Testimony of

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on State Laws Requiring Disclosure of Pharmaceutical Company Payments to Physicians

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Thank you for the opportunity to address the Committee on Aging on the issue of state laws requiring the disclosure of pharmaceutical company payments to physicians. These laws are on the ascendancy; the Minnesota statute dates from 1993, but since 2001 three states and the District of Columbia have enacted similar laws. Eleven states proposed disclosure laws in 2006.[1] To our knowledge, none became law.

Payment disclosure laws offer an important mechanism to monitor pharmaceutical industry marketing, a practice valued at $25.3 billion in 2003.[2] Pharmaceutical marketing to physicians includes free samples, promotional detailing, and continuing medical education activities, and has been shown to alter physician behavior. Physicians typically claim that they are unaffected by such interactions (although they are willing to acknowledge that their colleagues might be influenced).[3] But pharmaceutical companies would not be catering to the culinary and travel preferences of physicians if they thought their efforts were for nought. The evidence strongly suggests that the companies are right. For instance, contact with pharmaceutical company representatives is associated with changes in the prescribing practices of residents and physicians[4] and more rapid adoption of new drugs by prescribers.[5] Sponsorship of continuing medical education programs by a pharmaceutical company[6] and all-expenses-paid travel to

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[1] National Conference of State Legislatures. 2006 Prescription drug state legislation, November 6, 2006. Available at: http://www.ncsl.org/programs/health/drugbill06.htm.
[2] Pharmaceutical Marketing & Promotion. Pharmaceutical Research and Manufacturers of America, Fall 2004. Available at: http://www.phrma.org/files/Tough_Questions.pdf.
[3] Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. *American Journal of Medicine* 2001;110:551-7.
[4] Lurie N, Rich EC, Simpson DE, et al.Pharmaceutical representatives in academic medical centers: interaction with faculty and housestaff. *Journal of General Internal Medicine* 1990;5:240-3.
[5] Peay MY, Peay ER. The role of commercial sources in the adoption of a new drug. *Social Science and Medicine* 1988;26:1183-89.
[6] Bowman MA, Pearle DL. Changes in drug prescribing patterns related to commercial company funding of continuing medical education. *Journal of Continuing Education in the Health Professions* 1988;8:13-20.

conferences[7] are associated with increases in the prescribing rate of the sponsors' drugs. Finally, interactions with a pharmaceutical company representative are associated with an increased likelihood of requesting that the representative's company's drug be added to the hospital formulary.[8] Thus, as companies with a clear conflict of interest in promoting a specific product continue to influence physicians, the result can be prescribing based on marketing, rather than science. Moreover, if this effort results in the prescribing of unnecessary drugs or newer, more expensive drugs with little marginal benefit, it will needlessly add to health-care spending. These newer medications are more likely to have undiscovered dangers.[9]

Equally important, these interactions are eroding the public's trust in the medical profession. These conflicts bear a strong resemblance to the recently reported scandals in the student loan business; the difference is that in medicine they are formally condoned by the profession.

In 2002, the American College of Physicians, the nation's largest association of internists, issued a policy statement regarding pharmaceutical company payments to physicians.[10] It offered three criteria for determining the appropriateness of a payment, the first of which is: "What would my patients think about this arrangement? What would the public think? How would I feel if the relationship was disclosed through the media?" Payment disclosure laws in effect put these theoretical questions to the test.

Already, despite the limitations described below, these physician disclosure laws have yielded beneficial results. In Minnesota, the publication of our article in the *Journal of the American Medical Association* (*JAMA*; see Appendix 1)[11] in March 2007 and our provision of the underlying data to local newspapers have led to significant media interest and an undertaking by the Executive Director of the Minnesota Board of Pharmacy (to whom we also provided the data electronically) to post the data his office has collected on the internet. (We do not see such data posted at the present time.) After reading the press reports, which named specific doctors, several clinics contacted us, unaware that their physicians had been accepting such large payments from pharmaceutical companies. An article in the *New York Times*, using similar data, identified physicians being used by pharmaceutical companies to run clinical trials despite long histories of discipline for substandard medical care by the Minnesota Board of Medical Practice.[12] Another in the same series documented large payments to medical "thought leaders"[13] – those with a role in developing guidelines that might affect the prescribing of the company's drugs.

