



DRUG AND DEVICE PROMOTION: Charting a Course for Policy Reform

A White Paper

by

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& Policy

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Faculty from Seton Hall Law School also contributed to the one day Forum and the thoughtful exchange of ideas. The views expressed here represent the views of the faculty and researchers of The Center for Health & Pharmaceutical Law & Policy and are not the views of the Seton Hall University School of Law faculty at large, its Board of Visitors, or other Advisory Boards.

Table of Contents

Executive Summary	1
A. The Policy Context	1
B. Summary of Recommendations for Public Policy and Industry Practice	4
Policy Analysis and Recommendations	7
A. Achieving Transparency in Industry-Physician Relationships	7
B. Banning Gifts, Meals, and Other Perks	10
C. Setting Standards for Off-Label Promotion	12
D. Re-envisioning Funding for Continuing Medical Education.....	17
Conclusion	21
References	22
Appendices	33
A. Forum on Drug and Device Promotion	33
B. Forum Statement of Principles	36
C. The Center for Health & Pharmaceutical Law & Policy	38
D. Center Financial Disclosure Statement and Policies.....	39

EXECUTIVE SUMMARY

A. The Policy Context

The collaboration between industry and physicians is critical to scientific progress and the development of new drugs and devices. Individual patient care as well as broader public health goals depend on this collaboration to prevent, diagnose, and cure illness. At the same time, recent developments and trends underscore the need for policy reform to shore up the integrity of clinical practice and research, and restore public trust in the medical profession and industry.

Over the past decade, alarm has mounted among government policymakers, patient advocates, and leaders in academic medicine about the influence of the drug and device industries on clinical practice, medical education, and medical research.¹ Government enforcement actions, congressional hearings, and press coverage have generated intense scrutiny of the financial relationships between industry and physicians.

By and large, industry targets promotional efforts to physicians, who serve as gatekeepers for access to medications and medical devices.² Among other activities, industry sponsors in-person “detailing” of physicians. As reported by the American Medical Association, there is one pharmaceutical sales representative for every 4.7 physicians and each physician on average meets with 10 sales representatives a month.³ Industry also expends funds for a range of other marketing activities, including gifts and free meals.⁴ Financial relationships between industry and physicians encompass payments for consulting, clinical and marketing research, and promotional speaking. Companies also provide substantial funding for continuing medical education (CME). In addition to payments to physicians for speaking at such programs, physicians benefit from subsidies provided for their medical education. In short, industry money pervades physicians’ professional activities. One large national survey of physicians in six specialties found that 94% of physicians reported some type of financial relationship with industry; the most common being receipt of food in the workplace (83%), followed by receipt of drug samples (78%), payment of costs associated with continuing medical education (35%), and payments for lectures, consulting, and enrolling patients in clinical trials (28%).⁵

Payments for bona fide services at fair market value are critical to drug and device development, advancing both basic scientific research and clinical trials. However, payments outside the boundaries of fair market value, as well as gifts, meals, and other perks, raise concerns. Such payments can create a conflict, whether conscious or unconscious, between a physician’s fundamental ethical obligations to his or her patients and loyalty to a corporation, which owes its primary allegiance to its investors. Social science research supports the conclusion that even small gifts can influence behavior, generating an inclination to reciprocate.⁶

The pervasive financial ties between the drug and device industries and healthcare professionals have the potential to shape not just the physician-patient relationship, but also medical education and research. Commercial support for accredited CME, nearly all of it from drug and device manufacturers, grew from \$302 million in 1998 to \$1.2 billion in 2006.⁷ Industry funding for CME has reached a level that is only explicable if it also serves promotional goals. Similarly, industry’s significant role in medical research, publication, and dissemination of research results has led to increasing concerns about the integrity and balance

of medical scholarship. One consequence of eroding confidence in published research findings has been sharp debate about policies regarding industry's distribution of research results on "off-label" use of drugs. Most recently, this debate has focused on the U.S. Food and Drug Administration's (FDA) Guidance for Industry addressing the dissemination of journal articles and other scientific or medical publications on off-label uses.⁸ The Guidance for Industry follows over five years of litigation in which prior federal policies were successfully challenged as a violation of commercial free speech, leaving a policy vacuum that persisted until release of the Guidance for Industry on January 13, 2009.⁹ Issued in the waning days of an outgoing Administration, it is unlikely that the Guidance statement will end controversy about the best means to generate and disseminate needed scientific information about the safety and efficacy of off-label drugs and devices.

In 2002 and 2003, trade organizations representing the drug and device industries – The Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed), respectively – adopted voluntary guidelines governing the interactions between physicians and industry.¹⁰ These guidelines limit the value of gifts that can be provided, allow only "modest" meals, and bar other perks such as travel and payment for attending medical education programs in the absence of services provided. The guidelines curbed some of the most excessive practices, but left much discretion to industry and physicians about meals, entertainment, and other benefits routinely provided to physicians.¹¹

Government enforcement actions against pharmaceutical and device companies have focused on numerous marketing activities, alleging violations of the federal and state anti-kickback statutes, the False Claims Act, and the prohibition on off-label promotion. In 2007, the Department of Justice collected \$1.54 billion in health care fraud judgments and settlements, with the largest recoveries coming from pharmaceutical companies.¹² During the same period, the pharmaceutical industry paid \$264 million to state Medicaid programs to settle enforcement actions.¹³ In addition to large monetary penalties, government enforcement of the statutes and regulations governing product promotion has resulted in significant ongoing government supervision of companies subject to corporate integrity and deferred prosecution agreements.

Companies also face a growing number of qui tam actions brought by whistleblowers alleging that violations of the Anti-Kickback Law and the prohibition against off-label promotion implicate the False Claims Act. In these cases, the stakes are high; the False Claims Act imposes a financial penalty for each false claim as well as treble damages. If the government can prove that physicians received a financial incentive to prescribe the medication or that the company marketed the product for off-label use, each prescription submitted to the government for reimbursement could be counted as a false claim.

Private civil suits focusing on conduct arising out of the relationships between physicians and industry have also increased markedly.¹⁴ These include product liability and securities fraud cases, as well as actions by pension plans and private insurers seeking to recover payments for alleged illegal promotion practices. Civil recovery actions brought by states on behalf of their Medicaid programs, as well as consumer protection litigation brought by states, are also on the rise.

Concerned about the escalating costs of prescription drugs and lack of transparency in the funding provided by industry to physicians and medical institutions, Congress has intensified

its scrutiny of drug and device companies. In the past two years, Congress has held hearings on, among other things, academic detailing, commercial funding of CME, consulting payments by device makers to surgeons and other physicians, and the financial relationships between pharmaceutical companies and physicians.¹⁵ In addition, Congress has proposed legislation, the Physician Payments Sunshine Act (the Act), to mandate disclosure of the financial relationships between physicians and industry.¹⁶ The Act, which has received significant support from industry and consumer groups, follows on the heels of action by state governments to mandate disclosure. To date, five states and the District of Columbia have passed legislation requiring industry to disclose to government or to the public financial relationships with physicians.¹⁷

Finally, industry has been affected by the tide of negative publicity generated by enforcement actions, civil suits, and congressional hearings. Public opinion of the pharmaceutical industry has fallen dramatically in the past decade. According to a 2008 Harris Interactive poll, 52% of Americans have a negative impression of the pharmaceutical industry; only the tobacco industry fared worse.¹⁸ Reflecting the heightened public scrutiny, PhRMA revised its code of conduct in July 2008. AdvaMed made similar revisions to its code in December 2008, with added guidance in areas of particular relevance to device promotion. The new PhRMA Code, which went into effect in January 2009, bars “reminder items” such as pens and pads, bans the provision of entertainment, and bars restaurant meals with sales representatives, among other changes. These changes are notable; however, they still leave other practices and segments of industry unaffected.

The time is ripe for reform. The Center for Health & Pharmaceutical Law & Policy proposes the policy changes set forth below, designed to reduce potential conflicts, enhance transparency, and shore up public trust in both the medical profession and the drug and device industries. These goals in turn will strengthen the partnership between industry and medicine that is critical to biomedical research and public health advances.

B. Summary of Recommendations for Public Policy and Industry Practice

Achieving Transparency in Industry-Physician Relationships

- The financial relationships between industry and physicians should be publicly disclosed. Industry should be required to provide the information to establish a unitary national database of payments to physicians, including consulting and speaking fees, royalties, gifts, meals, and other benefits. Legislation that would mandate disclosure, the Physician Payments Sunshine Act, is now pending in Congress.
- The pending federal legislation provides a delay for mandatory public disclosure for funds for product development that would reveal trade secrets, until FDA approval of a new drug or two years, whichever occurs first. Disclosure of payments for clinical research that would reveal trade secrets would be delayed until the research must be reported to a public registry of clinical trials. Any reporting exceptions or delays should be carefully circumscribed to avoid undermining the intent of the law. Furthermore, financial support from industry should be routinely disclosed to participants in clinical trials as part of the informed consent process.
- In addition to federally-mandated disclosure by industry, disclosure by physicians of their receipt of industry funds would encourage self-reflection and monitoring by physicians of their own practices. States should retain the authority to require disclosure from physicians, consistent with their long-standing oversight of health care professionals. Disclosure by physicians would be most useful to patients if provided on physician websites or in office literature.
- Disclosure of financial relationships between industry and healthcare professionals who serve on formulary committees for health plans, pharmacy benefit management companies, group purchasing organizations, hospitals and other healthcare institutions should also be mandated as a matter of national policy. This recognizes the significant impact of formulary and coverage decisions by these entities on the market share of drugs and devices.

Banning Gifts, Meals and Other Perks

- Social science research establishes the power of even small gifts to influence behavior. Gifts to physicians should be banned, except for those with a de minimis value designed for patient education. Physicians who accept brochures or other written materials for patients have an obligation to ensure that any advice provided is consistent with their own clinical recommendations. Such materials can benefit patients but also generally advertise particular products. For this reason, it would be preferable for physicians to give patients educational materials that are independent of product promotion, or advise patients where they can find high quality information about their condition and self-care on the Internet.
- Consistent with recommendations by the Association of American Medical Colleges (AAMC), meals should no longer be provided onsite at hospitals or other health care institutions. The delivery of meals to physician offices for staff, a practice that has become routine in some locations, should also be barred. Other meals, whether provided to

physicians in their offices or at restaurants, should only be permitted if there is significant new information to convey, such as a new product, new approved use, or new safety information. Such meals should be provided within parameters that give some meaning to the term “modest”; one approach for public policy would be an overall annual limit for benefits each company can provide to physicians. This is the law in Minnesota, which permits annual benefits under \$50, excluding educational items for patients and drug samples.

- As provided in the 2008 revised PhRMA Code, all other perks, such as entertainment and travel expenses to CME and other events for non-speakers, should be banned.
- Self-regulation on gifts, meals and other benefits should be replaced by legislation that creates a level playing field for all industry sectors, including pharmaceutical, device and biotech companies. To date, the states have taken the lead on barring gifts and meals. Ideally, sound policy would be established in federal legislation so that one set of national standards would bind industry and establish the expectations for physicians regardless of where they practice.

