

## **Developing a Compliant Approach to Industry Support for Research and Education in a Climate of Scrutiny**

By

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### **I. Introduction**

Pharmaceutical companies and medical device manufacturers have increasingly directed their grant-making activities and charitable donations toward support for continuing medical education (CME), graduate medical education, and medical research. This support has benefited both the companies and health care providers by facilitating the training of health care professionals and encouraging innovation. However, financial support from industry has risen to a level which has caused both private industry watchdogs and the federal government to express concern about improper industry influence upon clinical decision making. The federal government has also conducted a number of investigations to determine, among other things, whether charitable donations were used to reward or induce referrals or to “line the pockets” of individual physicians in violation of the federal anti-fraud laws and the laws governing the operation of non-profit corporations.

Concerns regarding undue influence upon medical decision making through charitable donations and other payments have also led several states to enact legislation to limit funding from industry to health care providers or to require companies to report such funding to the government. Similar legislation has been proposed in connection with the health care reform bill now being considered by the United States Congress. Finally, in addition to such legislation,

various groups have developed innovative solutions to the problems associated with grant-making by pharmaceutical companies and medical device manufacturers. These solutions include adoption of voluntary codes published by industry trade associations, separation of a company’s sales and marketing department from its grant-making department, and the use of an independent third party to whom a corporate donor delegates authority for the selection of grant recipients.

Industry support is vital to the continued provision of medical education and research. If this support is to be sustained, it is imperative that industry provide funding in a manner that minimizes the associated legal and regulatory risks. By following the guidance published by the federal government and by industry groups in awarding grants or by electing to outsource grant-making to an independent third party, pharmaceutical and medical device manufacturers may continue to provide financial support for medical research and education without incurring significant legal risk.

### **II. Support for Medical Education and Research by Medical Device Companies and Pharmaceutical Companies**

According to a publication by the Association of American Medical Colleges (“AAMC”), medical schools and teaching hospitals have become increasingly reliant on funding by pharmaceutical companies and medical device companies in recent decades.<sup>2</sup> A survey conducted in 2006–07 and published in November 2009 in the journal *Health Affairs* found that 20% of the researchers who were the subjects

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<sup>2</sup> Association of American Medical Colleges, Industry Funding of Medical Education: Report of an AAMC Task Force (June 2008), available at [http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd\\_id=232](http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd_id=232).

of the survey had received industry support for research.<sup>3</sup> Providers have utilized industry funding to support fellowship and residency enhancement programs, to sponsor CME programs, and to fund medical research projects. Industry support for CME has recently received particularly close scrutiny. During a Senate hearing in July 2009, Senator Herb Kohl (D-Wis.) reported that industry funding of CME has quadrupled in the past decade and now totals more than \$1 billion annually.<sup>4</sup>

### **III. Regulatory Concerns with Grant-Making**

Companies that provide funding for graduate medical education, CME, and research enjoy increased exposure in the health care community, recognition as good corporate citizens, and an assurance that physicians will be able to use their products in a manner that is effective for patients. Health care providers also benefit from such funding in that they are able to receive training regarding innovative techniques and devices and are able to perform cutting edge research. Such specialized training and research undoubtedly benefits patients.

Nonetheless, the level of funding provided by industry to health care providers for CME, graduate medical education, and medical research has alarmed the government and industry groups. These parties are concerned that educational and research funding by pharmaceutical companies or medical device manufacturers to health care providers may bias clinical decision making by consciously or unconsciously swaying providers toward a particular company's products. Further, the government is concerned that companies may be using the educational and research grant funds to reward or induce referrals or to award individual physicians for product loyalty in violation of the federal anti-fraud laws.

