K&L GATES

Food, Drugs, Medical Devices and Cosmetics Alert

November 2010

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FDA TO PROSECUTE MORE AGGRESSIVELY WITH MORE POTENT WEAPONS

Throughout 2010, FDA has been sending an unmistakable and chilling message. Criminal prosecution will become a much more important component of its enforcement program. Numerous officials have warned that the agency will seek to impose strict criminal liability on corporate officials who can be held responsible for violative conduct. Recently, FDA's litigation chief stated that such prosecutions were needed to increase general deterrence and that pharmaceutical and medical device companies and executives should not assume the agency will issue a warning before the initiation of a criminal proceeding.

This aggressive policy will be supported by a substantially enhanced enforcement arsenal. In the Patient Protection and Affordable Care Act, Congress included FDA violations in the definition of a "Federal health care offense." Although this designation appears relatively benign, it has enormous ramifications. Prosecutors now can use an FDA violation to charge serious offenses that previously were reserved for more traditional forms of criminal conduct. Investigative capabilities were supplemented to empower the government to use administrative-type subpoenas. The Sentencing Commission was directed to increase both financial penalties and periods of incarceration for FDA offenses. Debarment was extended to include controlling companies and individuals convicted under the strict liability approach.

In light of these developments, FDA's enforcement vigor threatens to imperil the liberty of executives operating in these regulated industries.

FDA'S AGGRESSIVE ENFORCEMENT POLICY

Government officials have issued a series of warnings that FDA would pursue criminal prosecutions more frequently and aggressively, and that many of these cases would employ the strict liability theory. Under this theory, the commission of any of the "prohibited acts" listed in Section 301 of the Federal Food, Drug, and Cosmetic Act (FDCA) can be used to support a misdemeanor prosecution. The government is required to prove only that a "prohibited act" occurred and that an individual was in a position of responsibility but failed to prevent or detect the misconduct. There is no requirement for the individual to have participated in or even to have been aware of the illegal activity. The prosecution is premised on the failure to prevent the violation. The Supreme Court has stated that the FDCA, "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will ensure that a violation will not occur."[i]

FDA's aggressive enforcement policy was announced by Commissioner Hamburg in March 2010. The Commissioner directed a letter to Senator Grassley responding to GAO criticism of FDA's oversight of criminal investigations. The Commissioner promised to "hold responsible corporate officials accountable" by increasing "the

appropriate use of misdemeanor prosecutions."

This was followed by Congressional testimony from Deborah Autor, who is the Director of Compliance for the Center for Drug Evaluation and Research (CDER). The Director stated FDA is moving toward greater use of criminal prosecution as an enforcement tool. She testified, "The agency is working to increase our enforcement on the criminal side and to connect carefully what we do on the criminal side with what we do on the civil side."

This message has not been confined to FDA representatives. An Assistant Attorney General of the Department of Justice stated DOJ would review investigations of off-label promotion "with a view to charging responsible individuals." The Chief Counsel to the HHS Office of the Inspector General stated, "To change the corporate culture, the OIG will focus more closely on holding individuals accountable for health care fraud."

This issue recently was addressed by Eric Blumberg, the Deputy Chief for Litigation in FDA's office of the Chief Counsel. Blumberg reviewed the enormous financial penalties that have been paid by pharmaceutical and medical device companies related to off-label promotion. FDA, however, has concluded these monetary fines have not adequately deterred companies and executives from illegal conduct. Accordingly, criminal prosecutions – especially of individuals – are required and justified. Blumberg specifically warned that more individuals would be prosecuted for improper off-label promotion. He noted that neither the FDCA nor FDA policy require a warning before a criminal investigation can be instituted and a prosecution pursued. In his view, FDA should issue fewer Warning Letters and pursue more prosecutions.

The government's repetition of this consistent theme does not leave any room for doubt – FDA will prosecute more aggressively and much of this emphasis will be directed against executives.

