

**September
2004**

'Tis Always the Season for Giving

**A white paper on the practice and problems of
pharmaceutical detailing**

CALPIRG

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September 2004

Acknowledgements

The author gratefully acknowledges the academics, researchers, doctors and public service organizations that have already contributed important research on this topic. Many thanks specifically to Dr. Dan Shapiro for his valuable input, to the work of the Kaiser Family Foundation and to the research of Dr. Margaret Chren. The advice and editorial input of Steve Blackledge, CALPIRG's Legislative Director, are also much appreciated.

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A white paper on the practice and problems of pharmaceutical detailing

Desperate to rein in skyrocketing prescription drug costs, lawmakers, healthcare plans and individual consumers are taking a much closer look at the promotional practices of the pharmaceutical industry. One aspect that has come under heavy scrutiny is a marketing technique known as detailing. This white paper examines the mechanics and potential harms of pharmaceutical detailing, describes the steps that have been taken to address those problems, and explores policy options for addressing the issue.

The Process and Problems of Detailing

Pharmaceutical detailing is a marketing method that involves individual pharmaceutical sales representatives (detailers) meeting with doctors to promote specific medications. Detailing is a multi-billion dollar business with closely monitored targets and carefully crafted promotional presentations.

The process begins when drug companies buy – often without the knowledge or prior consent of doctors – the prescribing histories of individual physicians. Purchased from retail pharmacies and then aggregated by data processing companies, this information gives detailers precise information about which classes, forms and dosages of drugs each physician prescribes. Drug companies use this information for direct mail marketing to medical offices and detailers use it to specifically target their sales pitches when they meet with doctors.

Increasing Prevalence

Pharmaceutical detailing is on the rise. Between 1996 and 2000, the number of pharmaceutical sales reps in the U.S. more than doubled from 41,800 to 83,000.¹ Excluding drug samples, pharmaceutical companies spent a total of \$4.8 billion in one-on-one promotion in 2000.² With samples included, total detailing expenditures topped \$12.7 billion in 2000.³

As the practice of pharmaceutical detailing becomes more popular, it becomes increasingly competitive. Detailers have a harder time keeping a doctor's attention or even getting through the medical office door. To make a lasting impression, detailers commonly bring gifts and meals along with their promotional information. These gifts and meals can range from pens, notepads and pizza to watches, golf trips and five star dining. A recent New York Times article reports that five and even six figure checks have arrived, unsolicited, in doctor's offices as a means of inducing prescriptions.⁴ One former detailer explains the purpose of these gifts: "They buy you time with a doc, time that might change his mind."⁵

Several studies have demonstrated that this gift giving is having its desired effect – increasing the number of prescriptions written for the drugs that are promoted in meetings with detailers. According to research conducted by Dr. Margaret Chren of the University of California, San Francisco, "physicians were more likely to have requested drugs manufactured by specific companies if they had met with pharmaceutical

representatives from those companies or had accepted money from those companies.”⁶ Another study by J.P. Orłowski and L. Wateska showed that doctors exhibited a “significant increase” in prescribing a company’s drugs after attending an all-expenses-paid trip to a drug company symposium.⁷

Increasing Problems

Given the unique doctor-patient relationship and the already extraordinarily high cost of prescription drugs, this gift giving practice is a cause for concern for a number of reasons. The first problem is one of perception. Regardless of any effect that the promotion may have on the prescribing patterns of a given physician, accepting gifts from pharmaceutical salespeople can create the appearance of impropriety. According to an article by Dr. Michael Steinman in the *Journal of the American Medical Association (JAMA)*, “Surveys show that as many as 70% of patients believe these gifts significantly impact prescribing, and as many as two thirds believe they increase the overall cost of medications for the public.”⁸

Because physicians are in the unique position of choosing a specific product that someone else must purchase and use, patients must have absolute confidence in the process that leads a doctor to a prescribing conclusion. An editorial in the newspaper of the American Medical Association puts it like this: “The price to be paid for extravagant gifts isn't measured by the size of a drug company's marketing budget, but in the erosion of trust in the medical profession.”⁹

The price tag for this promotion is another reason for concern. A recent study estimates that, not including any meals, gifts or drug samples given to a doctor, the average fixed cost of a detailing call is \$142 for office-based physicians and \$179 for hospital-based physicians.¹⁰ According to the *New England Journal of Medicine*, when visits from all companies are factored in, this amounts to spending between \$6,000 and \$11,000 per doctor, per year, on direct promotion.¹¹ The U.S. total for detailing expenditures, excluding all medicine samples, is nearly \$5 billion a year. These costs are eventually passed through to the healthcare system and its consumers.