Clear Guidelines for Disseminating Publications on Off-Label Promotion

- FDA’s Guidance for Industry on the dissemination by companies of peer-reviewed publications on off-label uses of drugs and devices, released on January 13, 2009, has generated significant controversy. Among other comments, critics asserted that the Guidance, issued for public comment in February 2008, would substantially reduce the incentive for companies to file supplemental New Drug Applications (sNDA). The Guidance establishes a safe harbor from prosecution, not mandatory conduct. It therefore would not resolve the key underlying issue at stake in the debate – the authority of the FDA to mandate studies of safety and efficacy for off-label uses. Tied to complex First Amendment issues, the Guidance is a poor vehicle to address this important public policy question.
- A robust public debate is needed to determine how the FDA’s authority and oversight can best be structured to carry out its public health mission for off-label uses. The current regulatory scheme fails to generate needed scientific information about off-label uses and relies heavily on prosecution as the primary vehicle to advance policy goals more effectively addressed by prospective policies and oversight.
- One possibility would be to clarify that the FDA has authority under newly enacted federal legislation, the FDA Amendments Act, to mandate that companies conduct studies of safety for off-label uses. Another possibility would be to recognize that once an off-label use reaches certain high sales volumes, the use is presumptively intended or, in any event, sufficiently widespread and remunerative that its sales would justify and support the financial costs of studies on safety and efficacy, triggering FDA authority to mandate the studies.
- The Guidance for Industry on dissemination of scientific materials fills a long-standing policy vacuum. It contains valuable guidelines to promote the integrity and balance of scientific and medical material distributed by industry. Notably, consistent with the

mounting public outcry for transparency in industry-physician relationships, the Guidance when issued in final form added provisions requiring disclosure of the nature and amount of authors' relevant financial interests.

- Federal policy articulated in the Guidance for Industry would be strengthened by a policy precluding sales representatives from disseminating scientific materials on off-label uses. Sales representatives are trained and paid to promote products. Distribution of materials on off-label uses should occur in non-promotional contexts.
- The FDA cannot serve as the sole arbiter of scientific integrity and information about drugs and devices; confidence in the integrity of scientific research and publication must be preserved. All those engaged in medical research and publication, including medical professionals and institutions, medical journals, and industry, should undertake reforms to ensure the integrity of the medical literature. Transparency in the relationship of industry and physicians would be a critical tool in this effort.

New Limits on Industry Funding of Continuing Medical Education

- A paradigm shift to end commercial support for CME should be undertaken. This will require fundamental change in practice by industry and by organized medicine, which must design less costly, professionally-driven and controlled mechanisms for CME.
- In the interim, as CME makes this substantial transition, conflicts of interest in CME should be more fully disclosed and managed. Specifically, disclosure to CME providers and attendees by physicians and other speakers should identify the nature and magnitude of the speaker's financial interests, with such interests defined broadly to include financial relationships and support for the speaker's academic department.
- The Accreditation Council for Continuing Medical Education (ACCME) should issue more specific guidelines that address financial disclosure, circumstances when safeguards such as independent review are required to manage a conflict of interest, and criteria to determine when conflicts should preclude participation by a presenter. A physician's role promoting a product should preclude his or her participation as a speaker at an accredited CME event for that product.

POLICY ANALYSIS AND RECOMMENDATIONS

A. Achieving Transparency in Industry-Physician Relationships

Public disclosure of payments by industry to physicians is a critically needed policy reform to ameliorate the real and perceived conflicts of interest generated by the financial relationships between industry and physicians. Currently, companies must disclose payments to physicians or institutions under limited circumstances. For example, drug and device manufacturers must disclose to the FDA certain financial arrangements, including payments made to investigators or their institutions – other than payments to cover the costs of clinical studies – with a cumulative value in excess of \$25,000.¹⁹ Corporate integrity and deferred prosecution agreements, entered into between corporations and government in lieu of prosecution or exclusion from federal health programs, also frequently mandate regular disclosure to government of payments to physicians. In 2007, five of the largest manufacturers of orthopedic replacement devices entered into agreements (four of them deferred prosecution agreements and one a non-prosecution agreement) that mandate public disclosure of the payments they make to physicians. In addition, following congressional inquiries, some companies have independently adopted requirements to disclose payments to physicians and grants to outside organizations.²⁰

Significantly, state governments took the lead in mandating disclosure of industry payments to physicians. Five states – Maine, Massachusetts, Minnesota, Vermont, and West Virginia – as well as the District of Columbia have passed laws requiring that companies disclose payments to physicians; other states are considering adopting similar laws.²¹ These state laws are limited in certain respects.²² Most notably, only Minnesota requires disclosure to the public. Vermont's law contains an exception for trade secrets that substantially undermined the intent of the law; companies withheld some or all of the data for 72% of the payments made to physicians in 2007.²³ A follow-up study found that the majority of the items withheld as trade secrets were actually payments for promotional speaking and CME.²⁴

Despite this shortcoming, a report by the Vermont Attorney General about the data disclosed demonstrates the way in which disclosure laws can identify outliers and trends that could inform further government and public inquiry. Summarizing the disclosures made in 2007, the report notes that eleven psychiatrists were paid a total of \$626,379, or 20% of the total amount spent by industry on Vermont physicians in all specialties that year.²⁵ Similarly, disclosures made under the Minnesota law provided the data for articles by researchers and reporters that examined the financial ties to industry of physicians who serve on formulary and clinical guidelines committees.²⁶

In some circumstances, institutional policies and industry guidelines already obligate physicians to disclose the support they receive from industry. For example, many academic medical centers require physicians to disclose financial interests that could give rise to a conflict of interest in clinical research or purchasing. Authors who publish in medical journals must disclose financial support that could be a conflict of interest. Likewise, faculty at CME programs accredited by the ACCME are required to provide general information about financial conflicts to the CME provider and to attendees.²⁷ The new PhRMA Code calls for healthcare professionals who are members of committees that set formularies or develop clinical practice guidelines to disclose to the committee the existence and nature of any financial relationship they have with industry.²⁸ In addition, Public Health Service (PHS) regulations require physicians

who engage in PHS-funded research to disclose to their institutions financial interests that could affect the research and are significant, i.e., in excess of \$10,000 in value or representing more than a five percent ownership interest in a single entity.²⁹

Even taken together, the various disclosure requirements applicable to companies and physicians fail to cover many, if not most, physician-industry relationships. Moreover, as identified by a congressional investigation, prominent psychiatrists at academic medical centers had not disclosed all payments by industry, suggesting that even at major universities with strong disclosure policies, practices to monitor and enforce disclosure requirements may not be effective.³⁰ Furthermore, patients, who arguably have the most at stake when physicians face a conflict of interest, are rarely the recipients of physician disclosures.

Federal, state, and institutional policies should be crafted to advance transparency in the relationship of industry and medicine. The information could have a significant impact on industry and physician practice. Companies' internal compliance efforts would be enhanced if they were required to aggregate the amounts paid to physicians by different departments. Public disclosure could also affect physician behavior; disclosure of physicians' relationships with industry could prompt self-reflection and change, as physicians consider how the information would be perceived by their patients, peers, and health care institutions. A unitary national database to which drug and device companies reported all of their relationships with physicians would be a valuable resource for government and non-government policymakers. It would facilitate oversight by academic medical centers, community hospitals and other health care providers, medical journals, and specialty societies that develop practice guidelines. It would also enable federal and state prosecutors to identify trends for investigation and to target outliers that suggest potential abuses. Finally, individual healthcare consumers and the media would have access to the information, improving public understanding of the relationship between physicians and industry.

National disclosure policy should also encompass payments to physicians as well as other health care professionals who serve on formulary committees for health plans, pharmacy benefit companies, group purchasing organizations, hospitals, and other health care facilities. The formulary and coverage decisions by these entities shape the choices available to providers and patients, and should also be subject to public scrutiny.

Pending federal legislation, the Physician Payments Sunshine Act would require industry to disclose payments made to physicians.³¹ The current version of the Act would require each company to disclose, in a single, national database, all payments of more than \$25 which together total an aggregate annual value in excess of \$500 made to individual physicians; the payments would then be catalogued and available on a website.³² The Act, which would preempt state disclosure laws, would mandate public disclosure of financial payments and benefits to physicians, including consulting fees, honoraria and participation in CME programs, as well as gifts, food, travel, and entertainment. Significantly, the Act covers pharmaceutical, device, and medical supply manufacturers as well as group purchasing organizations.

In response to industry comments, the Act exempts disclosure of payments to physicians for: (1) product development for two years or until FDA approval, whichever occurs first; and (2) clinical research until such time as the information must be disclosed publicly under the newly enacted requirements for a public clinical trials registry.³³ This exemption to protect

trade secrets must be carefully defined in regulation and administered so that it does not allow the exception to swallow the rule, as occurred in the case of the Vermont disclosure law.³⁴ Furthermore, such exemption should distinguish disclosure to human subjects in research. Disclosures regarding conflicts of interest should be made routinely as part of the informed consent process to human research subjects.³⁵

The Act has broad support from professional organizations such as the AAMC and from consumer groups, including the National Coalition for Appropriate Prescribing, a coalition of consumer and healthcare advocacy organizations, as well as from the leading industry trade groups, PhRMA and AdvaMed, and many of their constituent member companies.³⁶ Both PhRMA and AdvaMed conditioned their support of the Act on preemption of state laws so that companies would not be required to comply with a myriad of state disclosure mandates.³⁷ The two organizations also successfully sought: (i) a significant reduction in penalties for noncompliance, with a cap for intentional and unintended noncompliance; (ii) a requirement that the website provide “proper context” for the payments; and (iii) a provision making small and physician-owned companies subject to the law.³⁸ At the same time, the broad coalition of consumer and professional organizations that support the Act has opposed the preemption clause, the \$500 threshold for reporting, the reduction in penalties, and the long delay in implementation until 2011.³⁹

Effective national legislation mandating disclosure would be preferable to a patchwork of state laws that set forth different reporting thresholds, timetables and reporting formats. The controversy surrounding federal preemption would be best addressed by establishing comprehensive national policy for disclosure by industry, and recognizing that state governments can mandate disclosure by physicians to supplement disclosure under federal law. This would preserve the authority long held by the states to oversee and license physician practice. It would also maintain the efficiency of a single standard applicable to companies nationwide, while allowing the states to seek additional information from physicians and tailor disclosure more effectively to patients. As proposed under the current draft of the Physician Payments Sunshine Act, the website that will present the information must be searchable by physician and location. Nonetheless, most patients will not be aware of the national database. State policy could determine how physician disclosure, whether in office literature or other means, would be most accessible to patients.

Some commentators criticize disclosure as insufficient to address conflicts of interest.⁴⁰ First, research suggests that those who are subject to conflicts of interest generally do not consciously set out to make biased decisions, but are influenced by unconscious bias.⁴¹ Critics have also challenged disclosure mandates on the grounds that patients and fellow physicians are unable to evaluate the significance of a conflict of interest resulting from industry support to individual physicians.⁴² In fact, some argue that disclosure may have a paradoxical effect, enhancing the perceived trustworthiness of physicians who disclose while undermining a physician’s sense that he or she must strive for objectivity.⁴³

Even if not sufficient alone to address conflicts of interest, disclosure is a critical tool for public policy. Indeed, significant benefits would flow from transparency: enhanced compliance by companies and physicians, data that could inform oversight by government, healthcare institutions, universities and medical journals, and patient access to information about their physicians. Transparency is also a crucial step to shore up public trust in physicians and industry.

