Requiring Disclosure of Gifts and Payments to Physicians: State Efforts and a Legal Analysis of Potential Federal Action

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Summary

A recent Senate hearing, state efforts, and media attention have brought the issue of pharmaceutical companies' gifts and payments to physicians into focus. Pharmaceutical companies sometimes give gifts or make payments to doctors as part of their marketing efforts. Senator Herb Kohl has expressed interest in introducing a federal bill that would mandate disclosure of such gifts and payments. This report briefly outlines the arguments for and against a federal disclosure measure. Next, it describes the state disclosure laws already in effect. Finally, it analyzes potential legal hurdles to a federal disclosure requirement.

Proponents of disclosure express concern that gifts and payments from pharmaceutical companies increase prescription drug costs and create incentives for physicians that obscure patients' best interests; they argue that disclosure would alleviate those problems by providing transparency. Opponents of disclosure emphasize the educational benefits that marketing provides; in addition, they argue that disclosure is unnecessary because existing professional codes, such as American Medical Association guidelines, discourage pharmaceutical representatives and physicians from engaging in unethical behavior.

Several states and the District of Columbia have enacted legislation requiring pharmaceutical companies to disclose gifts and payments made to physicians. The state laws require disclosure to the states of such gifts and payments on an annual basis. Certain categories of gifts and payments are exempted from reporting requirements under most of the state laws. For example, nearly all of the laws exempt product samples intended for free distribution to patients and gifts worth less than a certain amount. The state laws also provide for dissemination to the public or state legislatures of information disclosed pursuant to the laws.

If a federal disclosure requirement was enacted and subsequently challenged, it appears likely to survive judicial scrutiny on First Amendment grounds. If pharmaceutical companies challenged a federal disclosure measure, they would likely argue that it violates their First Amendment rights of freedom of speech or association. However, governmental interests, for example in transparency or patient protection, might be sufficient to survive the applicable tests under compelled speech, restricted speech, and private association precedents.

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Introduction[1]

State measures, media attention, and a recent Senate committee hearing have brought attention to the issue of pharmaceutical companies' gifts and payments to physicians.[2] Examples of gifts and payments mentioned in media reports and at the Senate hearing include meals, honoraria for speaking engagements, and travel expenses for conferences.

This report first discusses the arguments for and against a federal requirement that pharmaceutical companies disclose gifts and payments. Next, it briefly outlines the existing American Medical Association (AMA) guidelines to which the requirement's potential opponents refer. It then describes state disclosure laws already in effect. Finally, it analyzes potential legal hurdles to a federal disclosure requirement.

A Federal Disclosure Requirement: Supporting and Opposing Views

The Senate Special Committee on Aging recently held a hearing to explore ties between pharmaceutical companies and physicians.[3] Committee Chairman Herb Kohl explained that the hearing was prompted by evidence that "financial ties between doctors and drug companies are ... deepening."[4]

At the hearing, Senator Kohl announced his plan to "propose a national registry to require disclosure of payments and gifts."[5] It would appear that any proposal would likely require pharmaceutical companies to disclose gifts and payments made to physicians.

Groups opposing a federal disclosure provision argue that disclosure is unnecessary because existing guidelines within the medical and pharmaceutical-marketing professions discourage unethical behavior.[6] They also argue that gifts and payments often benefit patients, as physicians receive product samples, attend educational seminars, and receive detailed information about particular medications.[7]

At the Senate hearing, a representative from the pharmaceutical company trade association Pharmaceutical Research and Manufacturers of America (PhRMA) refuted the suggestion that

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[1] This report was prepared under the general supervision of (name redacted) and (name redacted), Legislative Attorneys, American Law Division.

[2] Medical entities and professionals other than physicians, e.g., hospitals and pharmacists, receive gifts and payments from pharmaceutical companies. However, in the context of its discussion of a federal disclosure requirement, this report refers only to payments made to physicians because the scope of discussion at the recent Senate hearing was similarly narrow.

[3] *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&.

[4] *Id.* (statement of Senator Kohl).

