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Requiring Disclosure of Gifts and Payments to Health Care Professionals: A Legal Overview

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Summary

In recent years, questions have been raised over the propriety of certain financial relationships between health care professionals such as physicians, and the pharmaceutical and other medical industries. As part of these relationships, companies may give gifts or make payments to healthcare professionals as part of their marketing efforts, or for other purposes. In an effort to promote transparency and prevent inappropriate relationships, there has been interest in requiring disclosure of certain types of payments. Several states and the District of Columbia have enacted legislation requiring pharmaceutical companies to disclose gifts and payments made to health care professionals. While companies are free to voluntarily disclose this information, there is currently no federal requirement to do so.

This report briefly outlines American Medical Association (AMA) guidelines addressing gifts to physicians from industry, and describes selected state disclosure laws already in effect. The report also discusses proposed federal legislation, in particular, the Physician Payments Sunshine Act of 2009 (S. 301, H.R. 3138). In addition, the report analyzes potential legal and constitutional considerations associated with a federal disclosure requirement, including how a court may evaluate a federal disclosure requirement if it were challenged on First Amendment grounds. If a federal disclosure requirement was enacted and subsequently challenged on these grounds, it appears likely to survive judicial scrutiny. This report supersedes CRS Report RL34094, *Requiring Disclosure of Gifts and Payments to Physicians: State Efforts and a Legal Analysis of Potential Federal Action*, by Anna C. Henning.

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Introduction¹

In recent years, the issue of industry gifts and other payments to health care professionals such as physicians, and the possible conflicts of interest that could arise from these payments, has been controversial.² Examples of gifts and payments mentioned in media reports include meals, honoraria for speaking engagements, and travel expenses for conferences. As Congress addresses health reform, there has been interest in increasing transparency, preventing inappropriate relationships, and requiring disclosure of gifts and other payments made to physicians. While companies are free to voluntarily disclose this information about gifts and other payments, there is no current federal requirement to do so.

Supporters of a federal disclosure provision emphasize concern about the effects of gifts and payments on both the cost of prescription medication and on health care quality.³ They may point to recent data showing that payments from pharmaceutical companies influence some physicians' decisions to prescribe certain medications, occasionally resulting in over-prescribing of the most expensive medications or even causing unnecessary health risks for patients.⁴ They also argue that the ethical guidelines such as the American Medical Association (AMA) code discussed below are insufficient deterrents because they "are not being followed."⁵ Groups opposing a federal disclosure argue that it is unnecessary because existing guidelines within the medical and pharmaceutical-marketing professions discourage unethical behavior.⁶ They also argue that gifts and payments can benefit patients, as physicians receive product samples, attend educational seminars, and receive detailed information about particular medications.⁷

This report outlines the existing AMA guidelines on disclosure and describes certain state disclosure laws and selected federal legislation, in particular, the Physician Payment Sunshine Act

¹ Portions of this report were prepared with the assistance of Benjamin Rodkin, Law Clerk, Congressional Research Service.

² It has been estimated that drug companies spend \$7 billion annually on promotion to medical professionals in the United States. Robert Steinbrook, *Physician-Industry Relations—Will Fewer Gifts Make a Difference?*, 360 *New England Journal of Medicine* 557 (Feb. 5, 2009).

³ A 2009 Institute of Medicine Report examining conflicts of interest in medicine found that the acceptance of gifts and other financial relationships are common between physicians and pharmaceutical, medical device, and biotechnology companies. The report also concludes that disclosure of financial relationships between industry and health practitioners is "a critical but limited first step" in identifying and responding to conflicts of interest. See Bernard Lo and Marilyn J. Field, Editors, *Committee on Conflict of Interest in Medical Research, Education, and Practice*, Institute of Medicine, *Conflict of Interest in Medical Research, Education, and Practice*, available at <http://www.iom.edu/CMS/3740/47464/65721.aspx>.

⁴ See, e.g., Gardiner Harris, *Psychiatrists Top List in Drug Maker Gifts*, *N.Y. Times*, June 27, 2007, at A14 (reporting that "the more psychiatrists have earned from drug makers, the more they have prescribed a new class of powerful medicines known as atypical antipsychotics to children, for whom the drugs are especially risky and mostly unapproved"); Gardiner Harris and Janet Roberts, *A State's Files Put Doctors' Ties to Drug Makers on Close View*, *N.Y. Times*, March 21, 2007, at A1 ("Research shows that doctors who have close relationships with drug makers tend to prescribe more, newer and pricier drugs.").

⁵ *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Senate Special Committee on Aging*, 110th Cong. (June 27, 2007), http://aging.senate.gov/hearing_detail.cfm?id=277848& (statement of Senator Herb Kohl).

⁶ *Id.* (statement of Marjorie E. Powell, Senior Assistant General Counsel, Pharmaceutical Research and Manufacturers of America).

