

STATE MARKETING DISCLOSURE LAWS

The Unintended Consequences



by Sarina D. Rivera, Esq.

In the state of Colorado, Nobel Prize winning professors are prohibited from collecting their monetary awards. The children of public employees cannot accept monetary scholarships. University employees are not allowed to receive aid from the Make-A-Wish Foundation or the Red Cross.

In the name of transparency, laws are being enacted in states such as Colorado with the goal of curbing the marketing practices of pharmaceutical companies. These laws may, however, impose onerous unintended consequences upon the academic and medical communities.

The first law requiring pharmaceutical companies to disclose the costs associated with marketing and detailing healthcare professionals was enacted by Minnesota in 1993,¹ spawning similar laws in three other states and the District of Columbia. In the first quarter of 2007, 15 states² introduced gift disclosure legislation. Many of the bills, however, are modeled after the Vermont law, enacted in 2002, that imposed reporting requirements on all pharmaceutical manufacturers engaged, either directly or indirectly through their sales representatives, in the marketing and direct promotion of pharmaceutical products to individuals authorized to prescribe in the state. At the conclusion of the 2007 legislative session, more states may be joining the ranks of Maine, Minnesota, Vermont, West Virginia and the District of Columbia.

Vermont's Law

Vermont's marketing disclosure law³ was enacted in 2002 to require pharmaceutical companies to publicly report promotional gifts and payments to healthcare professionals. Specifically, the statute requires pharmaceutical companies to annually disclose to the state board of pharmacy the "value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit" provided "in connection with detailing, promotional or other marketing activities by the company, directly or through its pharmaceutical marketers," or to any "physician, hospital, nursing home, pharmacist, health benefit

plan administrator or any other person in Vermont authorized to prescribe, dispense or purchase prescription drugs."⁴

The law exempts the following from disclosure: 1) free samples of prescription drugs intended to be distributed to patients; 2) payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials; 3) any gift, fee, payment, subsidy or other benefit valued at less than \$25; 4) scholarship or other support for medical students, residents and fellows to attend a significant educational, scientific or policy-making conference of a national, regional or specialty medical or other professional association if the recipient is selected by the association; 5) unrestricted grants for continuing medical education; and 6) prescription drug rebates and discounts.⁵

Each pharmaceutical company subject to the law must report the required information by December 1st for the 12-month period ending June 30 of the preceding fiscal year.⁶ The statute authorizes the Vermont Attorney General to file a civil suit for an injunction, costs and attorneys' fees against companies that fail to disclose the required information.⁷ Additionally, companies that fail to disclose also may be subject to a civil penalty of up to \$10,000 for each violation.⁸

On January 8, 2007, Vermont's Attorney General announced that he had entered into a settlement agreement with a pharmaceutical company charged with failing to report marketing costs for the 2003-2004 reporting period.⁹ As stated by the Attorney General, "With this settlement, pharmaceutical manufacturers are now on notice that the Vermont

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Attorney General's Office will be vigilant in our enforcement of the marketing disclosure law."¹⁰

Disclosing Gifts to Doctors

To date, four states—Maine, Minnesota, Vermont, West Virginia—and the District of Columbia, have enacted statutes that require the disclosure of gifts to physicians. Like the Vermont and Minnesota laws, these statutes generally require disclosure of the value, nature and purpose of gifts and other marketing activities, and exempt from disclosure the provision of free drug samples, payments for work on clinical trials and scholarships for medical education sponsored by a professional association. The District of Columbia differs in that it does not exempt free drug samples from its definition of “gift.”¹¹ Additionally, Minnesota's statute also contains provisions *prohibiting* certain gifts to healthcare professionals, and the trend toward gift bans is gaining momentum.¹²

Unlike Vermont and Minnesota, California does not impose a traditional gift disclosure or prohibition requirement on pharmaceutical companies. California has adopted a more flexible approach requiring companies to establish a Comprehensive Compliance Program (CCP) and annually declare their compliance with the Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Guidance) and the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals (PhRMA Code).¹³ Each company must establish in its CCP a specific annual dollar limit on gifts, promotional materials, or items or activities that the company may give or provide to an individual healthcare professional in accordance with the OIG Guidance and PhRMA Code.¹⁴

Targeting Drug Makers

Most recently, Louisiana and Colorado have enacted laws that impact pharmaceutical companies' interactions with public officials in those states. The confusion that ensued after these laws were enacted demonstrates how overly broad legislation can be interpreted in ways that the original drafters may not have intended.

In 2006, the Louisiana Board of Ethics (Board) issued two advisory opinions interpreting the state's Code of Governmental Ethics.¹⁵ The Code requires “lobbyists” to register with the board of ethics and file disclosure reports detailing

all expenditures incurred during the course of “lobbying.”¹⁶ Lobbying, in Louisiana, is “any direct act or communication with an executive branch official, the purpose of which is to aid in influencing an executive branch action.”¹⁷ The first Board opinion clarified that the definition of “executive branch action” included the educational and marketing activities of pharmaceutical representatives directed toward physicians practicing or affiliated with public hospitals, (i.e., executive branch officials).¹⁸ The second Board opinion held that pharmaceutical drug samples constituted “things of economic value” that public health officials (i.e., practitioners with privileges at public hospitals), could not accept.¹⁹

The opinions caused widespread concern throughout the pharmaceutical industry. Activities that had been considered common practice were suddenly “lobbying” and thus subject to the disclosure requirements or, in the case of receiving drug samples, flatly prohibited. Within months, the Louisiana legislature passed two new laws. The first law²⁰ amended the definition of “executive branch action” to exclude the

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acts of licensed healthcare professionals and the second law²¹ amended the definition of “thing of economic value” to exclude pharmaceutical drug samples. The law, however, still requires pharmaceutical representatives who “lobby” members of the Medicaid Pharmaceutical and Therapeutics Committee for the purpose of inclusion on a formulary to disclose marketing costs.²²

Confusion in Colorado

Like the Louisiana lobbyist disclosure law, Colorado's Amendment 41, and its subsequent interpretation, has been greeted by confusion. Colorado's Ethics in Government Law, Amendment 41, amended the state constitution to prohibit public officials, from accepting any thing of value from a “person” having either a fair market value or aggregate actual cost greater than \$50 dollars, including gifts, loans, rewards, promises or negotiations of future employment, favors or services, honoraria, travel, entertainment, or special discounts.²³ The law would additionally prohibit “professional lobbyists” (e.g., pharmaceutical representatives) from providing public

officials, including healthcare providers employed by state run hospitals, with “any gift or thing of value of any kind or nature.”²⁴ The law exempts remuneration given in exchange for lawful consideration.²⁵

Colorado AG’s Opinion

Similar to the events that took place in Louisiana, the Colorado Attorney General’s Office issued an opinion²⁶ addressing questions posed by University of Colorado President Hank Brown. In the opinion, the Attorney General concludes the following:

- ▶ *University employees may not receive monetary recognition from sources other than the employee’s employer, such as the financial component of the Nobel Prize.* Colorado’s law prohibits government employees from accepting gifts, unless lawful consideration is given in exchange for the gift. The opinion clarifies that past performance (i.e., conduct made prior to the subsequent consideration), is not lawful consideration. Therefore, the Nobel Prize and other similar awards may not be accepted if based solely on prior conduct.
- ▶ *Neither university employees, nor their dependents, may receive scholarships.* Using the same rationale applied to monetary recognition, the opinion concludes that scholarships based solely on the past performance of the recipient would be prohibited.
- ▶ *University employees may not receive a gift from someone who is not a relative or personal friend.* The opinion uses the examples of aid from a private or nonprofit entity connected to severe illness or disaster, such as the Make-A-Wish Foundation or the American Red Cross. According to the opinion, “As unfortunate as it may seem, poor drafting of the measure likely prohibits such gifts.”²⁷

The Attorney General concludes the opinion by expressing the hope that the “legislature will ultimately refer a corrective measure to the ballot, thereby giving voters the opportunity to narrow the measure specifically to those items intended to have a corrupting influence over public officials.”²⁸ The Louisiana legislature was quick to respond to the tumult caused by its own law by reversing the board’s interpretation. It remains to be seen if the voters will address this issue in Colorado.

The Louisiana and Colorado measures seek to promote ethical standards and transparency in government by limiting physician and pharmaceutical representative interactions. The practical consequences of such laws, however, are that inter-

actions that would otherwise be beneficial to the academic and medical communities are also being limited.

Universities Tighten Rules

The trend towards imposing bans on gifts to physicians has even made its way to some of the country’s most prestigious hospitals and universities. For example, in June of 2006, Stanford University School of Medicine adopted a policy and guidelines for interactions with industry representatives for medical staff, faculty, staff, students and trainees. Pursuant to the policy, University personnel are prohibited from accepting gifts, including items of nominal value such as pens and notepads.

