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Fact Sheet

The Prescription Project promotes evidence-based prescribing and works to eliminate conflicts of interest in medicine due to pharmaceutical marketing.

It is promoting policy change by working with

- *State and Federal Policymakers*
- *Academic Medical Centers*
- *Professional Medical Societies*
- *Private Payers*

Created with The Pew Charitable Trusts, the Project is led by Community Catalyst in partnership with the Institute on Medicine as a Profession.

REGULATING INDUSTRY PAYMENTS TO PHYSICIANS: IDENTIFYING & MINIMIZING CONFLICTS OF INTEREST

Physicians write more than 2 billion prescriptions a year¹, an average of 7 for every American. Intensifying competition to capture these sales has doubled pharmaceutical industry marketing expenditures directed at physicians from \$3.5 billion in 1996 to \$7.2 billion in 2005 (excluding pharmaceutical samples).² An undisclosed portion of that budget is spent on direct payments to physicians in the form of gifts, food, continuing medical education, travel, and consultancy fees. It is estimated that industry spending for lunches may alone total as much as \$1 billion a year.³ A recent survey published in the *New England Journal of Medicine* indicates that 94% of physicians have received food, drug samples or other reimbursements and payments from the industry.⁴

The Problem: Payments Influence Prescribing

Though many physicians claim industry payments do not affect their behavior, social science research indicates that individuals can not accurately assess their own bias. Studies indicate that gifts, even small gifts, create reciprocal behaviors.⁵ For physicians receiving industry payments, changes in prescribing may take the shape of subtle shifts in judgment outside the awareness of the recipient. According to a review published in *The Journal of the American Medical Association*, negative effects associated with industry/physician marketing and financial relationships include:

- Reduced generic prescribing
- Increased overall prescription rates
- Quick uptake of the newest, most expensive drugs including those of only marginal benefit over existing options with established safety records
- Formulary request for drugs with few if any advantages over existing drugs

Patients and physicians alike admit that without gifts and meals, their interaction with the industry would decline.⁶

Self-Regulation is Insufficient

The medical profession and the pharmaceutical industry have taken steps to regulate physician-industry interactions in the face of increased public scrutiny.

- The AMA issued guidelines on "Gifts to Physicians from Industry" in 1992.⁷ These guidelines limit gifts to an unspecified "modest" value and indicate they should be for the benefit of patients.
- The Pharmaceutical Researchers and Manufacturers of America trade association (PhRMA) updated its voluntary Code in 2008 and recommends that its members end the giving of non-educational gifts and practice-related items, such as pens, and tickets to sporting events and to put some limits on the provision of meals.⁸
- The federal government also issued "Compliance Program Guidance for Pharmaceutical Manufacturers" in 2003.⁹ The guidance includes a statement that specifies that companies offering gifts intended to promote prescription drug sales may be subject to anti-kickback prosecution.

These guidelines are insufficient responses to undue industry influence for several reasons.¹⁰ They continue to allow many types of gifts and financial relationships around marketing activities. The guidelines also lack measures to monitor and ensure compliance. PhRMA has never provided any evidence, despite having been requested to do so in public hearings, that its "Code on Interactions with Healthcare Professionals" is enforced. Indeed, several state laws that do monitor industry payments to physicians indicate widespread failure to comply with self-regulation.

Evolving State Policy Solutions

Several states and the District of Columbia have enacted so-called "sunshine laws" setting limits on industry payments to physicians and/or requiring disclosure of the payments. Existing laws are important first steps toward developing policies not only to detect existing conflicts of interests, but ultimately to prevent them and end inappropriate industry influence on prescribing.