In April 2007, the Senate Finance Committee drafted a report after studying pharmaceutical company

grants used to support CME. In the report, the Committee stated, "[i]n 2005, the Committee staff became aware through reports that pharmaceutical companies were routinely using educational grants to help build market share for their newer and more lucrative products."<sup>5</sup> The report went on to explain that "[d]rug companies routinely fund educational grants to support programs that favorably discuss the companies' newer and more lucrative products, thereby encouraging Physicians to prescribe those products and, ultimately, driving sales."<sup>6</sup> This concern, as well as concerns that companies were using graduate medical education grants, research grants, and other forms of remuneration to reward or induce referrals for their products, have led federal and state governments to investigate financial relationships between industry and health care providers and develop legislation to control such relationships.

### **IV. Recent Government and Industry Activity**

The federal government and state governments have recently increased the use of their legislative and investigatory powers to attempt to control financial relationships between health care providers and industry. For example, both the House and Senate health care reform bills contain significant transparency and disclosure requirements for pharmaceutical and medical device manufacturers as well as physicians and health care providers. These provisions are similar to several state laws that have recently been enacted. In addition, scores of pharmaceutical and medical device companies have found themselves the subject of federal investigations related to their financial relationships with health care providers.

A key example of this increased scrutiny is the investigation, launched in 2005 by the United States Attorney's Office for the District of New Jersey, of several orthopaedic medical device companies. In March 2005, the government began an inquiry into the marketing practices of the five largest hip and knee implant companies in the United States.

<sup>3</sup> See Jacob Goldstein, *At Top Schools, More Than Half the Profs Have Industry Ties*, WSJ Blogs: Health Blog—WSJ's blog on health and the business of health, Nov. 4, 2009, available at <http://blogs.wsj.com/health/2009/11/04/at-top-schools-more-than-half-the-profs-have-industry-ties/>.

<sup>4</sup> See MedPage Today, *Senate Committee Hears Testimony Blasting Industry Funding for CME*, available at <http://www.medpagetoday.com/PublicHealthPolicy/Ethics/15301>.

<sup>5</sup> U.S. S. Comm. on Finance, 109th Cong., *United States Senate Committee on Finance, Committee Staff Report to the Chairman and Ranking Member: Use of Educational Grants by Pharmaceutical Manufacturers* (2007).

<sup>6</sup> *Id.*

The original investigations focused on consulting relationships between the companies and health care providers. Subsequently, the investigation expanded into a review of all types of financial relationships between the companies and referral sources. Following a two-year investigation, on September 27, 2007, four of the companies entered into Deferred Prosecution Agreements with the government and one of the companies entered into a Non-Prosecution Agreement with the government. In addition, each of the companies entered into Corporate Integrity Agreements with the Office of the Inspector General of the Department of Health and Human Services (the "OIG"). The companies paid fines to the federal government totaling Three Hundred Eleven Million Dollars (\$311,000,000) as part of a settlement of the government's allegations. Finally, during the investigation, the government discovered a strong correlation between the academic medical centers that received fellowship grants funded by the companies and the academic medical centers that used or prescribed a particular company's products.

### **V. Industry Association Studies and Reports**

Recent industry studies and reports support such findings. In June 2008, the AAMC issued a report entitled "Industry Funding of Medical Education."<sup>7</sup> The report notes that over recent decades, medical schools and teaching hospitals have become increasingly dependent on industry support of their core educational missions. The report notes that industry has "developed and refined many practices designed to influence the behavior of physicians, including physicians working in academic medical centers"<sup>8</sup>, thus recognizing the potential for undue influence by companies that provide educational and research grants to health care providers. However, the report also discusses the importance of realizing the benefits of biomedical research and ensuring continued prevention, diagnosis, and treatment of disease through the partnership between academic medical

centers and health industries. The AAMC recommends in the report that academic medical centers adopt a series of safeguards if they intend to continue accepting industry support, including the creation of a central office to accept grant requests to prevent a particular department from accepting monies from a company from which it will be in a position to purchase products.

