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A New Era Of Post-Plea Compliance Obligations

Law360, New York (September 24, 2013, 9:56 AM ET) -- An important trend is emerging in pharmaceutical settlements with potential long-term ramifications for any company in the government's crosshairs. Now, even if a company pays millions or even billions of dollars to secure a resolution and bring closure to a costly multiyear U.S. Department of Justice investigation, it may nevertheless find itself in a long-term relationship with the DOJ that includes ongoing oversight and the risk of additional penalties. That is the new reality facing life sciences companies grappling with whistleblower-initiated government investigations.

The Justice Department has embarked on a new practice of demanding increasingly onerous post-plea compliance terms in health care fraud resolutions above and beyond those included in the corporate integrity agreements (CIA) imposed by the Health and Human Services (HHS) Office of Inspector General (OIG). Signs from the DOJ indicate that this new type of post-plea compliance obligation running directly to federal prosecutors will be a staple of health care fraud settlements going forward.

Because these continuing obligations imposed by the DOJ typically emerge from closed-door negotiations prior to the entry of a plea, they develop outside the confines of case law — in the context of a "common law" of settlements. While the roots of this new trend date back to Guidant's plea agreement in 2011, the DOJ significantly upped the ante with the post-settlement compliance measures it required as part of Abbott's $1.5 billion Depakote settlement in May of 2012.

Similar measures were included as part of GlaxosmithKline's landmark $3 billion settlement the following month. Notably, the DOJ demonstrated that these new measures are not reserved for large settlements when it required similar obligations in two much smaller resolutions with Par Pharmaceuticals and ISTA Pharmaceuticals earlier this year. All four cases warrant close scrutiny, as the DOJ will almost certainly use them as a baseline in future resolutions with life sciences companies.

This article discusses the emerging standard compliance terms included in the resolutions noted above. It then explores the impact of DOJ's newly asserted role on life sciences companies that enter into global civil and criminal settlements.

Emergence of a Trend

The Guidant case in 2011 marked the beginning of the DOJ's recent practice of seeking post-settlement compliance obligations. Ironically, however, the concept of placing Guidant on probation was driven by the court in that case, rather than the DOJ, which initially resisted the notion of probation. With the court leading the process — and perhaps due to the novelty of this approach — the Guidant compliance requirements were more limited than those included in more recent settlements. The Guidant probation terms require the company to:

1. ensure that any compliance program will adequately prevent or detect any further violations of law;
2. submit to regular and unannounced examinations of its records by the U.S. Probation Office;
3. provide quarterly notice of material developments involving certain devices; and
4. provide notice regarding any material changes in financial conditions.

Despite the DOJ's initial resistance to probation terms in the Guidant settlement, the court's insistence apparently triggered some rethinking at Main Justice's Consumer Protection Branch, as well as various United States Attorney's Offices around the country. Following Guidant, the DOJ began to impose more comprehensive terms in several of the settlements that followed.

The compliance obligations imposed on Abbott, GSK, Par and ISTA feature many similarities. Notably, in each of these cases except ISTA, the compliance requirements imposed by the DOJ were in addition to those included in lengthy CIAs. Although the obligations imposed by the DOJ and the OIG often overlap in significant respects, the imposition of onerous obligations running directly to federal prosecutors is a novel concept that leaves many unanswered questions.

To date, the DOJ has used two mechanisms to impose these new obligations. In the Guidant and Abbott cases, the terms were a condition of probation, which necessarily involves the oversight by the Probation Department, an arm of the U.S. district court. In the GSK, Par and ISTA cases, the compliance terms were included as part of the plea agreements themselves, leaving the DOJ with greater enforcement control. Notably, the imposition of probation does not appear to be correlated to the size of the criminal fine or global settlement amount.

For example, the DOJ did not seek probation in the largest settlement of all, GSK's $3 billion global resolution last year. Instead, in both GSK and Par, the DOJ cited the inclusion of compliance measures in the plea agreements (as well as the CIAs) as specific reasons not to impose a period of probation. In ISTA, the DOJ's emphasis on the legacy nature of the conduct may have influenced it not to pursue probation in that case. The government expressly stated that "this Plea Agreement relates solely to the conduct of defendant ISTA prior to its acquisition by Bausch + Lomb on June 6, 2012." However, the existence of a CIA alone in Abbott was not enough to dissuade the DOJ from requiring a term of probation.