- **MINNESOTA:** Minnesota was the first state to pass such legislation, in 1993. It requires reporting of payments over \$100 to physicians and bans gifts in value of \$50 or more. This and the Massachusetts law are the only statutes that include restrictions and make all disclosed data, including all physician-specific data, part of the public record. Unlike other disclosure laws however, it does not require annual summary reports to the state legislature, meaning that the state is under no obligation to analyze the data it collects. Indeed, industry payment report forms had not been formally analyzed before an independent analysis was conducted in 2006.¹¹ In order to be licensed, all wholesale drug distributors, including pharmaceutical manufacturers operating in the state, must comply with the law.
- **VERMONT:** Vermont's law requires disclosure of payments of \$25 and over. Due to a trade secret exemption, much of the data reported to the state is not made part of the public record. Annual summary reports by the Attorney General include average payment by prescriber specialty and type of service associated with payments.¹² A penalty of up to \$10,000 per violation of the law may be imposed.

- **MAINE:** Maine requires disclosure of payments of \$25 and over. Though physician-specific payment information is collected, it is not made publicly available. Payment information is made part of the public record only in the aggregate form. A fine of \$1,000 for each violation of the law may be imposed.
- **DISTRICT OF COLUMBIA:** Requires disclosure to the District of all payments of \$25 and over, including marketing, advertising and charitable contributions.
- **WEST VIRGINIA:** The weakest of these laws, West Virginia's requires disclosure only of the total number of prescribers who have received payments above \$100. No individual physicians are identified. Reporting is required for all marketing expenses, in addition to physician payments. There is no enforcement mechanism and initial compliance has been poor.
- **MASSACHUSETTS:** Massachusetts law includes disclosure provisions and sets limits on certain marketing activities. The law, passed in 2008, establishes a mandatory code of marketing conduct that is "no less restrictive" than the PhRMA and Advanced Medical Technology Association (AdvaMed) codes, effectively banning the provision of non-educational and practice related items, capping the value of educational gift items to physicians at \$100 and prohibiting direct industry funding for physician attendance at professional meetings. While establishing the PhRMA Code as a baseline, the law allows the Department of Public Health to go further. Several provisions of the legislation, including limits on CME funding, also go further than the industry code. The MA law also requires disclosure of all payments valued over \$50 to a prescriber or health care professional by pharmaceutical and medical device companies to the Commonwealth and is reported via a publicly searchable website.¹³ A penalty of up to \$5,000 per violation of the law may be imposed.

Numerous other states, including New York, continue to consider similar legislation.

Disclosure Data: Shining a Light on Conflicts of Interest

State disclosure data on industry payments to physicians has shed light on the magnitude of this previously hidden practice. The FY2007 report of the Vermont AG revealed that 84 pharmaceutical manufacturers reported spending \$3.1 million on fees, travel expenses, and other direct payments to Vermont physicians, hospitals, universities and others for the purpose of marketing their products. This is a 33% increase over reported expenditures for similar expenses in FY2006 and represents an average value of \$1,348 of payments from pharmaceutical companies per recipient. In Minnesota, 6,946 payments totaling \$31 million were disclosed over three years. This included 6,238 payments of \$100 or more. These figures are likely to have significantly underestimated the actual number and amount of payments due to poor compliance by industry and the widespread use of the trade secret exemption.

In Minnesota, the first state to require industry disclosure of individual physician names, the data has allowed identification of important conflicts of interest, including:

- payments of ten of thousands of dollars to an individual on a state committee that determines which drugs are used in the Medicaid programs;¹⁴
- a correlation among psychiatrists between payments from drug makers and prescribing of drugs made by those companies. Psychiatrists who received at least \$5,000 from drug makers wrote more prescriptions than those who received less or no money;¹⁵ and
- a number of physicians paid by drug companies to conduct clinical trials or promote certain medicines while under sanction by the State Board of Medicine for disregarding the welfare of patients.¹⁶

In Vermont, annual aggregate reports have revealed that:

