ABBOTT SETTLEMENT INCLUDES UNPRECEDENTED TERM OF PROBATION, MANDATORY COMPLIANCE MEASURES

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To Our Clients and Friends:

On May 7, 2012, the U.S. Justice Department ("DOJ") announced that Abbott Laboratories ("Abbott") pleaded guilty to a misdemeanor under the Food, Drug, and Cosmetic Act and agreed to pay $1.5 billion to resolve criminal and civil liability relating to allegations of off-label promotion of the prescription drug Depakote. Abbott also entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS-OIG").

These components of Abbott's settlement have become relatively standard in DOJ settlements with pharmaceutical companies. However, in a departure from past DOJ practices, the Abbott plea agreement not only incorporates several compliance requirements more typically found in CIAs, but, more importantly, imposes on Abbott court-supervised probation for a period of up to five years. This new development has a number of potential ramifications for drug and device companies.

CONDITIONS OF PROBATION

Abbott's plea agreement subjects the Company to several probationary conditions, including that the Company not commit any health care fraud offenses or felonies during the term of probation. In addition:

- The CEO must annually review the Company's compliance program and certify to a probation officer that, to the best of his or her knowledge, the Company has satisfied the compliance requirements in the plea agreement.
- The Board of Directors must annually review the Company's compliance program and submit to the probation officer a resolution stating that, to the best of its knowledge, the Company has policies and procedures in effect designed to prevent off-label promotion.
- The Company must periodically submit to the probation officer a report of any instances that a reasonable person would consider a probable violation of laws against off-label promotion ("Reportable Events"). A Reportable Event will not be considered a *per se* probation violation, but the probation officer will consider the following factors in determining whether a violation has occurred: (*i*) whether the event violated the Company's policies; (*ii*) whether the Company provided applicable training; (*iii*) whether the event was

an isolated or systemic occurrence; and (*iv*) the Company's response to the event and whether remedial actions were taken.

Additionally, if the Company is found to have breached the plea agreement, it can be prosecuted for the conduct covered by the settlement. Moreover, if probation is revoked, the Company can be resentenced and incur a fine of up to $300 million.

COMPLIANCE MEASURES IN PLEA AGREEMENT

The plea agreement requires that the Company continue to maintain certain policies and procedures designed to ensure compliance with FDA regulations. These include:

- Sales representative compensation must not incentivize off-label promotion.
- Decisions about funding Continuing Medical Education ("CME") grants must be made independently of the sales and marketing departments; CME grants may be provided only for programs that foster "increased understanding of scientific, clinical or health care issues"; and third-party CME providers must retain full responsibility and control over program content and faculty, among other things.
- Medical letters communicating information about the Company's products to health care professionals must be accurate and unbiased, and Company policy must prohibit the prompting of requests for such letters.
- Clinical trials funded or controlled by the Company must be approved by medical or scientific personnel; similar to CME grants, research and publications resulting from clinical trials must foster "increased understanding of scientific, clinical, or health care issues"; and scientific research must not be approved solely for the purpose of developing an article or reprint for use by sales representatives.
- Clinical investigators must disclose Abbott's support and any financial relationships with the Company, and the Company must maintain a policy to ensure that publications are developed in a transparent and consistent manner and report complete and accurate results with a discussion of a study's strengths and limitations.

RAMIFICATIONS

These unique aspects of the Abbott settlement have a number of implications, not the least of which is the prospect of another layer of regulatory oversight: in addition to the FDA, HHS-OIG, and the court in which the plea agreement was reached, the Company is now subject to oversight by a probation officer who will scrutinize the Company's compliance with its conditions of probation, will have discretion to determine whether there has been a violation, and can bring a violation proceeding in the event of such a determination.

There are two additional key takeaways that companies should focus on.

Upping the Ante on Compliance Programs. First, over the past ten years, the federal government's health care enforcement actions have transformed compliance programs in the pharmaceutical and medical device industries. By incorporating compliance requirements into Abbott's plea agreement, DOJ has again upped the ante. The threat that inadequate compliance measures may lead to a breach of a plea agreement and further prosecution and fines obviously provides heightened incentives to the subject company to implement an effective compliance program. Although the requirements incorporated into Abbott's plea agreement are fairly common aspects of many modern compliance programs, it is prudent for companies to consider reviewing their policies and procedures against those specified in the Abbott plea agreement and to consider whether to implement comparable measures.

Continued Focus on CEO and Director Oversight Role. Second, the Abbott settlement underscores the government's continued focus on what it views as the critical compliance oversight function and responsibility of senior executives and directors. Beyond the threat of a *Park* prosecution or health care program exclusion, the inclusion of CEO and director reporting requirements in the Abbott plea agreement is another way to incentivize CEOs and directors to take an active role in compliance, and provides DOJ with another means by which to hold these individuals responsible for the conduct of company employees. Further, the board reporting requirement largely mirrors a requirement in Abbott's CIA and in other CIAs, and provides an additional reason for company boards to perform—often with the assistance of outside advisors—careful and robust program effectiveness reviews.

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Please do not hesitate to call us if you have any questions or wish to discuss this development in greater detail.

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