In-House Perspective

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The Challenges of Managing Product Liability Litigation with a Pending Parallel Government Investigation

The incidence of what legal commentators and practitioners term "parallel proceedings"—that is, consecutive or concurrent government investigations and civil litigation stemming from the same conduct—is not new. However, its increasing frequency is making it more and more prudent for both in-house counsel and outside litigators to pay particular attention to the unique problems that can arise when confronted with parallel proceedings. In the pharmaceutical and medical device context, attorneys must be prepared for the possibility that conduct that was once the subject solely of civil product liability proceedings may also become the focus of a government enforcement action. This article intends to provide a brief overview of some of the most significant considerations for counsel handling parallel proceedings and to serve as a backdrop for a more robust discussion of on-the-ground strategy and planning from the perspective of in-house counsel well versed in managing the intricacies of the relevant issues.

Statutory Framework

U.S. government agencies use a variety of statutes to pursue criminal and civil claims against pharmaceutical and medical device companies. A small sampling of this statutory buffet includes the Foreign Corrupt Practices Act, the Anti-Kickback Statute, the False Claims Act, the Food, Drug and Cosmetic Act, and the Prescription Drug Marketing Act. Alleging violations of these and other related state laws can allow a government agency to prosecute companies that the government believes may have engaged in a range of wrongful conduct, including promoting products for off-label uses, providing improper payments or other benefits to physicians to induce them to write prescriptions or use specific devices, or paying foreign government officials to obtain business or regulatory approvals. Such prosecutions can mean a big payoff. In 2012, the federal government reportedly recovered approximately $5 billion from settlements and judgments in cases filed under the False Claims Act (FCA) alone.

The False Claims Act: The "FCA," 31 U.S.C. §§3729–3733, imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment" to the federal government. In other words, a company violates the FCA when it knowingly makes a material misrepresentation regarding a good or service that it provides and that misrepresentation leads to a payment from the government. The government itself can pursue an FCA action against a corporation, but the FCA also includes qui tam provisions, which allow a private citizen, called a "relator," to bring a lawsuit on behalf of the United States. In the product liability context, an FCA action may arise, for example, when a pharmaceutical company is alleged to have paid certain physician consultants for their participation in clinical trials, speakers' forums, meetings, and other marketing activities to induce them to write prescriptions for a particular drug. Damages and penalties under the FCA can be severe, including civil penalties of up to $11,000 for each "false claim" and treble damages reflecting the loss suffered by the government.

The Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act: The Food, Drug, and Cosmetic Act (FDCA) sets standards for food and drug safety. Unlike the FCA, the FDCA is a strict liability statute. A violation can be committed, and punished, without intent. The FDCA can be used to charge companies that have, for example, allegedly shipped misbranded medical devices. The Prescription Drug Marketing Act (PDMA) is incorporated into the FDCA and was designed to discourage the sale of counterfeit adulterated, misbranded, and expired prescription drugs. The PDMA prohibits a variety of conduct with respect to prescription drugs. *See* 21 U.S.C. §331(t). The government may punish a company found to have violated the FDCA by excluding the company from participating in federal healthcare programs. Certain violations—such as knowingly selling, purchasing, trading, or offering to sell, purchase, or trade a prescription drug sample—can be punishable by up to 10 years imprisonment.

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The Foreign Corrupt Practices Act: The Foreign Corrupt Practices Act, 15 U.S.C. §§78dd-1, *et seq.* (FCPA), was enacted for the purpose of making it unlawful for certain persons and entities to make payments to foreign government officials to assist in obtaining or retaining business. The FCPA contains both anti-bribery provisions and accounting requirements. The anti-bribery provisions prohibit the willful use of interstate commerce in furtherance of any offer, payment, promise to pay or authorization of payment to any person, with the knowledge that the money or thing of value will be offered to induce a foreign official to do an act in violation of his or her lawful duty. Under certain amendments made in 1998, the anti-bribery provisions not only apply to U.S. persons and corporations, but also to foreign persons and firms that commit a violation within United States territory. The FCPA accounting requirements apply to publicly traded companies and are intended to make it easier to detect corrupt payments and ensure that shareholders can accurately assess a company's finances. Many pharmaceutical and medical device companies have become the subject of FCPA actions led by the U.S. Securities and Exchange Commission (SEC), alleging, for example, improper payments to foreign subsidiaries to obtain business, regulatory approvals, or increased prescriptions for their products. An FCPA violation can be punished with civil penalties by the SEC, or the U.S. Department of Justice (DOJ) can pursue criminal charges and imprisonment.

The Anti-Kickback Statute: The Anti-Kickback Statute, 42 U.S.C. §1320a-7b, is a criminal statute that prohibits the exchange of anything of value for the purpose of inducing the referral of services paid for by federal health-care programs. A single violation of the statute can result in a fine of up to $25,000 and imprisonment for up to five years. Violators may also face exclusion from participating in federal health-care programs. The statute is intent-based and requires that a party knowingly and willfully engage in the illegal conduct. The statute itself does not permit private actions, and therefore anti-kickback violations are often pursued through FCA qui tam claims. Common scenarios falling under this statute's purview include a medical device company offering hospital employees incentives and bonuses to induce purchases of its equipment, or providing grants to clinicians for questionable scientific research in exchange for using a product. Because the scope of the statute is great and the lines indicating a violating can be gray, the Office of the Inspector General has developed regulatory "safe harbors," defining transactions that are technically prohibited by the statute but that will not be prosecuted.

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While these examples may reflect some of the most common statutory sources of government investigations against pharmaceutical and medical device companies, they are by no means the only ones. Indeed, the government, and private citizens through the *qui tam* process, has a panoply of weapons at their disposal when it comes to allegations of misconduct on the part of corporations and their executives.

The Chicken or the Egg: Which Comes First?

The U.S. Constitution does not bar simultaneous parallel proceedings. *United States v. Kordel*, 397 U.S. 1 (1970). While possibly a personal affront, there is nothing to protect a corporation or an individual from the onslaught of a civil product liability case at the same time as the government initiates an investigation regarding the exact same conduct or incident. However, counsel should keep in mind that "parallel" proceedings do not necessarily mean "simultaneous" proceedings. Sometimes private civil litigants will wait until the conclusion of a government investigation, referencing the criminal indictment and any fines or penalties imposed as "evidence" of corporate wrongdoing or fraud. Other times the government may seek to use information uncovered through a preexisting civil case to provide the basis for a criminal prosecution, given the broader and more permissible scope of civil discovery.

Some courts have placed limits on parallel proceedings, recognizing the special problems that such dual litigation can inflict. For example, in *United States v. Scrushy*, 366 F. Supp. 2d 1134 (N.D. Ala. 2005), the DOJ instructed the SEC how to conduct a deposition during the SEC civil investigation to facilitate the DOJ criminal investigation. The court held that the government could not later use the deposition to support a perjury prosecution because the government had failed to disclose the existence of the parallel criminal investigation while the SEC action was underway. Similarly, in *United States v. Stringer*, 408 F. Supp. 2d 1083 (D. Or. 2006), the United States Attorneys' Office began a criminal investigation of several individuals shortly after an SEC investigation had started regarding the same conduct. Here too, prosecutors took pains to keep the existence of their criminal investigation a secret while at the same time encouraging SEC attorneys to take testimony in a way that would facilitate a perjury prosecution. The district court dismissed the ensuing indictment on the ground that the U.S. Attorneys' Office violated due process by engaging in "trickery and deceit." The Ninth Circuit, however, disagreed and later overturned the dismissal, reasoning that the SEC civil investigation was not conducted in bad faith, and it did not affirmatively mislead the subject of its charges into believing that the investigation was solely civil in nature. 535 F.3d 929 (9th Cir. 2008);*see also United States v. Rutherford*, 555 F.3d 190, 197–98 (6th Cir. 2009) (finding denial of motion to suppress of evidence collected in civil IRS proceed-

ing proper where the government did not engage in "deception or trickery").

The lesson is that while government agencies can indeed "share" information, they must maintain independent investigations and cannot influence the direction or aims of a parallel proceeding. *See United States v. Harris*, 2010 WL 4967821 (N.D. Ga. Dec. 1, 2010) (denying defendants' motions to suppress civil deposition testimony in enforcement action brought by United States Attorney but noting that "the SEC and the USAO [U.S. Attorneys' Office] must keep their investigations on parallel tracks and cannot merge them by, for example, having the SEC take actions or seek evidence solely for the benefit of or at the direction of the USAO").

The Ins and Outs: Specific Issues to Consider

When confronting potential or actual parallel proceedings corporations and corporation counsel will want to understand in particular how privilege issues, including document production privilege waiver, joint defense agreements, "pleading the Fifth," and cooperating with the government may play out.

Privilege Issues

When a corporation engages defense counsel to aid in an internal investigation or civil proceeding, it is evident that communications between the company itself and counsel are protected by the attorney-client privilege. During an internal investigation, counsel is likely to interview employees, officers, and directors about the conduct at issue. The corporation may later assert the attorney-client privilege if and when it becomes the subject of a government investigation concerning the same conduct. A corporation should be careful to establish that the privilege does not extend to communications between individual employees and counsel. The threat inherent in this situation is that an employee may reasonably believe that his or her communications are privileged and then later seek to invoke the privilege once a government investigation is underway. This can pose a problem for a corporation seeking to waive the privilege in exchange for cooperation credit from a government agency.

Many courts have dealt with whether a corporate officer or executive can assert a personal privilege regarding his or her communications with counsel, even if the corporation itself has waived its privilege. The answer often involves the application of a five-part test, and to meet the test an executive must demonstrate that he or she approached counsel for legal advice with the specific request that it was in his or her role as an executive, and not as the corporation's agent, and he or she must show that the communications made did not involve matters within the company or the executive's role in the company. *See Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 805 F.2d 120 (3d Cir. 1986); *see also United States v. Graf*, 610 F.3d 1148 (9th Cir. 2010) (adopting *Bevill* test and finding that corporate founder did not hold personal attorney client privilege). However, in practice, it is difficult to envision a scenario in which a communication between a corporate executive and corporate counsel did *not* involve matters within the company or the executive's role within the company. As one court recently recognized, the only reason individual officers were sued in that case the first place was because of their position as officers or directors of the subject corporation. *See In re Equaphor Inc.*, 2012 WL 1682583, at *3-*4 (Bankr. E.D. Va. May 14, 2012) (finding that individual defendants had not satisfied the *Bevill* test and ordering counsel for corporation and individual defendants to turn over corporate representation file). It is difficult to completely separate their role in the corporation from their purposes for communicating with corporate counsel, and for this reason, corporate executives will be hard pressed to argue that they hold a personal attorney client privilege with respect to communications with corporate counsel.

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A corporation should therefore be particularly careful when initiating an internal investigation regarding conduct that could later become the subject of a government enforcement action. Counsel should be sure that employees are clearly informed about the extent and scope of the attorney-client privilege, particularly officers and directors who could be individually named as defendants in resulting lawsuits. To the extent possible, only factual information should be put into writing, and counsel should try to avoid memorializing impressions, conclusions, or legal advice in written documents. Privileged documents should be marked and stored separately and readily accessible in the event that the government initiates an enforcement action.

Joint Defense Agreements

When it comes to government prosecution, it is not only a corporation itself that can be subjected to liability, but corporate executives and other employees can also be held criminally liable for conduct allegedly committed by the corporation. *See U.S. v. Park*, 421 U.S. 658, 670 (1975). For example, a corporate executive or other individual—such as a pharmaceutical sales representative—can be convicted of misdemeanor off-label promotion of a pharmaceutical product or medical device based on a showing of negligence. *See* 21 U.S.C. §333.