B. Banning Gifts, Meals, and Other Perks

Many physicians accept gifts or meals or other perks from drug and device companies.⁴⁴ Beginning in 2002, trade and medical organizations started to adopt voluntary codes for gifts, meals, consulting fees and other payments from industry to physicians. PhRMA first promulgated its “Code on Interactions with Healthcare Professionals” in 2002 and recently revised the Code, effective January 2009.⁴⁵ In April 2003, the Office of Inspector General (OIG) of the Department of Health and Human Services issued its “Compliance Program Guidance for Pharmaceutical Manufacturers” (OIG Compliance Guidance) in which it opined that a company that complied with the PhRMA Code would “substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.”⁴⁶

Under the revised PhRMA Code, companies may give physicians items “primarily for the education of patients or healthcare professionals,” provided they are worth less than \$100 and are given on “an occasional basis.” Gifts cannot have value to a physician outside of his or her professional responsibilities. In a change from the 2002 PhRMA Code, reminder items (e.g., the pens, pads and clip boards with company logos common in physicians’ offices) are now prohibited. The new PhRMA Code also states that field sales representatives and their immediate managers may no longer provide restaurant meals to healthcare professionals. Nonetheless, consistent with the existing PhRMA Code, sales representatives can provide “occasional” and “modest” meals in office or hospital settings, as long as the meals are accompanied by a sales presentation.⁴⁷

In addition, companies may still provide meals at consultant and speaker training meetings; they can also fund meals at CME programs, albeit indirectly through the sponsor of the program. Companies can continue to provide free restaurant meals to physicians at speaker programs at which the presenter is not a member of the sales force or a district manager; physicians or others trained by a company to promote its products can present at such programs. Speaker programs have grown from 120,000 in 1998 to 371,000 in 2004.⁴⁸ In 2000, the top ten pharmaceutical companies spent nearly \$1.9 billion on these programs.⁴⁹ Taken together, the opportunities to provide free meals to physicians remain substantial.

Physician organizations such as the American Medical Association (AMA), the American College of Physicians (ACP), and the American Academy of Orthopaedic Surgeons (AAOS), have also issued voluntary guidelines for physician-industry relationships. The ACP recently announced a revised policy on gifts, leaving physicians responsible for gauging the acceptability of the gifts, but noting that “the acceptance of even small gifts can affect clinical judgment and heighten the perception and/or reality of a conflict of interest.”⁵⁰

The AAMC strongly urged a ban on gifts and meals in a report adopted in June 2008.⁵¹ In support of its recommendations, the AAMC cited a strong body of psychosocial and neurobiological evidence confirming the effects of interpersonal relationships and gifts on the choices and decisions of recipients.⁵² Notably, the AAMC’s recommendation of a total gift ban was not opposed by representatives from industry – the chief executive officers of Amgen, Eli Lilly, and Pfizer – who served on the task force that developed the recommendation. The editors of the *Journal of the American Medical Association*, in July 2008, also urged a ban on gifts and meals, among other steps to shore up the integrity of clinical research and publication.⁵³

Some academic medical centers already ban gifts, including the Cleveland Clinic, Memorial Sloan-Kettering, and UMass Memorial Health Care. Some also ban meals, but typically only on-site. In such instances, physicians and industry representatives can circumvent the ban by meeting at nearby restaurants. The AAMC's recent report recommends that institutions make clear that their rules governing interactions with industry apply both on and off-site.

State legislatures have focused extensively on marketing and promotion practices, with some states adopting partial or complete bans on gifts and meals. For example, California requires that companies set and abide by an annual limit for gifts and other transfers of value, and Minnesota limits gifts, including meals, to an annual total retail value of \$50.⁵⁴ In addition, the District of Columbia bars gifts to members of formulary committees. In Massachusetts, a measure signed into law in August 2008 directs the Department of Public Health to promulgate regulations at least as restrictive as the PhRMA Code. Other states have considered banning gifts, including New Jersey and New York.

The new PhRMA Code represents an improvement over the prior Code by eliminating all gifts except those for the education of patients or healthcare professionals, barring perks such as entertainment, and setting new limits on restaurant meals provided by sales force representatives. At the same time, the PhRMA Code remains voluntary, and sets no financial limits on restaurant meals that are part of a speaker program or meals delivered to physician offices. While the PhRMA Code specifies that meals must be “modest” and “occasional,” it presents no guidance on how these terms should be interpreted, leaving significant latitude. Such terms should be given meaningful parameters. In fact, meals should be provided only under circumstances appropriate for an educational event: a new product, new drug indication, or new safety information. Furthermore, public policy should take an approach similar to the one adopted in Minnesota with an actual limit set on all financial benefits, except those for fair market value for bona fide services.

Legislation rather than self-regulation should set the standards for gifts, meals and other perks accorded to physicians in drug and device promotion. Even if all companies commit to compliance with the PhRMA Code, in a competitive marketplace faced with physician expectations set by long-standing practice, voluntary compliance may be hard to achieve and sustain. Physicians receive little training on conflicts of interest and often believe that incentives affect peers, but not themselves.⁵⁵ Diverse institutional policies and a sense of entitlement among some physicians also present significant hurdles to voluntary reform. Legislation would create a level playing field for all industry sectors and establish clear parameters for physician expectations.

Legislation would also improve professional practices by providing clear prospective guidance from government regarding what is and is not permissible. This would be in contrast to the federal Anti-Kickback Law, which bans any payment made with the intent to induce purchases of or referrals relating to goods or services covered by a federal health care program. The Anti-Kickback Law's intent requirement can be a difficult litmus test to apply, leaving the boundaries of what is permissible unclear.

Industry resistance to a ban on gifts and meals has been founded in part on the belief that physicians will not meet with sales representatives without the incentive of a gift or a meal,

resulting in a loss of education for physicians. Yet, drugs and devices are essential to patient care and modern medical practice. Physicians have a fundamental ethical obligation to learn about treatment options for their patients. This obligation, rather than gifts, meals, or other perks, should drive the interaction between physicians and industry representatives.

Government-funded academic detailers trained to discuss all therapeutic options would be a more objective source of information. Pennsylvania, South Carolina, and Vermont, among other states, have adopted counter-detailing programs, and Oregon has an extensive program to inform physicians about more cost-effective medicines. Federal legislation has also been introduced to fund detailing programs.⁵⁶ In addition, according to a recent study, counter-detailing by Medicaid programs and insurance companies to encourage doctors to use generics is gaining momentum.⁵⁷

C. Setting Standards for Off-Label Promotion

Under the Federal Food, Drug and Cosmetic Act (FDCA) and its implementing regulations, drugs and devices that the FDA finds to be safe and effective for a particular use may be marketed for that use, and that use only.⁵⁸ Drug and device manufacturers may not advertise or promote their products to treat conditions or patient populations not approved by the FDA.⁵⁹ Once a drug is approved for a particular use, however, physicians are free to prescribe it for that use and others.⁶⁰ Companies can sell medications that may be prescribed off-label, but may not promote the products for any use outside the intended use stated on the labeling approved by the FDA.

Medications are widely used off-label, and certain uses are reimbursed by government and third-party payors.⁶¹ According to one study of 100 of the 500 most frequently prescribed medications, as well as 60 medications chosen at random, 21% of prescriptions for outpatient drugs are for off-label uses.⁶² Another estimate suggests that as many as 40% of all prescriptions issued are off-label.⁶³ In certain fields, such as psychiatry, pediatrics, and oncology, the majority of medications prescribed by physicians are for off-label uses.⁶⁴ There are a variety of reasons for off-label prescribing, including the fast pace of cancer research and discovery, and the fact that many medications, including psychotropic medications, have not been tested or approved for use in children.

For over a decade, a debate has simmered about whether companies can distribute reprints of peer-reviewed journal articles or reference publications (together, “scientific materials”) that discuss off-label uses of their products to healthcare professionals, or whether such distribution constitutes off-label promotion. Those in favor of allowing companies to disseminate scientific materials argue that physicians must be informed about off-label uses because, in many cases, such uses represent the state of the medical art and that drug manufacturers have both the incentive and the means to disseminate the information. Drugs prescribed off-label are essential to treatment for thousands of patients, including critically and terminally ill patients for whom the clinical trial and FDA review process is too slow.⁶⁵ In addition, for some uses, the population that benefits is too small to mount or to justify the expense of the clinical trials that would be required to obtain FDA approval.⁶⁶

On the other hand, a recent study concluded that 73% of off-label uses lack evidence of efficacy; for psychiatric drugs, 96% used for off-label purposes lack efficacy findings.⁶⁷ In

addition, serious concerns about the balance and objectivity of studies published in the medical literature have been raised in recent years.⁶⁸ A British House of Commons report estimates that of the clinical trials published in *Lancet*, *New England Journal of Medicine*, and *JAMA*, approximately 75% are industry funded.⁶⁹

In 1994, the Washington Legal Foundation (WLF) brought litigation challenging FDA policies that limit companies' ability to disseminate scientific materials as a constitutional violation of commercial free speech rights.⁷⁰ In the years that followed, the FDA issued two guidance statements on scientific materials. In addition, Congress passed Section 401 of the FDA Modernization Act of 1997 (FDAMA),⁷¹ providing that a company could only disseminate scientific materials discussing an off-label use if it met several conditions, the most onerous of which required the company to submit, or prepare a plan to submit, a supplemental New Drug Application (sNDA) for that use within certain time periods after distributing the scientific materials. In addition, among other requirements, the company had to submit the scientific materials to the FDA 60 days prior to dissemination and meet other standards related to the balance and integrity of the information.

WLF challenged first the FDA guidances and then Section 401 on the grounds that they violated the First Amendment.⁷² In decisions issued in 1998 and 1999, the district court sided with WLF, finding that Section 401 was an unconstitutional restriction on commercial speech, and the FDA appealed.⁷³ At oral argument, however, the FDA took the position that Section 401 was a safe harbor, meaning that compliance with its requirements was not legally mandated, but that adherence would protect companies from enforcement action.⁷⁴ Under this interpretation, FDAMA did not independently authorize the FDA to prohibit or sanction speech. As a result, there was no longer a First Amendment controversy; the District of Columbia Circuit Court of Appeals dismissed the appeal in 2000 and vacated the lower court's decisions and injunctions.⁷⁵ The FDA then withdrew its guidance statements, leaving a legal and policy vacuum that persisted until the FDA issued a new Guidance for Industry on January 13, 2009.⁷⁶

Prior to issuance of the 2009 Guidance for Industry, many manufacturers continued to distribute scientific materials on off-label uses for approved drugs and devices, looking to the general guidelines set forth by the district court in the *WLF* case.⁷⁷ While some high-profile government investigations and settlements have included allegations of off-label promotion through publication and dissemination of articles, both the Department of Justice and the FDA have stated that they will not base an enforcement action solely on distribution of reprints.⁷⁸ In fact, a Government Accounting Office report issued in July 2008 found that, even in the case of explicitly promotional materials, which are submitted to the FDA prior to dissemination, the FDA has no systematic review process.⁷⁹ In the 47 cases in which the FDA issued letters of violation for off-label promotion between 2003-2007, it took an average of seven months for the FDA to issue the letter and four months for corporations to take action.⁸⁰

The Guidance for Industry released in January 2009 sets forth guidelines for companies to disseminate scientific and medical literature in a manner that would not violate the federal ban against promotion of unapproved uses for drugs and devices.⁸¹ In the Guidance for Industry, the FDA recognizes the value of having new indications and intended uses approved by the FDA, and encourages sponsors of medical products to seek such approvals. At the same time, the Guidance for Industry states that important public policy reasons support dissemination by manufacturers of truthful, non-misleading medical journal articles and scientific reference

publications that discuss off-label uses. The Guidance for Industry also notes that such uses may be important and “may even constitute a medically recognized standard of care.”⁸²

Under the Guidance for Industry, among other requirements, articles distributed by manufacturers must be subject to peer-review and published in a journal that requires full disclosure of conflicts of interest by authors, contributors, and editors.⁸³ They must describe “adequate and well-controlled clinical investigations that are considered scientifically sound.”⁸⁴ Articles published in special, industry-funded supplements do not meet such standards, nor do articles primarily distributed by a manufacturer, or written, edited, excerpted, or published specifically for, or at the request of, a manufacturer. Articles edited or significantly influenced by a drug or device manufacturer or by individuals who have a financial relationship with the manufacturer also fall outside the Guidance requirements. The Guidance for Industry also addresses how articles should be disseminated. Among other requirements, the articles must be unabridged with no highlighting and cannot be physically attached to promotional materials.

