Regulation

States have their own standards for interactions between CME providers and industry sponsors, which can be stricter than the ACCME standards.[118] The Massachusetts Pharmaceutical and Device Manufacturer Code of Conduct, for example, provides that a pharmaceutical manufacturer "shall not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company."[119] The Massachusetts requirements, unlike the ACCME Standards for Commercial Support, provide no leeway for CME providers to solicit or accept advice or suggestions regarding topics, content, or speakers. This model arguably would limit industry influence on CME more effectively than the ACCME standards, assuming the code was properly enforced. Still, this approach is limited to the individual state in which it is implemented.[120]

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115. See generally ASS'N OF AM. MED. COLLS., INDUSTRY FUNDING OF MEDICAL EDUCATION: REPORT OF AN AAMC TASK FORCE (2008), available at https://members.aamc.org/eweb/upload/Industry%20Funding%20of%20Medical%20Education.pdf.

116. See STAFF OF S. COMM. ON FINANCE, 110TH CONG., USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS 16 (Comm. Print 2007)

117. Id.

118. See, e.g., Pharmaceutical and Medical Device Manufacturer Conduct, 105 MASS. CODE REGS. 970.000-.011 (West, WestlawNext through Dec. 6, 2013, Register #1249).

119. Id. § 970.007(3).

120. While payments to CME providers increased sixteen percent (over $1.2 million) between 2010 and 2011 after the Massachusetts Pharmaceutical and Medical Device Manufacturer Code of Conduct was amended, no data is currently available to determine the effectiveness of this particular provision in terms of limiting commercial bias. See Thomas Sullivan, Massachusetts Posts 2011 Payments to Healthcare Providers: 3% Drop in Payments, POLICYMED (Mar. 6, 2013, 5:41 AM), http://www.policymed.com/2013/03/massachusetts-posts-2011-payments-to-healthcare-providers-3-drop-in-payments.html.

### H. PhRMA Code and AMA Guidelines

PhRMA and the AMA have their own guidelines concerning industry support for CME, which largely defer to the ACCME standards.[121] The PhRMA Code provides that a drug company's CME grant-making should be completely separate from its sales and marketing departments.[122] Moreover, the Code provides that a drug company should develop objective criteria for making CME grant decisions to ensure that programs funded by the company are bona fide educational programs and that the financial support is not an inducement to prescribe or recommend a particular drug.[123] The company should not provide any advice or guidance to the CME provider regarding the content or faculty for a particular CME program funded by the company.[124] The PhRMA Code also provides that companies should not offer financial support for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending the event, nor should money be offered for time spent participating at the CME event.[125]

The AMA's guidelines concerning financial relationships between Industry and CME providers offer similar voluntary standards for physicians who organize or speak at CME activities.[126] The AMA guidelines state that physicians should be transparent about financial relationships that could influence educational activities and that the processes for making decisions about participation by physicians who may have a financial interest in the CME content should be transparent.[127] The guidelines also emphasize giving preference for faculty or content developer positions to similarly qualified experts without a financial interest in the subject matter.[128]

Though the PhRMA and AMA guidelines reflect efforts to encourage physicians and Industry parties involved in planning CME activities to

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121. See PHRMA CODE, supra note 17, at 6. The medical device industry has a similar code governing interactions with health care providers. See also ANVAMED, CODE OF ETHICS ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS (2009), available at http://advamed.org/res/112/advamed-code-of-ethics-on-interactions-with-health-care-professionals (click "Open").

122. Id. at 6.

123. Id. at 2, 10.

124. Id. at 4.

125. Id.

126. See AM. MED. ASS'N COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, FINANCIAL RELATIONSHIPS WITH INDUSTRY IN CONTINUING MEDICAL EDUCATION (2011), available at http://www.ama-assn.org/resources/doc/code-medical-ethics/90115a.pdf.

127. See id. at 6, 9.

128. Id. at 9.

minimize Industry influence on CME, the guidelines are only voluntary. Drug companies are not required to follow the PhRMA Code, and physicians are not required to comply with AMA guidelines on financial relationships with industry. Thus, the guidelines' effectiveness is limited by their lack of enforceability. Other than FDA and OIG's enforcement of off-label marketing and Anti-Kickback violations, the ACCME Standards for Commercial Support are the only mandatory standards with which CME providers must comply to obtain or retain their accreditation.

## I. Hospital CME Conflict of Interest Policies

Many hospital networks have their own conflict of interest policies, some of which are stricter than the ACCME Standards for Commercial Support. Partners Healthcare (Partners), for example, includes several hospitals that serve Harvard University and maintains a strict conflict-of-interest policy.[129] The Partners' policy presents another example of standards with which some CME providers must comply.