Simple intuition suggests that in actions involving multiple parties, coordination and cooperation among the defendants would prove beneficial. A joint defense agreement (JDA) is a contract to extend the attorney-client privilege and work product doctrine to all confidential communications that are part of an ongoing and joint effort to coordinate a common defense strategy between several defendants. A JDA is intended to facilitate the exchange of information between counsel and protect shared information and communications under the work product doctrine. It can also lower costs by eliminating the duplication of work, such as discovery, expert retention, or deposition preparation, and it can allow counsel to prepare

and file joint motions and share research and knowledge.

However, potential conflicts between defendants—different interests or goals, indemnity or contribution claims, varying defenses—can present challenges. A JDA can also increase the potential for attorney disqualification down the line. Before drafting and entering into a JDA, counsel should be convinced that their clients do indeed share a common interest and goal. Some courts have held that this "common" interest must in fact be an "identical" interest for a JDA to be appropriate. *See Frontier Refining, Inc. v. Gorman-Rupp Co.*, 136 F.3d 695 (10th Cir. 1998). Other courts require that a common interest be a legal interest and not simply a mutual commercial or business interest. *See Minebea Co., Ltd. v. Papst*, 228 F.R.D. 13 (D.D.C. 2005).

Certain discovery and other tasks, such as deposition preparation, may be more easily completed if all parties have the opportunity to cooperate. Counsel should be sure to draft JDAs to include the following provisions, at a minimum: each party is exclusively represented by his or her own attorney; each client waives any conflict of interest claim or right to disqualify any attorney who receives confidential information pursuant to a JDA; information shared will remain confidential both during and after withdrawal from the JDA and will not be disclosed without prior written consent or court order; and no confidential information shared under the JDA shall be admissible in evidence in any proceeding arising by one member of the JDA against another.

"Pleading the Fifth"

Counsel representing a corporate executive in a parallel proceeding may also have to decide whether or not to have the corporate executive client plead the Fifth Amendment privilege against self-incrimination or testify in a proceeding. Testifying can present significant risks—perjury prosecutions, accounting for events without the benefit of access to documents, and committing to a story in a civil case before criminal charges have been filed. However, remaining silent is not without risks either.

There are two primary problems with pleading the Fifth Amendment. First, even if a party refuses to testify, the same information could be found elsewhere, such as in corporate records or reports. Second, although jurors in a traditional criminal case cannot find guilt from the mere fact that a defendant refuses to testify, a fact finder in a civil action may draw an adverse inference from a witness's invocation of the privilege. *Baxter v. Palmigiano*, 425 U.S. 308, 318 (1976).

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One easy solution for defendants wrestling with this question within the context of parallel proceedings is to attempt to stay civil litigation until the criminal prosecution has completed its course. The stay allows counsel to focus on one investigation at a time and to avoid more burdensome civil discovery that could later be used to a company's disadvantage in a government investigation.

Document Production and Waiving the Privilege

Information produced in civil discovery can be used in a criminal prosecution, and grand jury information may be used in a civil action with court approval. Through processes such as "access requests," criminal enforcement agents can obtain copies of interview memos, testimony transcripts, and other documents generated in civil, regulatory, or administrative proceedings. Indeed, almost all courts have held that sharing documents with the government means that the sharing party has waived any privilege that might attach to those documents. *See, e.g.*, *In re Quest Communications, Inc.*, 450 F.3d 1179 (10th Cir. 2006) (adhering to the majority rule holding that the privilege is waived); *but see Diversified Indus. v. Meredith*, 572 F.2d 596 (8th Cir. 1978) (en banc) (finding privilege not waived). This situation arises most frequently in the context of parallel proceedings when a company hires attorneys to conduct an internal investigation regarding questionable activities. New policies and programs that grant "cooperation credit" attempt to induce companies to disclose information voluntarily, which consequently waive their privileges regarding internal investigations, otherwise non-discoverable documents, or information pertaining to legal fees that they have assumed for employees also under investigation.

