PERSPECTIVE

Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention?

David Grande, MD, MPA^{1,2}

¹Department of Medicine, University of Pennsylvania, Philadelphia, PA, USA; ²Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA, USA.

Concerns over the influence of pharmaceutical gifts on physicians have surged in recent years. This has prompted wide ranging legislative proposals in numerous states and in the federal government as well as stepped up efforts at self-regulation by the pharmaceutical industry and the medical profession. Policymakers face the decision of whether to defer to self-regulation or support government intervention. This commentary describes efforts at self-regulation by the pharmaceutical industry and the medical profession. The author examines and critiques the wide ranging legislative strategies pursued to limit the influence of pharmaceutical gifts on physicians and concludes with suggestions for policymakers and the profession to limit influence and preserve public trust.

KEY WORDS: medical professionalism; pharmaceutical marketing; conflicts of interest

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INTRODUCTION

In January 2009, new voluntary pharmaceutical industry guidelines on marketing to physicians went into effect¹. In announcing these guidelines, Billy Tauzin, President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA), declared a commitment “to ensure their medicines are marketed in a manner that benefits patients and enhances the practice of medicine”². These guidelines come at a time of mounting scrutiny of common marketing practices known to influence physician prescribing³. The complex financial entanglements between the pharmaceutical industry and the medical profession have called into question the objectivity and independence of physicians. The chief concerns have been rising pharmaceutical costs and drug safety^{4–6}. These concerns have increased as some heavily marketed drugs have been revealed to pose public health risks^{6–8}.

These new guidelines come at a time of intense legislative activity at the state and national level that seeks to limit the influence of pharmaceutical marketing on physicians. The wide

array of policies put forth by industry, the medical profession, and government raise important questions about who should be relied upon at this point to limit the influence of marketing. In addition, if government intervention is warranted, what types of regulation are most likely to achieve this goal?

Although pharmaceutical marketing directed at physicians encompasses a wide range of activities (e.g. detailing, samples, CME, journal advertising, consulting arrangements), this commentary focuses on approaches to limit the influence of pharmaceutical detailing and industry gifts which account for more than 80% of all promotional expenditures⁹. In this article, I review and critique recent efforts at self-regulation and government regulation ostensibly to limit the influence of gifts and conclude with recommendations toward this goal.

ATTEMPTS AT SELF-REGULATION

As far back as the 1960s, there has been vigorous debate concerning the appropriateness of marketing relationships between physicians and the pharmaceutical industry¹⁰. However, it was not until 1991 at a time of intensified scrutiny by policymakers that the American Medical Association (AMA) issued ethics guidelines addressing pharmaceutical marketing and industry gifts¹¹. Since that time, attention to pharmaceutical marketing has surged as marketing has intensified and drug prices have risen. In response, PhRMA issued voluntary guidelines in 2002¹², while the AMA published addenda to their original guidelines around the same time¹³. Under both guidelines, gifts valued less than \$100 are allowed if they primarily entail a benefit to patients or are associated with a physician's practice. Meals for physicians are acceptable if “modest” and provided in association with an educational component. PhRMA's latest guidelines, effective January 2009, prohibit non-educational and practice-related gifts such as pens but continue to permit company-sponsored meals, drug samples, and other “educational” gifts valued less than \$100.

Meanwhile, within academic medicine there has been a steady movement to restrict pharmaceutical marketing activities at academic medical centers (AMCs). Many of these changes followed a policy proposal issued by a group of academic leaders¹⁴. Recently, the Association of American Medical Colleges (AAMC) endorsed a similar set of policies and several AMCs have begun to publicly disclose relationships with pharmaceutical companies¹⁵.

The question facing U.S. policymakers today is whether the profession and the industry have gone far enough to limit the influence of gifts on physician prescribing. While a growing

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number of AMCs have adopted policy changes, a recent scorecard found only nine with a “model” policy based on published recommendations^{14,16}. In addition, there is little evidence that physician practices outside of academic medicine have undertaken significant changes to limit acceptance of gifts. A recent national survey of physicians found that 94% are involved in marketing relationships with pharmaceutical companies and accept some form of industry gifts or payments¹⁷. Another survey found that physicians were significantly less likely than patients to believe that industry gifts are influential with just 9% of physicians believing that a small textbook is influential compared to 37% of patients¹⁸.