The Guidance for Industry tracks the requirements of prior federal policy set forth in Section 401 to a certain extent, with several key omissions. The provisions of the Guidance for Industry designed to ensure the integrity and balance of disseminated scientific materials are in certain respects more stringent than the analogous provisions of Section 401.⁸⁵ Most notably, however, the Guidance for Industry does not require companies to submit an sNDA for off-label uses discussed in disseminated scientific materials. This significant change in policy sparked strong controversy when the Guidance for Industry was issued in draft form for public comment in February 2008.⁸⁶

Critics asserted that the change undermined needed federal oversight of off-label uses and research on safety and efficacy that must accompany an application to FDA for approval of a new use of an approved drug or device. Critics pointed to the weaknesses in the integrity of scientific findings on drugs and devices outside the purview of FDA review, noting that companies may choose not to conduct controlled clinical trials of off-label uses, may decide not to publish null or unfavorable findings, and may present study results in a way that puts their products in the best possible light.

The entire research enterprise, including study design, endpoint selection, and article preparation entails judgment and can therefore be subject to bias.⁸⁷ Recent cases have come to light in which pharmaceutical companies and vendors paid physicians to write articles about the company’s products, blurring the line between journal reprints and promotional materials.⁸⁸ In other cases, unacknowledged authors wrote journal articles with authorship attributed to academics who had little to do with the research; in still other instances, the authors had an undisclosed financial relationship with the manufacturer of the drug under study.⁸⁹

The Guidance for Industry, like Section 401 before it, relies heavily on peer review as a proxy for scientific soundness. Even absent conscious abuses, critics argue that the limitations of the peer-review process make it a poor substitute for the FDA approval process.⁹⁰ Unlike the FDA, peer reviewers do not have access to complete information regarding study protocols or to raw or unpublished data. In addition, peer review does not solve the problem generated by industry-funded studies that demonstrate high technical quality but reflect systematic bias.⁹¹ Journal editorial boards also labor under a conflict of interest. Publishing industry studies generates revenue because sponsors purchase reprints for distribution. In addition, advertisements by industry are a substantial source of journal revenue.⁹²

As discussed above, the *WLF* court recognized that the commercial right of free speech applies to industry dissemination of scientific materials. Similarly, in *Thompson v. Western States Medical Center*, the Supreme Court struck down as unconstitutional a provision of FDAMA restricting pharmacists' ability to advertise compounded drugs.⁹³ The FDA did not argue that the advertisements in question were misleading, but that the ban on advertising would preclude large scale drug compounding that should undergo safety and efficacy testing as part of the drug approval process.⁹⁴ The Court noted that there were less restrictive alternatives to banning advertising that could address any such concern, such as a warning on each compounded drug that FDA testing had not been conducted.⁹⁵

Both the *WLF* litigation and Supreme Court decision in *Western States* suggest that the government cannot constitutionally require companies that disseminate scientific materials on off-label uses to submit a sNDA within a certain time period after dissemination. At the same time, the district court in *WLF* recognized the substantial interest of government in the integrity of the FDA approval process and the fact that dissemination of journal articles, even if the articles are truthful and nonmisleading, is an effective form of promotion.⁹⁶ As noted by the Court, drug manufacturers disseminate medical and scientific materials "because they believe that such activity will increase the sales volume of their drugs."⁹⁷

For this reason, policy alternatives should be explored that squarely address the most severe criticism of the Guidance for Industry – that by eliminating the obligation to file an sNDA application, the Guidance for Industry undermines the primary mechanism to encourage companies to generate needed scientific and medical information about the efficacy and safety of off-label uses. In fact, tied to complex First Amendment issues, a guidance statement on dissemination of scientific and medical information is a poor vehicle to generate the needed evidence-base on off-label uses for drugs and devices. Moreover, as stated in the Guidance for Industry, the requirements it delineates are not mandatory, but are optional, to bring a company under the protection of a safe harbor. When the FDAMA safe harbor was still in effect, few companies submitted an sNDA, but instead many conformed their conduct to other aspects of the policies on article dissemination to minimize legal exposure.⁹⁸

Issued in the final days of an outgoing administration, the Guidance for Industry may be revisited.⁹⁹ Whether or not this occurs, a robust public debate should unfold to determine how FDA authority and oversight can best be structured to carry out FDA's public health mission in relation to off-label uses. The current regulatory scheme fails to meet critical public health goals. Moreover, the underpinning of the FDA's regulatory authority, that it can regulate only a product's "intended use," is highly fact-dependent, open to diverse interpretations, and can bring within its ambit speech that is both helpful and detrimental to the well-being of patients.

One policy response would be to clarify that the FDA has authority under the FDA Amendments Act (FDAAA) to require post-market safety studies and clinical trials of off-label uses.¹⁰⁰ Another possible avenue for public policy would be to recognize that once an off-label use reaches certain high sales volumes, the use is presumptively intended or, in any event, sufficiently widespread and remunerative that its sales would justify and support the financial costs of studies on safety and efficacy, thereby triggering FDA authority to mandate the studies. This approach is consistent with a recent study that identified 14 drugs as priorities for research on off-label uses, based on high volume, limited evidence of safety and efficacy, cost, and other factors.¹⁰¹

Along with a change in policy, the role that the FDA should play in administrative remedies and sanctions should be reconsidered. A 2007 study by the Government Accounting Office found that the FDA lacks the staff, structure, and resources to monitor companies' actions to promote off-label uses.¹⁰² As a result, regulatory oversight is effectuated primarily through prosecution by the Department of Justice, state governments, and qui tam plaintiffs.¹⁰³ While enforcement remedies under deferred prosecution and corporate integrity agreements increasingly seek to change the compliance culture and practices of corporations, the long-term impact of these remedies is uncertain.¹⁰⁴ In addition, enforcement by its nature focuses on wrongful conduct rather than the means to generate information needed to make sound public health decisions. Instead of relying by default on prosecution as the primary tool to promote safe and efficacious uses of off-label medication and devices, policymakers should seek to establish prospective policies that inform judgments that government, physicians, and consumers must make about off-label uses.

The Guidance for Industry, while not a good vehicle to address broad public health concerns about off-label promotion, provides important needed clarity about standards and procedures for disseminating medical and scientific articles on off-label uses. Notably, reflecting the mounting public outcry for transparency in the relationship of physicians and industry, the final Guidance for Industry included new provisions requiring companies that disseminate scientific materials to disclose with the materials the nature and amount of the authors' financial interests in the product or the manufacturer as well as compensation by the manufacturer.¹⁰⁵

Federal policy articulated in the Guidance for Industry would be strengthened if companies were barred from using sales representatives to disseminate the scientific materials; meetings with sales representatives are inextricably linked to promotion. Companies have other means to disseminate scientific materials that are less likely to be part of an overall promotional pitch. In addition, the policies should require companies to submit scientific and medical materials to the FDA before disseminating them, as provided previously by Section 401. This would establish the opportunity, but not a requirement, for FDA review and would create a public record of what has been distributed.

Finally, while the FDA must be revitalized to carry out its public health mission effectively, the FDA cannot be the sole bulwark for ensuring the accuracy and reliability of publically available scientific information on off-label uses.¹⁰⁶ Even with an infusion of new funds and staff for the FDA, change must also come from within the medical profession and medical and scientific publishing. Amidst other calls for reform of peer-review publication, the editors of *JAMA* have issued a proposal for needed reform which includes, among other steps: (1) adoption of authorship criteria; (2) disclosure of all author relationships and funding for articles; (3) consideration of funding sources when deciding to accept or reject an article; (4) limits on for-profit companies' control over data; (5) for industry-conducted studies, statistical analysis by a non-employee; and (6) an end to industry funding for CME, gifts, and promotional speaker bureaus.¹⁰⁷

D. Re-envisioning Funding for Continuing Medical Education

As noted above, commercial support for accredited CME grew from \$302 million in 1998 to \$1.2 billion in 2006. Beginning in 2003, the major source of support for CME has been grants from industry, with advertising, exhibit income, and participant and registration fees receding in importance on a percentage basis.¹⁰⁸ Over the past ten years, annual income from the provision of accredited CME has more than doubled, reaching \$2.4 billion in 2006. Profit margins have increased as well. In 1998, accredited providers had a 5.5% profit margin; by 2006, this had grown to 31%.

As industry expenditures on CME have increased, so too has concern about the integrity and quality of CME programming. The data suggest that medical education and communication companies (MECCs), as well as other types of CME providers, including professional societies, medical schools, and academic medical centers, rely too heavily on industry funding to be independent. A Senate Finance Committee report opined 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.”¹⁰⁹ Indeed, many, if not most, drug and device companies have obligations to their investors or shareholders that would prevent them from devoting significant funding to CME without an adequate return on the investment. The results of one study indicate a return on investment for CME of \$3.56 in increased revenue for every dollar spent, a higher return than estimated for detailing and direct-to-consumer advertising.¹¹⁰ As reported by the AMA’s Council on Ethical and Judicial Affairs, two other studies suggest that attendance at company-supported educational programming leads physician attendees to prescribe company products at a higher rate.¹¹¹

Commercial support for CME is potentially problematic for a number of reasons. Even if industry strictly adheres to guidelines that bar control over CME content or speakers, given the financial dependence of CME providers on industry funds, the choices made by CME providers, through the Request for Proposal process or other mechanisms, may be strongly influenced by such funding. For example, CME providers may choose to emphasize drugs and devices at the expense of other aspects of patient care. Consequently, CME would focus on physicians in their capacity as prescribers, not as clinicians overall, and would thereby fail to cover areas such as quality improvement, patient-physician communication, and the wide panoply of non-pharmaceutical and device treatments critical to patient care.¹¹² If industry funding shapes the choice of subject matter, and inclines CME providers to select speakers with close industry ties, CME will also fall short of the necessary balance for the drugs and devices discussed, especially if attendees are unaware of the extent of the presenter’s financial interest in a product.¹¹³

Commercially-funded CME may also be biased towards new therapies, especially newly-approved drug therapies, that are generally more expensive and not as well-studied as older drugs. Relatedly, CME may serve as a back door to off-label promotion.¹¹⁴ Finally, industry support for CME can be viewed as another form of payment to physicians, raising all of the concerns noted above in the discussion of disclosure and gifts to physicians.

