

Corporate Compliance Officer— Gatekeeper or Jailbird



by John R. Fleder

Most companies long ago acknowledged the government's and the courts' expectation that corporations should institute corporate compliance programs as an important tool to ensure their compliance with all applicable federal and state laws and regulations. An essential element of such programs is the retention of one or more in-house employees, who are called Corporate Compliance Officers (CCO).¹

A recent court ruling demonstrates the severe legal risks to individuals who are given the title of CCO, and the companies that employ them, when the government and a court believe that the CCO has not properly fulfilled his or her duties as gatekeeper over the company's compliance obligations.

On October 16, 2006, a federal judge in Chicago issued what he called the seventh and final opinion in a criminal case styled *United States v. Caputo*.² The court sentenced the Chief Executive Officer (CEO) of a medical device manufacturer to a ten-year jail sentence. More noteworthy is that the judge sentenced the company's CCO to a six-year jail sentence. In addition to their prison sentences, both defendants were ordered to pay more than \$17 million in restitution to the hospitals they had allegedly defrauded.

The court observed that whereas the CEO "is one of many corporate CEOs who have recently been tried and convicted," the CCO "is one of only a few CCOs ever tried and convicted in federal court."³ The court expressed its "hope that the readers of this opinion will come to the realization that the ten- and six-year sentences imposed here are in large measure part of our country's efforts to create an atmosphere of general corporate crime deterrence."⁴

Caputo underscores the principle that any company regulated by the Food and Drug Administration (FDA) must have in place an effective compliance program that, among other things, establishes a CCO to implement and monitor

the program. However, the CCO's failure to properly carry out that program, and his or her involvement in conduct deemed to be unlawful by the government pose grave risks to the company and indeed to the CCO.

The Case against AbTox

AbTox, Inc. manufactured a sterilizer, which it marketed to hospitals for use in sterilizing reusable medical devices. Following an eight-week trial, a jury found that AbTox's CEO and CCO committed numerous violations of the Federal Food, Drug, and Cosmetic Act (FDCA). The following discussion summarizes the court's recent opinion.

The government alleged that AbTox's 510(k) premarket notification withheld adverse test results from FDA. Despite being informed of these test results, the CEO signed the first 510(k), and the CCO served as "editor-in-chief" of the various submissions and as the company's primary contact with FDA.⁵ Subsequent to receiving clearance from FDA to market the device, AbTox marketed a sterilizer that had significantly different design and technological characteristics for uses beyond the scope of the clearance.

In response to a further 510(k) for the new uses, FDA sent AbTox a major deficiency letter followed soon thereafter by a warning letter. The court found that the company nonetheless continued marketing its uncleared sterilizer to hospitals and developed a strategy to vigorously promote the device for off-label use. Upon receiving notice from an AbTox salesperson that the company's marketed device had resulted in several situations that caused a rare and serious eye injury, the CCO failed to conduct an investigation or file Medical Device Reports (MDR). When ordered by FDA to file MDRs, the CCO filed false reports.

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In the words of the *Caputo* court, “[c]orporate compliance officers are very much today’s corporate ‘fire personnel.’ They are often the company’s ‘first-responders’ and must focus on both proactive and reactive efforts to be effective.”⁶ Here, the court concluded that the CCO’s actions “were woefully and criminally inadequate.”⁷ The court found that the CCO had aided and abetted illegal marketing plans, using his regulatory expertise “to further, shield, and cover up the offenses proven at trial.”⁸ In addition, the court emphasized that the CCO’s prior experience was limited to marketing and that he lacked any real training as a compliance officer.

Amended Sentencing Guidelines

In determining the appropriate sentence to be imposed under 18 U.S.C. § 3553(a), the *Caputo* court focused on the “critical framework” provided by the Sentencing Guidelines issued by the U.S. Sentencing Commission.⁹ The Amended Organizational Sentencing Guidelines, which became effective on November 1, 2004, emphasize that companies must promote an organizational structure that encourages ethical conduct and exercise due diligence to detect and prevent criminal activity. The court summarized the compliance standards set out in the Guidelines as follows:

- ◆ Standards and procedures to prevent and detect criminal conduct.
- ◆ Adequate resources and authority for the program.
- ◆ Personal screening related to the goals of compliance.
- ◆ Training in the standards and procedures at all levels.
- ◆ Non-retaliatory internal reporting systems.
- ◆ Periodic auditing, monitoring and evaluation of the program’s overall effectiveness.
- ◆ Incentives and discipline to promote compliance and ethical conduct.
- ◆ Reasonable, responsive and preventive steps upon detection of a violation.¹⁰

In addition, the OIG of the Department of Health and Human Services (HHS) has published compliance program guidances (CPG) for the healthcare industry, including pharmaceutical and certain device companies. The CPGs set forth seven elements of an effective compliance program, including the need for companies to designate a compliance officer.¹¹ The CCO’s primary responsibilities include reporting, on a regular basis, to the company’s board of directors, CEO or president, and compliance committee regarding compliance issues, and assisting them in establishing methods to reduce fraud and abuse; periodically revising the compliance program; conducting training and education for employees; ensuring that

independent contractors are informed of the requirements of the compliance program; and checking the List of Excluded Individuals/Entities with respect to all employees and independent contractors.¹² In addition, the CCO is responsible for reviewing and acting in response to reports of noncompliance; independently investigating and taking corrective action; and participating with the company’s counsel in reporting all self-discovered violations.¹³

Conclusion

Although *Caputo* is what the court called a “complex and unusual case,”¹⁴ a number of important lessons applicable to all food, drug, device, and cosmetic companies may be drawn from the opinion. For one, a CCO must have real training and experience as a compliance officer. In addition, a company cannot select someone as a CCO because its executives believe they can manipulate him or her. The CCO cannot act as a rubber stamp, but rather must take primary responsibility for ensuring prevention and deterrence of criminal violations and promotion of ethical corporate behavior. ▲

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1 See, e.g., OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731, 23,739-23,740 (May 5, 2003); Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36,368, 36,381-36,382 (July 6, 1999).

2 United States v. Caputo, 2006 WL 2946191, at *1 (N.D.Ill. Oct. 16, 2006), *appeal docketed*, No. 06-3612 (7th Cir. Oct. 2, 2006).

3 *Id.* at *1.

4 The court noted that the CCO had lived an exemplary life until his involvement with the product at issue in the case, did not have a criminal record, and was the subject of numerous favorable character letters submitted to the court. *Id.* at *15.

5 *Id.* at *2.

6 *Id.* at *14.

7 *Id.*

8 *Id.*

9 *Id.* at *8.

10 *Id.* at *14 (citing 8B2.1, United States Sentencing Guidelines).

11 64 Fed. Reg. at 36,371.

12 68 Fed. Reg. at 23,739-23,740; 64 Fed. Reg. at 36,381.

13 68 Fed. Reg. at 23,740; 64 Fed. Reg. at 36,381-36,382.

14 2006 WL 2946191, at *16.