- the top 100 recipients received a total of \$2,127,325 in FY 07, or 68% of the total payments
- among the top 100 payment recipients by prescriber specialty, psychiatrists received the most, an average of \$56,944 each
- five of the ten most heavily promoted products were mental health drugs; two for ADHD and three for depression
- in 2007 Vermont began to require that companies requesting trade secret exemptions explain why the payment constitutes a trade secret. Reversing a years-long trend, there was a 22% decline in trade secret declarations in 2007

Proposed federal legislation: the Physician Payments Sunshine Act

Proposed legislation in both the U.S House and Senate would require industry to disclose "transfers of value" to physicians. For more detail, see the Prescription Project Fact Sheet: The Physician Payments Sunshine Act.¹⁷

Transparency laws highlight the need for change, but unlike actual marketing restrictions, disclosure itself is unlikely to completely mitigate the influence of industry marketing on prescribing. In this regard, existing laws are important first steps toward developing policies to not only detect conflicts of interests, but ultimately to prevent them. The elimination of conflicts of interest in prescribing will:

- Increase the quality and safety of prescribing
- lower prescription drug costs
- repair the damaged credibility of the medical profession
- restore patient confidence

Other materials are available on the Prescription Project website (<http://www.prescriptionproject.org>) and <http://www.reducedrugprices.org/advertising.asp>

- ¹ Chimonas, S. and Rothman, D. J. New Federal Guidelines for Physician-Pharmaceutical Industry Relations: The Politics of Policy Formation. *Health Affairs*. 2005;24(4):949-960.
- ² Kaiser Family Foundation, *Prescription Drug Trends*, May 2007.
- ³ Saul, S. Drug Makers Pay for Lunch as They Pitch. *The New York Times*. July 28, 2006.
- ⁴ Campbell, E. G., et al. A National Survey of Physician-Industry Relationships. *NEJM*. April 26, 2007;356(17):1742-1750.
- ⁵ Dana, J. and Loewenstein, G. A Social Science Perspective on Gifts to Physicians from Industry. *JAMA*. 2003;290(2):252-255; Oldani, M.J. Thick prescriptions: Toward an Interpretation of Pharmaceutical Sales. *Medical Anthropology Quarterly*. 2004;18:328-356.
- ⁶ Wazana, A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA*. 2000;283(3):373-380.
- ⁷ Issued June 1992 based on the report "Gifts to Physicians from Industry." Adopted December 1990 (*JAMA*. 1991;265:501). Updated June 1996 and June 1998.
- ⁸ Pharmaceutical Research and Manufacturers of America. PhRMA Code on Interactions with Healthcare Professionals, Revised July 2008. Accessible at www.phrma.org.
- ⁹ Office of Inspector General, Department of Health and Human Services. Compliance Program Guidance for Pharmaceutical Manufacturers. *Federal Register*. May 5, 2003;68(86):23731-23743.
- ¹⁰ Brennan, T.A. et al. Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers. *JAMA*. 2006;295(4):429-433; Chimonas, S. and Rothman, D. J. (2005).
- ¹¹ Ross, J. S., et al. Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota. *JAMA*. 2007;297(11):1216-1223.
- ¹² Reports accessible at: <http://www.atg.state.vt.us/display.php?smode=151>
- ¹³ General Laws of Massachusetts. Chapter 111N: Pharmaceutical and Device Manufacturer Conduct (2008).
- ¹⁴ Harris, G. Doctors' Ties to Drug Makers Are Put on Close View. *The New York Times*, March 21, 2007; Lohn, M. Minnesota Law Sheds Light on Drug Companies, Associated Press, August 22, 2007.
- ¹⁵ Harris, G, Carey, B, Roberts, J. Psychiatrists, Children and the Drug Industry's Role. *The New York Times*, May 10, 2007.
- ¹⁶ Harris, G, Roberts, J. After Sanctions, Doctors Get Drug Company Payments. *The New York Times*, June 6, 2007.
- ¹⁷ The Prescription Project. Fact sheet: The Physician Payments Sunshine Act. http://prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf

