

Article Reprint # 52-02

What Pharma Companies Spend on Gifts to Docs

State Laws Require Declarations

By **John Mack**

According to the February 17, 2006, Daily Health Policy Report published by Kaisernetwork.org (a service of the Henry J. Kaiser Family Foundation), "at least nine states are considering bills that would require pharmaceutical companies to publicly report annual gifts to physicians, hospitals and pharmacists... Maine, Minnesota, Vermont, West Virginia and the District of Columbia currently have laws requiring the reporting of gifts. California requires that drug companies declare they are in compliance with federal and industry gift guidelines. Many of the state proposals under consideration this year are modeled after the Vermont law, enacted in 2002, which requires drugmakers to report to the state's attorney general all gifts of \$25 or more given to doctors, hospitals or pharmacists."

The California Health & Safety Code §119402 was enacted in 2005 as required by the passage of Senate Bill 1765 in August, 2004 (see "[No More Free Lunch in California?](#)"). Some details of

Vermont's Pharmaceutical Marketing Disclosure Law are presented below.

Vermont Law

Vermont law 33 V.S.A. § 2005 requires registration and financial disclosure by pharmaceutical manufacturing companies and pharmaceutical marketers.

The following information must be disclosed to the Vermont Office of the Attorney General: "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, 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 in this state. Disclosure shall include the name of the recipient." (33 V.S.A. §2005(a)(1))

<i>Item</i>	<i>Average</i>	<i>Median</i>
General educational gifts per person (items that primarily benefit the patient)	\$112	\$100
Higher end gifts per person (textbooks, anatomical models, etc.)	\$230	\$263
"Reminder" (branded) items per person (coffee mugs, notepads, pens, etc.)	\$19	\$25
Breakfast per person	\$38	\$25
Lunch per person	\$53	\$50
Dinner per person	\$114	\$125
Annual spending limit per person	\$1,561	\$1,500

TABLE 1: Marketech, Inc. surveyed the disclosure statements of 83 pharmaceutical companies in 2005. This research specifically looked at the annual spending rates as per California Health & Safety Code 119400-119402. All information was obtained from public postings on the Internet.

What is exempt from disclosure?

The following are exempt from disclosure:

- free samples of prescription drugs intended to be distributed to patients;
- the payment of reasonable compensation and reimbursement of expenses in
- connection with bona fide clinical trials;
- any gift, fee, payment, subsidy or other economic benefit the value of which
- is less than \$25.00;
- 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 of the
- scholarship or other support is selected by the association;
- unrestricted grants for continuing medical education programs; and
- prescription drug rebates and discounts.

Unrestricted grants for CME are exempt because they are not considered "marketing" or "promotional" under the statute. An unrestricted grant is "any gift, payment, subsidy, or other economic benefit to an educational institution, professional association, health care facility, or governmental entity which does not impose any restrictions on the use of the grant, such as favorable treatment of a certain product or an ability of the marketer to control or influence the planning, content, or execution of the education activity."

Non-prescribing Office Staff Also Covered

The Attorney General of Vermont will treat gifts to an office or office staff as gifts to the prescriber. The following example is offered: If the gift is a \$60 luncheon for an office of two physicians and three non-prescribing office staff, the gift amount is to be divided per prescriber, or \$30 each and is reportable. The gift may not be divided by five and considered as five separate and un-reportable \$12 gifts. That's a loophole closed!

Pharma Compliance with Reporting Requirements

Pharmaceutical companies have complied with these laws by adopting comprehensive compliance programs, posting notices on their web sites declaring their compliance with the laws, and, in many cases, also posting the dollar limits and amounts spent on reportable gifts to physicians.

Marketech, Inc., a company that specializes in staff training, strategic exhibit market planning, measurement and consulting, surveyed the disclosure statements of 83 pharmaceutical companies in 2005. This research specifically looked at the annual spending rates as per California Health & Safety Code 119400-119402. All information was obtained from public postings on the Internet (see TABLE 1, pg. 1).