Though it requires compliance with the ACCME Standards for Commercial Support for many of its policies, the Partners' policy goes further than the ACCME standards in several key respects. For example, industry support for a specific CME activity must come from more than one drug or device company, and no single industry entity can provide more than seventy percent of the total commercial support.[130] Industry support for a particular CME activity must also be disclosed to the participants prior to the beginning of the event.[131]

Two of the more progressive elements of Partners' policy are the Educational Review Board (ERB) and the President's Fund. Partners' institutions may not accept industry funding for any educational programs except through the ERB or the President's Fund mechanisms.[132] The ERB is responsible for approving, monitoring, and reviewing industry-supported educational programs.[133] It must review and approve all support from industry sponsors for any CME activities and conduct more specific content reviews of presentations and programs that it deems to present particular concerns with conflicts of interest before the CME event.[134] The

129. See PARTNERS HEALTHCARE, POLICY FOR INTERACTIONS WITH INDUSTRY AND OTHER OUTSIDE ENTITIES 62 (2012), available at http://www.partners.org/Assets/Documents/About-Us/OII/OII_Policy.pdf.

130. Id. § 3.3.4.

131. Id. § 3.3.6.

132. See id. §§ 3.1.2, 3.4.

133. Id. § 3.2.1.

134. Id. §§ 3.2.2-3.2.3.

President's Fund operates as a slush fund, set up at each hospital within the network to support CME activities determined by the individual hospital to be a topic of priority.[135] Drug and device companies are encouraged to contribute to the fund, though companies do not know what specific CME topics their money will support.[136] A company cannot target or direct its contribution to any specific educational program to any specific educational program.[137]

Partners designed both the ERB and the President's Fund to limit drug and device company influence on CME topics and content.[138] By screening CME presentations and content for commercial bias, the ERB ensures that CME activities offered by Partners present balanced viewpoints and accurately reflect the research performed on individual topics.[139] Partners only provides funding from the President's Fund for CME programming geared toward improving patient outcomes rather than the brand name drugs or devices.[140] However, these procedures cannot achieve widespread success in limiting industry bias because they are currently only implemented at the hospital network level.

### J. Disclosure over Prohibition: The Physician Payments Sunshine Act

Congress attempted to address the inefficiencies of the ACCME Standards for Commercial Support by implementing the Physician Payments Sunshine Act (Sunshine Act) as part of the Patient Protection and Affordable Care Act (PPACA). The Sunshine Act requires drug and device manufacturers to disclose any direct payments, indirect payments, or other transfers of value made to physicians.[141] CMS intends to eventually publish this data on a searchable online public database.[142] Failure to report any of these payments results in a fine of $1000 to $10,000 per violation, with a maximum fine of $150,000.[143] Knowingly failing to report results in a fine of $10,000 to $100,000 per violation, with a maximum total fine of $1

135. See id.
136. See id.
137. Id.
138. See id. §§ 3.2, 3.4.
139. See id. § 3.2.
140. See id. § 3.4.
141. Physician Payments Sunshine Act, 42 U.S.C.A. § 1320a-7h(a)(1)(A) (West, WestlawNext through P.L. 113-36).
142. Id. § 1320a-7h(c)(1)(C).
143. Id. § 1320a-7h(b)(1).

million.[144]

After issuing the proposed regulations under the Sunshine Act, CMS received many comments criticizing the requirement that CME providers report "indirect payments" to physicians who attend CME programs partially or fully sponsored by Industry.[145] Many commenters argued that the reporting requirements were overly burdensome and would deter funding for essential CME programming.[146] They opined that the reporting requirements of the Sunshine Act would be duplicative of the requirements of the ACCME Standards and would deter financial support from industry.[147] Further, they urged that requiring disclosure of payments to CME providers would result in higher admission costs for CME and fewer CME activities.[148] CMS agreed with these arguments in its final rules, which excluded payments to third-party CME providers from the definition of "indirect payment," if the drug or device companies do not select the speakers or provide a list of potential speakers.[149] Accordingly, drug and device manufacturers need not disclose payments to accredited third-party CME providers as long as the manufacturer does not condition its payment on use of any particular content or speakers.[150] In other words, drug and device companies are not required to report most payments routed through accredited CME providers.[151]

The exception for indirect payments contradicts the purpose of the Sunshine Act, which is to provide for transparency and accountability in the relationships between physicians and industry.[152] The regulatory loophole allows industry to conceal payments to physicians that would otherwise be disclosed under the PPSA when the payments pass through third-party accredited CME providers.[153] Instead of encouraging transparency in industry sponsorship of CME, the industry will essentially be able to avoid disclosure by "laundering" money through third party CME providers. The exception for indirect payments makes sense only if CME providers are truly independent and resistant to commercial influence.[154] Current federal

144. Id. § 1320a-7h(b)(2).
145. See Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9479-80 (Feb. 8, 2013) (codified at 42 C.F.R. pts. 402, 403).
146. Id.
147. See id.
148. See id.
149. See id.
150. See id. at 9524.
151. See id.
152. See id.
153. See id.
154. See id.

and private regulatory regimes are mostly ineffective at curbing industry bias. The Sunshine Act, which was supposed to present the first step in resolving some of these inefficiencies, similarly will do little to reduce industry influence on CME.