The fiscal impact of these promotions manifests itself directly in patient prescription costs as well. As indicated by a wide range of studies and the ever-increasing prevalence of the practice, this type of promotion is highly effective at changing the prescriptions that physicians write. According to the Center for Policy Alternatives, “Studies consistently prove that the practice of detailing causes doctors to prescribe the newest drugs, even when overwhelming medical evidence shows that less expensive, tried and true remedies would be much cheaper, just as effective, and often safer.”¹²

Because companies focus their promotions on their newest, most expensive medicines, virtually any time that a physician switches to a promoted drug, the price increases. Thus, whenever a physician-oriented promotion is successful, consumers, insurers and government programs pay a higher price for their medications. A recent study in Pennsylvania found that 40% of patients in a state assistance program were given hypertension medicines different than those recommended by medical guidelines. If

doctors had prescribed according to those guidelines, the state could have saved \$11.6 million, or nearly 24% of the total money it spent on hypertension medication. The study suggested that pharmaceutical promotion was partly at fault for the variance between the medicines that were recommended versus those that were prescribed.¹³

In addition to the public perception and financial considerations raised by the practice of pharmaceutical detailing, the quality of the information presented by detailers is of significant concern. Numerous academic articles have criticized the incomplete nature of presentations from detailers, and research shows that much of the information presented during these interactions is actually inaccurate. A study published in JAMA found that 11% of all statements made by detailers during monitored presentations were inaccurate and that only 26% of doctors who had seen the presentations were able to recall any false statements.¹⁴ The lack of complete and accurate information from detailers is particularly troublesome because companies promote their drugs most heavily as they first enter the market – a stage when little outside information is available for comparison and doctors are forced to rely more heavily on company sponsored materials and presentations.

Content and Inadequacies of Existing Codes and Guidelines

Content

The problems caused by pharmaceutical detailing have not gone unnoticed by regulators, doctors, consumers and the pharmaceutical industry itself. To address the concerns raised by various stakeholder groups, a number of voluntary guidelines have been developed.

American Medical Association (AMA) Guidelines

On December 4, 1990, in response to growing concern both inside and outside the medical community about the appropriateness of gifts from industry, the American Medical Association adopted a set of guidelines to help doctors determine appropriate limits for gifts and other industry supported programs. Two days later, the Pharmaceutical Manufacturer's Association (PMA), a predecessor of today's Pharmaceutical Research and Manufacturers of America (PhRMA), adopted the same voluntary guidelines.

The document consists of a number of guidelines that physicians should consider before accepting a gift, grant, subsidy or any other inducement from an industry representative. The recommendations advise physicians to avoid accepting any gift that is of substantial value or that does not entail a value for patients. They recommend that doctors only attend meetings and conferences where the primary purpose of the event and incentive for attending is the furtherance of medical knowledge. The guidelines also advise doctors against accepting any gift that is given conditionally.¹⁵

In 2001, as part of a campaign to remind doctors about the existence of the guidelines and to encourage compliance with them, the AMA published updated recommendations with a number of clarifications.¹⁶

Pharmaceutical Research and Manufacturers of America (PhRMA) Code

In response to heavy legislative and public scrutiny culminating in an \$875 million settlement against TAP pharmaceuticals regarding its marketing practices, PhRMA (an industry trade group and the successor to PMA) adopted a new code of conduct in July 2002. The preamble to the code openly acknowledges the industry's desire to limit the negative public reaction to gift giving. It states that "[w]e are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large."¹⁷

The PhRMA "Code on Interactions with Healthcare Professionals" lays out recommendations for many of the same situations addressed in the 1990 AMA guidelines. In addition to outlining advisable conditions for continuing medical education conferences and consulting agreements, the code recommends a few more specific limitations. It suggests that meals be only occasional and of modest value and that meetings no longer take place during entertainment and sporting events. The code advises that gifts only be offered occasionally, that they primarily entail a benefit to the patient and that no single gift exceed \$100 in value. It further states that cash and gifts intended for the personal use of a physician should no longer be offered. The code concludes with a number of clarifying questions and answers as well as an admonition that "[e]ach member company is strongly encouraged to adopt procedures to assure adherence to this Code."

Office of Inspector General (OIG) Guidance

In April 2003, to address concerns about abuses in federal healthcare programs, the Office of Inspector General of the U.S. Department of Health and Human Services issued a document entitled "Compliance Program Guidance for Pharmaceutical Manufacturers".¹⁸ The OIG guide gives pharmaceutical manufacturers recommendations for establishing a program to ensure compliance with applicable statutes, regulations, and requirements of federal healthcare programs.