The following are excerpts from selected pharmaceutical compliance notices found on company sites. Most companies reported a "limit" as distinct from an "average" amount actually spent.

Bristol-Myers Squibb: limit = \$1,500

"...with respect to business activity in California, BMS has established "a specific annual dollar limit on gifts, promotional materials, or items or activities that [BMS] may give or otherwise provide to an individual medical or health care professional." This annual dollar limit is \$1500. This limit primarily reflects dollars expended in association with programs designed to inform prescribing health care professionals about BMS products and the disease states these products help treat. It is important to note that this annual dollar limit is an upper limit. It is not an accurate representation of the average value of gifts, promotional materials, items or activities that BMS, a global pharmaceutical and related health care products company with many different divisions, medicines, and sales forces, may provide annually to a typical individual medical or health care professional. That average value, would be a significantly lower amount."

Pfizer: limit = \$2,500

"Subject to the law, the annual aggregate limit on covered promotional expenditures is \$2,500 per covered medical or health care professional for annual periods commencing on July 1, 2005. This limit may be revised by Pfizer from time to time."

Gifts: "The PhRMA Code allows pharmaceutical companies to provide "items primarily for the benefit of patients" and "items of minimal value . . . [that] are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar 'reminder' items with company or product logos)" if they are not" offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices." Given that these items have only nominal value, our annual aggregate limit on certain promotion-related expenditures excludes the provision of items

permissible under the PhRMA Code as being of minimal value and primarily associated with a healthcare professional's practice."

Promotional Materials: "Neither California SB 1765, nor the PhRMA Code, nor the OIG Guidance defines 'promotional materials.' For purposes of this Statute, Pfizer presumes that promotional materials are not materials that, under the PhRMA Code, form the basis of our interactions with medical and health care professionals. Accordingly, Pfizer does not include in its definition of 'promotional materials,' documents and information that inform medical or health care professionals about Pfizer products, provide scientific and educational data, or support medical research and education."

Other Items or Activities: "California SB 1765 also subjects to the per-medical or health care professional annual aggregate limit all other 'items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the [OIG Guidance] and with the [PhRMA Code].' We include, among other items in this category, the retail cost of meals provided to covered medical or health care professionals in connection with educational presentations. Historically, Pfizer has not limited attendance at these educational events. The per-medical or healthcare professional annual aggregate limit on certain promotional expenditures reflects Pfizer's commitment to responsible education and reasonable facilitation of attendance at educational programs in California. To comply with California SB 1765, Pfizer will monitor and limit, if necessary, the number of educational presentations medical or health care professionals may attend in any one year to ensure compliance with the annual aggregate limit."

Novartis: limit = \$2,500

"Although NPC has low promotional spend on average (<\$100 per licensed medical or health professional) in California and comprehensive controls to address specific risks related to pharmaceutical marketing and sales practices, NPC has established a specific annual dollar limit of \$2,500 per medical or health professional in California on promotional materials, healthcare practice items, and activities in accordance with Cal. Health & Safety Code §119402."

"Consistent with similar pharmaceutical marketing laws (e.g., Vermont, Maine, D.C.), certain items (e.g., plastic pens, small post notepads) or activities (e.g., in-office food or beverage provided

on an occasional basis) of limited value (less than \$25) will not be included in NPC's annual dollar limit."

AstraZeneca: limit = \$1,900

"AstraZeneca has established, as part of its comprehensive compliance program, an annual dollar limit concerning appropriate items covered by the California law ("Covered Items") that are provided to individual California medical and health care professionals as part of AstraZeneca's interactions with these professionals to enhance the practice of medicine and benefit patient care. Some examples of these Covered Items include medically-relevant items, such as medical textbooks and physician desk reference books, or modest meals provided in connection with AstraZeneca's efforts to advance the professionals' understanding of the efficacy, safety, and benefits of AstraZeneca's products. AstraZeneca's annual dollar limit is \$1,900 per individual health care professional."