In 1997, the FDA issued its Guidance for Industry on Industry-Supported Scientific and Educational Activities for drug manufacturers who wished to support CME without running afoul of the prohibition against off-label promotion.¹¹⁵ In the Guidance, the FDA indicated

that it does not regulate CME, as long as it is “truly independent” of the manufacturer and “nonpromotional.” The Guidance sets forth twelve factors the FDA considers in determining whether programming is truly independent, including control over speakers and content and whether commercial funding was disclosed.¹¹⁶ The FDA, however, does not monitor CME programs to ensure that the Guidance is followed and, according to the Senate Finance Committee, has received few complaints about CME.¹¹⁷

The OIG Compliance Guidance also addresses CME. The OIG recommends that companies should, among other steps, separate sales and marketing from grant-making, establish objective criteria to ensure that funded activities are truly educational, and ensure that manufacturers do not control the choice of speaker or the content of funded programs.¹¹⁸ The OIG, often acting in concert with the Department of Justice, oversees some CME programming, but almost, if not always, after the fact, using the blunt instruments of criminal prosecution and administrative sanction.

In 2004, the ACCME issued its “Standards for Commercial Support: Standards to Ensure the Independence of CME Activities.”¹¹⁹ The Standards, which were updated in August 2007, seek to promote independence in the content of CME programming.¹²⁰ Under the Standards, CME presentations must offer a balanced view of therapeutic options and “promote improvements or quality in healthcare,” as opposed to a business interest. The Standards require that the following decisions be made independently: (1) the identification of CME needs; (2) the determination of educational objectives; (3) the selection and presentation of content; (4) the selection of all persons and organizations that will be in a position to control the content of the CME; (5) the selection of educational methods; and (6) the evaluation of the activity.

As noted above, the ACCME Standards notwithstanding, CME organizers dependent on industry for funding are likely to choose speakers and determine program content with industry interests in mind. Moreover, as reported in a study by the United States Senate Finance Committee, ACCME does not provide proactive or real-time oversight of CME programming.¹²¹ There is no pre-approval and no direct monitoring of CME programs. The Committee also noted that in 2005 and 2006, 18 of the 76 CME providers reviewed by ACCME, or 24%, did not meet at least one of the standards to ensure independence.¹²² Finally, even when problems are identified, many years can pass before a CME provider loses its accreditation.¹²³

Under the newly-revised PhRMA Code, among other changes, companies must separate the department that makes grants for CME from the sales and marketing departments. This requirement is unlikely to effectuate meaningful change, however, because many pharmaceutical companies, in response to the OIG Compliance Guidance, have already eliminated the direct involvement of sales force representatives and sales and marketing departments in making educational grants.¹²⁴ This is in contrast to past practices whereby field representatives were often allowed to solicit grant requests for CME programs from the physicians they called on and to collect grant applications from them.¹²⁵ The revised PhRMA Code also requires that companies develop objective criteria for grantmaking, follow the edicts of ACCME or other accrediting entity, and decline responsibility for, or control over, the content of funded programming.

In June 2008, ACCME issued a call for comments on the advisability of completely eliminating commercial support for CME.¹²⁶ ACCME also sought comment on a proposed

“new paradigm” which would allow for commercial support as long as CME meets educational needs identified by an organization with no financial relationship with industry, addresses practice gaps corroborated by bona fide performance measurements, incorporates curriculum content designed by a professional organization, such as the AMA, and is found to be free of commercial bias.¹²⁷

The AAMC has also proposed reforms, including a centralized office within each academic medical center that would manage all commercial support for CME.¹²⁸ Several medical centers have already declined industry support for CME, providing more education on-site rather than at off-site locations.¹²⁹ Prominent physicians and public policymakers have also advocated an end to commercial support for CME.¹³⁰ Furthermore, on July 2, 2008, Pfizer Inc. announced that it has voluntarily stopped its prior practice of paying for-profit vendors to produce CME programming, although it will continue to fund CME offered by medical centers and medical societies.¹³¹

Some fear that banning industry support would severely curtail CME; however, the correlation between industry funding and hours of CME does not support this concern. MECCs receive more than half of all commercial support but produce only 8% of the total hours of CME.¹³² This is in contrast to medical schools which receive 21% of commercial support while providing almost half of the total hours of CME.¹³³ Furthermore, other professionals, such as accountants and lawyers, pay for their own continuing professional education. In addition, CME costs could be significantly reduced if lavish meals and settings were replaced with comfortable but less expensive sites for training. Technology could also be used to reduce the cost of CME programming.

The Center for Health & Pharmaceutical Law & Policy recommends that CME should not be supported by industry funds. Even with safeguards such as those contained in the revised PhRMA Code in place, industry support for CME is inconsistent with the need for the medical profession to assure that physicians receive balanced and complete educational programs to provide the highest quality medical treatment. Such educational programs should address the broad array of topics encompassed by medical care, not only drugs and devices. Medical education should be provided by the profession, either by professional societies, academic medical centers, or other forums controlled by physician leadership, without industry support for specific CME topics, and with clear rules for disclosure and management of conflicts of interest by presenters.

Short of an end to all industry funding, concerns about commercial influence could be minimized through an overhaul of the funding mechanism for CME.¹³⁴ For example, as proposed in a recent report by the Macy Foundation, an independent commission or some other entity could be established that would receive funds from any source to fund CME.¹³⁵ This approach no doubt would significantly diminish industry funding for CME, but would still allow purely philanthropic donations.

Either a realignment or elimination of industry funding for CME will take significant time to plan and effectuate. During that time, concrete policies, beyond those already in place, should be adopted. Such steps range from enhanced disclosure to active management of conflicts and disqualification where conflicts are fundamentally inconsistent with the provision of balanced educational content. Disclosure to CME providers as well as attendees should specify the

Drug & Device Promotion: Charting a Course for Policy Reform

nature of presenters' financial interests and the amount of the financial interest within certain ranges. ACCME should also revise its standards to provide more specific guidance about when independent peer review or other measures are needed to address a conflict. Finally, service as a promotional speaker for a particular product should preclude that physician from speaking at an accredited CME program.

CONCLUSION

The partnership between industry and medicine is essential to biomedical advances. Mounting public concern about preserving the integrity of the patient-physician relationship, medical education, and clinical research supports the need for policy reform. Industry self-regulation has made important strides, yet cannot create a level playing field in a highly competitive marketplace or assure compliance across all segments of industry engaged in financial relationships with health care institutions and practitioners. The policy changes proposed by the Center do not seek to stifle drug and device innovation, but to allow industry-medical collaboration to thrive on the premise that the products themselves are essential to public health and the well-being of patients.

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Executive Summary

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Policy Analysis and Recommendations

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- ²⁶ Medicare Payment Advisory Commission, Report to the Congress: Reforming the Delivery System (June 2008) at 155 http://www.medpac.gov/documents/Jun08_EntireReport.pdf (accessed Nov. 7, 2008).
- ²⁷ L. Kowalczyk, “UMass Policy Limits Doctor, Drug Maker Ties Conflict of Interest Rules Among Strictest in Country,” *The Boston Globe*, Dec. 24, 2007 (noting that most hospitals require members of committees that decide which drugs and devices the hospital should buy in bulk to disclose their financial relationships to their fellow committee members); R.S. Schwartz et al., “Full Disclosure and the Funding of Biomedical Research,” *N. Eng. J. Med.* 358, No. 17 (2008): 1850-1851 (discussing the disclosure requirements of academic journals); Accreditation Council for Continuing Medical Education (ACCME), “The ACCME Standards for Commercial Support: Standards to Ensure the Independence of CME Activities,” Standard 6 (2004, updated 2006, 2007) (providing that those with control over CME content must disclose to learners “the name of the commercial interest(s)” and “the nature of the relationship the person has with each commercial interest”).
- ²⁸ PhRMA Code, *supra* note 10 at 11. In addition to the direct support they provide for the development of clinical protocols, companies have relationships with the experts who develop the protocols. *See* J. Abramson and B. Starfield, “The Effect of Conflict of Interest on Biomedical Research and Clinical Practice Guidelines: Can We Trust the Evidence in Evidence-Based Medicine?” *J. Am. Board Fam. Pract.* 18, No. 5 (2005): 414-418; N.K. Choudhry et al., *supra* note 1 (noting that as many as 59% of the authors of clinical guidelines had financial relationships with companies whose drugs could be affected by the guidelines).
- ²⁹ 42 C.F.R. §§ 50.603 and 50.605.

- ³⁰ See, e.g., R. Waters, “Harvard Doctors Failed to Disclose Fees, Senator Says” (June 8, 2008) *Bloomberg.com* (accessed Dec. 10, 2008) (reporting that three doctors at Harvard Medical School failed to disclose at least \$3.2 million in industry funds, putting the school and Massachusetts General Hospital at risk of losing federal funds).
- ³¹ Physician Payments Sunshine Act, *supra* note 16.
- ³² The Act, as introduced in 2008 in the House of Representatives and 2007 in the Senate, does not include the \$500 threshold for reporting, federal preemption, or other changes discussed. These changes have been negotiated and are reflected in a draft bill. United States Senate, “Senators Praise Growing Support for Transparency in Drug Industry Payments to Physicians” (May 13, 2008) <http://finance.senate.gov/press/Gpress/2008/prg051308.pdf> (accessed Aug. 26, 2008).
- ³³ *Id.* (providing for delayed reporting for payments made pursuant to product development agreements (for two years or until FDA approval, whichever comes first) and for payments made to fund clinical trials (until posting is required under the Public Health Service Act)).
- ³⁴ J.S. Ross et al., *supra* note 22.
- ³⁵ As shown in one study, while only a minority of research subjects thought that information on financial conflicts of interest would influence their decisions, the majority thought that the information should be disclosed. C. Grady et al., “The Limits of Disclosure: What Research Subjects Want to Know about Investigator Financial Interests,” *J.L. Med. & Ethics* 34, No. 3 (2006): 592-599. Disclosure reflects an ethical obligation to patients and promotes the integrity of the research enterprise.
- ³⁶ The National Coalition for Appropriate Prescribing is an umbrella group representing 26 national and state-based consumer and healthcare advocacy groups.
- ³⁷ “Revised Physician Payments Sunshine Act Garners Industry Support,” *Rx Compliance Report VII*, No. 9 (2008) at 9.
- ³⁸ *Id.*
- ³⁹ Prescription Project, “Fact Sheet: The Physician Payments Sunshine Act” (May 30, 2008) http://www.prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf (accessed Oct. 21, 2008).
- ⁴⁰ See, e.g., J. Kassirer, “Fantasy at FDA: Protecting the Public from Drug Company Reprints,” *Health Affairs Blog* (Apr. 23, 2008) (“The notion that peer review and disclosure will protect the public is, in my judgment, magical thinking.”).
- ⁴¹ See D.M. Cain and A.S. Detsky, “Everyone’s a Little Bit Biased (Even Physicians),” *JAMA* 299, No. 24 (2008): 2893-2895 (“Navigating a conflict of interest is not only a problem for the intentionally corrupt, but also for well-meaning individuals who unintentionally succumb to conflicts but then post hoc rationalize their actions so as to appear (to themselves and others) to be objective.”); Report of the Council on Ethical and Judicial Affairs of the American Medical Association, “Industry Support of Professional Education in Medicine,” 1-A-08 at 5 (CEJA Report) (“[C]oncern about industry influence in professional education is often about subtle bias, not conscious corruption or wrongdoing.”).