Federal Rule of Evidence 502 is heavily implicated when it comes to parallel proceedings. If a company chooses to conduct an internal investigation in the face of potential parallel proceedings, that investigative record will be sought by other parties in the criminal or civil litigation. The rule, enacted in 2008, expressly limits its privilege waivers in certain circumstances. Federal Rule 502(a) provides that if a party discloses privileged information in a federal proceeding or to a federal agent, thereby waiving the privilege or work product protection, the waiver also extends to an undisclosed communication, creating a subject matter waiver on the entire topic in the federal or state proceeding *if the waiver was intentional*. If the privileged disclosure was inadvertent, Federal Rule 502(a) states that a subject matter waiver cannot occur. This rule applies in both federal and state proceedings.

Federal Rule 502(b) states that inadvertent disclosure of privileged information does not operate as a waiver in a federal or state proceeding if the holder of the privilege or work product protection took reasonable steps to prevent disclosure and reasonable and prompt steps to rectify the error. This is known as the "claw-back" provision. Federal Rule 502(c) states that whichever law, state or federal, is most protective against waiver will control. Finally,

Federal Rule 502(d) provides that if a federal court preemptively enters an order concluding that a privilege or protection is not waived by disclosure in a case before it, that disclosure cannot act as a waiver in another federal or state court proceeding.

When it comes to producing documents in parallel proceedings, counsel should be sure to coordinate closely between the two actions and ensure that a production in one case is not inconsistent with a production in another, related case. The safest strategy is for companies involved in parallel proceedings to structure document production in such a way to avoid or limit the production of privileged materials. Plaintiffs often request that all documents produced to the government be turned over in a civil case as well, and counsel should be prepared to push back against assertions that subject matter waiver applies.

Deciding Whether to Cooperate with the Government

Because most courts will not recognize a limited or selective waiver of privilege, choosing to cooperate with the government or other adverse party in exchange for cooperation credit can cause a company to waive privileges and protections that would otherwise apply to documents. In effect, third parties then may have access to a range of material used in a government investigation, which can in turn open discovery on the entire subject.

On August 28, 2008, the DOJ released a memo, known as the "Filip memorandum," which stated that cooperation credit would not depend on a corporation's waiver of the privilege or work product protection, but would instead focus on its willingness to disclose relevant facts. In other words, the memorandum effectively permits a government prosecutor to "punish" a corporation for withholding relevant facts—even those protected by the privilege or work product doctrine. This poses a particular problem when a corporation sponsored an internal investigation before the government initiated an enforcement proceeding: internal documents contain undoubtedly "relevant" information, yet also, naturally, contain an attorney's communications, distillation of facts, summaries of interviews, and opinions. The Filip memo further states that an organization can decide whether to conduct an internal investigation in a privileged manner or not, and when deciding whether or not to charge a corporation with wrongdoing, the government cannot take into account whether the corporation advanced attorneys' fees to its employees or entered into a JDA.

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The SEC, for its part, published its own cooperation credit policy in January 2010 explaining the terms if individuals choose to cooperate with SEC investigations to avoid a civil enforcement action or to receive reduced sanctions. The policy outlines four factors considered by the SEC to determine whether and how much to credit cooperation by individuals: (1) the assistance provided by the cooperating individuals in the SEC investigation or related enforcement actions; (2) the importance of the underlying matter in which the individual cooperated; (3) the societal interest in ensuring that the cooperating individual is held accountable for his or her misconduct; and (4) the appropriateness of cooperation credit based upon the profile of the cooperating individual.

More recently, in November 2012, the DOJ and SEC jointly released a highly anticipated FCPA resource guide, offering insights into the agencies' interpretation and enforcement strategy regarding the FCPA. The guide is nonbinding and offers little substantively that FCPA practitioners didn't likely already know, but it does provide several hypotheticals concerning common and recurring issues that can be illuminating for counsel dealing with FCPA issues. The guide provides suggestions about how to structure corporate compliance programs as well, recommending, for example, that training programs be tailored to a specific audience and given on a periodic basis, and encouraging companies to incentivize compliant behavior, such as tethering management bonuses in part to a compliance standard of performance.