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[7] Orlowski JP, Wateska L. The effects of pharmaceutical firm enticements on physician prescribing patterns. *Chest* 1992;102:270-3.
[8] Chren MM, Landefeld CS. Physicians' behavior and their interactions with drug companies. *Journal of the American Medical Association* 1994;271:684-9.
[9] Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. Timing of new black box warnings and withdrawals for prescription medications. *Journal of the American Medical Association* 2002;287:2215-20.
[10] Coyle SL. Physician-industry relations. Part 1: individual physicians. *Annals of Internal Medicine* 2002;136:396-402.
[11] Ross JS, Lackner JE, Lurie P, Gross CP, Wolfe S, Krumholz HM. Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. *Journal of the American Medical Association* 2007;297:1216-23.
[12] Harris G, Roberts J. After sanctions, doctors get drug company pay. *New York Times*, June 3, 2007, p. A1.
[13] Harris G, Roberts J. Doctors' ties to drug makers are put on close view. *New York Times*, March 21, 2007, p. A1.

Our comments today will address two principal areas: (1) a legal analysis of the strengths and weaknesses of all enacted state payment laws; and (2) a summary of our research examining the effectiveness of physician payment disclosure laws in Vermont and Minnesota.

A. Review of Existing State Physician Payment Disclosure Laws

In preparation for this testimony, we conducted a detailed analysis of the five state laws on doctor payment disclosure currently in place. A summary of the most important elements appears in the table below; the details are attached as Appendix 2 to this testimony.

		DC	ME	MN	VT	WV
Company Disclosures to Agency	**Itemized report of each payment**	Yes	Yes	No	Yes	No
	No payment categories exempt from disclosure	No	No	No	No	No
	Submission via internet	No	Yes	No	Yes	No
	Enforcement mechanism	Yes	Yes	Yes	Yes	No
Public Access to Disclosed Info	**Disclosures explicitly made public record**	No	No	Yes	No	No
Agency Reports to Legislature	**Required annual report of aggregate data**	Yes	Yes	No	Yes	Yes
	Easily accessible on the internet	Reporting not yet begun	Reporting not yet begun	N/A	Yes	Reporting not yet begun

Although these statutes are undoubtedly intended to increase the transparency of the physician-pharmaceutical company relationship, it is clear that all fall well short of their aspirations.

None of the statutes requires device or biologic manufacturers to report payments, although there is no basis for such a distinction. Two of the five states (Minnesota and West Virginia) do not require separate reporting of each payment, permitting various forms of aggregation either across payment type or by physician. In West Virginia, no physician names need be reported; each company is required only to report (in dollar ranges) the total value of payments in that year and

the number of physicians who received payments of that value. This is by far the weakest of the disclosure statutes so far enacted.

Although food, travel, and honoraria/consulting fees must typically be reported, exclusions from reporting are common. The threshold for any reporting ranges from $25 (District of Columbia, Maine, and Vermont) to $100 (Minnesota and West Virginia). Four states (all except Minnesota) exempt certain payments related to medical conferences and research studies from the reporting requirement, and all exempt free samples for patients. Such exclusions are not justified as long as each payment is clearly identified as being for a particular purpose. Researchers and patients can decide for themselves if they consider highly remunerative research relationships with manufacturers, for example, to be problematic.

Only two states (Maine and Vermont) permit electronic filing of reports and one state (West Virginia) has no enforcement mechanism available under the statute. Only the Minnesota statute makes all the disclosed information part of the public record, without exception, although the remaining four states require annual summary reports to the legislature. A model statute would require both.