⁷ *Id.*

of 2009 (S. 301, H.R. 3138). This report also analyzes various legal and constitutional considerations that may pertain to a federal disclosure requirement.

Existing AMA Guidelines

The AMA Code of Medical Ethics, which “serves as the primary compendium of medical professional ethical statements in the United States,”⁸ addresses ethical considerations for gifts given to physicians by companies in the pharmaceutical, device, and medical equipment industries.⁹ In the opinion of the AMA’s Council on Ethical and Judicial Affairs on “Gifts to Physicians from Industry,” it is acknowledged that while many gifts to physicians from the drug manufacturing and other industries may serve an important and socially beneficial function, other gifts may be considered inappropriate if they fall outside of certain guidelines. For example, gifts accepted by physicians “should primarily entail a benefit to patients and should not be of substantial value.”¹⁰ Items such as textbooks, modest meals, and other gifts are appropriate if they serve a genuine educational function. Cash payments should not be accepted. In addition, permissible gifts must be “related to the physician’s work,” and gifts such as pens and notepads are appropriate under the code. The guidelines also provide that while subsidies used to underwrite the costs of continuing medical education conferences or professional meetings are acceptable, subsidies from industry should not be accepted directly or indirectly to pay for the costs of travel, lodging, or other personal expenses of physicians attending conferences or meetings, nor should subsidies be accepted to compensate for the physicians’ time. In addition, physicians should not accept gifts with “strings attached.” For example, if gifts are given by a drug company in relation to the physician’s prescribing practices, the gift is considered improper. The AMA guidelines are self-regulating, and thus there may be no legal consequences for failure to adhere to these ethical standards.¹¹

Selected State Disclosure Measures

Legislation requiring pharmaceutical companies and other entities to disclose gifts and payments to health care professionals has been enacted in states such as Maine, Minnesota, Vermont, and Massachusetts, as well as the District of Columbia. Minnesota enacted the first disclosure law more than 10 years ago, and other disclosure laws were enacted relatively recently. The state laws have some similarities; they all require disclosure on an annual basis and exempt certain

⁸ *Id.*

⁹ AMA Code of Medical Ethics (2006), Opinion 8.061 - Gifts to Physicians from Industry, available at <http://www.ama-assn.org/ama/pub/category/2498.html>.

¹⁰ *Id.*

¹¹ It should also be noted that industry groups have also issued ethical guidelines relating to relationships with health care practitioners. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA), which represents pharmaceutical and biotechnology companies, has adopted and recently revised its voluntary Code on Interactions with Healthcare Professionals, available at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>. This code provides, among other things, that distribution of non-educational items (such as pens, mugs, and other “reminder” objects typically adorned with a company or product logo) to healthcare providers and their staff is prohibited. The code acknowledges that such items, even though of minimal value, “may foster misperceptions that company interactions with healthcare professionals are not based on informing them about medical and scientific issues.” In addition, the code states that companies should not provide any entertainment or recreational benefits to healthcare professionals, but that occasional meals are appropriate if they are provided healthcare professionals’ offices in conjunction with informational presentations.

categories of gifts and payments. However, states such as Vermont and Massachusetts prohibit certain gifts from being provided to health care professionals.¹² In addition, states such as Maine, as well as the District of Columbia, require the reporting of expenses relating to marketing products to the general public.

As authority for the disclosure requirements, states have invoked their responsibilities as regulators and as protectors of public welfare. They have also expressed concern with the rising cost of prescription medication and noted their role in reimbursing such medication through their Medicaid programs. For example, Maine's asserted purpose in its disclosure legislation focuses on the state's roles as "guardian of the public interest" and "administrator of prescription drug programs."¹³ In addition to states that have already enacted disclosure legislation, many other states have considered legislation to regulate the relationship between pharmaceutical companies and physicians.¹⁴

Minnesota

Minnesota's Wholesale Drug Distribution Licensing Act generally prohibits a "wholesale drug distributor"¹⁵ from offering or giving any gift of value to a practitioner.¹⁶ However, a gift does not include drug samples intended for free distribution to patients, items with a "total combined retail value, in any calendar year, of not more than \$50," educational materials, and salaries and benefits given to the pharmaceutical companies' own representatives.¹⁷ Minnesota's requirement is a licensing requirement; therefore, a penalty for non-compliance might be denial of a wholesale drug distributor license in the state.

Minnesota's act requires each "wholesale drug distributor" to submit an annual report to the state detailing (1) payments to sponsors of medical conferences; (2) honoraria and payments of expenses for practitioners who serve on faculties of professional or educational meetings; and (3) compensation of practitioners in connection with research projects. The report must identify the nature of value of any payments totaling \$100 or more to a particular practitioner during the year.¹⁸ In contrast to the other states, Minnesota does not require that an annual summary report be provided to its state legislature. However, the state law provides that information submitted pursuant to its disclosure requirement is "public data."¹⁹

¹² See generally, David Armstrong, *Two States Restrict Firms' Gifts to Doctors*, Wall Street Journal, July 1, 2009, at A3.

