Ethical Issues and Practical Challenges Raised by Internal Investigations in the Life Sciences Industry

By Abraham Gitterman

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OVER THE LAST four years, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a joint effort between the Department of Health and Human Services (HHS) and the U.S. Department of Justice, has recovered over $13.9 billion in healthcare fraud settlements, many involving pharmaceutical companies charged with the "off-label promotion"[1] of drugs to healthcare providers.[2] As an effort to change corporate culture, each of these settlements has included a corporate integrity agreement (CIA) with the Office of Inspector General (OIG) for HHS. Yet the deterrent effect of CIA's and deferred prosecution agreements (DPAs) is uncertain,[3] and even OIG has acknowledged that

[1] The Food, Drug, & Cosmetic Act prohibits manufacturers from marketing their drugs to individuals for unapproved or "off-label" uses that are not in the approved labeling of the product. The Food and Drug Administration (FDA) considers such marketing to "misbrand" the drug (21 U.S.C. §§ 331(a), 352) or to cause the introduction of a "new drug" that has not been approved into interstate commerce (21 U.S.C. §§ 331(d), 355(a)).

[2] *See* Press Release, U.S. Dep't. of Justice, *Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn NY; Pays $762 Million to Resolve Criminal Liability and False Claims Act Allegations* (Dec. 19, 2012), available at http://www.justice.gov/opa/pr/2012/December/12-civ-1523.html (last visited August 10, 2013).

[3] Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L. J. 1033, 1034 (2012) (the use of CIAs "has not led to demonstrable reductions in health care fraud").

billion dollar settlements are not sufficient to change corporate culture in pharmaceutical companies.[4] Some companies may even view paying these fines as merely the "cost of doing business," and several companies[5] that have previously settled with the government for significant amounts "have come under repeated scrutiny for unlawful promotion violations."[6]

One reason for the lack of deterrence is that companies may believe they are "too big" to be excluded[7] by OIG because of the risk it would pose to the welfare of government healthcare beneficiaries. While some alternatives have been offered,[8] OIG has responded by indicating its intent to exclude executives in the life sciences industry from federal healthcare programs "under a broader range of circumstances,"[9] including the responsible corporate officer (RCO) doctrine.[10] In fact, OIG has recently excluded several life science executives[11] and the Department of Justice (DOJ) and the Food and Drug Administration (FDA) have collectively expressed their intent to pursue future cases against executives as well as mid-level managers and officers.[12]

The mounting number of government inquiries into corporate practices, coupled with the increased focus agencies are placing on charging corporate executives and managers, has caused growing uncertainty for in-house and outside counsel with respect to ethical issues relating to internal investigations, representation of

[4] *Hearing on Improving Efforts to Combat Health Care Fraud*, *Subcomm. on Oversight of U.S. House Comm. on Ways & Means* (2011) (Lewis Morris, Chief Counsel to Inspector Gen., HHS) (hereinafter "Morris Testimony"), available at http://waysandmeans.house.gov/news/documentsingle.aspx?DocumentID=253951 (last visited August 7, 2013).

[5] Companies that have entered into multiple CIAs include Pfizer, Merck, Novartis, GlaxoSmithKline, and Eli Lilly.

[6] Vicki W. Girard, *Reducing Unlawful Prescription Drug Promotion: Is the Public Health Being Served by an Enforcement Approach that Focuses on Punishment?* 2 FDLI, Food & Drug Pol'y Forum 1, 3 (2012).

[7] Exclusions are remedial in nature, not punitive. If excluded, the government may not make any payment for any items or services billed to a federal healthcare program by the excluded individual or entity. 42 U.S.C. § 1320a-7.

[8] Copeland, *supra* note 3 at 1075ff (e.g., clinical trial funding, compulsory licensing, and more targeted exclusions).

[9] Morris Testimony, *supra* note 4 at 6. OIG is concerned that the "pattern over the last 10 years doesn't indicate that forcing companies to pay money has really changed behavior." *Id*.