Current circumstances suggest that relying on ethics guidelines to guide self-regulation has been slow to bring about substantive change. First, evidence from state gift disclosure laws suggests that many physicians do not follow the AMA’s ethics guidelines¹⁹. Second, the guidelines themselves continue to allow gifts and payments valued up to \$100. While large gifts are a more visible example of commercial influence, there is evidence that small gifts are influential as well²⁰. Given these shortcomings, government has an important role in further limiting marketing influence.

GOVERNMENT APPROACHES TO REGULATING PHARMACEUTICAL GIFTS TO PHYSICIANS

In recent years, state legislators have proposed and adopted numerous statutes aimed at curbing the influence of pharmaceutical gifts in physician practices. In addition, the Department of Health and Human Services Office of the Inspector General (OIG) has weighed in by issuing “guidance” to the industry that spells out what marketing activities might run afoul of existing anti-kickback statutes²¹. In this 2003 guidance, OIG endorsed the industry’s 2002 voluntary guidelines by stating that compliance offers “substantial” protection thus adding significant enforcement potential to the guidelines^{22,23}.

Government regulation can be a highly effective strategy to alter professional behaviors. The mere threat of regulation can motivate changes in professional and industry behavior as seems to have occurred in recent years with scrutiny by the press and policymakers. Credible legal enforcement provides a strong incentive to comply with government regulation. Writing and enforcing regulations is not without challenge. Regulated parties often find loopholes in laws, challenge their validity, or simply flout them when enforcement is difficult. In addition, regulations can transform the prevailing perceptions of an issue from professional in nature to purely legal in nature, thereby replacing virtue with compliance. Government regulations need to be carefully crafted to address the fundamental issue of influence while minimizing unintended consequences.

Disclosure of Physician Payments and Gifts

Some states have enacted “sunshine laws” that require pharmaceutical companies to disclose payments or gifts to physicians¹⁹. These laws often require disclosure of other forms of promotion beyond detailing such as consulting payments but most still contain significant exemptions. Gifts or payments totaling \$100 or more in Minnesota²⁴ and \$25 or more in Vermont²⁵ must be disclosed. The disclosures are

public information; in Vermont, however, companies may classify certain gifts and payments as “trade secrets” based on guidelines from the State. Disclosure legislation has been adopted in other states (ME, DC, WV) with Massachusetts being the most recent to adopt a similar statute (\$50 threshold)^{26,27}. Federal legislation (Physician Payments Sunshine Act) introduced in the last Congress had been endorsed by the pharmaceutical industry due to a provision that preempts state statutes and its much higher reporting threshold (\$500 per year)^{28,29}. However, when the Act was reintroduced in 2009, the reporting threshold was lowered to \$100 and the degree of preemption was scaled back³⁰. Several companies recently announced their intent to self-disclose gifts and payments using the \$500 threshold in what appears to be a preemptive action to limit the scope of regulation³¹.

The use of disclosure to address conflicts of interest has intuitive appeal. However, there are several reasons to question its efficacy. First, while the disclosure statutes’ reporting thresholds may ease administrative burdens on both pharmaceutical companies and government, they diminish scrutiny of smaller gifts. Evidence on gifts suggests that even “trivial” gifts may create influence²⁰. Second, patients have no clear way to use disclosure information to correct for bias. Third, disclosure may provide implicit permission or “moral licensing”³² for conflicts of interest, so long as they are disclosed. These potential unintended consequences of disclosure have been demonstrated experimentally where disclosure can actually increase the level of bias of information provided by conflicted individuals while simultaneously increasing trust in the information by others³². Despite these shortcomings, there have been indirect benefits of disclosure statutes. The data made available through public disclosure has been vigorously pursued by the press and resulted in heightened public scrutiny of industry-physician relationships. Individual stories of physicians receiving lucrative industry payments have formed the basis for a series of high profile media stories and Congressional inquiries^{6,33–35}.

A recent study examining the statutes in Minnesota and Vermont found that the data were not readily accessible and that some pharmaceutical companies exploited the trade secret provision by classifying most gifts and payments as trade secrets¹⁹. Incomplete and difficult-to-access data undermines the intent of a disclosure law and limits its benefits. To avoid these shortcomings, policymakers need to ensure transparency and public accessibility of all disclosures and require drug manufacturers in the absence of gift bans to disclose all gifts rather than relying on arbitrary financial limits.