¹³ Me. Rev. Stat. Ann. tit. 22, §2698-A(1) (2004 & Supp. 2007).

¹⁴ See National Conference of State Legislatures, 2008 Prescription Drug State Legislation, available at <http://www.ncsl.org/IssuesResearch/Health/2008PrescriptionDrugStateLegislationNCSL/tabid/14418/Default.aspx>.

¹⁵ Under the Minnesota statute, a "wholesale drug distributor" is "anyone engaged in wholesale drug distribution" and includes manufacturers, drug warehouses, and others. Minn. Stat. §151.44(b). The definition does not include a "medical device manufacturer that distributes drugs as an incidental part of its device business." Minn. Stat. §151.461.

¹⁶ According to the Minnesota Board of Pharmacy, a gift would include any money, real or personal property, a service, a loan, a forbearance or forgiveness of indebtedness, or a promise of future employment, that is given and received without the giver receiving consideration of equal or greater value in return. See Minnesota Statutes § 151.461 – Gifts to Practitioners Prohibited, Frequently Asked Questions, available at <http://www.phcybrd.state.mn.us/forms/giftsfaq.pdf>.

¹⁷ Minn. Stat. §151.461. A gift does also not include the three categories of payments that are subject to the reporting requirements discussed infra. See the text accompanying footnote 18.

¹⁸ Minn. Stat. §151.47(f).

¹⁹ Minn. Stat. §151.47(f).

Vermont

In 2008, Vermont amended its disclosure legislation to ban certain gifts from manufacturers of prescribed products and wholesale distributors to health care providers.²⁰ A gift is defined by the state statute to include something of value provided to a health care provider for free, including any payment, food entertainment, or anything else of value. The statute makes an exception from the ban for certain specified allowable expenditures.²¹

Under the amended disclosure requirements, manufacturers are required to annually disclose to the Vermont Attorney General the value, nature, purpose, and recipient information about allowable expenditures given to health care providers, academic institutions, or certain organizations serving health care providers.²² The attorney general must report annually on the disclosures to Vermont's General Assembly and the governor and must make the reported data publicly available on a website. The state attorney general may also sue violators for civil penalties not to exceed \$10,000, plus attorneys' fees. While Vermont's earlier disclosure law required the attorney general to keep confidential all trade secret information, this provision was repealed by the 2008 legislation.²³

District of Columbia

The District of Columbia's disclosure law applies to every "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District."²⁴ The District requires each pharmaceutical manufacturer or labeler to annually report expenses associated with items such as educational or informational programs or materials; food, entertainment, and gifts; trips and travel; and product samples.²⁵ Furthermore, each report must provide the "value, nature, purpose, and recipient" of each expense.²⁶ However, like Minnesota and Vermont, the District exempts certain categories of items from the reporting requirements, including expenses worth less than \$25, "reasonable reimbursement" for clinical trials, product samples if they will be distributed to patients for free, and scholarships for attending "significant" conferences if the attendee is chosen by the association sponsoring the conference.²⁷ Violators of the disclosure law may be subject to a fine of \$1,000 plus attorneys' fees.²⁸ The District of Columbia requires the D.C. Department of Health to compile an annual report presenting the disclosed information in "aggregate form."²⁹ In addition to the provisions relating to physicians, it mandates disclosure of expenses associated

²⁰ Vt. S.48 § 2 (2008).

²¹ Allowable expenditures include sponsor of an educational, medical, scientific, or policy-making conference or seminar; honoraria; expenses related to bona fide clinical trials; and certain royalties and licensing fees. 18 V.S.A. § 4631a(a).

²² 18 V.S.A. § 4632(a)(1).

²³ See discussion of trade secrets, *infra*.

²⁴ D.C. Code §48-833.01.

²⁵ D.C. Code §48-833.03(a)(2).

²⁶ D.C. Code §48-833.03(a).

²⁷ D.C. Code §48-833.03(b).

²⁸ D.C. Code §48-833.06.

²⁹ D.C. Code §48-833.04.

with advertising to the public at large, including through television advertisements, “as they pertain to District residents.”³⁰

Maine

Under Maine’s disclosure law, pharmaceutical manufacturers and labelers must file an annual report that discloses, among other things, all expenses associated with (1) educational or informational programs or materials; (2) food, entertainment, and gifts; (3) trips and travel; and (4) product samples.³¹ Maine’s law also exempts expenses worth less than \$25, reasonable reimbursement for clinical trials, product samples if they will be distributed to patients for free, and scholarships for attending “significant” conferences if the attendee is chosen by the association sponsoring the conference.³² As in the District of Columbia, violators may be subject to a fine of \$1,000 plus attorneys’ fees.³³ The Maine disclosure statute also resembles the District’s law in that it contains a broad reporting requirement that extends to expenses associated with marketing to the general public.³⁴ Maine requires that a report summarizing the aggregate data and a report providing analysis be provided to the Maine attorney general’s office and the state legislature each year by November 30 and January 1, respectively.³⁵

