

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.

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

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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 educational conference or meeting can be given meals. In addition, according to an online FAQ document published by the state (www.phcbrd.state.mn.us/forms/giftsfaq.pdf) a meal is not considered a gift if the doctor is providing “substantial [cont. on pg 24 >>](#)

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professional and consulting services as part of a genuine research project.” Meals under \$50 are of course also permitted. Free drug samples that are intended for patient distribution are exempt as is payment of reasonable compensation or reimbursement made in connection with clinical trials. Unrestricted grants made in connection with Continuing Medical Education are also exempt.

Another gray area concerning gifts is the trade secret loophole. Several states note that when reporting gift expenditures, the doctor’s name does not need to be disclosed if the doctor is working with the company on research that could be considered a trade secret. Since, by definition, a trade secret is just that—a secret—it is difficult to confirm the accuracy of reports. Furthermore, the definition of trade secret is broad. Any interaction pertaining to clinical trials could qualify as a trade secret—an aspect with obvious relevance to oncology. For example, gifts related to patient recruitment for clinical trials or postmarketing surveillance might be allowed under the trade secret clause.

Yet, another gray area concerns the varying interpretations that laws tend to invite. For example, what if a doctor treats more than one therapeutic area? Some companies seem to consider this a reason for increasing the maximum allowable amount to be spent per year.

A study published in the *Journal of the American Medical Association* (Ross JS et al. 2007;297:1216-1223) demonstrates the layers of challenges and potential ineffectiveness of the new laws. The investigators analyzed publicly available data on gifts given to doctors in Vermont and Minnesota. The stated

objective of the study was to “determine the accessibility and quality of the data...and to describe the prevalence and magnitude of disclosed payments.” The findings showed that 61% of reported payments in Vermont were not made accessible because they were classified as trade secrets.

Accessing the records for the study proved tedious work: in Vermont, this required heavy negotiation with the attorney general’s office; while in Minnesota, where the bill was signed into law 14 years ago, it meant manual photocopying of individual disclosures. The records showed that the median gift amount in Vermont was \$177 (range, \$100–\$20,000) and in Minnesota the median payment was \$1,000 (range, \$100–\$922,239).

Another tangled thread of the new laws pertains to how states want companies to report gift activities. Creating a single database within a company is difficult, let alone creating one that is structured to comply with the different laws in each state. “It’s not something [companies] have carved out in [their] budgets,” notes John Mack, editor and publisher of the online magazine *Pharma Marketing News*. Such a database needs to track the amount spent on any given physician and also needs to perform some kind of alert function that tells when the limit for that doctor’s state has been reached. Further, the system would need to track the specific type of payment. Needless to say, there is resistance in the corporate community to this kind of internal database. “The pharma industry does not want to systematize this and have records that can become public by a court case,” says Mack. “It’s a very touchy area.”

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It is difficult to clearly measure the effectiveness of the laws, since a concrete figure regarding the amount spent on gifts annually by pharmaceutical companies is unattainable. However, based on the *JAMA* report, it would appear that it may take some time for states to build the infrastructure needed to properly administer these new laws.

Still, companies must comply. Budgets for tracking mechanisms have been increased so that financial relationships, even those involving as little as \$25, can be documented and publicly disclosed. The lack of standardization among the laws of different states makes streamlining such mechanisms nearly impossible, but everyone from senior management to junior salespeople is being educated about tracking these expenses.

The wear is beginning to show. As vague or confusing as the laws may be their impact on the pharmaceutical industry is quite tangible. “These new laws have triggered a variety of course adjustments in the marketing and sales practices for most companies,” says Paul Ross, Chief Compliance Officer at Onyx Pharmaceuticals. “The heightened awareness in the industry now borders on paranoia due to a legal landscape that lends itself to the creation of lucrative opportunities for whistleblowers.” As Ross explains, Qui Tam (whistleblower) lawsuits are becoming more commonplace because the requirement to limit and disclose gifts has simply created more circumstances for those wishing to profit from a company’s violations. As required by law, the compliance pages on pharmaceutical corporate websites encourage anyone with concerns about violations to approach internal company management.

In addition, as this issue becomes increasingly prominent, organizations such as No Free Lunch (www.nofreelunch.org), a registry and advocacy group for physicians who have voluntarily given up accepting gifts from pharmaceutical sales reps, are seeing increasing enrollment. It may be that the media coverage and publicity associated with these laws will have as great an impact—if not greater—than the law itself.

However, one reason for the evolution of ethical marketing laws goes deeper than public perception of the pharmaceutical industry. “The impetus lies in the Deficit Reduction Act and efforts to reduce overspending in the Medicare/Medicaid system,” Ross surmises. It seems that government crackdown on pharmaceutical marketing practices may be a response to the assertion that misleading marketing can lead to a violation of The False Claims Act. This law is designed to protect the government against fraudulent billing: off-label promotion contributes to physician off-label usage, which in turn results in the submission of a false reimbursement claim to the Medicare system. “Prosecutors connect the dots and directly attribute the cause of the fraudulent claim, and thus, damages to the company engaged in off-label marketing,” says Ross. In Ross’s opinion, this is one of the primary drivers for the heightened scrutiny.