In sum, all existing statutes are deficient in at least one significant respect. Only one (Minnesota) requires physician-specific data to be made public and all are subject to major exemptions from disclosure.

B. Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota

In our *JAMA* paper, we examined the effectiveness of the physician payment laws in Vermont and Minnesota, enacted in 2001 and 1993, respectively. We had three research objectives: (1) to determine the accessibility of the data available in Vermont and Minnesota; (2) to assess the quality of the public data; and (3) to describe the prevalence and magnitude of disclosed payments to physicians of $100 or more. The $100 cutoff was selected to facilitate comparisons between two states with different disclosure thresholds and because the guidelines of both the American Medical Association (AMA)[14] and the Pharmaceutical Research and Manufacturers of America (PhRMA)[15] suggest that gifts be under $100 in value and should benefit patients.

Accessibility of Payment Data

In both states, payment disclosures can be obtained, although obtaining the records required much effort. In Vermont, payment data were released by the Attorney General's office as Internet-accessible annual summary reports to the legislature. These reports do not provide physician-specific payments; rather, they provide aggregated data, broken down by company, recipient type, form of payment, and purpose.

[14] American Medical Association. Opinion E-8.061, gifts to physicians from industry. Available at: http://www.ama-assn.org/ama/pub/category/4001.html.
[15] Pharmaceutical Research and Manufacturers of America. PhRMA code on interactions with health-care professionals, revised January 2004. Available at: http://www.phrma.org/files/PhRMA%20Code.pdf.

In order to obtain physician-specific data, we entered into extensive negotiations with the Attorney General's office, while simultaneously submitting a Freedom of Information Act request. After nearly 12 months, the state did release physician-specific payment data, but withheld all data designated by the companies as trade secret. In the most recent year, 30 of 68 companies (44%) designated at least some of their payments as trade secret.[16] We subsequently initiated a lawsuit against the Attorney General of Vermont to obtain those payments designated as trade secret; numerous pharmaceutical companies were eventually joined in the litigation. Most of these companies have settled, providing some form of redacted data but setting no precedent for release to others. It is unrealistic to expect individual patients to engage in this sort of litigation to obtain their doctor's payment information.

In Minnesota, payment data have never been made available as a public report. Indeed, the disclosure forms submitted have literally sat in boxes for up to a decade, gathering dust and never being analyzed. In order to obtain the records, we were required to travel to the Minnesota Board of Pharmacy office in Minneapolis and to photocopy each form at a fee of $0.25 per page. Again, this hardly qualifies as adequate public disclosure.

Quality of Payment Data

Vermont provided us with data that had been entered into an Excel spreadsheet. However, despite a statute requiring separate reports for each payment, some entries described payments made to multiple physicians/healthcare professionals, whereas others described payments made to individuals. Moreover, many companies designated their records trade secret, and the AG refused to disclose such records. In our study, during the first year, 13 companies designated their payments as trade secret and nine additional companies did so in the second year, despite having released information during the first year.

In Minnesota, some disclosures were typed while others were hand-written (with varying degrees of legibility). As in Vermont, some entries described payments made to multiple physicians/healthcare professionals, whereas others described all payments made to individuals. Data quality was poor, with many entries providing no information on payment purpose or else generically quoting the Minnesota payment disclosure law (e.g., "reasonable honoraria or payment of the reasonable expenses of a practitioner …"). Overall, 60 companies disclosed payments, but only 15 companies did so in each of the three years we studied.

