

October 2004

New California Law Requires Pharmaceutical Companies to Adopt Corporate Compliance Programs

On September 30, 2004, California Governor Arnold Schwarzenegger signed a new law that requires pharmaceutical companies to adopt corporate compliance programs that are consistent with the previously voluntary corporate compliance guidelines and industry standards marketing incentives for healthcare professionals. See Senate Bill 1765, *to be enacted* Cal. Health & Safety Code §119402 *et seq.* The statute, effective July 1, 2005, *requires* pharmaceutical companies to implement a Comprehensive Compliance Program in accordance with the voluntary guidelines published by the United States Department of Health and Human Services Office of Inspector General (“HHS OIG”) and Pharmaceutical Research and Manufacturers of America (“PhRMA”). In particular, the statute mandates that pharmaceutical companies establish a Corporate Compliance Program that (1) sets forth internal policies governing company interactions with healthcare providers; and (2) establishes dollar limits for gifts and other marketing incentives for “medical and health professionals.” The statute also establishes specific reporting requirements with which companies must comply.

According to the legislation’s sponsors, the new law is intended to make pharmaceutical companies’ marketing practices more transparent, as well as address a public perception of inappropriate relationships between healthcare providers and pharmaceutical companies. The highlights of this statute are set forth below.

I. Adoption of Mandatory Corporate Compliance Program

The new law will require every pharmaceutical company to adopt a Corporate Compliance Program in accordance with the HHS OIG’s 2003 Guidance, *Compliance Program Guidance for Pharmaceutical Manufacturers*. All compliance programs must also include policies in accordance with the PhRMA 2002 *Code on Interactions with Health Care Professionals*. Companies must also ensure that their programs are updated within six months of any updates made to either guidance. See Cal. Health & Safety Code § 119402 (a)-(b) (2004) (effective July 1, 2005). The law applies to all companies who pursue or have existing contacts with medical or health professionals in California (e.g., companies with sales representatives who market to doctors in California).

II. Requirements Surrounding Gifts and Incentives

The legislation requires pharmaceutical companies to establish explicit guidelines for the specific annual dollar amount that may be spent on gifts, promotional marketing materials, or any

other items or activities that the company may provide for “medical or health professionals.” See Cal. Health & Safety Code § 119402(d)(1) (effective July 1, 2005).

The following forms of support are exempt from such monetary restrictions *if provided in conformity to both the HHS OIG’s 2003 Guidance and the PhRMA 2002 Code*:

- Drug samples given to medical or health professionals that are intended for free distribution to patients;
- Financial support for continuing medical education forums;
- Funding provided for health educational scholarships; and
- Payments for legitimate professional services provided by a medical or health professional including, but not limited to, consulting services, provided that such service does not exceed the fair market value of the services rendered.

III. Additional Compliance Obligations

In addition to providing guidelines, the legislation requires drug companies to adopt the following mechanisms designed to ensure greater public knowledge of compliance efforts:

- Provide an annual written declaration confirming compliance with their respective compliance programs and state law;
- Provide public access to their compliance programs by posting both the compliance program and the written declaration on the company website; and
- Provide a toll-free number where copies of the compliance program and the written declaration of compliance may be obtained.

See Cal. Safety & Health Code § 119402(e) (effective July 1, 2005).

IV. Key Definitions

The scope of the new law turns on a number of terms that are defined as follows:

Dangerous drug: “[A]ny drug that is unsafe for self-use and includes either of the following: (1) Any drug that bears the legend ‘Caution: federal law prohibits dispensing without prescription,’ ‘Rx only,’ or words of similar import[;] (2) Any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. ‘Dangerous drug’ does not include labeled veterinary drugs.”

"Medical or health professional "(1) A person licensed by state law to prescribe drugs for human patients; (2) A medical student; or (3) A member of a drug formulary committee."

Pharmaceutical company: "[A]n entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. 'Pharmaceutical company' also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. 'Pharmaceutical company' also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a pharmaceutical company. 'Pharmaceutical company' does not include a licensed pharmacist."

V. Enforcement

There are no separate enforcement provisions in the statute to address violations. However, failure to comply with the provisions of this statute may subject a company to a lawsuit under California's "Unfair Competition Law" ("UCL"). The UCL is a broadly-worded (and widely used) statute that permits both government and private citizens to bring a suit against "any unlawful, unfair or fraudulent business act or practice" in addition to false or misleading "advertising." Cal. Bus. & Prof. Code § 17200 *et seq.* The UCL has been wielded against pharmaceutical companies in the past; and it would not be surprising if a government agency and/or private citizens used this law to challenge companies' compliance with the new corporate compliance program law. Successful plaintiff's can recover civil penalties, attorneys fees ,and costs under the UCL.

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If you have questions about the new California law, or would like assistance in responding to its requirements, please do not hesitate to contact us:

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