Massachusetts

The Massachusetts Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Healthcare, enacted in 2008, requires pharmaceutical or medical device manufacturers that employ a person to sell or market a drug, medicine, or medical device in the commonwealth to adopt and comply with a “marketing code of conduct,” as established by regulation.³⁶ Under this code of conduct, the provision or payment for things such as meals (subject to exception); entertainment or recreational items of value (e.g., tickets to sporting events); and financial support for the costs of lodging, travel, and other expenses of non-faculty health care practitioners attending a continuing medical education (CME) event, conference, or professional meeting may be prohibited.³⁷ However, the provision, distribution, or dissemination of peer-reviewed academic, scientific, or clinical information, and the provision of prescription drugs to a health care practitioner solely for the use of the practitioner’s patients, among other things, are permitted by the code of conduct.

In addition, every pharmaceutical or medical device manufacturing company must annually disclose to the department of public health the value, nature, purpose and particular recipient of any fee, payment, or other economic benefit of at least \$50, which the company provides to persons authorized to prescribe, dispense, or purchase prescription drugs or medical devices in

³⁰ D.C. Code §48-833.03(a)(1).

³¹ 22 M.R.S. §2698-A(4)(B).

³² 22 M.R.S. §2698-A(5).

³³ 22 M.R.S. §2698-A(8).

³⁴ 22 M.R.S. §2698-A(4)(A).

³⁵ 22 M.R.S. §2698-A(3).

³⁶ See Mass. SB. 2863 (July 31, 2008), available at <http://www.mass.gov/legis/bills/senate/185/st02pdf/st02863.pdf>. See also 105 C.M.R. § 970.000 et seq.

³⁷ ALM GL ch. 111N, § 2.

the commonwealth.³⁸ The department of public health is responsible for making all disclosed data publicly available and easily searchable on its website. In addition, the department must report to the attorney general items of value provided in violation of the market code of conduct.

Federal Proposals Requiring Federal Disclosure of Gifts and Other Payments

Legislation has been introduced in the 111th Congress that would require disclosure of gifts and other transfers of value from manufacturers of a covered drug, device, biological, or medical supply³⁹ to health care provider recipients. The Physician Payments Sunshine Acts of 2009, as introduced in the House (H.R. 3138) and the Senate (S. 301), contain similar but not identical provisions. In addition, other versions of these bills have been included in health reform proposals considered in various House and Senate committees.⁴⁰

Under S. 301 and H.R. 3138, a manufacturer of drugs and other medical products that provides a payment or other transfer of value to a covered recipient (e.g., a physician, a physician medical practice, or a physician group practice) or a recipient's designee would be required to annually submit specified information to the Secretary⁴¹ about the recipients and the payments or other transfers of value, including a description of the form of transfer of value such as cash or stock, and the nature of the transfer of value (e.g., consulting fee, gift, food, entertainment, charitable contribution). Exceptions would be made for certain transfers of value of a small dollar amount, product samples for patient use that are not intended to be sold, and educational materials that directly benefit patients or are intended for patient use. In addition, manufacturers and other entities would be responsible for submitting to the Secretary information regarding certain ownership or investment interests held by a physician or a physician's immediate family member, not including interest in a publicly traded security or mutual fund.

Manufacturers and other entities that fail to submit the required information in a timely manner in accordance with regulations would be subject to an annual civil monetary penalty of at least \$1,000 but not more than \$10,000 for each payment or transfer of value not reported, up to a maximum of \$150,000. Any entity that knowingly fails to submit information would be subject to a civil monetary penalty of at least \$10,000 but not more than \$100,000 for each payment or transfer of value, and may not exceed \$1,000,000 in total for each annual submission of information. In addition, under both bills, the Secretary must make the submitted information available through a website that is searchable, in a format that is clear and understandable, and that meets various other requirements. The bills would also preempt state laws and regulations that have analogous requirements to the federal bill, but would not interfere with state laws that mandate the reporting or disclosure of information not required under the federal bill.

³⁸ ALM GL ch. 111N, § 6.

³⁹ A "covered" drug, device, biological, or medical supply is one for which payment is available under Medicare, Medicaid, or the State Children's Health Insurance Program. See, e.g., Section 2 of H.R. 3138.

⁴⁰ See, e.g., H.R. 3200, 111th Cong. (2009).

⁴¹ Presumably, "Secretary" as referred to in the bills means the Secretary of Health and Human Services.

Legal Analysis of a Federal Disclosure Requirement

In enacting a federal disclosure requirement, Congress may consider the following statutory and constitutional considerations. These considerations include the prohibition of certain payments under the anti-kickback statute, and the question of whether payments to physicians could be considered trade secrets, which require certain legal protections. Another issue is whether requiring a pharmaceutical company or other entity to make a disclosure would violate the freedom of speech guaranteed under the First Amendment.