[5] *Id.*

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

[7] *Id.*

unethical ties between pharmaceutical representatives and physicians are prevalent.[8] She stated that pharmaceutical representatives associated with PhRMA adhere to a strict ethical code, one that "starts with the fundamental principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience."[9] A representative from the American Medical Association (AMA) similarly highlighted the ethical codes already in place within the medical profession, discussed below, which he believes discourage improper conduct.[10] He also stated that pharmaceutical company representatives provide physicians with the "necessary tools to make the right prescribing decisions" and stressed that physicians depend on close relationships with pharmaceutical industry representatives in order to receive "valid scientific information."[11]

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. They 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.[12] They also argue that the ethical guidelines such as the AMA rules discussed below are insufficient deterrents because they "are not being followed."[13]

At the Senate hearing, Senator McCaskill argued that the same concerns that prompted federal limits on gifts from lobbyists to politicians apply to pharmaceutical company-physician relationships.[14] Also at the hearing, a medical school professor testified that "the medical profession has become excessively dependent on the largesse of [the pharmaceutical] industry."[15] He further asserted that such dependence has a "negative influence on the quality and cost of patient care."[16] Similarly, a researcher testified that although most physicians deny any such influence, research shows that contact between physicians and pharmaceutical representatives often influences prescribing habits.[17] Regarding disclosure as the specific mechanism for addressing these issues, Senator Kohl stated that disclosure would provide needed

[8] *Id.*

[9] *Id.*

[10] *Id.* (statement of Robert Sade, Chair, AMA's Council on Ethical and Judicial Affairs).

[11] *Id.*

[12] *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.").

[13] *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).

[14] *Id.* (statement of Senator McCaskill).

[15] *Id.* (statement of Jerome P. Kassirer, Professor, Tufts University School of Medicine).

[16] *Id.*

[17] *Id.* (statement of Peter Lurie, Deputy Director, Public Citizen's Health Research Group) (citing N. Lurie, E.C. Rich, and D.E. Simpson, et. al., *Pharmaceutical Representatives in Medical Centers: Interaction with Faculty and Housestaff*, 5 J. of Int'l. Med., 240-43 (1990)).

"transparency,"[18] perhaps by creating a public record of financial ties between pharmaceutical companies and prescribing physicians.

Existing AMA Guidelines

Two sets of AMA guidelines provide ethical guidance to practicing physicians. First, AMA's Principles of Medical Ethics provide "standards of conduct which define the essentials of honorable behavior" for physicians.[19] Second, the AMA Code of Medical Ethics "serves as the primary compendium of medical professional ethical statements in the United States."[20]

The Principles, last revised in 2001 by AMA's House of Delegates,[21] are nine "ethical statements."[22] Perhaps the two most relevant of these statements are the statement requiring physicians to uphold "standards of professionalism" and the statement that physicians shall "regard responsibility to the patient as paramount."[23]

AMA's Council on Ethical and Judicial Affairs regularly updates the AMA Code.[24] In the most relevant section, the Code states that "physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products."[25] The same section requires that physicians make decisions regarding prescriptions based "solely on medical considerations and patient need and reasonable expectations of the effectiveness of the drug."[26]

State Disclosure Measures

Legislation requiring pharmaceutical companies to disclose gifts and payments to physicians is already in effect in Maine, Minnesota, Vermont, West Virginia, and the District of Columbia. Minnesota enacted the first disclosure law more than ten years ago. The other disclosure laws were enacted relatively recently. The state laws are fairly similar; they all require disclosure on an annual basis and exempt certain categories of gifts and payments. Also, although the methods differ, all states provide for dissemination of the disclosed information to the public or to state legislatures.[27]

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[18] *Id.* (opening statement of Senator Herb Kohl).

[19] *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 Robert Sade, Chair, AMA's Council on Ethical and Judicial Affairs).

[20] *Id.*

[21] American Medical Association, History of the Principles of Medical Ethics (2005), http://www.ama-assn.org/ama/pub/category/4256.html.

[22] American Medical Association, Principles of Medical Ethics (2001), http://www.ama-assn.org/ama/upload/mm/369/2001_principles.pdf.

[23] *Id.*

[24] AMA Code of Medical Ethics (2006), http://www.ama-assn.org/ama/pub/category/2498.html.

