

Reducing the Impact of Pharmaceutical Marketing to Physicians and Promoting Appropriate Prescribing and Drug Safety

The pharmaceutical industry spends nearly \$30 billion annually on marketing. The majority (including samples) is spent on direct marketing to physicians (Donohue, NEJM, 2007).

Nationwide, prescription drug spending rose 500% (from \$40.3 billion to 200.7 billion) between 2000 and 2005 (Kaiser Family Foundation, 2007).

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Fact Sheet

Addressing Cost and Quality: The Physician Payments Sunshine Act

Inappropriate Prescribing Compromises Access to Care

Increased prescribing of heavily marketed drugs drives up costs and leads to underuse of older, high-quality medicines. The most marketed drugs often results are often unnecessary or inappropriate medicines. Consumers, taxpayers, and state and federal programs pay through the increased cost of these drugs. This drain on resources diminishes state Medicaid budgets, compromising access to care.

Prescription Expenditures and Marketing

Physicians write more than two billion prescriptions a year¹, an average of seven for every American. To capture these sales, the pharmaceutical industry spent \$20.4 billion in marketing during 2007.² Expenditures directed at physicians totaled \$7.2 billion in 2005 (excluding pharmaceutical samples).³ 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. A national survey found that 94% of physicians have a relationship with the industry.⁴ While the drug and device industry trade organizations do have their own codes of conduct on marketing interactions with prescribers, company compliance is strictly voluntary and unenforced.⁵ More info on industry marketing can be found at:

http://www.prescriptionproject.org/tools/solutions_factsheets/files/0013.pdf

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.⁶ Negative effects associated with industry/physician marketing and financial relationships include:

- increased overall prescription rates
- reduced generic prescribing
- quick uptake of the newest, most expensive drugs including those of only marginal benefit over existing options with established safety records
- formulary requests for drugs with few if any advantages over existing drugs

Transparency and Safety

New, more heavily marketed drugs are more likely to be recalled for safety reasons or receive black box warnings than older medications⁷. The FDA estimates 88,000-139,000 cardiac events due to the heavily-marketed drug Vioxx (35,000-55,000 deaths)⁸. Doctors were paid to enroll patients in seeding trials before the release of Vioxx⁹. Seeding trials are clinical trials designed with the intent to build market share of a drug and are not genuine research. It is often impossible to differentiate marketing masquerading as science from the genuine thing. Disclosure of all payments is crucial to identifying such

inappropriate marketing practices.

State Disclosure Laws and Other Existing Disclosure Policies Are Difficult to Enforce and Are Inconsistent

Maine, Massachusetts, Minnesota, Vermont, West Virginia and the District of Columbia have enacted "sunshine laws" setting limits on industry payments to physicians and/or requiring disclosure of the payments. Each state and institution has unique limits on payments and processes for disclosure, some lacking any resources or mechanism for enforcement.

Senate Finance Committee investigations and numerous media articles have uncovered frequent failures to disclose financial relationships with drug and device manufacturers by prescribers, often reaching hundreds of thousands of dollars, and in violation of NIH and institutional policies. Many of those criticized for failing to disclose their relationships have been prominent physicians, thought leaders in their fields. Selected news articles on this subject can be found at:

http://www.prescriptionproject.org/tools/solutions_reports/files/0022.pdf

Federal Legislation: The Physician Payments Sunshine Act (PPSA)

The Physician Payments Sunshine Act (S.301) will require drug and medical device manufacturers to publicly report payments to physicians, such as gifts, consulting payments and speaking contracts. The information would be available on an easily searchable website. The bill does not limit any activity, and only creates transparency. As the legislation is written, all the reporting is done by industry; there is no burden on doctors. See the fact sheet at:

http://www.prescriptionproject.org/tools/solutions_factsheets/files/0008.pdf

Transparency laws highlight the need for change and are important steps toward developing policies not only to detect conflicts of interests, but also 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

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 Verispan. Verispan year in review – 2007. 2008. Available at:

http://www.ammonline.org/uploadedFiles/AMM/Archives/Verispan_June08_YearReview.pdf ³ Kaiser Family Foundation, *Prescription Drug Trends*, May 2007.

⁴ Campbell, E. G., et al. A National Survey of Physician-Industry Relationships. *NEJM*. April 26, 2007; 356(17): 1742-1750.

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⁵ PhRMA and AdvaMed Codes available at:

http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf and http://www.advamed.org/MemberPortal/About/code/ ⁶ Dana, J. and Loewenstein, G. A Social Science Perspective on Gifts to Physicians from Industry.

^o 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.

⁷ Lasser KE, Allen PD, Woolhandler SJ, et al. Timing of new black box warnings and withdrawals for prescription medications. *JAMA* 2002;287:2215-20.

⁸ Testimony of David J. Graham, MD, MPH, November 18, 2004 to the U.S. Senate Finance Committee Available at:

http://www.senate.gov/~finance/hearings/testimony/2004test/111804dgtest.pdf Accessed August 22, 2007.

⁹ Hill, K.P., Ross, J.S., Egilman, D.S., Krumholz, H.M. (2008). The ADVANTAGE Seeding Trial: A Review of Internal Documents. *Annals of Internal Medicine*, *149*(4), 251-258.

