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## No More Free Lunch in California?

California Legislature Passes SB 1765: Requires Pharma Companies to Comply with PhRMA and OIG Guidelines

By **John Mack**

The pharmaceutical industry has often been accused of lavishing gifts and free meals on doctors with the intention of influencing their prescribing decisions. That is the premise, for example, of a report published recently by the California Public Interest Research Group (CALPIRG) entitled "Tis Always the Season for Giving."

The report cites research conducted by Dr. Margaret Chren of the University of California, San Francisco, which concluded that "physicians were more likely to have requested drugs manufactured by specific companies if they had met with pharmaceutical representatives from those companies or had accepted money from those companies."

CALPIRG claims that to increase their chances of face time with a doctor, drug reps come armed with more than a few pens and notepads. They bring chocolates and watches and offer expensive meals and trips. The cost of these freebies, claims CALPIRG, is passed on to the consumer in higher prices paid for drugs. "The bottom line," said Emily Clayton, CALPIRG's Healthcare Associate and author of the report, "is our drugs don't have to cost as much as they do. If drug companies stopped trying to influence prescription-writing by giving gifts to our doctors, then consumers, insurers and the government could all save money on prescription drugs."

### Voluntary Guidelines

Of course, several voluntary private, government, and industry guidelines have been developed to address the concerns raised by the practice of gift giving. These include:

- "Gifts to Phys: Ethical Guidelines for Gifts to Physicians From Industry," American Medical Association,
- "Compliance Program Guidance for Pharmaceutical Manufacturers," Office of the Inspector

General (OIG) of the Department of Health and Human Services, and

- "Code on Interactions with Healthcare Professionals," Pharmaceutical Research and Manufacturers of America.

According to CALPIRG, "Without binding legislative action, there is no way to guarantee or monitor compliance with any set of guidelines or recommendations" and companies can easily "skirt" the guidelines without fear of repercussion. Accordingly, CALPIRG sponsored SB 1765 (aka, "fair drug marketing bill") in the California Senate that would require pharmaceutical companies – and also any person who engages in pharmaceutical promotional activities on behalf of a pharmaceutical company – doing business in California to "adopt and update a Comprehensive Compliance Program (CCP) for interactions with health care professionals." SB 1765 would make adherence to voluntary guidelines mandatory.

Other organizations supporting SB 1762 include:

- AARP California
- AIDS Healthcare Foundation
- American Federation of State, County, & Municipal Employees
- California Labor Federation
- Consumer Federation of California
- Consumers Union
- Health Access California
- Senior Action Network
- Service Employees International Union
- Western Center on Law and Poverty

On August 30, 2004, the California Senate passed SB 1765 and sent it to Governor Schwarzenegger for signing.

### Provisions of the Bill

To comply with SB 1765, which if signed into law, would become effective on July 1, 2005, pharmaceutical companies and any "person who engages in ... promotional activities or other

marketing of a [prescription] drug in [California] on behalf of a pharmaceutical company” to:

1. adopt and update a CCP for interactions with health care professionals that is in accordance with existing PhRMA and OIG guidelines,
2. include in its CCP the specific limits on gifts or incentives provided to medical or health professionals,
3. establish explicitly in its CCP a specific annual dollar limit on gifts, promotional materials, or items or activities that the “pharmaceutical company” may give or otherwise provide to an individual medical or health care professional in accordance with existing PhRMA and OIG guidelines,
4. annually declare in writing that they are in compliance with their CCPs and the limits on gifts or incentives provided to medical or health professionals established by the bill, and
5. make its CCP and its annual written declaration of compliance with the program available to the public on the pharmaceutical company's Web site and also provide a toll-free telephone number where a copy/copies of the CCP and written declaration of compliance may be obtained.

#### Exemptions

SB 1765 specifically exempts from any limits the following types of “gifts” popular with physicians:

- drug samples given to physicians and healthcare professionals intended for free distribution to patients,
- financial support for continuing medical education forums, and
- financial support for health educational scholarships
- payments made for legitimate professional services provided by a health care or medical professional, including, but not limited to, consulting, provided that the payment does not exceed the fair market value of the services rendered

#### Agencies Also Affected

According to the Senate analysis, PhRMA is opposed to this bill saying that it may result in extensive, expensive and unnecessary litigation. It doesn't seem that PhRMA waged an all-out campaign to defeat this bill. Perhaps PhRMA members really have little to fear – they probably already have comprehensive compliance programs in place. However, agents acting on behalf of pharma companies in California, who are also subject to this bill, may not have CCPs in place nor understand the ramifications. So it may be time for you to bone up on this law as well as the PhRMA and OIG guidelines.

#### Schwarzenegger in a Tight Spot?

CALPIRG now accuses drug companies of using the same gift-giving tactics with Governor Schwarzenegger, presumably intending to influence his upcoming decisions about several prescription drug bills on his desk, including SB 1765. Clayton noted that Pfizer, Amgen, and Abbott Laboratories helped pay for the governor and his staff to fly to the Republican National Convention in New York and contributed to the reception he held there for California delegates.

“SB 1765 gives Governor Schwarzenegger the opportunity to stand up to one of the powerful special interests in Sacramento, the drug industry,” added Clayton. “He campaigned on this, and now he has his chance.”

**Pharma Marketing News**

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#### Resource List

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The following resources were consulted in the preparation of this issue or cited within this issue.

“New Report Shows Drug Manufacturers Use Gifts, Travel and Meals to Influence Doctors”, CALPIRG. See [http://calpirg.org/pdfs/White\\_Paper\\_-\\_Detailing1.pdf](http://calpirg.org/pdfs/White_Paper_-_Detailing1.pdf)

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#### Pharma Marketing News

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