## III. RECOMMENDATIONS TO REDUCE COMMERCIAL BIAS AND ENSURE INDEPENDENCE FOR CME PROVIDERS

Any form of regulating CME must balance the interests of preserving the integrity of CME with the need for industry sponsorship to allow quality CME programming to exist in the first place. The primary reason many drug and device companies readily pay hundreds of millions of dollars annually to CME is to sell their products.[155] The 2007 Senate Finance Committee report found that it seems "unlikely that this sophisticated industry would spend such large sums on an enterprise but for the expectation that the expenditures will be recouped by increased sales."[156] Pharmaceutical companies would likely not spend hundreds of millions of dollars per year on CME sponsorship it did not yield significant profits by influencing physicians' prescribing behaviors.[157] Indeed, the directors and corporate officers of pharmaceutical companies have a fiduciary obligation to their shareholders to increase profits.

Without drug and device companies' financial support for CME, the availability of accredited CME programming would be diminished. This argument has merit, as restricting or prohibiting industry funding of accredited CME would fundamentally alter the way CME is created and funded. However, it is possible to restrict industry funding or prohibit it altogether without reducing the availability of quality CME. There are several changes Congress, CMS, and other entities can make to improve the reliability and independence of CME in the United States without making CME admission costs prohibitively expensive.

### A. Amend the Sunshine Act Regulation to Require Disclosure of Indirect Payments to Accredited CME Providers

Passing the Sunshine Act was a positive step in terms of increasing transparency and accountability in the relationships between industry and medical practitioners.[158] As it had done in its proposed rules, CMS should

155. See, e.g., Nissen Testimony, supra note 11.

156. USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS, supra note 116, at 16.

157. See Husten, supra note 13.

158. Physician Payments Sunshine Act, 42 U.S.C.A. § 1320a-7h(a)(1)(A) (West,

include in the definition of "indirect payment" any payments to speakers at accredited CME events, regardless of whether the industry sponsor recommended any speakers.[159] Otherwise, Industry sponsors could merely route payments through CME providers to avoid disclosure, which would contradict the purpose of the statute. Broader disclosure of industry payments to accredited CME providers is an essential step toward reducing commercial bias in CME.

### B. Congress Should Designate Industry Funding of CME as Taxable Income Rather than a Charitable Contribution

Currently, drug and device companies' financial support for accredited CME is tax-deductible as a charitable business expense, which encourages industry to fund accredited CME.[160] However, because drug and device companies likely fund CME because they expect a return on their investment, CME support is more akin to marketing expenses than charity. If the government taxed commercial support for CME like any other taxable business expense, it would likely limit the amount of industry funding for CME, thereby driving down industry bias on CME content and topics. The most significant issue facing CME providers with any proposal that would limit industry funding is how such providers would establish alternative sources of funding. Recommendations for obtaining other, more reliable funding sources are discussed below.

### C. Create a Public-Private Oversight Board to Replace the ACCME

As the IOM recommended in its 2009 report on the status of CME, establishing a national inter-professional institute would foster improvements in CME.[161] This public-private entity would involve a full spectrum of stakeholders in healthcare delivery and CME, including representatives from CMS, IOM, the Agency for Healthcare Research and Quality (AHRQ), and industry stakeholders.[162] It would be charged with developing and overseeing comprehensive change in the way CME is conducted, financed, regulated, and evaluated.[163] Collectively, the

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Westlaw through P.L. 113-36).

159. See Transparency Reports and Reporting of Physician Ownership or Investment Interests, 78 Fed. Reg. 9458, 9524 (Feb. 8, 2013) (codified at 42 C.F.R. § 403.904).

160. See Jerry Avorn & Niteesh K. Choudhry, Funding for Medical Education: Maintaining a Healthy Separation from Industry, 121 CIRCULATION 2228, 2232 (2010).

161. INST. OF MED., supra note 1, at 1.

162. Id. at 3.

163. Id.

stakeholders could develop conflict-of-interest policies and identify more consistent funding sources to replace funding from industry stakeholders.[164] This entity would replace the ACCME and its Standards for Commercial Support with more rigorous standards, and the entity would also have a more active role in seeking out funding for CME providers than the ACCME currently does.