With regard to pharmaceutical marketing and detailing, the OIG report recommends that pharmaceutical companies carefully scrutinize certain types of relationships and promotional practices in order to avoid liability under existing federal law.

The primary law addressed by the guidance is the federal anti-kickback statute (42 USC § 1320a-7b(b))¹⁹. The anti-kickback statute "is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business."²⁰ The statute and the guidance both deal exclusively protecting with public healthcare programs, including Medicaid and Medicare, from unscrupulous marketing and purchasing behaviors.

Inadequacies

Despite the propagation of these codes and guidelines, there are still significant shortcomings in the regulation of pharmaceutical detailing.

The OIG guidance, while essential to safeguarding the integrity of federal healthcare purchases, is extremely narrow in scope. Neither the guidance nor the anti-kickback statute addresses two key aspects of pharmaceutical detailing. First, the federal statute has no provisions regulating detailer interactions with healthcare providers who have no connection to public health care business. Second, the anti-kickback statute does not address the offer, acceptance or reporting of any gift or other remuneration not intended to solicit or reward government contracts, regardless of the relationship between the recipient and the federal government. Thus, the everyday interactions between most physicians and detailers are not regulated by the OIG guidance or the anti-kickback statute.

The AMA and PhRMA guidelines suffer from both their vagueness and their lack of enforcement mechanisms. While the revised AMA guidelines and the PhRMA code do recommend a few specific numbers (\$100 upper limit for gifts), they remain ambiguous in many areas. Suggestions that only “occasional meals” of “modest” value should be offered and that gifts “should not be offered on more than an occasional basis” are largely subjective and open to a tremendous degree of abuse. In an interview with the *Washington Post*, a pharmaceutical company spokesman admitted that the AMA guidelines “are not specific enough to be a practical guide for everyday practice in our industry.”²¹

Because the guidelines are discretionary, they are essentially unmonitored recommendations for members of the respective organizations. Violations of the voluntary guidelines have no legally enforceable consequences. The TAP Pharmaceuticals settlement and the fact that PhRMA was forced to issue a new code of conduct in 2002 indicate the failings of this voluntary system. TAP’s marketing violations were not prevented by the code and were actionable only because they involved federal healthcare programs. PhRMA’s new guidelines, while commendable, are a tacit admission of the failure of the first PMA code and still contain no legally binding enforcement mechanisms.

The voluntary nature of the guidelines can also create a business quandary for manufacturers. If following the guidelines would put a company at a competitive disadvantage with a company that disregards the rules, the first company has little choice but to ignore the guidelines as well. As a former detailer posed the problem, “Here you are, working for a company that wants to abide by the guidelines, and you can’t compete with a guy who’s giving away tickets.”²² With no punitive mechanism for those who violate the recommendations, gift giving can escalate into an arms race with neither side willing to unilaterally disarm. A more uniform and enforceable standard for appropriate interactions would level the playing field for all companies.

Policy Options

Without binding legislative action, there is no way to guarantee or monitor compliance with any set of guidelines or recommendations. To address the shortcomings of voluntary

self-regulation and to create a level playing field, legislators have considered and undertaken a number different of policy options.

Caps and Bans

In the past year, at least five states have considered either strict monetary limits or outright bans on gifts from pharmaceutical companies to doctors. Minnesota was the first state to set a firm cap on gift value (\$50 per gift, with some exceptions) in 1993. A total ban on gifts, while ardently opposed by the pharmaceutical industry, would entirely eliminate any appearance of impropriety in industry-physician relationships. It could also free up a large part of the \$4.8 billion a year currently spent on detailing for research or lowering the cost of prescription drugs. A legally mandated cap on either per gift or per capita spending could achieve those same goals to a lesser degree.

Disclosure

In the past two years, Maine and Vermont have enacted, and more than 15 state legislatures have considered, some disclosure requirements for manufacturers or doctors. While some bills would place the reporting requirement on doctors, most would require pharmaceutical companies to report the value, nature, and purpose of any gift or economic incentive over a certain value given to a healthcare provider. Because of the increased possibility for public scrutiny, this type of reporting would require both drug companies and doctors to carefully consider what types of gifts they give and accept. It would also give regulators and the public a clearer picture of the degree to which the voluntary regulations have brought about compliance.

Codification of existing guidelines

Another policy approach that can be taken to regulate pharmaceutical marketing is the legislative codification and enforcement of existing guidelines. Maine is currently considering a bill that would prohibit marketing practices that violate the PhRMA code or induce physicians to breach the AMA code. The California Legislature has passed legislation, Senate Bill 1765 (Sher), that would require pharmaceutical manufacturers to establish a compliance program that encompasses both the OIG guidelines and the tenets of the PhRMA code. That legislation would also require companies to publish firm, per doctor promotional spending caps and to declare each year that the company is in compliance with its own program and caps. Solutions like these take into account the steps that AMA members and PhRMA companies have already taken toward compliance, and simply work to ensure that all companies play by the same rules. While leaving room for individualized approaches to compliance, this policy option will guarantee substantial public scrutiny of industry gift giving.

