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Stakes Are High For Companies Negotiating CIAs

Law360, New York (October 02, 2012, 1:27 PM ET) -- Large pharmaceutical companies continue to resolve health care fraud investigations with epic settlements. As the dollars climb, the corporate integrity agreements (CIAs) typically filed in connection with these settlements are becoming increasingly onerous and stringent enforcement tools. GlaxoSmithKline PLC's July 2012 $3 billion settlement with the United States Attorney's Office for the District of Massachusetts has garnered attention not only due to its size, but also because of the unprecedented compliance obligations set forth in the corresponding CIA.

The $3 billion fine — the largest health care fraud settlement between a drug company and the U.S. Department of Justice — resolves criminal and civil allegations relating to GSK's sales, promotional, and pricing practices. GSK's five-year CIA with the U.S. Department of Health and Human Services Office of Inspector General includes several novel provisions.

Perhaps the most significant is the "claw back" provision that requires GSK to recoup annual performance pay and other bonuses from certain current and even former executives when "triggering events relating to misconduct" occur. There are also more stringent training provisions, additional restrictions on how to respond to physician inquiries, and more burdensome policy requirements.

This CIA enforcement trend becomes even more imposing as the DOJ targets the same companies multiple times, investigating one product after another. Companies find themselves settling their second or even third investigation, in rapid succession. In doing so, they face what is now an increasingly common dilemma: How will a CIA signed pursuant to a new settlement impact CIA obligations that may already be in place?

Amended CIAs

Some subsequent settlements have resulted in either amendments or addenda to the original CIA. There does not appear to be a meaningful distinction between the terms "amendment" and "addendum" — both have historically extended the term of CIAs by a number of years and added new obligations. Recent examples of CIA amendments and addenda include: the 2011 Serono Addendum (three-year extension, plus new provisions); the 2011 CVS Caremark Amendment (one-year extension, plus new provisions); the 2006 Schering-Plough Addendum (two-year extension, plus new provisions); the 2005 GSK Addendum (two-year extension, plus new provisions); and the 2003 Bayer Addendum (three-year extension, plus new provisions). New provisions address a range of obligations, including training, independent review and executive accountability.

Very infrequently, an amendment or addendum will not result in an extension of the prior CIA, even though the OIG insists on new CIA terms. For example in May 2009, Aventis Pharmaceutical Inc. (API) paid $95.5 million to settle civil allegations that it misreported drug prices in order to reduce its Medicaid Drug Rebate obligations. In connection with the settlement, API signed an addendum that ran concurrently with the CIA put in place after an earlier settlement in 2007.

Superseding CIAs

A subsequent settlement sometimes resulted in a new, superseding CIA. For example in 2011, Merck Sharp & Dohme paid $950 million to resolve criminal and civil claims related to its promotion of the painkiller Vioxx. Three years earlier, in 2008, Merck and the OIG had entered into a CIA in connection with a separate settlement. In 2009, Merck merged with Schering-Plough which had amended its own CIA in 2006. Following the merger, in 2010, Merck adopted a “unified” CIA superseding each company’s pre-existing CIA. With the 2011 settlement, Merck and the OIG entered into a new superseding CIA.

No New Terms

On rare occasions, OIG has determined that a new settlement does not require modifications to an existing CIA. This occurred in 2007, when Pfizer Inc. settled civil and criminal claims of off-label promotion and kickbacks, after voluntarily disclosing the issues leading to the settlement to the relevant government agencies.

In the case of multiple settlements, in-house attorneys and their outside counsel should be prepared to negotiate with OIG’s over the following terms:

- extension of the time period covered by the CIA;
- broadening the scope of obligations to specifically address the conduct in the later settlement and incorporate OIG’s latest priorities;
- whether OIG will agree to “sunset” particularly onerous provisions when negotiating a subsequent resolution;
- the impact of a voluntary disclosure on whether or not there will be additional CIA terms imposed; and
- if any additional settlements are anticipated when negotiating a CIA, how best to avoid an amendment or addendum down the road.

There is no doubt, whatever strategy is pursued, that the current enforcement environment makes it a highly risky proposition for industry to renegotiate CIA terms. Counsel should proceed carefully and strategically.

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