Procter & Gamble Pharmaceuticals" limit = \$1,000

"P&GP has established an annual limit for meals and gifts that can be provided to an individual health care professional in California of one-thousand dollars (\$1000)."

Meals: "P&GP may provide modest meals to healthcare professionals on an occasional basis, but only if such meals are accompanied by a presentation regarding our products or a relevant disease state. The "modesty" of a meal will be established relative to local standards, but should generally not exceed \$75 per person. P&GP should not pay for meals for spouses of healthcare professionals."

Gifts of Educational and Practice-Related Items: "P&GP can provide occasional gifts to healthcare professionals, as long as such gifts primarily benefit patients (e.g., anatomical models or diagnostic instruments) and are helpful to the healthcare professional's medical practice. The market value of these items must be \$100 or less. Branded "premium" items of nominal value (less than \$15) such as pens and notepads may also be provided to healthcare professionals."

Entertainment, Recreational or Social Events: "P&GP may not pay for the attendance of healthcare professionals at entertainment or recreational events (e.g. at concerts or shows, sporting events, to play a round of golf, drinks at a bar). In legitimate fee for service arrangements (e.g., consulting services) with healthcare

professionals, limited entertainment, recreational or social events in conjunction with these services are permitted, provided they are otherwise compliant with this policy as it relates to those activities, and clearly subordinate to the provision of the services to P&GP by the healthcare professional.”

Educational or Research Grants: “P&GP may provide grants for continuing medical education programs. P&G will fund educational programs through appropriate organizations (e.g., established CME providers) and institutions (e.g., hospital CME departments), and will not pay individual healthcare professionals (e.g., a faculty member for a CME program) to provide these educational programs. P&GP can provide research grants to support investigator-initiated research in areas of legitimate interest to the company, provided that such grants requests are first reviewed by an appropriate scientific review committee at P&GP.”

Legitimate Fee for Service Arrangements: “P&GP can enter into fee for service arrangements with healthcare professionals, provided that such arrangements serve a legitimate bona fide need of P&GP, and provided that such fees reflect the fair market value for the services.”

Reimbursement of Travel Expenses of Healthcare Professionals: “P&GP will not pay for the travel expenses of healthcare providers who are attendees at promotional events or educational programs. In limited cases, P&GP may provide funds to medical schools to support the attendance of fellows at independent medical meetings, provided that the selection of the individuals who will attend (and benefit from the P&GP funds) is done by the medical school and not P&GP. Healthcare providers in legitimate fee for service arrangements with P&GP (e.g., consultant services) may receive reasonable reimbursement for associated travel costs.”

Organon: limit = \$2,040 (calculated on a yearly basis)

“Organon has established a spending limit for marketing activities directed toward healthcare professionals in California of \$850.00 for the period July 1-December 31, 2005. As set forth in the California Law, this limit expressly does not include samples, grants for medical education, scholarships, and consulting services.”

Centocor: limit = \$2,500

“Centocor has established an annual limit of \$2,500 for meals and educational or practice-related item as the aggregate value of the items or

activities that may be provided to California healthcare professionals...”

Policy on Business Meals: “Centocor occasionally may offer a modest meal as part of an educational presentation or a business discussion. The appropriate focus of these activities is directed to an informational presentation or discussion; therefore, venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted. Modesty is to be judged by local standards, but in general cost of meals with customers should not exceed \$25 for breakfast, \$50 for lunch or \$125 for dinner.”

Policy on the Provision of Educational and Practice-Related Items: “On occasion, Centocor representatives may provide patient or practice-related items to customers. These items must be of reasonable value (less than \$100) and infrequent.”

“Promotional items of nominal value (less than \$25) such as coffee cups, pens, and notepads are permitted under Centocor policy. These items usually feature a company or product logo.”

Policy on Travel Expense Reimbursement for CME, Promotional, or Product Training Meetings: “Centocor will not, with very limited exceptions that are in accordance with nationally recognized standards, reimburse for travel and lodging expenses of attendees at promotional and educational programs.”

Pharma Marketing News

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