Payment Disclosure and the Anti-Kickback Statute

While current federal law does not require disclosure of industry payments to health care professionals, it may prohibit certain payments from being given or received. Under the federal anti-kickback statute, it is a felony to knowingly and willfully offer, pay, solicit, or receive anything of value (i.e., “remuneration”), directly or indirectly, overtly or covertly, in cash or in kind, in return for a referral or to induce generation of business reimbursable under a federal health care program such as Medicare or Medicaid.⁴² The statute prohibits both the offer or payment of remuneration for patient referrals, as well as the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or ordering of any item or service that is reimbursable by a federal health care program. Persons found guilty of violating the anti-kickback statute may be subject to a fine of up to \$25,000, imprisonment for up to five years, and exclusion from participation in federal health care programs for up to one year. However, a number of statutory and regulatory “safe harbors” to the anti-kickback statute protect various business arrangements from prosecution. Safe harbors include certain types of investment interests, personal services and management contracts, referral services, space rental or equipment rental arrangements, warranties, discounts, and employment arrangements. As mentioned above, the anti-kickback statute only applies to referrals for services reimbursable under a federal health care program. Thus, if a company were to offer a kickback or other type of remuneration that did not involve reimbursement from the federal government, the anti-kickback statute would not be implicated.

In 2003, the Department of Health and Human Services’ Office of the Inspector General (OIG) issued Compliance Program Guidance for Pharmaceutical Manufacturers (CPG),⁴³ designed to assist pharmaceutical manufacturers in developing and implementing internal controls and procedures that promote compliance with applicable statutes, regulations, and requirements of federal health care programs.⁴⁴ In addition, the CPG alerted companies and health care practitioners to activities that could lead to prosecution under the anti-kickback statute as well as other federal laws.⁴⁵ Among other things, the CPG explains that pharmaceutical companies and their employees and agents often engage in a number of arrangements that offer benefits to physicians or others in a position to make or influence prohibited referrals under the anti-kickback statute. Examples of remunerative arrangements between pharmaceutical manufacturers

⁴² 42 U.S.C. § 1320a-7b(b).

⁴³ 68 Fed. Reg. 23731.

⁴⁴ *Id.*

⁴⁵ See Rebecca Dresser, *Pharmaceutical Company Gifts: From Voluntary Standards to Legal Demands*, The Hastings Center Report, Vol. 36 Iss. 3, May/June 2006.

and parties in a position to influence referrals that were cited by OIG included entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations, as well as gifts, gratuities, and other business courtesies. OIG indicated these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company. While the CPG guidelines for companies to follow in developing or maintaining compliance programs are not legally binding, the document puts manufacturers on notice as to certain arrangements that OIG may see as suspect.⁴⁶

Physician Payments Designated as Trade Secrets?

A trade secret can be defined as secret, commercially valuable information.⁴⁷ It is a company's proprietary interest in such information that is protected from disclosure, theft, or unauthorized use under both state⁴⁸ and federal law.⁴⁹ The U.S. Supreme Court has explained that for subject matter to be protected as a trade secret, the material must meet minimal standards of novelty and inventiveness to avoid extending trade secret protection to matters of general or common knowledge in the industry in which it is used.⁵⁰ Whether information qualifies as a "trade secret" under federal or state law, however, is a question of fact that is to be determined by a jury.⁵¹ Confidential commercial information can lose its trade secret status through unprotected disclosure. For example, a trade secret may lose its legal protection by accidental or intentional disclosure by a company's employee.⁵² Once a trade secret is exposed to the public, its protected character is lost forever and cannot later be retrieved.⁵³

Some pharmaceutical companies have attempted to shield certain physician gift and payment information from public disclosure by designating it as confidential trade secrets, in order to prevent their competitors from gaining information about drugs under development, their marketing practices, and their consulting and research arrangements.⁵⁴ Until recently, Vermont law allowed pharmaceutical companies to protect such data as trade secrets, thus preventing the state's attorney general from publicly disclosing the information.⁵⁵ This exemption in Vermont's

⁴⁶ *Id.*

⁴⁷ UNIFORM TRADE SECRETS ACT § 1(4), available at <http://www.law.upenn.edu/bll/ulc/fnact99/1980s/utsa85.pdf>. See also the definition of "trade secret," RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 39 ("A trade secret is any information that can be used in the operation of a business or other enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.").

⁴⁸ The Uniform Trade Secrets Act (UTSA) was published in 1979 by the National Conference of Commissioners on Uniform State Laws and codifies the common law concerning trade secrets. The UTSA has been adopted by 46 states and the District of Columbia.

⁴⁹ Economic Espionage Act, codified at 18 U.S.C. §§ 1831 et seq.