In addition to cooperation credit, corporations can also enter into corporate integrity agreements with the government. As part of a corporate integrity agreement, a corporation agrees to be more transparent in its business dealings. Several pharmaceutical companies have entered into such agreements. One final compliance-related tactic that the government pursues is deferred prosecution agreements (DPA) or non-prosecution agreements (NPA). The section of the *United States Attorneys' Manual* titled "Principles of Federal Prosecution of Business Organization" contains a list of factors to assist prosecutors in determining whether or not to charge a corporation under the FCPA or to enter a DPA or NPA. Those factors include the following: the nature and seriousness of the offense; the organization's history of similar misconduct; the corporation's willingness to disclose wrongdoing and to cooperate; the corporation's remedial actions; the existence of harmful collateral consequences of charges or agreements, including to investors and the public; and the adequacy of non-criminal remedies.

Special Considerations for Corporations Doing Business on the International Front

The FCPA is the primary vehicle through which United States agencies can regulate wrongful conduct abroad—specifically, alleged bribes involving foreign officials that can give certain companies an edge when doing business in foreign markets. However, in addition to U.S. agencies, for-

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eign governments may sometimes attempt to impose sanctions on American companies' subsidiaries acting within their jurisdiction as well.

Foreign business has offered opportunities for an ever-increasing profit margin to American-based pharmaceutical and medical device companies. China in particular is a promising market for drug and device business, and international firms are competing for sought-after leverage in the country. However, wide-scale corruption may drastically affect the playing field. Government influence permeates every aspect of the Chinese market, especially when it comes to drug manufacture and marketing. Chinese government officials have begun cracking down on alleged bribery and other rule-bending behavior between pharmaceutical companies and health care professionals. China-based divisions of international firms are becoming the subject of Chinese government investigations. It remains to be seen how the new aggressive stand toward alleged bribery will affect business for international corporations, although what is already clear is that counsel will need to start turning a watchful eye toward corporate activity and regulatory enforcement emanating from abroad.

Practical Implications and Tips

Practical tips generally fall into seven categories: evaluation, preservation, stay of proceedings, coordination, consistency, prevention, and exclusion.

Evaluation: Consider whether an internal investigation would be prudent to determine whether a company has any criminal liability. Such proactive actions may decrease the likelihood of a government investigation.

Preservation: Remember that documents can be shared between civil litigation and government investigations; counsel should assume that the various authorities share information and perhaps even coordinate strategies. Investigation counsel should make sure to structure and conduct an internal investigation to preserve the applicable evidentiary privileges maximally. Documents and attorney work product should be carefully marked as confidential so that if litigation does ensue, a Federal Rule of Evidence 502 protective order can protect parties from claims of privilege waiver.

Stay of Proceedings: Counsel may want to consider a stay of civil proceedings, or a protection order at the very least, to preclude disclosure of written discovery or depositions when a criminal interest develops. A stay of the civil litigation can allow corporate defendants to avoid discovery that may result in disclosure of defense theories, privileged statements, and other sensitive information that the government could not obtain under the federal criminal rules. Even a limited stay can alleviate the risk of an adverse inference being imputed to a company if an employee invokes his or her Fifth Amendment rights in the civil case. The government too may prefer a stay of civil proceedings, pending the resolution of criminal investigation.

Coordination: The importance of corresponding early on with co-counsel involved in parallel litigation cannot be overstated. Have regular conference calls to share any new developments, and keep informed about potential ways the parallel litigation might affect a corporation's interests.

Consistency: All parties considering entering into a JDA should ensure that they have a consistent ultimate goal and that the JDA is drafted in a way that minimizes risks of conflicts of interest and attorney disqualification.

Prevention: A corporation's chief compliance officer should develop a satisfactory compliance program, including training sales representatives on U.S. Food and Drug Administration-approved uses of drugs and medical devices, explanations of the key statutes and regulations covered in this article, and instructions on how to answer specific questions from physicians on appropriate uses of products sold.

Exclusion: Counsel should be prepared to exclude evidence of a criminal or government enforcement action from subsequent civil product liability litigation. Motions to dismiss and protective orders should be used as soon as possible on the grounds that such evidence is irrelevant, unduly prejudicial, and often constitutes hearsay. IDQ