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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 to physicians.

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 2005.² 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 largesse for lunches alone may total as much as \$1 billion a year.³ A recent survey published in the *New England Journal of Medicine* indicates that a remarkable 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, exert unconscious demands for reciprocity.⁵ For physicians receiving industry payments, “payback” 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 interactions 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 real-world safety records
- Formulary request for drugs with few if any advantages over existing drugs

Residents 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.
- PhRMA’s 2002 “Code for Interaction with Healthcare Professionals” sets a limit of \$100 on the value of gifts to physicians.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 gifts despite evidence that even small gifts have untoward effects. They also lack measures to monitor and ensure compliance. 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 to not only detect existing conflicts of interests, but ultimately 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. It is the only such law that makes 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
- **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.
- **MAINE:** Maine requires disclosure of payments of \$25 and over. Though it collects physician-specific payment information, it is not made publicly available. Payment information is made part of the public record only in the aggregate form.
- **DISTRICT OF COLUMBIA:** Requires disclosure of payments of \$25 and over.
- **WEST VIRGINIA:** The weakest of these laws, West Virginia’s requires disclosure only of the total number of prescribers who have received payments within given dollar ranges. No individual physicians are identified. Reporting is not required for payments below \$100. There is no enforcement mechanism.

Eleven other states, including New York, are currently considering enacting their

own version of such legislation. Extensive testimony evaluating existing legislation was recently given before the Senate Special Committee on Aging.¹² The Committee is considering federal legislation requiring disclosure of industry payments to physicians through a national registry.

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. In Vermont, 12,227 payments totaling \$2.18 million were disclosed over two years. This included 2,416 payments of \$100 or more. In Minnesota, 6,946 payments totaling \$30.96 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 Vermont (for an additional 3.4 million in payments).¹³

Disclosure data has also identified conflicts of interest that might have otherwise gone undetected. Minnesota data that is linked to specific physicians has revealed:

- payments of ten of thousands of dollars to individuals on high stakes committees such as those that develop clinical guidelines or determine which drugs are used in Medicaid programs;¹⁴
- as payments from drug makers to psychiatrists in that state increased, so did the writing of prescriptions for drugs made by those companies. Those psychiatrists who received at least \$5,000 from drug makers appear to have written more prescriptions than those who received less or no money;¹⁵ and
- a number of doctors who had and continue to be paid by drug companies to conduct clinical trials or promote certain medicines had been sanctioned by the State Board of Medicine, for disregarding the welfare of patients.¹⁶

Research suggests that a complete ban on industry gifts to physicians would be the most effective means of eliminating their negative effects, and indeed Iowa and Massachusetts are considering such bans.¹⁷ While existing state disclosure laws and limited gift bans may be imperfect in this and other respects, data emerging from them are shining a bright light on conflicts of interests and are highlighting the need for change. 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, July 1, 2002. Accessible at www.pharma.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 Testimony of Peter Lurie before the Senate Special Committee on Aging, June 27, 2007. Accessible at www.citizen.org.
- ¹³ Ross, J. S. (2007).
- 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 Haris, G, Roberts, J. After Sanctions, Doctors Get Drug Company Payments. *The New York Times*, June 6, 2007.
- ¹⁷ Ross, J. S. (2007).