The policy, however, does not stop at prohibiting gifts. Sales and marketing materials from pharmaceutical and device companies cannot be left with medical faculty or staff. According to the University’s Q&A on the policy, “The reason for this is to avoid any expectation on the part of the company, and to ensure that we do not promote a company or its products to our patients. If information about a product is needed, then this information may be obtained online or through the library.”²⁹

*The University policy also prohibits the pharmaceutical industry from paying for educational brochures that would be provided to patients. The Q&A acknowledges that such materials “may be valuable to patients,” but asserts that such materials could be “perceived as promotional, or create a sense of obligation for the department.”*³⁰ The policy would also prohibit industry representatives from distributing free drug samples for the benefit of needy patients. According to the policy, free drug samples that are given directly to healthcare professional are “personal gifts.”³¹ The policy does, however, allow industry representatives to distribute samples to the University’s pharmacies.

A number of other hospitals and universities, including University of California-Davis, University of Pennsylvania, University of Michigan and Yale School of Medicine have proposed similar policies that also would limit pharmaceutical representative and faculty interactions.

Conclusion

As marketing disclosure laws gain national prominence, states will continue to introduce measures designed to protect the integrity of the practice of medicine by requiring disclosure of relationships between healthcare professionals and pharmaceutical manufacturers. Unfortunately, as these

laws are applied, activities that would otherwise benefit and advance America's healthcare system are being stymied.

Industry groups, such as PhRMA, argue that recently implemented industry standards and guidelines governing the provision of gifts to healthcare professionals—for example, the PhRMA Code and the American Medical Association Guidelines—make gift disclosure measures unnecessary. The feverish rate at which such legislation is being introduced, however, demonstrates the belief among the state legislatures that self-imposed industry standards are insufficient. As this debate rages on, companies must continue to monitor states laws and be prepared to adjust their marketing practices for the unexpected. ▲



¹ Minn. Stat. 151.47(f)(1993).
² The following states have introduced gift disclosure legislation: Arizona, Connecticut, Hawaii, Massachusetts, Nebraska, Nevada, New Hampshire, New Jersey, New York, Oklahoma, Oregon, Rhode Island, Texas, Washington and Wisconsin.
³ Vt. Stat. Ann. tit. 33, § 2005 (2002).
⁴ *Id.* at § 2005(a)(1).
⁵ *Id.* at § 2005(a)(4)(A-F).
⁶ *Id.* at § 2005(a)(1).
⁷ *Id.* at § 2005(b).
⁸ *Id.*
⁹ Complete text of the press release available at: <http://www.atg.state.vt.us/display.php?pubsec=4&curdoc=1242>. (Last visited Mar. 19, 2007).
¹⁰ *Id.*
¹¹ D.C. Code § 48-833.03(a)(2)(D).
¹² Minn. Stat. 151.461 (2004).
¹³ Cal. Health & Safety Code § 119402 (2005).
¹⁴ *Id.* at § 119402(d).
¹⁵ La. Rev. Stat. Ann. § 49:71-78 (2004).
¹⁶ *Id.* at § 49:74(A).
¹⁷ *Id.* at § 49:72(6).
¹⁸ See Louisiana Ethics Board Docket No. 2005-560, Jan. 17, 2006. Complete text of the opinion available at: <http://domino.ethics.state.la.us/Rulingsa.nsf/34f11fd546943b1b862567f900759946/e742a68ea52532b2862570fa0064aa42?OpenDocument>. (Last visited Mar. 19, 2007).
¹⁹ See Louisiana Ethics Board Docket No. 2005-560, (Feb. 10, 2006).
²⁰ See Louisiana Senate Bill 320 (2006).
²¹ See Louisiana House Bill 1203 (2006).
²² See Louisiana Senate Bill 320 (2006).
²³ See Article XXIX of the Colorado Constitution (hereinafter "Amendment 41") (2006). The term "person" is broadly defined in Amendment 41 to mean "any individual, corporation, business trust, estate, trust, limited liability company, partnership, labor organization, association, political party, committee, or other legal entity." *Id.* at Section 2(4).
²⁴ See Amendment 41 at Section 3(4). This provision of Amendment 41 prohibits a specific type of "person", i.e., the "professional lobbyist" from providing a public official with any gift, regardless of value.
²⁵ *Id.*
²⁶ Complete text of Colorado Attorney General's Office letter available at: http://www.ago.state.co.us/press_releases/lettertohankbrownrea41.pdf (Last visited Mar. 19, 2007).
²⁷ *Id.*
²⁸ *Id.*
²⁹ Complete text of the policy available online at: <http://med.stanford.edu/col/siip/faqs.html>. (Last visited Mar. 19, 2007).
³⁰ *Id.*
³¹ *Id.*

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