- ⁴² See, e.g., D.M. Cain et al., “The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest,” *J. Legal Studies* 34 (2005): 1-25 (“[D]isclosure unfairly places the burden of managing the conflict on those to whom the disclosure is made charging them with determining how skeptical to be about the objectivity of the individual with the potential conflict. It is not reasonable to expect physician learners who are attending an educational event to acquire new knowledge to be in a position to fully discern what ‘information’ provided by the presenter is objective or biased.”).
- ⁴³ J. Kassirer, *supra* note 40 (“[M]any people believe that disclosing a financial conflict—or two or three or twenty—gives the conflicted person a ticket to say just about anything, biased or not, with impunity.”).
- ⁴⁴ E.G. Campbell et al., “A National Survey of Physician-Industry Relationships,” *supra* note 4; A. Wazana, “Physicians and the Pharmaceutical Industry: ‘Is a Gift Ever Just a Gift?’” *JAMA* 283, No. 3 (2000): 373-380; Department of Health and Human Services, Office of Inspector General, “Prescription Drug Promotion Involving Payments and Gifts: Physicians’ Perspectives” (1992) (available at <http://www.oig.hhs.gov/oei/reports/oei-01-90-00481.pdf>).
- ⁴⁵ Similar to the PhRMA Code, the AdvaMed Code permits gifts of less than \$100 if they “benefit patients or serve a genuine educational function.” AdvaMed makes an exception to the \$100 cap for medical textbooks and anatomical models used for education.
- ⁴⁶ Department of Health and Human Services, Office of Inspector General, “Compliance Program Guidance for Pharmaceutical Manufacturers,” 68 Fed. Reg. 23,731-743 (May 5, 2003) (OIG Compliance Guidance).
- ⁴⁷ Industry spends heavily on the on-site meals which were permitted under the old PhRMA Code and are still expressly permitted under the new PhRMA Code. See S. Saul, “Drug Makers Pay for Lunch as They Pitch,” *N.Y. Times*, July 28, 2006, at A1 (reporting that some offices get breakfast and lunch every day and that drug makers spend hundreds of millions of dollars a year on these meals; one drug maker stated that its representatives spend \$500 to \$750 a month on lunches, while the owner of a lunch delivery business stated that the average pharmaceutical representative with whom he does business has a monthly lunch budget of close to \$2,000); R. Lowes, “What Drug Rep Visits Cost You,” *Medical Economics* (Aug. 3, 2007) (reporting that “[a]t the practice of FP Scott Jordan in White House, TN, a different rep treats the 25-member staff to lunch each day”); “The Drug Lunch,” *CancerDoc.blogspot.com* (accessed Aug. 14, 2008) (“Take my own practice, for example. ... There has been a long history of drug lunches there. The staff gets a free lunch every day of the week and for those that make under \$40,000 or \$50,000 per year, a free lunch every day of your work life adds up.”).
- ⁴⁸ M.A. Gagnon and J. Lexchin, “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States,” *PLoS Medicine* 5, No. 1 (2008): 0029-0033.
- ⁴⁹ *Id.*
- ⁵⁰ F.E. Turton and L. Snyder, Comment Regarding “Physician-Industry Relations,” *Annals of Internal Medicine* 146, No. 6 (Mar. 20, 2007).
- ⁵¹ AAMC, *supra* note 1 at 14, 21.
- ⁵² *Id.* at 1.
- ⁵³ C.D. DeAngelis and P.B. Fontanarosa, *supra* note 1.

- ⁵⁴ Publications and educational materials are excepted from Minnesota’s gift ban. Minn Stat. § 151.461(6) (2006).
- ⁵⁵ E.G. Campbell et al., “A National Survey of Physician-Industry Relationships,” *supra* note 4.
- ⁵⁶ Independent Drug Education and Outreach Act of 2008, H.R. 6752, 110th Cong. (2008).
- ⁵⁷ J.D. Malkin et al., “The Changing Face of Pharmacy Benefit Design,” *Health Affairs* 23, No. 1 (2004): 194-199.
- ⁵⁸ *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51, 54-55 (D.D.C. 1998) (*WLF II*) (reviewing the statutory and regulatory framework governing off-label promotion).
- ⁵⁹ *Id.* The FDA does permit companies to disseminate information about off-label uses in response to unsolicited physician requests. See K. Hessler Carver, “Analyzing the Laws, Regulations, and Policies Affecting FDA-Regulated Products: A Global View of the First Amendment Constraints on FDA,” *Food Drug L.J.* 63, No. 1 (2008): 211-212.
- ⁶⁰ See *WLF II*, 13 F. Supp. 2d at 55 (citing 59 Fed. Reg. 59820, 59821 (1994) in which FDA restates its policy that actual prescription choices are left to physician discretion).
- ⁶¹ *Id.* and, for example, Medicare Benefit Policy Manual, 50.4.2 – Unlabeled Use of Drug, <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf> (accessed Aug. 24, 2008) (providing for coverage of “medically accepted” indications even if not included on the official label).
- ⁶² D.C. Radley et al., “Off-Label Prescribing Among Office-Based Physicians,” *Archives of Internal Med.* 166 (2006): 1021-1026.
- ⁶³ S. Greene, *supra* note 3 (citing D. Armstrong & A. Wilde Mathews, “More Off-Label Drug Use is Seen,” *Wall St. J.*, May 14, 2004, at B1).
- ⁶⁴ One recent study that prioritized the need for safety and efficacy studies for off-label uses based on volume, the extant evidence-base for the use, safety concerns, cost, and marketing, among other considerations, concluded that a substantial number of high volume drugs lacked adequate scientific support for the use, especially for psychiatric medications. The authors noted that there are not necessarily harms associated with off-label uses, but that physicians are prescribing in the absence of reassurance that the uses are safe and efficacious. S. Walton et al., “Prioritizing Future Research on Off-Label Prescribing: Results from a Quantitative Evaluation,” *Pharmacotherapy* 28, No. 12 (2008); 1443-1452.
- ⁶⁵ The clinical trial and FDA review process can be slow and expensive. See S. Keyhani et al., “Are Development Times for Pharmaceuticals Increasing or Decreasing?” *Health Affairs* 25, No. 2 (2006): 461-468 (finding that the median total post-IND development time for all drugs studied was 6.4 years). FDA has mechanisms in place to speed the approval of drugs that treat serious diseases and fill unmet medical needs, offer major advances in treatment, or provide treatment where no adequate treatment exists. For an overview of these mechanisms see <http://www.fda.gov/oashi/fast.html> (accessed Jan. 14, 2009).
- ⁶⁶ To mitigate this problem, Congress enacted the Orphan Drug Act of 1983, which provides manufacturers with special incentives, including tax credits and a period of marketing exclusivity, to develop treatments for diseases that affect fewer than 200,000 persons.
- ⁶⁷ D.C. Radley et al., *supra* note 62.

Drug & Device Promotion: Charting a Course for Policy Reform

- ⁶⁸ B.M. Psaty and W. Ray, “FDA Guidance on Off-Label Promotion and the State of the Literature from Sponsors,” *JAMA* 299, No. 16 (2008): 1949-1951.
- ⁶⁹ J. Abramson and B. Starfield, *supra* note 28.
- ⁷⁰ *Washington Legal Foundation v. Henney*, 128 F. Supp. 2d 11, 12 (D.D.C. 2000) (*WLF V*) (discussing history of dispute).
- ⁷¹ Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 11 Stat. 2296 (FDAMA).
- ⁷² *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333-334 (D.C. Cir. 2000) (*WLF IV*).
- ⁷³ *See WLF II* and *Washington Legal Foundation v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999) (*WLF III*).
- ⁷⁴ *WLF IV*, 202 F.3d at 335.
- ⁷⁵ *Id.* at 337. *See* M. Gilhooley, “Drug Regulation and the Constitution after *Western States*,” *U. Rich. L. Rev.*, 37, No. 3 (2003): 901-933 at 922 (explaining that, in the wake of the *WLF* litigation, FDA policy “reflect[ed] simply its traditional objection to a manufacturer’s distribution of materials intended to promote unapproved uses of drugs”).
- ⁷⁶ Section 401 ceased to be in effect in 2006. The FDA released a draft Guidance for Industry on February 15, 2008, with a subsequent period for public comment. *See* Notice of Availability published at 73 Fed. Reg. 9342 (Feb. 20, 2008). The final Guidance became available on January 13, 2009. *See* Notice published at 74 Fed. Reg. 1694 (Jan. 13, 2009).
- ⁷⁷ Those guidelines include, among other requirements, that the articles must: (1) be truthful and nonmisleading; (2) include notification that the use is not approved by the FDA; and (3) be published in a bona fide peer review journal with independent expert reviewers. *WLF II*, 13 F. Supp. 2d at 53-54. In fact, while some raised concern that the Guidance for Industry would open the floodgates to dissemination of articles on off-label uses, companies have been widely distributing the articles for many years, without clear policy guidance. *See* S. Gottlieb, “From FDA, A Good Framework for Distributing Information on Off-Label Uses,” *Health Affairs Blog* (Apr. 23, 2008) (noting the “reality” that “many drug firms went well beyond sec. 401 and widely engaged in the distribution of journal reprints, with no consequence”).
- ⁷⁸ *See* Gottlieb, *supra* note 77.
- ⁷⁹ Government Accounting Office Report, “Prescription Drugs: FDA’s Oversight of the Promotion of Drugs for Off-Label Uses” (July 2008).
- ⁸⁰ *Id.* at 6.
- ⁸¹ *See* FDA, Guidance for Industry, *supra* note 8.
- ⁸² *Id.*
- ⁸³ *Id.*
- ⁸⁴ *Id.*

- ⁸⁵ At least one commentator has suggested that this may mean that certain kinds of articles that would be circulated today, for example, articles from special supplements or from journals without disclosure policies, could not be circulated under the final Guidance. *See* Gottlieb, *supra* note 77.
- ⁸⁶ *See* Comments to “Draft Guidance for Industry on Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices,” Docket No. FDA-2008-D-0053, <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA-2008-D-0053> (accessed Jan. 14, 2009).
- ⁸⁷ B.M. Psaty and R.A. Kronmal, “Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment: A Case Study Based on Documents from Rofecoxib Litigation,” *JAMA* 299, No. 15 (2008): 1813-1817.
- ⁸⁸ J.S. Ross et al., “Guest Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation,” *JAMA* 299, No. 15 (2008): 1800-1812.
- ⁸⁹ C.D. DeAngelis and P.B. Fontanarosa, *supra* note 1.
- ⁹⁰ B.M. Psaty and W. Ray, *supra* note 68.
- ⁹¹ *See* B.M. Psaty and R.A. Kronmal, *supra* note 87 at 1816 (“For reviewers and journal editors, attention to methodological quality of a manuscript may provide an incomplete picture of study quality.”)
- ⁹² R. Smith, “Medical Journals Are an Extension of the Marketing Arm of Pharmaceutical Companies” *PLoS Medicine* 2, No. 5 (2005); Letter from Henry A. Waxman, Chairman House Committee on Oversight and Government Reform to The Honorable Andrew C. von Eschenbach (Nov. 30, 2007) (challenging the underlying premise of the Draft Guidance, namely that “peer-reviewed reports provide accurate, validated information and that even if individual articles are biased, the published literature as a whole can provide balance”).
- ⁹³ 535 U.S. 357 (2002).
- ⁹⁴ *Id.* at 370-371.
- ⁹⁵ *Id.* at 374-375.
- ⁹⁶ *WLF II*, 13 F. Supp. 2d at 60-62 and 64-67.
- ⁹⁷ *Id.* at 35-36.
- ⁹⁸ *See* Gottlieb, *supra* note 77.
- ⁹⁹ For example, immediately following release of the Guidance for Industry, Congressman Waxman issued a statement in which he expressed the hope that the Guidance will “be carefully re-examined by the new administration.” L. Richwine, “FDA Lets Drugmakers Advise Doctors on Unapproved Uses,” Reuters.com (Jan. 12, 2009) <http://www.reuters.com/article/domesticNews/idUSTRE50C0QK20090113> (accessed Jan. 15, 2009).

