TEN TIPS FOR DEFENDING PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES IN GOVERNMENT INVESTIGATIONS

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Pharmaceutical, medical device and biotechnology companies are under unprecedented scrutiny from federal and state prosecutors for potential violations of healthcare fraud matters. During the past 10 years, federal prosecutors alone have recovered more than $3 billion dollars in criminal fines and civil settlements against pharmaceutical and medical device companies. Prosecutors have pursued these cases to the highest levels within companies and have brought charges against a CEO, General Counsel, Vice President for Regulatory Affairs and senior sales and marketing executives, as well as against more junior company personnel. These cases are often the result of whistle-blower suits filed under the *qui tam* provisions of the federal False Claims Act.[2]

Defending companies in government investigations, particularly investigations involving claims of fraud against federal and state programs, is challenging. The purpose of this article is not to provide an exhaustive list of tips and advice in such cases. Rather, this article focuses on specific suggestions for how to defend pharmaceutical, medical device, and other medical technology manufacturers in federal and state healthcare fraud cases, particularly cases involving allegations of unlawful inducements (*i.e.,* kickbacks), off-label promotion, and government pricing and reimbursement.

1. Read and Understand the Approved Product-Labeling

One of the first things a defense lawyer should do is to read and understand the approved labeling for the product at issue in the company's investigation, particularly if the case involves potential allegations of off-label promotion. This review should go beyond the current product label. Defense counsel should gain a solid understanding of when the product was first approved by the FDA, as well as any significant changes in the product label. Particular attention should be paid to whether the product has a boxed warning (often erroneously referred to as a "black box" warning), the product's indications and contraindications, whether the product is restricted to certain patient populations or age groups (*e.g.*, whether the product is approved for children) and significant safety information about the product. In addition, it is important to understand the history of the company's discussions with the FDA over the product-labeling. In recent settlements, prosecutors have expressed particular concern that the companies promoted the product for indications that had been rejected by the FDA.[3] Understanding the history of negotiations with the FDA will help identify potential "soft spots" in the company's defense. In some cases, counsel should consider other sources of information about FDA efficacy or safety concerns, such as issues raised during any FDA advisory committee meeting. A practical tip:

Early in the case, ask to meet with a knowledgeable member of the company's Medical Affairs group to give you a full download on these issues.

2. Understand How the Product Is Paid for under Federal and State Healthcare Programs

Federal and state healthcare fraud prosecutions frequently are premised on the theory that a company's unlawful activities caused some financial loss to federal or state healthcare programs. The coverage and payment rules for pharmaceutical and medical devices can be complicated, and can vary dramatically among federal and state programs. Coverage under Medicare, for example, may be different than coverage under the VA healthcare system, TRICARE or state Medicaid programs. Getting a handle on federal and state reimbursement, however, can be a challenge. Many coverage, coding, and payment rules are contained in sub-regulatory notices and guidance documents issued by agencies (or contractors to such agencies). Also, payment rules change over time, and it is important to understand what payment and coverage rules were in place at the time of any alleged misconduct. Compiling such information can feel like an archeological dig, where documents have to be unearthed from obscure sources such as no-longer published program memoranda or transmittal letters sent to healthcare providers. Keep in mind that coverage rules may vary geographically in the Medicare system, and it may be important to compile the specific guidance and rules in effect in a particular geographic region where the company's alleged misconduct took place. Relying on published information, agency web sites, or *Federal Register* notices is generally far from sufficient to understand the specific coverage coding and payment rules at issue in a healthcare fraud prosecution.

3. Keep in Mind Affirmative Regulatory Reporting Obligations

Pharmaceutical and medical device companies operate in a highly regulated environment and are subject to a variety of affirmative reporting obligations. While the obligation to report adverse events (pharmaceutical manufacturers) or MDRs (device manufacturers) is generally well-known, companies also face other affirmative reporting requirements. For example, the FDA's regulations implementing the Prescription Drug Marketing Act require companies to affirmatively report violations involving drug samples to the FDA. In the course of an internal investigation, or in preparing to defend a company in a civil or criminal investigation, counsel may come across problems or information that would trigger such reporting requirements. Keeping an eye out for such requirements is an important and continuing obligation for in-house and outside counsel representing any FDA-regulated entity.