The DOJ and the companies involved in these types of matters may both prefer to avoid a term of probation. Compliance with conditions of probation are monitored by the Probation Office, which is designed to deal with individual defendants and thus may lack the infrastructure and experience to handle overseeing an extensive corporate compliance program. In addition to ceding control over the monitoring function, the DOJ may be wary of adding yet another party to the mix in case future disputes arise over whether a company has breached its compliance commitments. In the nonprobation agreements, it is the DOJ alone that adjudicates whether a violation has occurred and, on the basis of its sole judgment, imposes monetary sanctions.

Compliance Terms

The May 2012 Abbott settlement was the first resolution with extensive compliance terms and obligations outside the context of a CIA. The terms included in the subsequent GSK, Par and ISTA settlements built upon Abbott. Common terms include:

Annual Management Reviews & Certifications: Each of the four post-Guidant settlements requires an annual management review of the company's compliance program, followed by management certifications. The review and certification process must ensure that the compliance program continues to institute the policies, procedures, and other terms agreed to by the company. The nature of the

required certifications vary as they pertain to the conduct at issue in the settlement. For example, the Par agreement requires management to certify that, among other things, there have been no violations regarding "unlawful marketing." The ISTA agreement requires management to certify that the company's compliance program has been "effective in preventing violations of Federal health care program requirements and the Federal Food, Drug and Cosmetic Act regarding sales, marketing, and promotion of prescription pharmaceutical products." In the case of the GSK and Abbott agreements, the certifications also must specifically address compliance with the critical reportable event provisions, described in more detail below.

Annual Board of Directors Resolution: The Abbott, GSK and ISTA settlements also require the board of directors to conduct an annual review regarding the effectiveness of the compliance and ethics program as it relates to the marketing and promotion of pharmaceutical products. At a minimum, this review must include updates and reports from compliance personnel, including the chief compliance officer. The ISTA and GSK agreements require the board to then resolve that it has "concluded that, to the best of its knowledge, [the company] has implemented an effective Compliance Program." Notably, Abbott requires only a resolution that the company has in place policies designed to prevent violations.

Compensation Structure Modifications: The Par, GSK and Abbott settlements each require structural modifications to incentive-based compensation for sales representatives. The GSK settlement requires that sales compensation must be revised to "ensure that financial incentives do not inappropriately motivate prescriber-facing field sales professionals or their direct managers to engage in improper promotion, sales, and marketing of GSK's prescription pharmaceutical products." The GSK and Par agreements go on to specify that the companies must include mechanisms "to exclude from incentive compensation sales that may indicate off-label promotion of prescription pharmaceutical products," and that financial rewards or discipline not be linked to sales volume.

Notice to DOJ of Reportable Events: The GSK and Abbott settlements include a critical reportable "incident" or "event" provision requiring quarterly disclosures by the company to the DOJ of any "matter that a reasonable person would consider to be a violation" of the FDCA or related statutes. The term specifies that such incidents or events "may be the result of an isolated event or a series of occurrences." While reportable event terms have been a staple of CIAs for years, the notion of directly notifying federal prosecutors (who can quickly turnaround a subpoena) of every misstep by one of thousands of sales representatives or other personnel is quite unsettling. The agreements contain no limitations on what the DOJ can do with such information. It remains to be seen whether such provisions will trigger new DOJ investigations in response to these self-reported events.

Public Notification of Settlement: The GSK, ISTA and Par settlements each require the companies to directly notify health care providers about the settlement. The ISTA settlement specifies the language of the letter, which includes providing recipients a mechanism to report any concerns. ISTA must log any message received and disclose that log to the government annually. In addition to a notification letter, the Par settlement also requires a prominent website notification regarding the plea agreement that includes links to the settlement documents.

Separation of CME from Sales & Marketing: The Abbott, GSK and ISTA settlements require that continuing medical education (CME) grant decisions be made and approved by corporate functions separate from sales and marketing. The terms also require that independent CME providers be solely responsible for the content, faculty, educational methods, materials and venue.

Other noteworthy terms in these agreements include requiring the referral of all requests for information regarding off-label uses to Medical Affairs (GSK, ISTA), additional guidelines regarding scientific publications (Abbott, GSK), and ensuring separation of the research and sales functions (Abbott).

Enforcement Mechanisms

The enforcement mechanisms for the post-plea compliance terms mandated by DOJ vary based on whether a term of probation was imposed. In Abbott, where the terms are conditions of probation, violations provide the DOJ with the right to declare the plea agreement void, file new charges, and seek greater penalties. The court can also impose fines for probation violations.

