



**The Pharmaceutical /
Health Care Practice of
Sidley Austin Brown & Wood LLP**

Our Pharmaceutical Industry/Health Care Practice represents participants in all facets of the health care industry, including pharmaceutical companies, pharmacies, manufacturers of dietary supplements, and medical device companies. Our lawyers combine a strong background in the complexities of health care financing and delivery, including coding, reimbursement, and coverage issues, privacy and security, trade regulation, and competition. We have extensive experience representing drug and device manufacturers on enforcement and regulatory matters before the Food and Drug Administration, the Centers for Medicare and Medicaid Services, the Office of the Inspector General for the Department of Health and Human Services, Federal Trade Commission, and state enforcement agencies.

**For further information on the
Practice, please contact:**

Paul E. Kalb
202.736.8050
pkalb@sidley.com

Jim C. Dechene
312.853.7275
jdechene@sidley.com

Bill Sarraille
202.736.8195
wsarraille@sidley.com

To receive future copies of the
Pharmaceutical Industry Alert via
email, please send your name,
company or firm name and email
address to jyeh@sidley.com

This **Pharmaceutical Industry Alert** has been prepared by Sidley Austin Brown & Wood LLP for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

**New Amendment to Maine Drug Price
Reporting Requirement Revises CEO
Certification Requirement; Additional
Maine Disclosure Law Passed**

The State of Maine recently amended 22 Me. Rev. Stat. § 2698-B, the Maine statute requiring pharmaceutical manufacturer's to make quarterly disclosures of pricing information to the State (Drug Price Reporting Law). In a separate action, Maine also passed a law related to (1) clinical trials conducted or sponsored by pharmaceutical manufacturers, and (2) pharmaceutical manufacturer advertisements.

Amendment to Drug Price Reporting Law

The Drug Price Reporting Law currently requires manufacturers to report certain pricing information to the State, and further requires the manufacturer's president or chief operating officer (CEO) to certify the information submitted to the state is accurate. The amendment modifies the certification requirement so as to permit the certification to be signed by the CEO, other chief officer, or an employee of the manufacturer "in a position that reports directly to the [CEO] or chief financial officer who has been delegated authority to sign" on behalf of the CEO or chief financial officer. See 2005 Me. ALS 402. The Maine Governor's Office of Health Policy and Finance (Governor's Office), which has been working closely on laws applicable to pharmaceutical manufacturers, indicated that the change to the certification requirement is intended to track the certification requirements related to the federal Medicaid price disclosure requirements.

In addition, the Drug Price Reporting Law was also amended to eliminate reporting and certification requirements for disclosures related to average wholesale price (AWP) and wholesale acquisition cost (WAC). Average manufacturer price (AMP) and best price (BP) must still be reported on a quarterly basis. The elimination of reporting and certification requirements for AWP and WAC was not unexpected, as the Maine Bureau of Medical Services (Bureau) previously issued a letter to pharmaceutical manufacturers indicating that AWP and WAC pricing information need not be reported. A June 30, 2005, mailing from the Bureau to pharmaceutical manufacturers indicated that pricing information can be submitted electronically at www.mainearepdl.org.

Although the Drug Price Reporting Law amendment was enacted as an emergency amendment (and therefore should have taken effect immediately upon passage on June 17, 2005), the Governor's Office has indicated that the amendment will take effect on September 15, 2005. Until that time, manufacturers are expected to submit quarterly certifications signed only by the CEO or president. As a legal matter, it is not clear that the emergency amendment did not take effect upon passage, however, it would be most prudent to submit a second quarter certification by either the CEO or president.

Disclosure Law Related to Clinical Trials

Beginning on October 15, 2005, pharmaceutical manufacturers required to disclose marketing costs pursuant to 22 Me. Rev. Stat. § 2698-A (the Maine marketing disclosure law) will be further required to disclose, with regard to those prescription drugs, the following information with respect to any clinical trial conducted or sponsored in *any* jurisdiction by the manufacturer on or after October 15, 2002: (1) the name of the entity that conducted the clinical trial, (2) a summary of the purpose of the clinical trial, (3) the dates during which the trial took place, and (4) information concerning the results of the trial, including potential or actual adverse effects of the drug (the Clinical Trial Disclosure Requirement). The required information must be posted on either the National Institutes of Health (NIH) website or any other publicly accessible website. *See* 2005 Me. ALS 392. Because the law is limited to those drugs for which the manufacturer reports marketing costs to the State of Maine, a reasonable interpretation of the law suggests that manufacturers need only report clinical trial information with respect to drugs which are FDA-approved and should not be required to report clinical trial information regarding drugs under development (*i.e.*, "pipeline" drugs).

Additionally, beginning April 1, 2006, the Clinical Trial Disclosure Requirement requires manufacturers providing drugs to Maine residents through various state payor

programs to pay to the State a fee of \$1,000 per company per calendar year in order to support the State's activities related to 2005 Me. ALS 392.

Violations of 2005 Me. ALS 392 are deemed violations under the Maine Unfair Trade Practices Act. The law provides that each day a manufacturer is in violation of a requirement is considered a separate violation.