In June 2009, the AMA released the revised report of the AMA's Council on Ethical and Judicial Affairs entitled "Financial Relationships with Industry in Continuing Medical Education." The report concludes that relationships with industry can offer enormous benefit to the medical profession and the patients it serves. However, it also recognizes that commercial funding for professional education can pose significant ethical challenges to medicine's ability to focus primarily on the needs of patients and ensure quality education for physicians. The report offers two key ethical recommendations regarding the acceptance of industry funding for CME. The AMA states first that it is preferable that CME providers accept funding only from sources that have no direct financial interest in a physician's clinical recommendations. The AMA also recommends that those involved in CME have no current, recent, or potential direct financial interest in the subject matter and are not currently, or have not recently, been involved in a compensation relationship with a commercial entity that has a financial interest in the educational subject matter.<sup>9</sup> These two restrictions recommended by the AMA represent a conservative approach to structuring CME events that receive industry funding. However, these recommendations have not been codified, and they are not legal restrictions. At this time, therefore, the best approach to supporting CME is to follow the ACCME or other applicable accreditation guidelines and comply with applicable law.

### **VI. Relevant Law and Guidance**

In addition to the ethical considerations set forth in the various industry reports, companies and health care providers must be aware of the potential legal risks associated with their financial relationships. Specifically, the provision of grants by medical

<sup>7</sup> Association of American Medical Colleges, Industry Funding of Medical Education: Report of an AAMC Task Force (June, 2008), available at [http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd\\_id=232](http://services.aamc.org/publications/showfile.cfm?file=version114.pdf&prd_id=232).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

device companies and pharmaceutical companies to health care providers may implicate the Medicare and Medicaid Anti-Kickback Statute<sup>10</sup> and analogous state laws. The Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration, overtly or covertly, in cash or in kind (1) in exchange for the referral of any item or service that may be reimbursed under any federal health program; (2) in exchange for the ordering or purchasing of an item or service reimbursed under any federal health program; or (3) in exchange for arranging for or recommending the referral, order, or purchase of an item or service reimbursed under any federal health program. The OIG has issued regulations setting forth numerous safe harbors to exempt certain types of financial arrangements from the Anti-Kickback Statute. However, none of the safe harbors protects charitable grants provided by industry to potential referral sources.<sup>11</sup>

In addition, an increasing number of states have implemented laws banning charitable donations by industry to health care providers or mandating the disclosure of remuneration paid by pharmaceutical companies or medical device companies to health care providers. For example, Vermont recently passed a comprehensive gift ban law which prohibits charitable donations to health care providers, with exceptions. Specifically, the law allows for payments to health care providers for bona fide research projects and allows certain payments to support CME. However, the law does not exempt direct payments to health care providers to support fellowships and residency enhancement programs from the gift ban.<sup>12</sup> Finally, the law requires pharmaceutical and medical device manufacturers to disclose annually to the Vermont Attorney General any allowable expenditures and gifts to academic institutions and professional, educational, or patient organizations representing or serving health care providers

or consumers.<sup>13</sup> Massachusetts law is more liberal, in that it allows charitable donations to support graduate medical education and all types of CME. Under Massachusetts law, a donation made for the purpose of providing an economic benefit to a covered recipient<sup>14</sup> must be disclosed to the Massachusetts Department of Public Health.<sup>15</sup> While Massachusetts and Vermont are regarded as two of the most stringent states regarding disclosure laws, Minnesota, Maine, Washington D.C., and West Virginia also have various disclosure laws.

Certain of these laws may be preempted upon the passage of a federal health care reform bill. Both the Senate's version of the health care reform bill and the House of Representatives' version of the health care reform bill require companies to disclose certain payments or transfers of value to covered health care providers to the government. Both versions of the health care reform bill would preempt state law reporting requirements to the extent that such state laws require a company to disclose the same information as is required under the proposed bills.

## VII. Potential Solutions

This final section discusses several approaches to grant-making for pharmaceutical companies and medical device companies to allow them to comply with applicable law when making grants to health care providers.