- ¹⁰⁰ The FDA's authority to require safety studies of off-label uses under FDAAA is unclear. Based on both the text of Section 901 of FDAAA governing safety studies and trials and on the legislative history of FDAAA as a whole, a credible argument can be made that the FDA has this authority. However, given the uncertainty of FDA's authority to require studies and take other actions in relation to off-label use, the authority under FDAAA could be challenged. Notably, FDA has already used its new FDAAA-granted authority to order label changes to address a safety issue arising in the context of the off-label use of certain anti-psychotic drugs to treat dementia-related psychosis.
- ¹⁰¹ See Walton, *supra* note 64.
- ¹⁰² See Government Accounting Office Report, *supra* note 79.
- ¹⁰³ C.D. Zalesky, "Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests; Moving Beyond Regulation-Through-Litigation," *J. Health L.* 39, No. 2 (2006): 235-264. See also V.W. Girard, "Punishing Pharmaceutical Companies for Unlawful Promotion of Approved Drugs: Why the False Claims Act is the Wrong Rx" (Georgetown Law and Economics Faculty Working Paper No. 1195714).
- ¹⁰⁴ K. Boozang and S. Handler-Hutchinson, "The Justice Department's Fight Against Corporate Corruption," *Am. J.L. & Med.* (forthcoming) (Spring 2009).
- ¹⁰⁵ See FDA, Guidance for Industry, *supra* note 8.
- ¹⁰⁶ A. Mundy, "Grassley, Dingell Lead Calls For Overhauling FDA," *Wall St. J.*, July 30, 2008; J. Schmidt, "Report: FDA So Underfunded, Consumers Are Put at Risk," *USA Today*, Dec. 2, 2007; A.J.J. Wood, "Playing 'Kick the FDA' – Risk-free to Players but Hazardous to Public Health," *N. Eng. J. Med.* 358, No. 17 (2008): 1774-1775.
- ¹⁰⁷ C.D. DeAngelis and P.B. Fontanarosa, *supra* note 1.
- ¹⁰⁸ R. Steinbrook, *supra* note 1 at 104.
- ¹⁰⁹ Senate Grant Report, *supra* note 14 at 16.
- ¹¹⁰ CEJA Report, *supra* note 41 at 3 (citing RxPromoROI, "The RAPP Study: Executive Summary," http://www.rxpromoroi.org/rapp/exec_sum.html (accessed Sept. 23, 2008)).
- ¹¹¹ *Id.* at 3-4. See also R. Steinbrook, *supra* note 1 (citing L.L. Casebeer and R. S. Shillman, "What's ROI Got to Do with CME?" *Medical Marketing Media*, Aug. 1, 2002).
- ¹¹² For a thoughtful evaluation of the impact of industry-funded CME on medical education and treatment, see the Josiah Macy Jr. Foundation Report, "Continuing Education in the Health Professions: Improving Health Care through Lifelong Learning," <http://www.josiahmacyfoundation.org> (accessed Aug. 10, 2008).
- ¹¹³ Current rules, put forth by the ACCME, require that physicians disclose that a conflict of interest exists, but do not mandate disclosure of the amount of the financial interest. ACCME, *supra* note 27, Standard 2.1.

- ¹¹⁴ Several major settlements in recent years provide examples. In 2004, Pfizer Inc. entered into a \$430 million settlement with the federal government ending litigation in which it was alleged that Warner-Lambert (which Pfizer had acquired) funded purportedly independent educational programs that had promoted off-label uses of Neurontin. Warner-Lambert allegedly selected speakers and controlled the content of their presentations. In 2005, Serono entered into a \$704 million settlement encompassing, among other things, claims that it funded educational programs that were not actually independent and which promoted Serostim for off-label uses. Finally, Purdue Pharma, the maker of OxyContin, entered into a \$634 million settlement which encompassed claims that the company designed educational programs to meet the same strategic goals as its detailing visits. The Senate Finance Committee concluded that “[t]he off-label promotion risk of educational grants appears to pose the greatest threat to the Federal health care programs and beneficiaries,” while noting that this was difficult to demonstrate conclusively. Senate Grant Report, *supra* note 14 at 18.
- ¹¹⁵ See FDA, Final Guidance on Indus. Supported Scientific Ed. Activities, 62 Fed. Reg. 64074, 64097-99 (Dec. 3, 1997).
- ¹¹⁶ *Id.*
- ¹¹⁷ Senate Grant Report, *supra* note 14 at 7.
- ¹¹⁸ OIG, Compliance Guidance, *supra* note 46 at 20-21, 34-35.
- ¹¹⁹ Professional organizations including the AMA and the American College of Physicians have also issued guidelines, for physicians as opposed to industry, intended to ameliorate the conflicts and potential conflicts created by industry funding of CME.
- ¹²⁰ On January 1, 2008, ACCME adopted a revised definition of “commercial interest.” Under the new definition, MECCS can no longer be accredited as providers of CME if they are owned or controlled by advertising or marketing firms, as these firms are now considered to be commercial interests. MECCs can continue to be accredited if they have a “sister company” that is a commercial interest, however, provided there is an adequate corporate firewall in place. See ACCME, “Commercial Support and Disclosure,” (Aug. 2007) http://www.accme.org/index.cfm/fa/Policy.policy/Policy_id/9456ae6f-61b5-4e80-a330-7d85d5e68421.cfm (accessed Dec. 11, 2008).
- ¹²¹ Senate Grant Report, *supra* note 14 at 13.
- ¹²² *Id.* at 14.
- ¹²³ *Id.* at 13-14. As part of its response to the Senate Grant Report, ACCME has announced that going forward it will require CME providers found to be out of compliance to bring themselves into compliance within a matter of weeks. See ACCME, “ACCME Expects Providers to Fix Noncompliance Finding More Quickly” (June 2008) http://www.accme.org/dir_docs/doc_upload/d6b96a50-084c-485b-b71a-6b405b9c07d8_uploaddocument.pdf (accessed Dec. 11, 2008).
- ¹²⁴ Senate Grant Report, *supra* note 14 at 15.
- ¹²⁵ *Id.*
- ¹²⁶ See ACCME, “The ACCME Believes that Due Consideration be Given to the Elimination of Commercial Support of Continuing Medical Education Activities” (June 2008) http://www.accme.org/dir_docs/doc_upload/d6b96a50-084c-485b-b71a-6b405b9c07d8_uploaddocument.pdf (accessed Dec. 11, 2008).

¹²⁷ *Id.*

¹²⁸ AAMC, *supra* note 1.

¹²⁹ E. Silverman, “Stanford University to Restrict CME Financing” *Pharmalot* (Aug. 26, 2008) <http://www.pharmalot.com/2008/08/stanford-university-to-restrict-cme-financing/> (accessed Aug. 26, 2008); D. Kovaleski, “No Pharma Funding” *MeetingNet*, Jan. 1, 2008 http://meetingsnet.com/cmepharma/cme/no_pharma_funding_012808/ (accessed August 24, 2008) (reporting that CME at Memorial Sloan-Kettering is “alive and well” one year after the end of commercial support). The AMA’s Council on Ethical and Judicial Affairs also recently opined that individual physicians, medical schools, teaching hospitals, and professional organizations should not accept industry funding to support professional education activities, with the exception of technical training when new diagnostic or therapeutic devices and techniques are introduced. The AMA did not adopt the Council’s recommendation, determining that “further refinements and recommendations” were needed.

¹³⁰ T.A. Brennan et al., *supra* note 2 at 431 (“Manufacturers wishing to support education for medical students, residents, and/or practicing physicians should contribute to a central repository (e.g., a designated office at an [academic medical center]), which in turn would disburse funds to ACCME-approved programs.”); C.D. DeAngelis and P.B. Fontanarosa, *supra* note 1 (recommending no industry input and an end to industry funding).

¹³¹ Press Release, Pfizer Inc., “Pfizer Changes Its Funding of Continuing Medical Education in the U.S.” (July 2, 2008).

¹³² CEJA Report, *supra* note 41 at 7.

¹³³ *Id.*

¹³⁴ For example, at UMass Memorial Medical Center, funding for CME is funneled through the UMass Memorial Foundation and can be directed to a specific department but not to a specific topic or physician. The Medical Center reviews donations over \$10,000 for conflicts of interest. See M. Iskowitz, “Will Pharma Grants Run Dry at UMass,” *Medical Marketing Media*, Feb. 1, 2008, <http://www.mmm-online.com/Will-pharma-grants-run-dry-at-UMass/article/104874/> (accessed Aug. 24, 2008).

¹³⁵ Josiah Macy Jr. Foundation Report, *supra* note 108 at 139.

APPENDICES

Appendix A

Forum on Drug and Device Promotion

On January 30, 2008, the Center hosted a Forum on drug and device promotion, *Drawing the Line Between Physician Education and Product Promotion: Charting a Course for Public Policy*. Building on participation from leaders in government, industry, medicine, academia, consumer organizations, and accrediting bodies, the Forum provided the venue for a thought-provoking exploration of policy solutions to enhance transparency and minimize conflicts of interest in drug and device promotion, including a potential ban on gifts, disclosure of industry-physician relationships, industry funding for continuing medical education, and off-label promotion of drugs and devices.

Twenty-seven individuals attended the one-day Forum (see Appendix A). Tracy Miller, the Center's Executive Director, and Kathleen Boozang, Seton Hall Professor of Law, facilitated discussion during the one-day meeting. The agenda included a presentation on "Industry Funding to Physicians and Academic Medical Centers: What Does the Data Tell Us?" by Eric Campbell, Ph.D., Associate Professor, Harvard Medical School and the Institute for Health Policy. Dr. Campbell presented extensive research he has conducted on the nature and extent of the financial relationships between industry and physicians. His presentation was followed by discussion of the data.

Throughout the remainder of the day, the Forum participants engaged in a lively exchange of views about key topics on the agenda. The Forum did not strive to reach consensus among the participants, but, rather, sought a variety of perspectives. The participants, whose names are listed below, were advised in advance that individual comments, suggestions, and positions would not be quoted or attributed to them.

The discussion among the Forum participants provided insight, information, and diverse perspectives on critical issues covered throughout the day. We wish to underscore, however, that the views and recommendations stated in this paper are solely those of the Center, not the Forum participants.