Bans on Physician Gifts

Several states have considered outright bans on industry gifts to physicians, but until recently Minnesota was the only state to have enacted a statute³⁶. Minnesota prohibits pharmaceutical manufacturers from giving practitioners gifts with a total annual combined retail value in excess of \$50. The statute exempts drug samples, payments to sponsors of education programs, honoraria and payment for course faculty, compensation for research consulting, and educational materials. The Massachusetts Department of Public Health recently issued final regulations effective July 1, 2009 that are the most comprehensive restrictions on industry gifts in the nation. The regulations include a ban on all gifts except for modest

meals in the provider's practice setting, drug samples, and indirect support for educational programs³⁷.

The experience in Minnesota suggests that exemptions, loopholes, and enforcement are the biggest challenges. Although the statute was enacted in 1993, press reports suggest that meaningful enforcement did not occur until 2005³⁸. According to the same report, visits by pharmaceutical sales representatives to Minnesota primary care physicians declined at twice the nationwide rate following more strict enforcement. This national trend likely reflects the decreasing number of patent-protected blockbuster drugs that justify significant physician marketing³⁹. The greater reduction in Minnesota suggests that bans on gifts prompts doctors to see pharmaceutical sales representatives less frequently, which may ultimately reduce the influence of detailing on prescribing. Yet few other states have pursued a similar legislative strategy - many more have opted for some form of disclosure or restrictions on other forms of marketing.

Limits on the Sale of Prescribing Data for Marketing Purposes

In 2005, New Hampshire enacted a statute banning the sale of physician prescribing data for commercial marketing purposes⁴⁰. Currently, pharmacies sell patient de-identified prescription records to data aggregators that construct physician prescribing profiles. Pharmaceutical companies purchase these profiles to target physicians based on prescribing habits, to develop tailored marketing messages, and to measure physician responses to marketing¹⁰. It is difficult to know how much physician profiling contributes to marketing influence but one industry market research study suggests that it can increase the uptake of new drugs by 30%⁴¹. While bans on the sale of prescribing data will not eliminate undue influence on prescribers, removing this data from sales representatives' available tools is likely to curb the influence of marketing.

A federal district court found the law unconstitutional because of its restrictions on commercial speech but New Hampshire prevailed in its appeal before the First Circuit Court⁴². Vermont and Maine have enacted similar laws. The AMA has started their own "opt-out" program⁴³, but it has suffered from low awareness and participation¹⁰. The challenge underscored in these cases has been how a data rich environment creates new opportunities to influence physicians for commercial purposes⁴⁴. However, the recent Circuit Court ruling suggests that government is within its rights to impose restrictions on the use of data tracking physician practice patterns. It may also open the door to heightened scrutiny of other data uses focused on commercial marketing.

Licensing of Pharmaceutical Sales Representatives

Several states have introduced legislation to require licensure of pharmaceutical sales representatives. The District of Columbia was the first jurisdiction to pass legislation (SafeRx Amendment Act of 2008)⁴⁵. The District's licensure standards mandate that pharmaceutical detailers adhere to a code of ethics developed by the Board of Pharmacy and meet minimum educational requirements. The statute also prohibits detailers from engaging in any "deceptive or misleading marketing."

Using licensure to regulate interactions between physicians and sales representatives raises several concerns. First, licensure implicitly defines pharmaceutical sales as a professional activity when motives underlying such activities seem at odds with the traditional definition of professions. Pharmaceutical sales representatives are not bound by any ethical duty to patients - their primary goal is to increase the number of prescriptions written for their company's product. Aligning this goal with strong ethical norms would be challenging. Second, affording sales representatives professional status would seem to enhance their standing as educators for physicians and potentially increase the reliance of physicians on industry sources by validating this role. Rather than encouraging the profession to take ownership of its education, embracing sales representatives as professionals and educators would appear to be a step in the opposite direction. On the other hand, if licensure violations jeopardize the employability of a sales representative, it could serve as a powerful mechanism to ensure compliance with government regulations. In addition, licensure would establish minimum educational and training requirements for sales representatives that would help ensure a level of scientific understanding of pharmaceutical products. There is no empiric evidence to date examining the effects of the District's statute.