### a. Follow Industry Codes and OIG Compliance Guidance

Several industry trade associations have developed codes of conduct to regulate interactions between pharmaceutical companies and medical device

<sup>10</sup> 42 U.S.C. 1320a-7b(b).

<sup>11</sup> Many states have their own anti-kickback laws, some of which are more onerous than the Anti-Kickback Statute. For example, the Cal. Welf. & Inst. Code § 14107.2 provides that "Any person who solicits or receives any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind" in return for certain referrals or the purchase, lease, or ordering of certain items is subject to penalties under California law. This is in contrast to the federal Anti-Kickback Statute which requires that such prohibited action be "knowing and willful."

<sup>12</sup> 18 Vt. Stat. Ann. tit. 18, § 4631a.

<sup>13</sup> 18 Vt. Stat. Ann. tit. 18, § 4632.

<sup>14</sup> See 105 Mass. Code. Regs. 970.004, "Covered Recipient" is defined as "a person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care practitioner. A person who otherwise meets this definition but is a bona fide employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient. Additionally, consumers who purchase prescription drugs or medical services are not covered recipients."

<sup>15</sup> Mass. Gen. Laws ch. 111N, § 6.

companies and health care providers. These voluntary industry codes provide guidance to industry on acceptable practices in relationships with referral sources and have been widely adopted, but do not guarantee compliance with the Anti-Kickback Statute or analogous state laws. Several of the codes applicable to the medical device industry and pharmaceutical industry include the PhRMA Code on Interactions with Healthcare Professionals (“PhRMA Code”) adopted by the Pharmaceutical Research and Manufacturers of America (“PhRMA”), the AdvaMed Revised Code of Ethics on Interactions with Healthcare Professionals adopted by the Advanced Medical Technology Association (“AdvaMed”), and the Medical Device Manufacturers Association (“MDMA”) Revised Code of Conduct on Interactions with Healthcare Providers (the “MDMA Code”) adopted by MDMA.<sup>16</sup> Companies that are members of PhRMA have voluntarily undertaken to comply with the PhRMA Code. Similarly, companies who are members of AdvaMed and the MDMA have voluntarily undertaken to comply with their respective codes, which contain similar restrictions to the PhRMA Code.

All three voluntary codes have similar provisions regarding charitable donations. The AdvaMed and MDMA Codes recommend that a company should: (a) adopt objective criteria for providing such grants and donations that do not take into account the volume or value of purchases made by, or anticipated from, the recipient; (b) implement appropriate procedures to ensure that such grants and donations are not used as an unlawful inducement; and (c) ensure that all such grants and donations are appropriately documented.<sup>17</sup> The PhRMA Code provides, “No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the

independence of a healthcare professional’s prescribing practices.”<sup>18</sup>

In May 2003, the OIG issued Compliance Program Guidance for Pharmaceutical Manufacturers (“CPG”).<sup>19</sup> The CPG is applicable to both pharmaceutical and medical device manufacturers.<sup>20</sup> The CPG indicates that the OIG considers grants as a specific risk area for manufacturers<sup>21</sup> and advises compliance with the PhRMA Code.<sup>22</sup> While the CPG provides that compliance with the PhRMA Code will substantially reduce the risk of fraud and abuse and helps demonstrate a good faith effort to comply with applicable federal health care program requirements, it cautions that compliance with the PhRMA Code will not protect a manufacturer as a matter of law under the Anti-Kickback Statute.<sup>23</sup>

#### **b. Separate Grant-Making from Sales and Marketing**

The Anti-Kickback Statute is an intent-based statute. Therefore, if sales personnel contribute, even to a limited extent, to a grant-making decision, the government might allege that the grant was intended, at least in part, to reward purchasing decisions in the donor’s favor. In order to avoid such allegations, grant-making decisions should be separated entirely from sales and marketing activities. The CPG specifically recommends that pharmaceutical companies insulate research grant-making from their sales and marketing departments to ensure that grant decisions are not influenced by marketing motivations.<sup>24</sup>