By contrast, the plea agreement addendum compliance terms do not contain clauses that allow the DOJ to void the agreement for a violation. Instead, the agreements provide the DOJ with the sole, and non-appealable, right to determine if a breach of the agreement has occurred. Penalties for noncompliance range from $3,000 per day (ISTA) to $20,000 per day (Par and GSK). The agreements are in effect for three years in the case of ISTA, and five years in the case of Par and GSK.

Impact

Traditional CIAs result in oversight by the OIG, but the addition of compliance commitments directly to the DOJ could result in a one-two punch for companies that face two sets of overlapping obligations.

First, these companies will face the logistical burden of instituting a second set of compliance terms and adhering to multiple reporting requirements. Life sciences companies, many of whom are accustomed to working with OIG personnel and adhering to a single set of post-settlement compliance terms, will now face the burden of complying with two sets of terms being overseen by two sets of regulators. How the DOJ will exercise its newly asserted oversight role remains to be seen, introducing a host of post-settlement uncertainties.

Second, companies now face more severe consequences should they violate — or, in the eyes of the DOJ, be deemed to have violated — a compliance obligation owing directly to federal prosecutors.

The “reportable event” clause will pose a particular implementation burden for life sciences companies. Given the reporting requirements’ quarterly frequency, companies may need to institute enhancements to their compliance functions, particularly those covering internal investigations and monitoring. Companies will need to ensure that their structure and resources for conducting internal investigations will allow them to determine, in a robust and consistent manner, whether potential misconduct, in fact, qualifies as a “matter that a reasonable person would consider to be a violation of” the FDCA or similar statutes.

What the DOJ will do when confronted with a potential violation of a compliance term remains an open question. The DOJ has not spelled out the ramifications for violations beyond stipulated monetary penalties. Also left unanswered is whether violations might lead the DOJ to open new investigations. These are uncharted waters, and life sciences companies have little past practice to examine for guidance.

In cases where probation is instituted, even more ominous consequences loom. The violation of a probation term can result in the voiding of the settlement agreement, reassessment of any related fines, and new charges. The mere threat of such a nuclear option could be used by the DOJ to extract broadened terms, an extension of probation, or other onerous conditions.

What’s Next?

If the steady evolution of CIAs in past years is any analogue, the DOJ’s emergence in post-settlement compliance should not be dismissed as an aberration. The common law of health care settlements is incremental, with the government’s working assumption that tomorrow’s settlements will include at least as much as the DOJ obtained in yesterday’s resolution, perhaps with a few more bells and whistles.

Aggressive negotiation in the period before reaching an agreement in principle is imperative. For any company in the midst of settlement negotiations with the DOJ, or which contemplates such discussions, close scrutiny of these agreements — and those to come — is essential.

P. 1 Pullout: "The Justice Department has embarked on a new practice of demanding increasingly onerous post-plea compliance terms in health care fraud resolutions above and beyond those included in CIAs."

P. 3 Pullout: "DOJ demonstrated that these new measures are not reserved for large settlements when it required similar obligations in two much smaller resolutions with Par and ISTA earlier this year."

P. 2 No Pullout: see settlement summary below.

P. 4 Pullout: "If the steady evolution of CIAs in past years is any analogue, DOJ's emergence in post-settlement compliance should not be dismissed as an aberration."

Summary of Settlements Subject to DOJ Oversight

The Justice Department is increasing requiring post-settlement obligations as part of pharmaceutical settlements. The body of settlement precedent on which the DOJ will draw includes these four cases:

- Abbott Laboratories (May 2012): $1.5 billion global settlement for anti-kickback violations and misdemeanor misbranding, including off-label promotion of Depakote to treat aggression in dementia patients and schizophrenia. Compliance terms were included as conditions of a five-year term of probation.

- GlaxoSmithKline (June 2012): $3 billion global settlement for misdemeanor misbranding for unapproved uses of several pharmaceutical products and failing to report safety information to the FDA. Compliance obligations to the DOJ running for five years were included in the plea agreement.

- Par Pharmaceuticals (January 2013): $45 million global settlement for misdemeanor misbranding to promote use of Megace in non-AIDS patients. Allegations included deliberately targeting elderly patients despite known adverse side-effects and unsupported superiority claims. Compliance terms running to the DOJ for five years were included in the plea agreement.

- ISTA/Bausch + Lomb (May 2013): $33.5 million global settlement for kickback and felony misbranding charges, including allegations that ISTA employees were instructed by management to conceal certain physician interactions concerning off-label uses. Employees allegedly provided physicians with free ISTA products and other remuneration to induce referrals. Compliance terms lasting for three years were included in an addendum to the plea agreement. ISTA was purchased by Bausch + Lomb in the midst of the investigation.

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