[10] Under the RCO doctrine, "a corporate agent, through whose act, default, or omission the corporation committed a crime" in violation of the Food, Drug, & Cosmetic Act may be held criminally liable for the wrongdoing of the corporation or lower-level corporate employees. *See* United States v. Park, 421 U.S. 658, 670 (1975).

[11] OIG has excluded three executives from Purdue Pharma; four former Synthes, Inc. executives; the former CEO of InterMune, W. Scott Harkonen, M.D.; and the former KV Pharmaceutical Chair and CEO Marc Hermelin.

[12] *See e.g.*, United States Food and Drug Administration, *Special Procedures and Considerations for Park Doctrine Prosecutions*, Regulatory Procedures Manual, 6-5-3 (hereinafter "FDA *Park* Procedures") available at http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm#SUB6-5-3 (last visited August 7, 2013). Joanne S. Eglovitch, *FDA Resurrects Park Doctrine in Enforcement of Pharmaceutical GMPs*, The Gold Sheet (Apr. 2011) available at http://www.elsevierbi.com/publications/the-gold-sheet/45/4/fda-resurrects-park-doctrine-in-enforcement-of-pharmaceutical-gmps (last visited August 7, 2013) (quoting former DOJ attorney Michael Loucks who noted that OIG and FDA "are going to be pushing the DOJ to make decisions going forward in true *Park* cases where there is no criminal [or] willful intent and no knowledge by the executives").

the corporation (including counsel's relationship with the corporation's constituents), conflicts of interest, and the attorney-client privilege. Among these, internal investigations for life science companies present unique challenges. The nature and complexity of interactions life science companies have with private and government entities and individuals, and the tremendous frequency with which these interactions occur, create countless opportunities for fraudulent conduct to occur that may implicate the company and its executives. Such interactions may take place in numerous countries, which may implicate the Foreign Corrupt Practices Act (FCPA) or other foreign bribery or kickback laws. Internal investigations may reveal legal obligations and liabilities outside of traditional healthcare fraud concerns, such as shareholder, product liability and consumer protection litigation, and parallel but separate actions by State prosecutors and agencies.

This article analyzes the special factors and circumstances FDA and healthcare attorneys must consider when conducting an internal investigation. This article first provides an overview of internal investigations, including *Upjohn* warnings, in the life sciences industry. This article then provides a detailed overview of the principles the Department of Justice considers when charging corporations and the various factors and circumstances the agency may consider when resolving investigations. This article also offers practical advice for counsel to consider in carrying out internal investigations and concludes with observations and predictions for future trends in the life sciences industry.

I. Internal Investigations

An internal investigation is an inquiry performed by a company or its agent after the company is made aware of a serious and reasonably plausible allegation of corporate misconduct. If allegations of corporate misconduct are credible and sufficiently serious, or otherwise trigger a mandatory duty to investigate, an internal investigation is necessary. While there are several triggers that may lead to an internal investigation, the most common in the life sciences industry is the internal discovery of a possible violation by an employee, also known as a "whistleblower" or *qui tam* action.[13] A government subpoena or the initiation of an investigation by FDA, CMS, HHS, OIG, the Department of Veterans Affairs (VA), the FBI, or a self-regulatory organization also triggers an internal investigation. Companies also conduct internal investigations in response to allegations raised in product liability or tort litigation, and in the performance of due diligence in connection with mergers