⁵⁰ *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 476 (1974) ("[S]ome novelty will be required if merely because that which does not possess novelty is usually known; secrecy, in the context of trade secrets, thus implies at least minimal novelty.").

⁵¹ 4 ROGER M. MILGRIM, MILGRIM ON TRADE SECRETS § 15.01.

⁵² *Religious Tech. Ctr. v. Netcom On-Line Communication Servs.*, 923 F.Supp. 1231, 1256 (N.D. Cal. 1995).

⁵³ *In re Remington Arms Co.*, 952 F.2d 1029, 1033 (8th Cir. 1991).

⁵⁴ Jacob Goldstein, *Drug Industry Trade Secrets: Speaking Fees, Education Subsidies*, WALL STREET JOURNAL HEALTH BLOG, Nov. 4, 2008, available at <http://blogs.wsj.com/health/2008/11/04/drug-industry-trade-secrets-speaking-fees-education-subsidies>.

⁵⁵ VT. STAT. ANN. tit. 18 § 4632(a)(3) (Supp. 2005) ("The office of the Attorney General shall keep confidential all trade secret information... In the event that the Attorney General receives a request for any information designated as a (continued...)

disclosure law, however, was criticized for being too widely used by the companies and thus severely restricting public access to detailed physician payment information.⁵⁶ In May 2009, the Vermont legislature passed a law,⁵⁷ effective July 1, 2009, that eliminates the trade secret exemption.⁵⁸

Neither the Senate or House version of the Physician Payment Sunshine Act 2009 permits a company to characterize physician payment data as trade secrets to avoid public disclosure. However, legislation introduced in the 110th Congress, the Drug and Medical Device Company Gift Disclosure Act (H.R. 3023), contained a provision that would have directed the FDA commissioner to “keep confidential any information disclosed to or otherwise obtained by the Commissioner ... that relates to a trade secret ...”⁵⁹

Constitutional Considerations of a Federal Disclosure Requirement

If Congress were to enact a federal disclosure requirement, it would likely survive judicial scrutiny. A preliminary question when considering the constitutionality of any federal statute is whether any power enumerated in the Constitution authorizes Congress to take such action. A disclosure requirement would likely pass that preliminary threshold. Congress has broad authority to regulate activities under its Commerce Clause⁶⁰ power, including the authority to regulate activities as long as they “substantially affect” interstate commerce.⁶¹

The second question in determining the constitutionality of a federal statute is whether the statute violates any constitutional provision. The First Amendment is one plausible basis for a constitutional challenge to a disclosure provision. Specifically, pharmaceutical and other companies might argue that mandatory disclosure of gifts and payments to physicians violates their First Amendment freedoms of speech and association.⁶²

Companies might identify two different manifestations of “speech” implicated by a federal disclosure provision. First, they might argue that the disclosure of information regarding gifts and payments is unconstitutionally compelled speech. Second, they might argue that the gifts and

(...continued)

trade secret, the Attorney General shall promptly notify the company of such request. Within 30 days after such notification, the company shall respond to the requester and the Attorney General by either consenting to the release of the requested information or by certifying in writing the reasons for its claim that the information is a trade secret.”)

⁵⁶ *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Senate Special Committee on Aging*, 110th Cong. (June 27, 2007) (statement of Peter Lurie, Deputy Director, Public Citizen’s Health Research Group).

⁵⁷ Available at <http://www.leg.state.vt.us/docs/2010/bills/Passed/S-048.pdf>.

⁵⁸ Natasha Singer, *Doctor: Gifts To Be Public In Vermont*, N.Y. TIMES, May 20, 2009, at B1 (noting that pharmaceutical companies had declared 83% of their payments to physicians to be trade secrets under Vermont’s pharmaceutical marketing disclosure law before the statute was amended).

⁵⁹ H.R. 3023, §2.

⁶⁰ The Commerce Clause of the U.S. Constitution empowers Congress “[t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.” U.S. Const. art. II, §8, cl. 3.

⁶¹ See, e.g., *United States v. Lopez*, 514 U.S. 549, 558-59. For a discussion of Commerce Clause jurisprudence, see CRS Report RL32844, *The Power to Regulate Commerce: Limits on Congressional Power*, by Kenneth R. Thomas and Todd B. Tatelman.

⁶² For a general discussion of First Amendment jurisprudence, see *Constitution of the United States of America, Analysis and Interpretation*, Congressional Research Service, p. 1076 et seq.

payments are, themselves, speech that the law unconstitutionally restricts. As a threshold matter, it is not clear that gifts and payments made to physicians are “speech.” The Supreme Court has treated monetary transactions as “speech” in the past, most notably in the area of campaign finance.⁶³ However, the payments at issue here are arguably distinct from campaign contributions because they are not “political expression” or “discussion of governmental affairs” as were the transactions in the campaign finance arena.⁶⁴ If the gifts and payments are not speech, then they fall outside of First Amendment protection.