A public-private structure has advantages over a private structure operated by professional societies and organizations. For example, a purely private organization would have fewer incentives to convene regularly, and there would be less accountability for a private oversight board than there would be for a public-private structure.[165] Similarly, a purely public organization would be less advantageous than a public-private structure, as it could not as readily incorporate collaborative decision-making and could be limited by procedural and financial requirements.[166]

Though the organization would broadly communicate with and gather input from the Industry and field members, it would ideally have a committee that would be accountable to the Secretary of HHS.[167] The organization's decisions would be based solely on votes of the committee members.[168] The committee might consider adopting a policy similar to the Educational Review Board (ERB) of the Partners Healthcare policy to screen any CME programming that involves industry funding.[169] It might also use a slush fund mechanism similar to the Partners President's Fund for industry sponsors to donate money without knowing which CME program their money would go toward, thus reducing topic bias.[170] Adopting stricter rules regarding commercial support and seeking out alternative sources of funding would also mean that CME providers could develop topics based on quality gaps rather than treatments that involve drug and device companies' products, directly benefiting physicians and patients.

### D. CME Tax on Healthcare Entities

If the previously mentioned measures are taken to reduce or eliminate voluntary industry funding, CME providers must find another source of funding. One solution would be for Congress to impose a "CME tax" on

164. Id. at 7.
165. See id. at 6.
166. Id.
167. See id. at 7.
168. Id.
169. See PARTNERS HEALTHCARE, supra note 129.
170. See id. § 3.4.1.

commercial medical firms, insurers, medical facilities, and possibly even physicians.[171] A federal authority would then allocate the funds raised from the tax to government certified not-for-profits that would distribute the funds to independent CME providers.[172] Drug and device companies would be prohibited from donating funds to CME providers, even indirectly.[173] The tax would earn enough revenue for CME activities, eliminating the demand for Industry support.[174]

This novel proposal calls for a fundamental shift in the way CME is funded, created, and monitored.[175] It would place much of the burden of funding CME on drug and device manufacturers, which would either absorb the cost or pass the cost onto payors (i.e., insurers and individuals).[176] The overall cost to the public, however, would likely be relatively small.[177] On the other hand, increasing taxes in this political climate is arguably less feasible. The public-private committee discussed above could be charged with locating more consistent and reliable sources of alternative funding. Still, the CME tax is a viable option Congress should consider implementing.

## IV. CONCLUSION

The current state of CME regulation is complex and inefficient. The entity in the best position to eliminate industry bias – the ACCME – has relatively weak accreditation standards that still allow commercial sponsors to influence CME content. Moreover, the ACCME does not strictly enforce its own standards. Other guidelines that go further than the ACCME Standards for Commercial Support are only voluntary or limited in scope. Although the medical community is hesitant to reduce or eliminate industry support because of concern over how CME providers would make up the lost funding, other funding mechanisms exist.

If the medical community and the federal and state government wish to eliminate commercial bias from CME, thereby improving the overall

171. Rodwin, supra note 10, at 812.

172. Id.

173. Id.

174. Id. at 813.

175. For additional reading on the CME tax, see MARC A. RODWIN, CONFLICTS OF INTEREST AND THE FUTURE OF MEDICINE: THE UNITED STATES, FRANCE, AND JAPAN (Feb. 2011).

176. Rodwin, supra note 10, at 813.

177. Id. (estimating that, based on country's health care spending in 2008 and annual industry support for CME of $2 million, the cost to the public would be approximately $6.58 per person).

quality of CME and the quality of care patients receive, they need to acknowledge that industry bias occurs in more subtle ways than a drug company requiring a CME provider to use certain content or speakers. As a first step, CMS should require disclosure of industry payments to accredited CME providers, regardless of whether a drug company requires the CME provider to use certain speakers. Next, Congress should begin taxing industry support for accredited CME, as the money is more akin to a marketing budget than charitable donations. Congress should also create a public-private entity responsible for developing and enforcing standards for commercial support that are stricter than the ACCME's standards. This entity would also be in charge of ensuring that CME topics fill quality gaps, as well as locating alternative and more permanent sources of funding. Finally, Congress should consider adopting a CME tax to raise funds for CME activities in lieu of the current structure obtaining commercial support. Because CME and industry have become so intertwined over the past several decades, any solution to reduce or eliminate industry bias will involve a fundamental restructuring of the way CME is created, funded, and maintained. Avoiding the problem because the reforms required are too drastic is not a sufficient reason to let the current regulatory regime continue at the cost of quality patient care.