[25] American Medical Association, Code of Medical Ethics, § E-8.06 - Prescribing Drugs and Devices (2007).

[26] *Id.*

[27] For an analysis of the difference between the states' laws, see *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Senate Special Committee on Aging*, 110th Cong. (June (continued...)

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."[28]

In addition to the states highlighted below, California and New Hampshire have enacted measures to address pharmaceutical representative-physician relationships. However, neither state requires disclosure. California's law requires pharmaceutical companies to adopt a Comprehensive Compliance Program in accordance with the U.S. Department of Health and Human Services Office of Inspector General April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers."[29] New Hampshire enacted a law prohibiting pharmacists from releasing information regarding prescriptions to data companies, whose major clients are pharmaceutical companies. However, the New Hampshire law was invalidated on First Amendment grounds by a U.S. District Court.[30]

In addition to states that have already enacted disclosure legislation, many other states are considering or have recently considered legislation to regulate the relationship between pharmaceutical companies and physicians.[31] As the number of state measures increases, at least one expert has suggested that some state efforts risk federal preemption claims by regulating areas usually left to the federal government.[32]

Minnesota

In 1993, Minnesota became the first state to require pharmaceutical companies to disclose gifts and payments to physicians. Minnesota requires each "wholesale drug distributor"[33] 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

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27, 2007), http://aging.senate.gov/hearing_detail.cfm?id=277848& (statement of Peter Lurie, Deputy Director, Public Citizen's Health Research Group).

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

[29] Cal. Health & Safety Code §§119400-119402.

[30] IMS Health Inc. v. Ayotte, No. 06-cv-280-PB, 2007 WL 1244077, 1 (D.N.H., April 30, 2007). An appeal is currently pending.

[31] National Conference of State Legislatures, 2007 Prescription Drug State Legislation, at 2, http://www.ncsl.org/programs/health/drugbill07.htm. *See also* Jennifer Medina, *Drug Lobbying Kills Gift Disclosure Bill*, N.Y. Times, June 29 2006, at B5.

[32] *See* Christopher D. Zalesky, *Pharmaceutical Marketing Practices: Balancing Public Health and Law Enforcement Interests: Moving Beyond Regulation-Through-Litigation*, 39 J. Health L. 235 (2006) (citing Pac. Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n, 461 U.S. 190, 212-13 (1983) ("When the federal government completely occupies a given field or an identifiable portion of it... the test of preemption is whether 'the matter on which the State asserts the right to act is in any way regulated by the Federal act'" (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 236 (1947))).

[33] 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 (2005 & Supp. 2007).

educational meetings, (3) compensation of practitioners in connection with research projects, and (4) "the nature and value of any payments totaling $100 or more, to a particular practitioner during the year."[34]

The Minnesota law exempts several categories of gifts and payments from its reporting requirements. Specifically, it exempts 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.[35] Minnesota's requirement is a licensing requirement; therefore, a penalty for non-compliance might be not receiving a wholesale drug distributor license in the state.

In contrast to the other states, Minnesota does not require that an annual summary report be provided to its state legislature. However, Minnesota is unique in providing that information submitted pursuant to its disclosure requirement is "public data."[36]

Recent reports have summarized data collected pursuant to Minnesota's requirement. For example, one recent article reported that between 1997 and 2005, "drug makers paid more than 5,500 doctors, nurses and other health care workers in the state at least $57 million."[37] Reports also suggest that Minnesota's data collection process has encountered problems, including difficulties with ensuring pharmaceutical companies' compliance with the reporting provisions.[38]

Vermont

Vermont enacted disclosure legislation in 2003. Its disclosure law applies to "pharmaceutical manufacturing companies."[39] Vermont requires such companies to disclose, on an annual basis, the "value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company ... to any physician ... or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs."[40]

Like Minnesota, Vermont exempts several categories of gifts and payments from its reporting requirements. Exemptions under the Vermont law include gifts and payments with a value of less than $25; free product samples intended for distribution to patients; prescription drug rebates or discounts; scholarships for medical students, residents, or fellows to attend "significant" educational, scientific, or policy-making conferences; unrestricted grants for continuing medical education; and "reasonable compensation" for clinical trials.[41] The state Attorney General may sue violators for civil penalties not to exceed $10,000, plus attorneys' fees.[42]

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[34] Minn. Stat. §151.47(f).