Unfortunately, all companies have to bear the burden of these new laws, regardless of whether they had anything to do with the circumstances leading to their creation. “For those companies operating well within the limits of the law like Onyx, it has created many logistical reporting challenges to which the company may not have [cont. on pg 26 >>](#)

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been otherwise subjected,” says Ross. Also, even though larger pharmaceutical companies tend to spend more on the types of gifts being restricted, all companies, regardless of their size, have to spend just as much on their compliance infrastructure. Furthermore, many state laws propose penalties of up to \$10,000 per reporting violation, an amount that may mean much less to a large company than it does to a small one.

An increasing number of states are considering legislature to regulate gifts (see sidebar). Ross estimates that the number of states with these laws may triple in the near future.

Regarding CME Grants

Importantly, some of the proposed legislation regarding marketing disclosures includes CME grants. For the most part, it appears that legislators currently acknowledge the need for medical education and are thus unlikely to significantly interfere with the conduct of these activities, as long as certain criteria are met that establish independence of the program from the influence of the sponsoring company. However, medical education branches of pharma companies may want to keep abreast of the new bills as they wend their way through state legislatures over the next couple of years, particularly in light of the Senate Finance Committee’s recommendations, issued earlier this year, for creating better checks and balances in the grant-making process (www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf).

Final analysis

Currently, the bills being considered trend toward requiring disclosure of gifts valued

above a specified dollar amount, typically \$25. Some states are considering banning gifts altogether (see sidebar), but it may be that this more severe action will take a back seat to disclosure, a gauntlet that some legislators may see as easier to run through the tricky landscape of politics. Some states have considered disclosure laws that would preserve the anonymity of the doctors. If the purpose of the law is to help prevent potential bias in prescribing practices resulting from gifts, then one can certainly question the usefulness of disclosing the amount spent if the doctor remains anonymous.

As may be evident, although numerous bills are circulating through various legislative committees across the country, the slow pace of government may allay some concerns.

In addition, enmity between political parties and pharmaceutical lobbying both impact the legislative process.

The lack of stringency, the multiple gray areas, and the complicated reporting systems all conspire to dampen the impact these laws could have. “There is no enforcement and there are lots of loopholes, so it’s not really going to make much of a difference” says John Mack of the already approved laws. “It’s really an administrative headache for pharmaceutical companies.”

However, as long as distrust of the pharmaceutical industry persists, along with the possibility of False Claims Act allegations, states will continue to try to do something about it. The issue has also reached the federal level. The “Physician Payment Sunshine Act of 2007” was introduced by Senator Charles Grassley of Iowa with multiple

cosponsors this past September. For the time being, the success in actually making this information available to the public may

hardly seem worth the effort it requires of the pharmaceutical industry. But across the country, states may eventually get their Acts together. **W**

A Sampling of Bills Currently Under Consideration

In Illinois, bill number HB872, the Prescription Drug Ethical Marketing Act, would require disclosure of the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit related to detailing or promotional or other marketing activities.

In Massachusetts, House bill 2197 is a broad legislative initiative that would place a ban on gifts altogether. Another bill, house bill 2251 heard on September 12, 2007, by the Joint Committee on Public Health, requires disclosure of gifts and other items given by pharmaceutical companies to doctors and other healthcare professionals.

In New York, the Pharmaceutical Drug Manufacturer and Wholesaler Disclosure Act (A03794, also numbered S2971 and A7468) would require disclosure of gifts (with no limit on gifts being imposed) along with the creation of a publicly available guidebook on gifts made to healthcare providers.

And, in Oregon, bill HB2523, which requires disclosure of gifts, was killed by its supporters in the hope that the action would allow HB2648, which prohibits gifts entirely, could move forward.

Table 1 provides a partial list of other states with bills under consideration.

Table 1. Other Proposed State Legislation

State	Bill Number	Link to Bill Text
Arizona	SB1519	www.azleg.gov/legtext/48leg/1r/bills/sb1519p.pdf
Connecticut	SB1189	www.cga.ct.gov/2007/TOB/S/2007SB-01189-R00-SB.htm
Hawaii	SB816	www.capitol.hawaii.gov/session2008/bills/SB816_HD1_.htm
Mississippi	SB2107	billstatus.ls.state.ms.us/documents/2007/html/SB/2100-2199/SB2107IN.htm
Nebraska	LB675	uniweb.legislature.ne.gov/FloorDocs/Current/PDF/Intro/LB675.pdf
New Jersey	S2660	www.njleg.state.nj.us/2006/Bills/S3000/2660_11.pdf
Texas	SB414	www.capitol.state.tx.us/tlodocs/80R/billtext/pdf/SB00414I.pdf
Washington	SB5917	www.leg.wa.gov/pub/billinfo/2007-08/Pdf/Bills/Senate%20Bills/5917-S.pdf
Wisconsin	AB12	www.legis.state.wi.us/2007/data/AB-12.pdf



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