[13] *See* Randall L. Christian, et al. *Pharmaceutical Companies, Off-Label Promotion And Qui Tam Actions*, Business Crimes Bulletin, 3 (July 2011) (in 2009, 65% of *qui tam* suits alleged healthcare fraud), available at http://www.bowmanandbrooke.com/insights/~/media/Documents/Insights/News/2011/07/Pharmaceutical%20Companies%20Off Label%20Promotion%20and%20__/Files/Pharmaceutical%20Companies%20OffLabel%20Promotion%20and%20__/FileAttachment/Business%20Crimes%20Bulletin%20Off%20Label%20and%20Qui%20Tam%20-__ (last visited August 7, 2013). *See also* Antonia F. Giuliana, *DOJ/HHS Releases New Statistics About Sealed Qui Tam Cases*, FCA Alert (Feb. 2, 2011) (noting that in 2011, 66% of cases alleged health care fraud and that 180 cases under seal alleged fraud in connection with the pricing and marketing of pharmaceuticals), available at http://www.fcaalert.com/2011/02/articles/dojhhs-releases-new-statistics-about-sealed-qui-tam-cases/ (August 7, 2013); *Fraud Statistics-Health and Human Services*, Civil Division, U.S. Dep't. of Justice (Oct. 24, 2012) (showing 412 healthcare *qui* tams in 2012).

and acquisitions.[14] Claims made by third parties, media reports of industry-wide problems, and discoveries by internal or external auditors[15] or compliance officers can also trigger an internal investigation.

"Regardless of the origin of the investigation, or the depth of the organization's potential involvement in the matter, the first priority should always be to get the facts."[16] Since the government typically proceeds "with limited information while it collects additional information," companies that fully understand the facts can "develop a relationship with the investigating agency" and "can influence the way the government perceives the case by guiding investigators through documents and witnesses."[17] A complete understanding of the facts by counsel and compliance officers also enhances personal credibility, which may give an organization the "benefit of the doubt" rather than "added scrutiny."[18]

To begin fact collection, companies often either ask in-house counsel or retain outside counsel to conduct the investigation. Outside counsel is typically preferred in the life sciences industry because they "may be more objective in assessing practices" because they "are less familiar with the company's activities and personnel."[19] Moreover, the government may view in-house counsel "as lacking independence due to their status within the management structure," and "it may be more difficult for in-house counsel to establish and maintain privilege because they are frequently called upon to provide business advice."[20] Employee and third party interviews are critical to obtaining the underlying facts about the misconduct.

Middle- and low-level-employees "frequently … possess the [relevant] information needed by the corporation's lawyers" and can "embroil the corporation in serious legal difficulties."[21] Due to the repeated nature of many off-label cases, several common areas of investigation have emerged including, but not limited to: (a) off-label promotion or misbranding; (b) false statements or omissions to FDA, such as inaccurate or incomplete clinical data for a product application;[22] (c) financial conflicts of

[14] Eric Palmer, *Top Biopharma M&A Deals – 2012,* FiercePharma (Feb. 13, 2013) (showing 194 M&A deals worth $75 billion in 2010, 216 M&A deals worth $92 billion in 2011, and 146 M&A deals worth $57 billion in 2012) available at http://www.fiercepharma.com/special-reports/top-biopharma-ma-deals-2012 (last visited August 7, 2013).

[15] *See e.g.*, §10A of the Securities Exchange Act of 1934 requires auditors who detect potential misconduct to inform the audit committee or the board; SOX requires attorneys that represent public companies to report to specified officers or directors when they become aware of a possible material violation of certain laws.

[16] Kirk Ogrosky, *Internal Investigation Strategies In Healthcare Fraud & Abuse Matters*, Health Care Compliance Institute (Apr. 2013) at 3.

[17] *Id.*

[18] *Id.*

[19] *Id.* at 7.

[20] *Id.* at 6–7 ("This problem is exacerbated when information obtained in the internal investigation is shared by in-house counsel with auditors, accountants, underwriters and corporate officials not involved in defending the organization," which may lead to waiver in related civil litigation). For example, *see id.* at 12 n. 13 (citing *In re* Columbia/HCA Healthcare Corp. Billing Practices Litig., 293 F.3d 289 (6th Cir. 2002); *In re* Subpoena Duces Tecum, 738 F.2d 1367 (D.C. Cir. 1984)) (quotation marks omitted).

[21] Upjohn v. United States, 449 U.S. 383, 391 (1981).