[35] *Id. See also* §151.461(1).

[36] Minn. Stat. §151.47(f).

[37] 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.

[38] *Id.*

[39] Vt. Stat. Ann. tit. 33 §2005(a)(1) (Supp. 2005).

[40] *Id.*

[41] §2005(a)(3).

[42] §2005(b).

Under the statute, the Vermont Attorney General's office must "report annually on the disclosures made under this section to the general assembly and the governor."[43] Vermont's law provides that "the office of the attorney general shall keep confidential all trade secret information."[44] At least one researcher has noted that this trade secret restriction limits access to the data by researchers and the public.[45]

Recent articles have highlighted early results from Vermont's disclosure requirement. For example, one article reported that of physicians with the highest earnings from pharmaceutical companies in 2006, psychiatrists received a larger average amount of gifts and payments during the year than other types of Vermont physicians.[46]

District of Columbia

The District of Columbia enacted a disclosure law in 2004. The law applies to every "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District."[47]

The District of Columbia requires each pharmaceutical manufacturer or labeler to report, on an annual basis, expenses associated with: (1) educational or informational programs or materials, (2) food, entertainment, and gifts, (3) trips and travel, and (4) product samples.[48] Furthermore, each report must provide the "value, nature, purpose, and recipient" of each expense.[49] However, like Minnesota and Vermont, the District exempts certain categories. Namely, it 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.[50] Violators can be sued for a fine of $1,000 plus attorneys' fees.[51] The District of Columbia requires the D.C. Department of Health to compile an annual report presenting the disclosed information in "aggregate form."[52]

The District of Columbia's disclosure requirement is broader than Minnesota and Vermont's requirements. In addition to the provisions relating to physicians, it mandates disclosure of expenses associated with advertising to the public at large, including through television advertisements, "as they pertain to District residents."[53]

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[43] §2005(a)(1).

[44] §2005(a)(3). *See also* Vt. Stat. Ann. tit. 1 §317(c)(9) (2003 and 2006 Supp.) (defining "trade secrets").

[45] *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 Peter Lurie, Deputy Director, Public Citizen's Health Research Group).

[46] Gardiner Harris, *Psychiatrists Top List in Drug Maker Gifts*, N.Y. Times, June 27, 2007, at A14.

[47] D.C. Code §48-833.01 (Supp. 2006).

[48] §48-833.03(a)(2).

[49] §48-833.03(a).

[50] §48-833.03(b).

[51] §48-833.06.

[52] §48-833.04.

[53] §48-833.03(a)(1).

Maine

The first reports pursuant to Maine's disclosure law were due from pharmaceutical companies on July 1, 2007.[54] Maine's law applies to every "manufacturer or labeler of prescription drugs dispensed in the State that employs, directs, or utilizes marketing representatives in [the] State."[55]

Maine's law is virtually identical to the District of Columbia requirement. Namely, pharmaceutical manufacturers and labelers must disclose all expenses associated with: (1) educational or informational programs or materials, (2) food, entertainment, and gifts, (3) trips and travel, and (4) product samples.[56] 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.[57] As in the District of Columbia, violators can be sued for a fine of $1,000 plus attorneys' fees.[58] The Maine disclosure statute also resembles the District of Columbia's law in that it contains a broad reporting requirement that extends to expenses associated with marketing to the general public.[59]

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 30th and January 1st, respectively.[60] The first reports pursuant to this provision will be due in November 2007 and January 2008.[61]

West Virginia

Several years ago, West Virginia created a Pharmaceutical Cost Management Council, to which pharmaceutical manufacturers and labelers must report advertising costs based on "aggregate national data."[62] West Virginia's law is generally broader and weaker than the other states' laws. It does not specify any exemptions, nor does it require disclosure of individual payments or data regarding receiving physicians. In addition, in contrast to other states' laws, which authorize civil or other penalties for non-complying companies,[63] West Virginia's law does not contain any mechanism for enforcement.

[54] Me. Rev. Stat. Ann. tit. 22 §2698-A(3) (2004 & Supp. 2006).

[55] §2698-A.