A federal provision would likely survive a compelled speech challenge. The First Amendment generally prohibits the government from compelling speech.⁶⁵ However, two case law trends suggest that a court would uphold a federal provision compelling disclosure of gifts and payments made to physicians or other health care professionals. First, a court might analyze the disclosure by pharmaceutical companies in the context of compelled commercial speech.⁶⁶ Commercial speech is “speech that *proposes* a commercial transaction.”⁶⁷ Although the disclosures would not themselves propose commercial transactions, they report transactions made for the purpose of increasing business. In the compelled commercial speech category, under applicable case law, the government’s interest need only be “reasonably related” to the disclosure requirements to survive judicial scrutiny.⁶⁸ Mandatory disclosure of gifts and payments to health care professionals appears reasonably related to potential governmental interests, such as transparency and patient protection. Second, even if the compelled speech at issue is viewed as non-commercial, a court would likely uphold the provision. Although the Court has invalidated nearly all laws it has reviewed in the non-commercial compelled speech category,⁶⁹ most of the Court’s non-commercial compelled speech cases addressed political speech, which garners a greater level of constitutional protection than other types of speech.⁷⁰ In contrast, the speech implicated here, if not commercial, is medical rather than political. Therefore, a federal disclosure provision would likely survive a compelled speech challenge under the First Amendment.

A mandatory disclosure provision would likewise probably survive a restricted speech challenge. Such a challenge would allege that the provision unconstitutionally restricts pharmaceutical companies’ gifts and payments to health care professionals. If gifts and payments are “speech,” then such transactions are likely also commercial speech, because a likely message conveyed by

⁶³ See *McConnell v. FEC*, 540 U.S. 93, 120 (2003) (citing *Buckley v. Valeo*, 424 U.S. 1, 14-23 (1976)).

⁶⁴ *Buckley*, 424 U.S. at 14.

⁶⁵ See *Riley v. National Federation of the Blind of North Carolina, Inc.*, 487 U.S. 781, 797 (1987).

⁶⁶ Most commercial compelled speech cases have addressed mandatory disclosures in advertising. See, e.g., *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) (upheld a state law mandating disclosure of specific payment information in lawyers’ advertisements for contingency fee services). The disclosure at issue here would seem to differ from advertising disclosures because it involves direct disclosure to the government rather than to consumers. However, a court might analyze the disclosure involved here in the commercial context despite this difference because it, like advertising disclosures, would compel information regarding business transactions, with one potential purpose being to disseminate the disclosed information to a public audience.

⁶⁷ *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989) (emphasis in original).

⁶⁸ *Zauderer*, 471 U.S. at 651.

⁶⁹ One exception is *Meese v. Keene*, in which the Court upheld a law mandating disclosure of associations with foreign governments by distributors of political propaganda, finding that such disclosures did not “prohibit, edit, or restrain the distribution of advocacy materials.” 481 U.S. 465, 480 (1987).

⁷⁰ See, e.g., *Wooley v. Maynard*, 430 U.S. 705 (1977) (invalidating a New Hampshire law making it a misdemeanor to not display the slogan “Live Free or Die” on one’s license plate); *West Virginia State Bd of Ed. v. Barnette*, 319 U.S. 624 (1943) (invalidating a state law requiring school children to recite the Pledge of Allegiance).

the gifts and payments is, for example, that doctors should prescribe the promoted drugs. Commercial speech garners less constitutional protection than political or other types of speech.⁷¹ The applicable test for determining the constitutionality of commercial speech is the four-part *Central Hudson* test.⁷² Under the *Central Hudson* framework, the preliminary questions are (1) whether the speech is protected by the First Amendment (i.e., is not unlawful or misleading), and (2) whether the government's asserted interest in regulation is "substantial."⁷³ If the regulation satisfies both preliminary questions, the third and fourth prongs then apply: (3) whether the regulation directly advances the government's asserted interest, and (4) if so, whether the regulation is no more extensive than is necessary to serve that interest.⁷⁴

Assuming that the gifts and payments made to health care professionals are not unlawful or misleading, a court would find that the first *Central Hudson* prong is satisfied. A court would also likely find that a federal disclosure requirement satisfies the second prong. In *Rubin v. Coors Brewing Co.*, the Supreme Court found "substantial" the government's interest in deterring efforts by beer companies to advertise the most potent beer.⁷⁵ Here, the government's potential interests—for example, transparency, reduced drug costs, and patient protection—would seem likely to be at least as "substantial" as the interest asserted in *Rubin*.