Participants at the Forum on Drug and Device Promotion

Sheldon Bradshaw, Esq., Partner, Food & Drug Practice, Hunton & Williams LLP,
Former Chief Counsel, Food and Drug Administration, 2005-2007

Joseph Braunreuther, Esq., General Counsel, Pharmaceutical Division, Johnson & Johnson

Eric Campbell, Ph.D., Professor, Institute for Health Policy, Massachusetts General
Hospital, Harvard Medical School

Nancy DiLella, Esq., Managing Attorney, Hoffmann-La Roche Inc.

Terry Fadem, Managing Director, Office of Corporate Alliance, University of Pennsylvania
School of Medicine

William Frishman, M.D., Chairman and Professor of Medicine, New York Medical College

Tom Forrester, Esq., Corporate Compliance Officer, sanofi-aventis

Scott Gottlieb, M.D., Resident Fellow, American Enterprise Institute; Former Director of
Medical Policy Development, Food & Drug Administration, and Senior Policy Advisor,
Centers for Medicare & Medicaid Services

Freddy Jiménez, Esq., Assistant General Counsel, Johnson & Johnson

Sharon Joyce, Esq., Assistant Attorney General in Charge of Professional Boards, Office of
the Attorney General for the State of New Jersey

John Kamp, J.D., M.D., Executive Director, Coalition for Healthcare Communication

Stephen Kanovsky, Esq., Associate General Counsel, sanofi-aventis

Murray Kopelow, M.D., MSC, FRCPC, Chief Executive, ACCME

John Krayniak, Esq., Assistant Attorney General, Medicaid Fraud Control Unit of New
Jersey Office of Attorney General

Arthur Aaron Levin, MPH, Director, Center for Medical Consumers

Ann Lewis, Esq., Vice President & Senior Counsel, Bristol-Myers Squibb Co.

Michael B. McCulley, Esq., Assistant General Counsel, Johnson & Johnson

Kathleen McGuan, Esq., Partner, Reed Smith LLP; Former Chief Counsel for Medicare &
Medicaid Services and Associate General Counsel of Health & Human Services

Kathleen Meriwether, Esq., Principal, Ernst & Young LLP; Former Assistant United States
Attorney, Eastern District of Pennsylvania, Department of Justice

Lisa Miller, Executive Director, Healthcare Education & Liaison Programs, Purdue Pharma

Kevin O’Dowd, Esq., Health Care Fraud Coordinator, U.S. Attorney’s Office, District of New Jersey

Karen Overstreet, EdD, RPh, FACME, Past-President, NAAMECC

Laura Pawloski, Esq., Office of the Chief Counsel, U.S. Food & Drug Administration

Lori Queisser, Senior Vice President, Global Compliance & Business Practices, Schering Plough Corporation

Denise Rodgers, M.D., Executive Vice President for Academic and Clinical Affairs and Professor of Family Medicine, UMDNJ

Michael Shaw, Esq., Global Head, Ethics & Compliance, Novartis Oncology, Novartis

John Spinnato, Vice President and General Counsel, sanofi-aventis

Gregg Vicinanza, Esq., Associate General Counsel, Becton, Dickinson and Company

Bert Weinstein, Esq., Vice President, Corporate Compliance, Purdue Pharma

Participants from Seton Hall Law School

Patrick Hobbs, Dean

Kathleen Boozang, Associate Dean for Academic Advancement & Professor of Law

Carl Coleman, Professor of Law & Director of the Health Law & Policy Program

Margaret Gilhooley, Professor of Law

Denise Pinney, Assistant Dean of Health, Science & Technology Law

Participants from The Center for Health & Pharmaceutical Law & Policy

Tracy Miller, Executive Director, The Center for Health & Pharmaceutical Law & Policy

Simone Handler-Hutchinson, Health Care Compliance Program Director & Faculty Fellow

Appendix B

Forum Statement of Principles

Drawing the Line between Physician Education and Product Promotion: Charting a Course for Policy Reform: Statement of Principles

This statement of principles was prepared by the Center for Health & Pharmaceutical Law & Policy as a starting point for discussion at the Forum on drug and device promotion. The Center did not seek agreement on the document, but welcomed comments from the participants on the principles and goals presented.

Principles Underlying Public Policy for Promotion of Drugs, Devices and CME

The development of new drugs and medical devices has played a central role in modern medical advances, leading to reduced mortality, improved health, and better treatment options. Many of these advances have emerged from the collaboration between pharmaceutical and device manufacturers, clinicians, and medical scientists. Public policy should foster this collaboration and address the following concerns basic to public life and health:

- the well-being of patients;
- the appropriateness and quality of medical treatment;
- the integrity of the physician-patient relationship;
- the dissemination and advancement of medical knowledge;
- trust in the pharmaceutical and medical device industries; and
- the cost of medical treatment to government, employers, and patients.

Public policy on promotion of drugs and devices should advance the following goals:

1. Interactions between healthcare professionals should benefit patients, enhance the practice of medicine, and advance public health.
2. Information disseminated to physicians about drugs and medical devices should be accurate, current, and objective. It should present the risks and benefits of treatment, as identified by a balanced assessment of the extant body of clinical literature and evidence.
3. The valuable role off-label use of medications and devices plays in medical treatment should be recognized, especially for some patient populations, including patients with advanced cancer and children. Public policy should encourage the dissemination of accurate, scientifically sound information about drugs and devices that would advance clinical practice.

4. Physicians have an obligation to their patients to seek out balanced, evidence-based information about drugs and devices. This is inherent in their duty to patients and their role as professionals. This obligation, not any personal financial benefit, should drive physician requests for information, attendance at educational meetings, and contact with sales representatives of drug and device manufacturers.
5. Physician prescribing practices should be motivated exclusively by the interests of patients, except in rare cases when the patient's condition raises public health concerns. Given that this principle is core to the integrity of the physician-patient relationship, the profession has an obligation to preserve this principle in medical education, academic policies, and professional guidelines.
6. Purchasing decisions for drugs and devices by all providers of healthcare services, including, hospitals, nursing homes, home care agencies, and clinics, should also be unaffected by any conflict of interest.
7. Promotion of drugs and devices, as well as continuing medical education ("CME"), should be conducted in a manner that promotes public trust in the medical profession and the pharmaceutical and medical device industries.
8. CME should assure that physicians have up-to-date, scientifically accurate and balanced information.
9. Decisions about the objectives, agenda, content, speakers, and materials for CME should be made solely to advance medical knowledge and practice, independent of any conflict of interest.
10. Public policy, and in particular the lines delineating activities that may trigger enforcement action by government, should be clear and consistent, as reflected in prospective guidance as well as coordination among the various government agencies with jurisdiction.

Appendix C

The Center for Health & Pharmaceutical Law & Policy

Launched in April 2007, the Center for Health & Pharmaceutical Law & Policy at Seton Hall University Law School advances scholarship and recommendations for public policy on cutting edge issues posed by pharmaceutical and health law. The Center also serves as a forum to convene leaders in government, industry, academia, medicine, and consumer organizations to examine the issues posed by clinical and policy developments and explore potential solutions. The Center builds on the nationally recognized scholarship in health law, conferences on key public policy questions, and the compliance training program generated by the Health Law & Policy Program at Seton Hall Law School.

The Center:

- Researches, reviews, and develops policy recommendations on key issues on health and pharmaceutical law to inform and shape policy at the state and national levels;
- Produces scholarship through journal publication and white papers on emerging legal, ethical, and social issues in health and pharmaceutical law;
- Provides a neutral forum to convene leaders in government, industry, academia, and medicine to engage in an informed dialogue, consider pressing policy questions, and explore potential solutions;
- Offers educational programs on health and pharmaceutical issues by leading experts from the public and private sectors to examine important policy and legal issues; and
- Holds compliance education and training programs on state, federal and international regulatory requirements that govern the research, approval, promotion, and sale of drugs and devices.

The Center operates with a full-time Executive Director, Tracy Miller, and Staff. In addition to their expertise in public policy, health and pharmaceutical law, ethical issues in medicine, and compliance, the Center draws upon the intellectual strength of the Seton Hall Law School faculty. Faculty members bring to the Center's work nationally recognized expertise in pharmaceutical and health care law, not-for-profit governance, intellectual property law and bioethics, among other areas.

Appendix D

Center Financial Disclosure Statement and Policies

The Center for Health & Pharmaceutical Law & Policy of Seton Hall Law School is committed to independent academic inquiry focusing on health and pharmaceutical law and policy. As a part of Seton Hall University, the Newark-based Law School is a nonprofit 501(c)(3) organization. The University and Law School engage in fundraising from alumni and other contributors. Remaining committed to examining divergent perspectives on policy issues related to health and pharmaceutical law and policy is critical to the mission of the Center.

Law School faculty members and Center Staff are devoted to academic independence in their research and transparency in their relationships. As such, funding sources are announced on all published materials and on the Law School Web site. Regardless of whether financial support is received in the form of an endowment, as unrestricted funds or for a specific project, Law School and Center donors are not involved in the academic work of Law School professors or Center Staff. Grants and donations are only accepted if they do not limit the faculty's or the Center's ability to carry out research free of outside influence and consistent with the Center's mission and values.

Seton Hall Law School funds the salaries of the Executive Director and faculty affiliated with the Center for Health & Pharmaceutical Law & Policy. Research and administrative support for the Center are jointly funded by Seton Hall Law School and by unrestricted funds provided by pharmaceutical companies, with the Law School currently providing the majority of the funding.

The Center for Health & Pharmaceutical Law & Policy and its faculty assume sole responsibility for the content of its publications and position statements. The Center does not issue publications or statements on behalf of any donor or other entity.

The pharmaceutical companies that have provided funding to the Center or to the Law School are listed below.

- Bristol-Myers Squibb provided a \$5 million endowment in 2005 in support of the Harvey Washington Wiley Chaired Professorship in Corporate Governance & Business Ethics. The Law School is recruiting candidates for this position.
- Johnson & Johnson provided \$100,000 in 2009 as seed funding for two projects: (i) a program on "Strategies for Compliance Professionals: Honing Decision-Making Skills," and (ii) creation and implementation of an international compliance program. In 2008, Ortho-McNeil Janssen Scientific Affairs, a subsidiary of Johnson & Johnson, provided \$49,900 in unrestricted funds. Johnson & Johnson provided \$50,000 in 2007 and \$100,000 in 2006 in unrestricted funds to support the Center. Two of Johnson & Johnson's subsidiaries, Centocor, Inc., and Ortho Biotech, provided \$125,000 in unrestricted funding to the Center in 2007.

Drug & Device Promotion: Charting a Course for Policy Reform

- In 2006, sanofi-aventis provided \$500,000 to Seton Hall Law School in “support and development of the Center for Health & Pharmaceutical Law & Policy and the programs and activities associated with the Center.”
- In 2006, Schering-Plough Corporation made a \$2.5 million commitment, to be paid over five years, to partially endow a tenured track/tenured faculty position dedicated to health care regulation. The Law School will begin to recruit candidates for this position in the 2009-2010 academic year.
- In 2008, Purdue Pharma provided \$25,000 in unrestricted funding for the Center for Health & Pharmaceutical Law & Policy.
- In 2008, Roche provided \$50,000 for a symposium sponsored by the Gibbons Institute of Law, Science & Technology, the Seton Hall Law Review, and the Center on “Preparing for a Pharmaceutical Response to Pandemic Influenza.”

For further information about
programs and publications of
The Center for Health & Pharmaceutical Law & Policy
please see our website at law.shu.edu

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