The Maine Clinical Trial Disclosure Requirement raises important issues as to the relationship of state and federal law. Many clinical trials are subject to oversight by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FDCA). *See, e.g.*, 21 U.S.C. 355(i); 21 C.F.R. part 312. As a general matter, the FDCA contemplates that information generated from clinical trials of new drugs will be provided to patients after FDA reviews the data and incorporates them into labeling. The health care practitioner plays a central role in this system by ensuring that information about drug risks is provided to patients in the context of a discussion of its benefits. The practitioner also, unlike FDA, can forecast the risk-benefit profile for the particular patient (as opposed to populations). In this system there is arguably no room for communication of clinical trial results directly to the public.

The Requirement also raises issues under the Supremacy Clause and, potentially, the Commerce Clause. Additionally, even if the scope of the requirement were limited to Maine, the reporting obligation is ambiguous with respect to cooperative trials, IST trials that may include financial support from multiple manufacturers, and Phase I trials that are typically not reported on the NIH website.

The State of Maine also recently passed another law related to the transparency of clinical trials. This law requires the Maine Department of Health and Human Services (Department) to "study the accessibility of information regarding the results of certain clinical trials of pharmaceuticals, treatment options and medical devices and

the enrollment of certain persons in those trials.” See 2005 Me. ALS 77. The law further requires the Department to “post on its website links to public information regarding clinical trials of pharmaceuticals, treatment options and medical devices” by November 15, 2005. Although there are no requirements for manufacturers under this law, manufacturers should be aware of the Department’s efforts with respect to transparency of clinical trial activities.

New Requirement Regarding Regulated Advertisements

Beginning October 15, 2005, pharmaceutical manufacturers may not “present or cause to be presented in the State a regulated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations.” 2005 Me. ALS 392. “Regulated advertisement” is defined by the new law as “the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is (1) broadcast on television or radio that is physically

located in the state; (2) broadcast over the internet from a location in the state; or (3) printed in magazines or newspapers that are printed, distributed or sold in the state.” *Id.* Given that the new regulated advertisement provision applies only to advertisements presented to the “general public,” it appears the law is limited to only direct-to-consumer advertising, and does not affect advertisements directed toward healthcare professionals. The State of Maine, however, has not yet provided clarification on this point.

The new regulated advertisement requirement is contained in the same law that contains the Clinical Trial Disclosure Requirement. As with the Clinical Trial Disclosure Requirement, violations of the regulated advertising provision are deemed violations under the Maine Unfair Trade Practices Act.

★ ★ ★ ★ ★

Pharmaceutical manufacturers should continue to monitor state legal developments carefully with the assistance of their counsel to ensure compliance.

The affiliated firms, Sidley Austin Brown & Wood LLP, a Delaware limited liability partnership, Sidley Austin Brown & Wood LLP, an Illinois limited liability partnership, Sidley Austin Brown & Wood, an English general partnership and Sidley Austin Brown & Wood, a New York general partnership, are referred to herein collectively as Sidley Austin Brown & Wood.



SIDLEY AUSTIN BROWN & WOOD LLP
AND AFFILIATED PARTNERSHIPS

BEIJING BRUSSELS CHICAGO DALLAS GENEVA HONG KONG LONDON LOS ANGELES
NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE TOKYO WASHINGTON, D.C.

www.sidley.com

* * *

If you have any questions regarding this Alert, please contact any of the Sidley attorneys listed below.

Washington, D.C.

Bill Sarraille	202.736.8195	wsarraille@sidley.com
Paul E. Kalb	202.736.8050	pkalb@sidley.com
Patrick Morrissey	202.736.8228	pmorrissey@sidley.com
Greer O. Lautrup	202.736.8117	glautrup@sidley.com
John Wester	202.736.8162	jwester@sidley.com
James C. Stansel	202.736.8129	jstansel@sidley.com
Eileen L. Kahaner	202.736.8599	ekahaner@sidley.com
Anna L. Spencer	202.736.8445	aspencer@sidley.com
Dan E. Troy	202.736.8304	dtroy@sidley.com
Coleen Klasmeier	202.736.8132	cklasmeier@sidley.com
Julie A. Muroff	202.736.8341	jmuroff@sidley.com
Peter V. Lindsay	202.736.8991	plindsay@sidley.com
Spencer K. Turnbull	202.736.8247	sturnbull@sidley.com
Jennifer Razor	202.736.8544	jrazor@sidley.com

Chicago

Jim C. Dechene	312.853.7275	jdechene@sidley.com
Karen O. Dunlop	312.853.2223	kdunlop@sidley.com
Meena Datta	312.853.7169	mdatta@sidley.com
Lara Leniton Liss	312.853.0579	lliss@sidley.com

San Francisco

Hae-Won Min	415.772.1227	hmin@sidley.com
George E. Kenny	415.772.7459	gkenny@sidley.com

Los Angeles

Kimberly A. Dunne	213.896.6659	kdunne@sidley.com
Julie A. Paluch	213.896.6000	jpaluch@sidley.com

The affiliated firms, Sidley Austin Brown & Wood LLP, a Delaware limited liability partnership, Sidley Austin Brown & Wood LLP, an Illinois limited liability partnership, Sidley Austin Brown & Wood, an English general partnership and Sidley Austin Brown & Wood, a New York general partnership, are referred to herein collectively as Sidley Austin Brown & Wood.



SIDLEY AUSTIN BROWN & WOOD LLP
AND AFFILIATED PARTNERSHIPS

BEIJING BRUSSELS CHICAGO DALLAS GENEVA HONG KONG LONDON LOS ANGELES
NEW YORK SAN FRANCISCO SHANGHAI SINGAPORE TOKYO WASHINGTON, D.C.

www.sidley.com