[56] §2698-A(4)(B).

[57] §2698-A(5).

[58] §2698-A(8).

[59] §2698-A(4)(A).

[60] §2698-A(3).

[61] *Id.*

[62] W. Va. Code §5A-3C-13 (2006).

[63] *See, e.g.*, D.C. Code §48-833.06 (Supp. 2006) (providing that the District of Columbia disclosure law can be enforced in a civil action).

Legal Analysis 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 clause[64] power, including the authority to regulate wholly intrastate activities as long as they "substantially affect" interstate commerce.[65]

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 companies might argue that mandatory disclosure of gifts and payments to physicians violates their First Amendment freedoms of speech and association.

Pharmaceutical 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 payments are, themselves, speech that the law unconstitutionally restricts.

A federal provision would likely survive a compelled speech challenge. The First Amendment generally prohibits the government from compelling speech.[66] However, two case law trends suggest that a court would uphold a federal provision compelling disclosure of gifts and payments made to physicians. First, a court might analyze the disclosure by pharmaceutical companies in the context of compelled commercial speech.[67] Commercial speech is "speech that *proposes* a commercial transaction."[68] 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.[69] Mandatory disclosure of gifts and payments to physicians 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,[70] most of the Court's non-commercial compelled speech

[64] U.S. Const. art. II, §8, cl. 3.

[65] *See* Gonzalez v. Raich, 545 U.S. 1, 17 (2005).

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

[67] 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.

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

[69] Zauderer, 471 U.S. at 651.

[70] 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 (continued...)

cases addressed political speech, which garners a greater level of constitutional protection than other types of speech.[71] 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 physicians. 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.[72] 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.[73] If the gifts and payments are not speech, then they fall outside of First Amendment protection.

If they are "speech," then such transactions are likely commercial speech, or "speech that *proposes* a commercial transaction,"[74] because the likely message conveyed by the gifts and payments is that doctors should prescribe the promoted drugs. Commercial speech garners less constitutional protection than political or other types of speech.[75] The applicable test for determining the constitutionality of commercial speech is the four-part *Central Hudson* test.[76] 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."[77] If the regulation satisfies both preliminary questions, the third and forth 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.[78]

Assuming that the gifts and payments made to physicians 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.[79] Here, the government's potential interests—for

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distribution of advocacy materials." 481 U.S. 465, 480 (1987).

[71] *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).

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

[73] Buckley, 424 U.S. at 14.

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

[75] 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 (name redacted).

[76] 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).

[77] Central Hudson, 447 U.S. at 566.

[78] *Id.*

[79] 514 U.S. 476 (1995).

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.[80] 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."[81] 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.[82] 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 physicians.

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 prong merely requires a reasonable "fit" between the legislature's ends and the means chosen to accomplish those ends.[83] 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.[84] 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."[85] To be constitutional, a disclosure law must have a "relevant correlation" or "substantial relation" to the asserted government interest.[86] 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.[87]

[80] Edge Broadcasting, 509 U.S. at 501-502.

[81] Edenfield v. Fane, 507 U.S. 761, 771 (1993).

[82] *Id.*

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

[84] Buckley v. Valeo, 424 U.S. 1, 68 (1976).

[85] *Id.* at 64.

[86] *Id.*

[87] *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).

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.[88] 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.[89]

Conclusion

In sum, state efforts, media attention, and a recent Senate committee hearing have highlighted the issue of the relationship between physicians and pharmaceutical companies. Senator Herb Kohl and others have indicated support for the introduction of federal legislation that would require pharmaceutical companies to disclose gifts and payments made to physicians, arguing that such a measure is necessary in order to prevent a negative result for health care cost and quality. Opponents argue that such a measure is unnecessary because existing guidelines such as AMA's Principles of Medical Ethics and the AMA Code of Medical Ethics discourage unethical behavior.

Several states have already enacted legislation requiring pharmaceutical companies to disclose gifts and payments to physicians. The state laws require pharmaceutical companies to submit annual reports detailing gifts and payments. Most state laws exempt certain categories of gifts from the reporting requirements, including product samples intended for free distribution to patients and gifts worth less than a specified amount.

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.

[88] Buckley, 424 U.S. at 61.

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

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