Public Funding of Academic Detailing Programs

Several states are attempting to counter the influence of pharmaceutical detailing not by regulating it, but instead by doing it themselves. Specifically, some states are funding academic detailing programs that rely upon many of the same sales tactics employed by the pharmaceutical industry to influence physician prescribing in concordance with evidence based guidelines. The Independent Drug Information Service, a program sponsored by Pennsylvania's Department of Aging and administered in partnership with Harvard University, is just one example of a state funded program⁴⁶. Congress recently convened hearings to explore the development of a similar program nationwide⁴⁷.

A recent Cochrane review concluded that academic detailing has a modest effect on physician compliance with evidence based guidelines⁴⁸. Recent experiences in Pennsylvania suggest that cost savings in public insurance programs are likely to at least offset program costs⁴⁹. However, the scale needed to have a large impact on prescribing practices may be difficult to achieve. Pharmaceutical companies employ 1 sales representative for every 5 office-based physicians⁵⁰. Pennsylvania's program employs just 10 academic detailers for a state with 48,000 doctors⁵¹. It seems unlikely that any state could scale up to a level that would rival the pharmaceutical industry. Academic detailing programs are a good way for states to increase evidence-based prescribing but the programs alone are not a complete answer to the larger challenge of moderating the influence of pharmaceutical gifts on physicians.

A WAY FORWARD FOR THE PROFESSION, PHARMACEUTICAL INDUSTRY, AND LEGISLATORS

Although government regulation is not a perfect solution, the medical profession and pharmaceutical industry have fallen short in reducing the influences of gifts through self-regula-

tion. Payments and gifts from the pharmaceutical industry to physicians are ubiquitous despite ample evidence demonstrating their influence on prescribing preferences and decisions. It is possible that market forces and evolving regulatory policies that increase generic competition, expand the role of prescription drug formularies, or reduce profit margins in other ways could decrease the importance of detailing and gifts over time. However, it does not diminish the significance of addressing this issue. In addition, how diminished profit margins might affect marketing decisions by pharmaceutical firms or investments in research and development has not been well described.

Gifts associated with pharmaceutical detailing are motivated by a single goal - to increase the sales of a company's products. There is no ethical basis for allowing these types of financial exchanges to continue. In this case, the government should assert its regulatory role by banning all gifts. Given the evidence that gifts of any value influence the recipient²⁰, states should follow the leadership of Massachusetts and avoid setting financial thresholds that would define the permissibility of gifts. However, they should go further by banning all gifts rather than exempting some such as office-based meals.

Disclosure as a remedy to financial conflicts of interest has its flaws. Financial relationships with the sole purpose of influencing prescribing should not be disclosed, but prohibited. However, as a supplement to gift bans, disclosure can play a valuable role in monitoring more complicated relationships such as consulting arrangements. If combined with a gift ban, a payment reporting threshold of \$25 (as in Vermont) would likely capture most financial relationships. Disclosure would contribute information to the public record to ensure that policymakers, the media and consumer advocacy groups can monitor and scrutinize physician-industry relationships.

Independent of policy discussions concerning pharmaceutical promotion, public sector support of academic detailing programs makes sense to promote evidence-based prescribing. The pharmaceutical industry has mastered the art of influence - using these same techniques to encourage quality improvement could benefit patients and is worthy of public investment.

Even with these government approaches, self-regulation remains important and is not at odds with government regulation. Government regulations will contain loopholes and the pharmaceutical industry will find new ways to promote its products. Professional ethics and strong professional norms can better respond to complex and changing relationships and promote a stronger ethical foundation to enhance social trust.

What will it take for the medical profession to begin to clean its own house of ethically problematic industry relationships? The AMA guidelines do not seem to be a meaningful driver of professional change. Perhaps it is time for medical organizations to develop professional enforcement or reward mechanisms for compliance with ethical standards. For example, physician practices achieving a level of compliance could receive special professional recognition that would be on display to the public. In addition, professional medical societies could begin to provide leadership by weaning themselves of industry dependence as called for in a recent JAMA editorial⁵².

While governmental regulatory actions are needed, the medical profession needs to reclaim its professional independence from industry. Current relationships are eroding public

respect for medical professionals; further loss of social trust threatens to undermine the profession's future. Regulation alone can't fully address the negative influences of marketing. In the end, government should play an important role but physicians themselves need to cleanse the profession of undue commercial influence.

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Corresponding Author: David Grande, MD, MPA, Leonard Davis Institute of Health Economics, University of Pennsylvania, 3641 Locust Walk - Room 407, Philadelphia, PA 19146, USA (e-mail: dgrande@wharton.upenn.edu).

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