[22] *See e.g.,* Thomas Sullivan, *GSK and other Pharmaceutical Companies Prepare to Release Global Patient Level Clinical Data*, Policy & Medicine (Dec. 13, 2012) (noting that the GlaxoSmithKline 2013 settlement alleged that company had not disclosed clinical data related to the diabetes medicine Avandia) available at http://cmecoalition.org/content/gsk-and-other-pharmaceutical-companies-prepare-release-global-patient-level-clinical-data (last visited August 7, 2013).

interest among investigators or journal authors; (d) ghostwriting; (e) using journal articles that were insufficient to support the safety and efficacy of off-label uses and improperly obtaining listings in medical compendia in an effort to establish that the off-label uses were medically accepted, and thereby eligible for coverage by federal health care programs;[23] (f) providing kickbacks in various forms to healthcare professionals or institutions; (g) providing sham educational grants to continuing education providers; (h) misreporting the "best price" that pharmaceutical companies report to Medicare; (i) overcharging for "340B" Program Drugs; and (j) FCPA violations. Other new areas of investigation and enforcement that are likely to grow include violations of current good manufacturing practices (cGMP) regulations,[24] medical devices involving defects or failures to make required reporting,[25] and "corrupt payments that may have influenced the reliability of data in clinical trials performed outside the US."[26] Interviewing employees regarding these types of misconduct requires a case-by-case approach for counsel to determine the appropriate nature, level, and order of questioning.

Regardless of what approach counsel chooses, lawyers have an ethical duty to clarify to employees that communications made during an interview are governed by an attorney-client privilege that belongs to the corporation, not individual employees. Lawyers must ensure that an employee is not under the impression that counsel is representing the employee individually. Otherwise, the lawyer may establish an attorney-client relationship with the employee and may be disqualified from representing the corporation under the conflict of interest rules.[27] In making this determination, courts often look to whether the employee received an "Upjohn warning," which takes its name from *Upjohn v. United States*,[28] where the U.S. Supreme Court ruled that the corporate attorney-client privilege applied to certain corporate employees beyond the corporate "control group."[29]

In *Upjohn*, the pharmaceutical company began an internal investigation to determine the nature of certain questionable payments made to foreign government officials in order to secure government business. Through interviews and surveys, employees provided information

[23] *See e.g.,* Thomas Sullivan, *Amgen Settlement and Corporate Integrity Agreement*, Policy & Medicine (Feb. 19, 2013) available at http://www.policymed.com/2013/02/amgen-settlement-and-corporate-integrity-agreement.html (last visited August 7, 2013).

[24] Thomas Sullivan, *DOJ to Target Pharma and Device Current Good Manufacturing Practices (cGMP) Violations*, Policy & Medicine (Feb. 26, 2013) available at http://www.policymed.com/2013/02/doj-to-target-pharma-and-device-current-good-management-practices-cgmps-violations.html (last visited August 7, 2013).

[25] Thomas Sullivan, *FDLI: Insights in Enforcement, Litigation & Compliance for Pharmaceutical and Medical Device Manufacturers*, Policy & Medicine (Dec. 18, 2012).

[26] Thomas Sullivan, *DOJ Targets Pharmaceutical Manufacturers In FCPA Probe*, Policy & Medicine (Aug. 16, 2010) available at http://www.policymed.com/2010/08/doj-targets-pharmaceutical-manufactures-in-foreign-corrupt-practices-act-probe.html (last visited August 7, 2013).

[27] Barbara J. Duffy and Connor B. Shively, *Legal Concerns in Specific Health Care Delivery Settings*, 3 HEALTH L. PRAC. GUIDE §49:4 (2012).

[28] 449 U.S. 383 (1981).

[29] Duffy & Shively, *supra* note 27. "The control group test focuses on the authority of the individual communicating with the attorney to act upon the advice of counsel, as well as their ability to establish corporate policy, and retain legal counsel. Generally, members of the control group are top executives." *Id.*

to Upjohn's in-house and outside counsel, "at the direction of corporate superiors, in order to secure legal advice … concerning compliance with securities and tax laws, foreign laws, currency regulations, duties to shareholders, and potential litigation in each of these areas."[30] Despite the government's attempt to obtain this information, the Court held that the responses to the survey and notes reflecting responses to interview questions were privileged.