FDA'S ENHANCED ENFORCEMENT ARSENAL

FDA's more aggressive approach will be supported by substantially enhanced enforcement powers. In certain instances, the government now will be authorized to treat a violation of the FDCA in a manner similar to organized criminal activity. The Patient Protection and Affordable Care Act (PPACA) is commonly referred to as the health care reform statute. It addressed many aspects of payment for medical care. Buried in its provisions, however, were substantially increased enforcement powers.

The PPACA amended the section of the federal criminal code that defines a "Federal health care offense."[ii] This criminal provision was expanded to include the commission of any of the "prohibited acts" listed in Section 301 of the FDCA if that violation "related" to a health care benefit program. Similarly, a violation of the anti-kickback statute also was included in this definition.[iii]

This relatively benign amendment produces significant consequences. A conviction for a violation of the FDCA now can trigger a criminal forfeiture. The forfeiture statute provides, "The court, in imposing sentence on a person convicted of a Federal health care offense, shall order the person to forfeit property, real or personal, that constitutes or is derived, . . . from gross proceeds traceable to the commission of the offense." [iv] Thus, in addition to financial penalties imposed under the sentencing provisions, defendants now are subject to an additional payment reflective of the gross proceeds stemming from the questionable conduct.

Moreover, a violation of the FDCA now can support a charge for laundering of monetary instruments. The money laundering statute prohibits conducting a financial transaction involving proceeds of "specified unlawful activity." The definition of such activity includes "any act or activity constituting an offense involving a Federal health care offense." [v] A conviction for money laundering can result in a sentence of 20 years of incarceration.

The amendment to the definition of a "Federal health care offense" also subjects companies and individuals to prosecution for obstruction of a health care investigation. This broad and ambiguous statute addresses not only conduct that prevents or obstructs an investigation, but also that which misleads or delays. [vi] Certainly, the government is accorded substantial discretion to determine when an investigation has been "delayed."

The PPACA amendment also expands the government's investigatory authority. Because of the inclusion of a violation of the FDCA in the definition of a "Federal health care offense," the government now is empowered to use administrative subpoenas during the investigative stage. A grand jury investigation no longer is required before the government will be able to compel the production of documents and testimony. [vii]

Of course, no expansion of enforcement power would be complete without an increase in the penalties to be imposed. The PPACA also addressed this issue. It created a presumption that the amount of the "intended loss" from criminal conduct should be "the aggregate dollar amount of fraudulent bills submitted." [viii] This amendment becomes significant because the loss calculation drives the determination of the sentence, and often the funds actually received will be far less than the amount billed. The United States Sentencing Commission was instructed to increase the period of incarceration required by relatively low amounts of loss, and directed to ensure that sentences "reflect the serious harms associated with health care fraud."

This march toward more draconian enforcement decisions and penalties has been joined by the OIG of HHS. Recently, guidelines were issued addressing permissive exclusion of individuals. [ix] The guidelines state that individuals can be excluded based solely on their position in a sanctioned entity, irrespective of their knowledge of the problematic conduct. To be in jeopardy of exclusion, an individual does not have to be convicted of an offense or proven to have participated in or been aware of illegal activity. Clearly, the OIG intends to hold individuals accountable for corporate misdeeds.

There can be no doubt that pharmaceutical and medical device companies and their executives will be targeted more frequently and treated more harshly. If you would like to discuss the government's enforcement initiative or if you become involved in an investigation, please consider contacting us. K&L Gates has white collar criminal defense lawyers with extensive experience in FDA-related investigations and prosecutions. When appropriate, they can team with the firm's extensive FDA regulatory group to provide effective and experienced counsel and representation.

[i] *United States v. Park*, 421 U.S. 658 (1975)
[ii] 18 U.S.C. § 24
[iii] 42 U.S.C. § 1320a-7b
[iv] 18 U.S.C. § 982(a)(7)
[v] 18 U.S.C. § 1956(3)
[vi] 18 U.S.C. § 1518
[vii] 18 U.S.C. § 3486(a)(i)
[viii] United States Sentencing Guideline, § 2B1.1(b)(1)
[ix] Guidance for Implementing Permissive Exclusion Authority under § 1128(b)(15) of the Social Security Act (October 20, 2010)