4. Assess the Company's Conduct in Light of Industry Codes

Many healthcare fraud cases involving manufacturers turn on whether a company or individual acted with knowledge or intent (*mens rea*). For example, the federal Anti-Kickback Statute[4] requires proof that the defendant "knowingly and willfully" engaged in certain conduct. Because intent can be difficult to prove, prosecutors may consider whether the conduct violated well-established industry codes of conduct in determining whether the defendant's action was knowing or willful. For manufacturers, these codes include the PhRMA *Guidelines on Interactions with Healthcare Professionals,* AdvaMed *Guidelines on Interactions with Healthcare Professionals*, Accreditation Council for Continuing Medical Education *Standards for Commercial Support,* and the Healthcare Industry Group Purchasing Association's *Code of Conduct.*[5]

5. Understand the Unique Privilege Issues in FDA Regulatory Matters

While most defense lawyers take an expansive view of the attorney-client privilege work-product doctrine and other privileges, some courts take a narrow view of privilege claims in the context of regulatory activities. A recent decision by the federal district court in Massachusetts highlights the concern.[6] A grand jury was investigating a company for allegedly distributing an adulterated and misbranded medical device and issued a subpoena seeking testimony from the company's attorney along with notes he took during various conference calls with the FDA. The court concluded that negotiations between a company attorney and the FDA, even in the context of an FDA investigation, are not sufficiently in anticipation of litigation to qualify for work product protection. The court also suggested (but appears ultimately not to have decided) that because the company continued to ship adulterated product after it was on notice that the product was failing more frequently than specified in the label, the crime-fraud exception precluded denial of production of notes as work product. While there are good arguments that the case was wrongly decided, counsel should keep in mind that conversations and notes from routine (and perhaps not so routine) interactions with the FDA may not be protected from disclosure.

6. Assess the Impact on Patient Health and Safety

One of the most important issues to consider in any healthcare fraud case is whether the alleged misconduct posed a risk to patient health and safety. Offering an unlawful inducement to encourage physicians to prescribe a drug with serious potential side effects is the type of fact pattern that is likely to trigger significant interest from prosecutors. Similarly, the promotion of an unapproved product with a significant risk-profile is likely to be of serious concern to government prosecutors.[7] Counsel should not settle for an explanation of these issues by the

company's sales and marketing personnel, who might be unfamiliar with or downplay such issues. A company's medical affairs department frequently is the best and most efficient place to start gathering such information. When a patient health or safety issue is identified early in a matter, counsel may want to discuss whether some type of affirmative action is warranted (such as a "Dear Doctor" letter) both to address any serious patient safety issues and to demonstrate to prosecutors and regulators that the company takes such issues seriously (but see below regarding collateral proceedings).

7. Look *Where* the Government Will Look

Many government prosecutors have significant experience with pharmaceutical and medical device fraud cases. They know where to look for documents that are likely to be incriminating, particularly with respect to sales and marketing activities. Prosecutors are fond of requiring companies to subpoena sales representative call notes, field contact reports (*i.e.*, periodic reports from first-level sales managers documenting their interactions with individual sales representatives), weekly or monthly sales reports to regional or national sales management officials, incentive compensation and bonus plans for sales personnel, and company marketing plans. Counsel conducting an internal investigation should ask the company for these types of documents as early in the process as possible as they're likely to provide early evidence of whether a potential violation(s) exists and whether the problem is isolated or widespread.

8. Look *How* the Government Looks

Prosecutors generally do not focus on any one transaction to determine whether to prosecute a company or individual for healthcare fraud. Rather, prosecutors are most interested in cases where the wrongdoing is widespread or involves improper actions by management. For example, in several recent off-label promotion cases, the government examined a number of company activities - advisory boards, marketing plans, comments by sales representatives, etc. - and concluded that such activities *when taken together* constituted an unlawful scheme to promote the company's product for an unapproved use. The point is that the government frequently looks at the cumulative intent and effect of a company's activities in determining whether such activities violate the law and if so, whether they are worth prosecuting under civil or criminal statutes. Defense counsel frequently will want to examine the sales and marketing practices of an entire product or group of products in assessing a company's exposure.

9. Pay Attention to Collateral Proceedings

Medical technology manufacturers involved in healthcare fraud investigations should expect additional lawsuits from a variety of entities. First, manufacturers may face product liability claims. Second, companies may face shareholder derivative or other securities litigation. Once a case settles, companies should expect (or at least prepare for) suits from private payers seeking recovery of allegedly improper payments. These collateral proceedings can seem less important or peripheral to the defense of a company in a criminal investigation, where the consequences involve potential exclusion of the company from federal or state healthcare programs or imprisonment of individual defendants. Nevertheless, experienced counsel can and should be mindful of the potential for collateral litigation and take steps to protect the company in such matters without compromising the defense of the government investigation. Frequently, a company will have more than one law firm involved in defending these various types of suits. It is imperative for outside defense counsel to cooperate fully with each other and to make the client's interests paramount over more self-interested concerns about billings, control, or other inappropriate considerations. In-house counsel should establish clear expectations about cooperation from their outside firms—and hold their firms accountable for their actions.