The third and fourth *Central Hudson* prongs could be closer issues, but would still likely result in a finding of constitutionality. When applying the third prong, the Supreme Court has indicated that courts should consider the effect of the regulation in its general application, rather than as applied to the particular group challenging the law.⁷⁶ In a case invalidating a law on the basis of the third prong, the Supreme Court stated that the government must "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."⁷⁷ Although it seems likely that the government could identify a real harm caused by gifts and payments to physicians, some question exists as to whether mandatory disclosure of such gifts and payments would "materially alleviate" that harm. The Court noted in the above case that the government offered "no studies" giving evidence of the asserted harm and failed to present even "anecdotal" evidence that the law would address the harm identified.⁷⁸ Thus, the question might be whether the government can present sufficient studies and anecdotal evidence to show that the disclosure would alleviate any identified harm created by gifts and payments to health care professionals.

Regarding the fourth *Central Hudson* prong, the Supreme Court has clarified that "no more extensive than necessary" should not be interpreted strictly to require the government to use the "least restrictive means" of all available alternatives to accomplish its purpose; rather, the fourth

⁷¹ *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418 (1993). For more information on treatment of commercial speech, see CRS Report 95-815, *Freedom of Speech and Press: Exceptions to the First Amendment*, by Henry Cohen.

⁷² *Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557, 566 (1980). Note, however, that in the most recent Supreme Court commercial speech case, the Court noted that some justices "have expressed doubts" about the *Central Hudson* test's applicability in certain circumstances. *Thompson v. Western States Medical Center*, 535 U.S. 357, 367 (2002).

⁷³ *Central Hudson*, 447 U.S. at 566.

⁷⁴ *Id.*

⁷⁵ 514 U.S. 476 (1995).

⁷⁶ *Edge Broadcasting*, 509 U.S. at 501-502.

⁷⁷ *Edenfield v. Fane*, 507 U.S. 761, 771 (1993).

⁷⁸ *Id.*

prong merely requires a reasonable “fit” between the legislature’s ends and the means chosen to accomplish those ends.⁷⁹ Thus, a court need only find a reasonable fit between a disclosure rule and the government’s asserted interest in order to uphold the government action. For laws affecting political speech, in contrast, the more onerous “least restrictive means” test applies. Nonetheless, in a disclosure case involving political speech in the context of campaign finance, the Court stated that disclosure is generally the “least restrictive means” of addressing corruption in government.⁸⁰ Since the fourth *Central Hudson* prong is less onerous than the “least restrictive means” test, it is likely that disclosure would survive First Amendment scrutiny in the commercial speech arena.

A federal disclosure requirement would likely also survive a freedom of association challenge. The Supreme Court has stated that “compelled disclosure, in itself, can seriously infringe on privacy of association and belief.”⁸¹ To be constitutional, a disclosure law must have a “relevant correlation” or “substantial relation” to the asserted government interest.⁸² It is unclear whether the right of association would extend to an “association” between a pharmaceutical company and a physician, since the Supreme Court cases to date have generally invalidated laws on freedom of association grounds only when political or membership associations were at issue.⁸³

Even if a court found that the pharmaceutical company-physician relationship constituted an “association” such that it triggered right of association claims under the First Amendment, it is unlikely that a court would find that a disclosure law violated privacy of association rights because the Court has upheld disclosure laws against freedom of association challenges in other contexts. For example, in *Buckley v. Valeo*, the Supreme Court upheld federal laws mandating disclosure of certain campaign finance activities, holding that the government’s interest in regulation outweighed the private association concerns raised by the requirements.⁸⁴ It seems likely that government interests asserted here would similarly outweigh the pharmaceutical companies’ freedom of association concerns.

Finally, it is telling in assessing a federal disclosure requirement’s constitutionality that the state disclosure laws now in effect have faced no significant legal challenges. Although a U.S. district court recently invalidated on First Amendment grounds a New Hampshire law regulating prescription information, that law was distinct from the possible federal requirement discussed here because it prohibited disclosure of prescription information.⁸⁵

Conclusion

In sum, there have been recent efforts to crack down on perceived conflicts of interest between health care professionals and the pharmaceutical and other medical industries, in particular through disclosure of certain gifts or other payments. Several states have already enacted

⁷⁹ *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989).

⁸⁰ *Buckley v. Valeo*, 424 U.S. 1, 68 (1976).

⁸¹ *Id.* at 64.

⁸² *Id.*

⁸³ *See, e.g., Rumsfeld v. Forum for Academic and Inst. Rights, Inc.*, 547 U.S. 47 (2006) (finding no violation of plaintiffs’ associational rights where the “association” mandated by the law did not involve membership).

⁸⁴ *Buckley*, 424 U.S. at 61.

⁸⁵ *IMS Health Inc. v. Ayotte*, No. 06-cv-280-PB, 2007 WL 1244077 (D.N.H., April 30, 2007).

legislation requiring companies to disclose gifts and payments to these professionals. Federal legislation has also been introduced, which would require disclosure of gifts and other transfers of value from the pharmaceutical and other entities to health care provider recipients.

A federal disclosure requirement would likely survive a legal challenge. Pharmaceutical companies might challenge the provision on First Amendment grounds. However, it appears likely that it would survive judicial scrutiny under the various applicable tests of constitutionality.

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