Disclosed Payments

According to the summary reports released by the Vermont Attorney General's office, 58 pharmaceutical companies disclosed to the state $5.58 million in payments between July 1, 2002, and June 30, 2004. Of these, 12,227 payments totaling $2.18 million were publicly disclosed. Thus, in dollar terms, 61% of all payments reported to the state were withheld on trade secret grounds. Of the publicly disclosed payments, 2,416 (20%) were to physicians for $100 or more, totaling $1.01 million; the median payment was $177 (range: $100-$20,000). Sixty-eight percent of these payments were in the form of food, clearly providing no patient benefit and therefore

[16] Sorrell WH. Marketing disclosures. Vermont Attorney General, June 15, 2006. Available at: http://www.atg.state.vt.us/upload/1150802902_2006_Pharmaceutical_Marketing_Disclosures_Report.pdf.

potentially violating the AMA and PhRMA guidelines. By number, 28% of these payments were for educational activities, 26% were for detailing, and 16% were for unspecified purposes. In dollar terms, 35% of payments were for speaking activities, 20% were for unspecified purposes, and 17% were for educational activities.

In Minnesota, between January 1, 2002, and December 31, 2004, pharmaceutical companies disclosed 7290 payments. Of these, 6,238 (86%) were to physicians for $100 or more, totaling $22.39 million; the median such payment was $1,000 (range: $100-$922,239). By number, 46% of such payments were for unspecified purposes, 27% were for educational activities, and 13% were for speaker activities. In dollar terms, 42% of these payments were for unspecified purposes, 20% were for educational activities, and 16% were for research activities. Because the name of the recipient was fairly consistently provided and because, unlike in Vermont, all disclosed payments must be publicly available, we were able to identify particular physicians who had received multiple payments. We identified 2388 distinct physician recipients, approximately 14% of the 17,445 physicians holding an active license and who had a home address within the state. For these individual physicians, the median number of payments of $100 or more was 1 (range: 1-88) and the median total amount received was $1000 (range: $100-$1,178,203).

In summary, we identified large numbers of payments to physicians but, due to deficiencies in the laws and their enforcement, these estimates are likely substantial underestimates of the actual value of payments from pharmaceutical companies to physicians and the number of physicians involved.

C. Conclusions

The extraordinary measures taken by pharmaceutical companies to influence prescribers bear little resemblance to actual public health needs. Payment disclosure laws are a first step toward addressing the problem, but they are not the only method or even necessarily the most effective one. No-one requires physicians to accept the gifts offered. Certain prominent medical schools have recently decided to exclude pharmaceutical company representatives from their clinics and hundreds of physicians have personally undertaken to refuse all gifts (Goodman R, personal communication, June 24, 2007).[17] The guidelines of the major medical associations must be tightened but, due to their voluntary nature, these guidelines are likely to be more effective at staving off legislation than reducing marketing excesses. Enforcement of existing restrictions on marketing must be more strenuously enforced at the levels of the Justice Department, Federal Trade Commission, Food and Drug Administration and state governments.

We would like to conclude with some recommendations based on our research. An overarching point is that the disclosure laws should include device and biologic companies. But the most important recommendation is this: Due to the overall poor quality of the statutes and their implementation to date, and because the physician payment issue is a national one, not a state one, the most rational approach to this issue is a national reporting requirement. Our more specific recommendations would apply equally to state and national disclosure statutes and are detailed below.

[17] www.nofreelunch.org

D. Recommendations

Company Reports to Agency

1) Itemize each payment to each prescriber.
2) Allow for electronic submission.
3) Permit no payment categories to be exempt from disclosure.
4) Standardize entries to minimize missing information, such as by using drop-down menus and by linking payments to a unique National Provider Identifier. This would facilitate aggregation of data on specific providers within and between companies.
5) Create enforcement mechanisms that will maximize compliance. Substantial fines and/or penalties for non-reporting are needed. Penalties could include:
    a. suspending interactions between physicians and pharmaceutical companies for periods of time; or
    b. excluding products for which there is a satisfactory therapeutic alternative from Medicaid or state and county hospital formularies.

Public Access to Disclosed Information

1) Make all individual disclosures available free and online.
2) Develop web tools to permit patients to search and aggregate payments by physician and payment type.

Agency Reports to Legislature

1) Require the implementing agency to annually report aggregate data.
2) Make annual reports easily accessible online.