#### **c. Use an Independent Third Party**

In order to sever the tie between the donor and the recipient and thereby eliminate potential undue influence on the clinical decision making of health care

<sup>16</sup> The PhRMA Code on Interactions with Healthcare Professionals was revised effective January 2009. The AdvaMed Revised Code of Ethics on Interactions with Healthcare Professionals was revised effective July 1, 2009. The Medical Device Manufacturers Association Revised Code of Conduct on Interactions with Healthcare Providers was adopted July 1, 2009.

<sup>17</sup> Advanced Medical Technology Association, Revised Code of Ethics on Interactions with Health Care Professionals (2009).

<sup>18</sup> Pharmaceutical Research and Manufacturers of America, The PhRMA Code on Interaction with Healthcare Professionals (2009).

<sup>19</sup> Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,743 (May 5, 2003).

<sup>20</sup> *Id.* at Endnote 5.

<sup>21</sup> *Id.*

<sup>22</sup> Pharmaceutical Research and Manufacturers of America, The PhRMA Code on Interaction with Healthcare Professionals (2009).

<sup>23</sup> *Id.*

<sup>24</sup> Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,743 (May 5, 2003).

providers, pharmaceutical companies and medical device companies may consider supporting research and education through an independent third party. Several organizations have developed such programs, including charitable organizations supporting the fields of orthopaedic research and education and neurosurgical research and education. In fact, such a model may be used in any field of medicine.

In order to minimize the risk that donations will be viewed as an effort to induce or reward referrals or otherwise bias clinical decisions, the third party should be an independent non-profit organization. The independent organization should ensure that its board members are not also members of the board of a medical device company or pharmaceutical company that may provide charitable donations to the organization. To the extent that members of the board of the organization have consulting relationships or other financial relationships with a medical device company or pharmaceutical company, such relationships should be structured to comply with applicable law. Finally, it is preferable that the independent organization not be structured as a trade association or other type of member-based organization, the goal of which is to serve the interests of members, as this will necessarily taint the independence of the organization in its grant-making role.

To administer a grant program effectively, a non-profit organization must have the ability to award grants to qualified CME programs, graduate medical education programs, and medical researchers with no input or influence from the companies that provide the donations. The grant agreement between the donor and third party should provide that the donor shall not have right to recommend, veto, or support any particular applicant that has applied for funding.

The review of applications for grant funding and the awarding of grants to qualified programs should be conducted by individuals who are free from conflicts with donors and recipients, ensuring a review and

grant award process that is conducted with the utmost independence. The organization should have strict conflict of interest policies and mandatory conflict disclosure applicable to all individuals who are awarding grants. If the organization has multiple donors, grants should be awarded to applicants in a blinded manner, with monies matched to applicants without regard to the funding source.

This model of an independent organization receiving grant money, reviewing applications, and donating money to recipients in a “donor blind” manner allows donors to continue to distinguish themselves as good corporate citizens. In addition, it allows recipients to continue to receive money to train new physicians for the betterment of patients. Of critical importance, the model is consistent with voluntary industry codes and many of the current state laws limiting contributions by industry to health care providers.

### **VIII. Conclusion**

Charitable grants from medical device companies and pharmaceutical companies support important research and educational activities that benefit health care providers and, ultimately, improve patient care. However, such monetary support may taint the clinical decision making of health care providers and may run afoul of certain federal and state health care fraud and abuse laws. Thus, in order to continue making grants to health care providers, medical device companies and pharmaceutical companies must ensure that they make such grants in a manner that complies with applicable law. In order to facilitate such compliance, the companies may decide to follow applicable industry codes of conduct and OIG compliance guidance, separate their marketing function from their grant-making function, and/or donate to an independent third party which makes grants to health care providers in a neutral, non-biased manner.