10. Respect the Role of Government Personnel Handling the Case

Effectively defending a client in a healthcare fraud case demands that counsel understand and respect the role of the prosecutors, investigators and regulatory agencies involved in the matter. While this is true in many types of white-collar (and other) cases, it's particularly true in healthcare cases against manufacturers because prosecutors know they hold powerful cards: conviction for kickback and certain other Social Security Act violations can result in *mandatory* exclusion from federal healthcare programs; permissive exclusion is a risk in many other contexts.

Thus, it is important to maintain a respectful and cooperative attitude with prosecutors, particularly in the early stages of a case where the goal is to persuade the government not to pursue the case or to pursue it solely as a civil matter. Of course, this does *not* mean that outside counsel must agree with the government's perspective, nor should defense counsel not be zealous in defending the company. The point is that the effective defense of a company requires an understanding and appreciation of the role of the prosecutor, investigators and other agencies. It's important to understand that each of these agencies has a different role and that the government is not a monolithic entity, but rather is composed of numerous agencies or offices working (more or less) together. The perspectives of Main Justice and individual U.S.

Attorney's offices, for example, can differ markedly as can the perspectives of the U.S. Attorney and the investigative agencies involved in a case. Knowing and appreciating these roles and perspectives can help a company in marshaling evidence and arguments in a manner that persuades the government to exercise its enforcement discretion in favor of the company.

A respectful approach also will be important for large, publicly-traded firms (and many smaller companies) where the company's reputation with FDA, CMS, and other regulatory agencies will be important to the company's long-term commercial success. How a company conducts itself in the course of an investigation (including the conduct of its outside counsel) can have an important impact on the company's regulatory reputation. Effective counsel will understand these concerns and represent the company in a manner that achieves a successful result in the government investigation and protects the company's long-term reputation with key governmental and regulatory agencies.

Conclusion

The defense of pharmaceutical and medical device companies in healthcare fraud cases can be challenging, raising issues that arise in any white collar prosecution and unique issues for health technology manufacturers. This article offers a number of tips, some obvious and some less so, that outside counsel should keep in mind when representing clients in these cases.

ENDNOTES

1. The views expressed in this article are those of the author and not necessarily those of King & Spalding LLP or any of its clients. This article provides practical advice on defending clients in government investigations. It is not, and should not be relied upon as, legal advice. John T. Bentivoglio is a partner in the Washington, D.C., office of King & Spalding LLP and co-chairs the firm's FDA/Healthcare Group. He can be reached at (202) 626-5591 or jbentivoglio@kslaw.com.

2. 31 U.S.C. §§ 3729-33. A recent report by the Government Accountability Office (GAO) found that two-thirds of recent recoveries in healthcare fraud settlements involved whistle-blower suits. Information on False Claims Act Litigation, GAO, January 2006 (GAO-06-320R).

3. See, e.g., Sentencing Memorandum of the United States in United States v. Warner-Lambert Company LLC (Criminal No. 04-10150 RGS), June 2, 2004, at 24 ("Neurontin Sentencing Memorandum") ("Nonetheless, Parke-Davis actively promoted Neurontin for monotherapy before it applied for FDA approval, before it received the FDA's response, and, most amazingly, *after* the FDA had rejected its application for monotherapy") (emphasis in original).

4. 42 U.S.C. § 1320a-7(b)b.

5. These guidelines are on the web site of each organization. www.phrma.org/code_on_interactions_with_healthcare_professionals/; www.advamed.org/publicdocs/coe.html; www.accme.org (click on "Standards for Commercial Support"); and www.higpa.org/about/code.

6. In re Grand Jury Subpoena, 2004 WL 516651 (D.Mass., March 16, 2004). The facts in the case are somewhat complicated and worth reviewing to understand the rationale of the court's decision.

7. See, e.g., Neurontin Sentencing Memorandum at 22-3 ("One of the psychiatric uses for which Neurontin was promoted by Parke-Davis, bipolar disorder, was particularly troubling because the Company had very weak evidence of Neurontin's efficacy in treating this condition. Indeed, in one study sponsored by Parke-Davis, the placebo was as effective as or more effective than was Neurontin").