THE FUTURE OF THE PRESENT:

A LOOK AT CURRENT AND PROPOSED STATE LEGISLATURE TO REGULATE AND DISCLOSE GIFTS

By Jessica Wapner

How is the regulation on the practice of gift-giving affecting pharma? While the focus seems to be on federal law, it is the individual states that are actively passing legislation to restrict the practice of gift-giving by the drug industry.

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If the *New York Times* article, “Doctors Reap Millions for Anemia Drugs” (May 9, 2007), which reported on physicians receiving rebates for anemia drugs, does not convey the public’s attitude toward the pharmaceutical industry clearly enough, the subsequent online readers comments leave nothing to the imagination. “Another example of how corporate greed dictates our quality of life,” one commenter said, “An outrage,” said another. “Disgusting,” said one more. One would-be congressional candidate said his motive for running for office is “directly related to the raping of consumers by the drug industry.” A handful of posts defended physicians and called out the *New York Times* on some questionable reporting, but the overall tone was clear: The pharmaceutical industry—Big Pharma—is bad and needs to be stopped.

This negative perception is one of the reasons behind an increasing amount of proposed and enacted state legislation set out to regulate certain practices of the pharmaceutical industry. Among the targeted practices is that of gifts provided as part of detailing. A survey published in the *New England Journal of Medicine* reported that 83% of the 3,167 physicians who responded receive food gifts in the workplace as part of their interactions with the pharmaceutical industry (Campbell EG et al. 2007;356:1742-1750).

Another survey of disclosure statements of 83 pharmaceutical companies conducted in 2005 by Marketech Inc. found an average annual spending limit per healthcare professional of $1,561 (median, $1,500). The Pharmaceutical Researchers and Manufacturers of America (PhRMA) issued guidelines for this type of marketing in 2002; in 2003, the Health and Human Services Office of the Inspector General (OIG) issued its own guidelines as well.

However, asserting that these guidelines are vague, not strong enough, or not being followed, several state politicians want the practice of gift-giving to be regulated by state laws. These laws aim to limit the permitted value of gifts given to physicians by sales reps and/or require disclosure of what was given when to whom and why. Politicians say that such laws are necessary in order to ensure the public of unbiased medical judgment and to potentially reduce drug costs.

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In the past few years, several such laws have been passed. Many more are currently making their way through state legislatures. The laws supposedly stem from the concern that gift-giving influences subsequent prescribing methods and that a doctor who receives a gift—pens, chocolate, dinner—from a company is more likely to prescribe that company’s drug over another company’s competing drug.

But although these new laws purport a tightening of the reins for pharma, studies show that their effectiveness is questionable at best. Thus far, the greatest impact of the regulations seems to be the logistical nightmare they pose for the pharmaceutical industry. Furthermore, the motive behind the laws may not be what it seems.

Enacting Disclosure Laws

To date, 8 states have enacted laws requiring the disclosure of marketing and advertising spending for pharma companies. Included among the activities to be disclosed is gift-giving. In Minnesota, statute 151.461

says that the total value of gifts given to any single practitioner may not exceed $50 per year. Gifts, as defined by the state, include "money, real or personal property, a service, a loan, a forbearance or forgiveness of indebtedness, or a promise of future employment…" This definition also includes modest meals, cash payments for participation in marketing surveys, and anything else totaling over $50 in value.

In addition to regulating the value of gifts, states such as Vermont and Minnesota require public disclosure of said gifts. Pharmaceutical companies are required to report to a central state-run database any gifts they give to physicians. This database is made available to the public and, theoretically, allows an individual to find out what gifts his or her doctor may have accepted and from what companies. In Vermont, the attorney general issues an annual report on disclosed expenditures. For example, the fourth report, for fiscal year 2006 notes that 81 companies spent a total of $2.25 million on fees, travel, and other marketing-related expenses (with 69% of that total going to psychiatrists). Per Vermont law, the amount stated in the report does not include the many payments that are exempt from disclosure requirements.

Perhaps California's Health and Safety Code §19400–19402 law is the best known. Any pharmaceutical company that markets in the state is required to follow a Comprehensive Compliance Program (CCP) to ensure compliance with the OIG guidelines and PhRMA's Code on Interactions with Health Care Professionals. Specifically, pharmaceutical companies must:

- set a dollar limit on gifts given to doctors and other healthcare professionals
- declare compliance with their CCP and the California bill in writing
- make their CCP and declaration of compliance available for the public online
- provide a toll-free telephone number for obtaining copies of the CCP and written declaration

The result of this legislation is a testament to the long arm of the law as declarations of compliance can now be found on the websites of every pharmaceutical company whose drugs are marketed in California. Entire departments have been formed around this issue, each with a Chief Compliance Officer and a staff given the specific responsibility of monitoring compliance. In addition, the department must handle any complaints to the contrary. The websites note the maximum amount that the companies allow to be spent on an individual doctor in a given year (e.g., AstraZeneca: $1,900; Novartis: $2,500; Pfizer, $2,500; Bristol-Myers Squibb: $1,500).

Evolving Problems and Challenges

In practice, perhaps not surprisingly, the new laws have run into some problems. First, back to the definition of gifts. Several exceptions leave enough gray areas to fill a lifelong prescription. For example, Minnesota practitioners serving on the faculty for an

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