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- ¹ From Scott-Levin, a pharmaceutical industry-tracking firm, as cited at <http://www.usatoday.com/news/health/2001-05-16-perks-usat.htm>. Accessed 3 May 2004.
- ² “Prescription Drugs and Mass Media Advertising, 2000,” National Institute for Health Care Management Research and Educational Foundation, March 2002. Available at <http://www.nihcm.org/DTCbrief2001.pdf>.
- ³ “Prescription Drugs and Mass Media Advertising, 2000,” National Institute for Health Care Management Research and Educational Foundation, March 2002. Available at <http://www.nihcm.org/DTCbrief2001.pdf>.
- ⁴ Harris, Gardiner. “As Doctors Write Prescriptions, Drug Companies Write Checks”. *The New York Times*, 27 June 2004.
- ⁵ Capaldi, Ralph, as quoted in “Visits from Pharmaceutical Reps,” by Elizabeth Ellen. *Psychiatric Times*, Volume XVIII, Issue 1, January 2001. Available at <http://www.psychiatrictimes.com/p010121.html>.
- ⁶ Chren MM, Landefeld CS. “Physicians' behavior and their interactions with drug companies: a controlled study of physicians who requested additions to a hospital drug formulary”. *JAMA*. 1994; 271,684-689.
- ⁷ Orłowski J, Wateska L. “The Effects of Pharmaceutical Firm Enticements on Physician Prescribing Patterns: There's No Such Thing as a Free Lunch”. *Chest*, 1992; 102, 270-273
- ⁸ Steinman, Michael. “Gifts to Physicians in the Consumer Marketing Era”. *JAMA*. 2000; 284:2243. Available at <http://jama.ama-assn.org/cgi/content/full/284/17/2243>.
- ⁹ Editorial Staff. “Pharmaceutical Marketing to Physicians: Free gifts carry a high price.” *American Medical News*, 10 June 2002. Available at <http://www.ama-assn.org/amednews/2002/06/10/edsa0610.htm>.
- ¹⁰ ROI Analysis of Pharmaceutical Promotion. Available at http://rappstudy.org/Rapp_Study/definitions.html.
- ¹¹ As cited by Shapiro, Dan. “Drug Companies Get Too Close for Med School’s Comfort”. *The New York Times*, 20 January 2004. Accessible at <http://www.globalaging.org/health/us/2004/medschool.htm>
- ¹² Center for Policy Alternatives, Prescription Drug Marketing 2004. Available at <http://www.stateaction.org/2004agenda/35.pdf>.
- ¹³ Associated Press article reprinted in the Boston Herald. “Study: Doctors prescribe expensive drugs instead of those preferred under medical guidelines”. April 20, 2004.
- ¹⁴ M. G. Ziegler, P. Lew and B. C. Singer. *Journal of the American Medical Association*. Volume 273, No. 16. April 26, 1995.
- ¹⁵ The text of the original guidelines can be found at <http://www.ama-assn.org/ama/pub/article/4001-7922.html>.
- ¹⁶ The text of the updated guidelines can be found at <http://www.ama-assn.org/ama/pub/article/4001-4388.html>.
- ¹⁷ The text of the PhRMA code can be found at <http://www.phrma.org/publications/policy//2004-01-19.391.pdf>.
- ¹⁸ Office of Inspector General, “Compliance Program Guidance for Pharmaceutical Manufacturers,” April 2003. Accessible at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>
- ¹⁹ Text of the anti-kickback statute is accessible at <http://www4.law.cornell.edu/uscode/42/1320a-7b.html>
- ²⁰ p. 13, Office of Inspector General, “Compliance Program Guidance for Pharmaceutical Manufacturers,” April 2003. Accessible at <http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>
- ²¹ Petkus, Douglas, as quoted in “Drug Makers Still Lavish Pricely Gifts on Doctors,” by Bill Brubaker. *The Washington Post*, 19 January 2002. Available at <http://www.washingtonpost.com/ac2/wp-dyn/A5328-2002Jan18?language=printer>.
- ²² Capaldi, Ralph, as quoted in “Visits from Pharmaceutical Reps,” by Elizabeth Ellen. *Psychiatric Times*, Volume XVIII, Issue 1, January 2001. Available at <http://www.psychiatrictimes.com/p010121.html>.