Although some have suggested that *Upjohn* rejected the control group test and the Supreme Court adopted a "subject matter test," the Court expressly refused to adopt any concrete test.[31] The Supreme Court instead adopted a case-by-case approach, relying on five factors: (1) the communications were made by employees at the direction of corporate superiors to enable the corporation to obtain legal advice; (2) the communications concerned matters within the scope of the employee's duties; (3) the information was not available from upper-level directors; (4) the employees were aware that the purpose of the communications was to enable the corporation to obtain legal advice; and (5) the communications were intended to be kept confidential and were not disseminated outside the corporation.[32] Many states currently follow the subject matter test or a similar version, others have not yet decided the issue, and some states continue to use the control group test through either legislative enactments or common law.[33] As a result, there still remains ambiguity whether the corporation solely holds the attorney-client privilege or if an interviewed employee can claim the privilege as well.

II. Federal Law Enforcement and Internal Investigations

A company's willingness to proactively investigate internal allegations of wrongdoing may significantly affect the sanctions, penalties, or fines the government might seek to impose.[34] Companies that conduct an internal investigation to voluntarily inform the government of potential wrongdoing and cooperate with the government in a timely and thorough manner may mitigate monetary fines under chapter eight of the Federal Sentencing Guidelines Manual (the "Guidelines").[35] To be timely, the cooperation must begin essentially at the same time as the organization is notified of misconduct or a criminal investigation. To be thorough, the cooperation should include the disclosure of all pertinent information known by the organization, which should be sufficient for law enforcement to

[30] *Upjohn*, 449 U.S. at 384. The communications regarded employees' corporate duties, and the employees were aware that the questioning was for the corporation to obtain legal advice.

[31] Timothy M. Middleton, *"Watered-Down Warnings:" The Legal and Ethical Requirements of Corporate Attorneys in Providing Employees with* "Upjohn Warnings" *in Internal Investigations*, 21 GEO. J. LEGAL ETHICS 951, 954 (2008).

[32] ATTORNEY-CLIENT PRIVILEGE AND CONFIDENTIALITY, § 5:6 (West, 2011) (citations omitted).

[33] *See* Brian E. Hamilton, *Conflict, Disparity, and Indecision: the Unsettled Corporate Attorney-Client Privilege*, 1997 ANN. SURV. AM. L. 629, 633–646 (1999).

[34] They may also reduce the likelihood that employees will report allegations directly to the government or media.

[35] United States Sentencing Commission, GUIDELINES MANUAL, 496 (2010). The Guidelines provide only for monetary fines for organizations convicted of federal criminal violations.

identify the nature, extent, and individual(s) responsible for the criminal conduct.[36] In addition, the Guidelines list six factors to assess a company's culpability, four of which enhance the level of culpability: (1) involvement in or tolerance of criminal activity; (2) prior history of criminal misconduct; (3) violation of an order; and (4) obstruction of justice. The two other factors—(5) the existence of an effective compliance and ethics program and (6) the organization's self-reporting, cooperation and/or acceptance of responsibility—mitigate the organization's culpability.[37]

In addition to the Guidelines, federal prosecutors follow the "Principles of Federal Prosecution of Business Organizations," issued by the Office of the Deputy Attorney General, to determine whether to charge companies with criminal misconduct. The guidelines instruct prosecutors to consider whether an internal investigation: (1) led to the timely disclosure of any wrongdoing; (2) was voluntary; and (3) produced a general willingness to cooperate with the government.[38] In assessing a company's willingness, prosecutors may look at whether a company: (1) identified the persons responsible for the violation (including senior executives); (2) made witnesses available; (3) disclosed completely and thoroughly the results of the company's internal investigations; and (4) waived attorney-client and work product privileges.[39]

When evaluating cooperation credit, the current Principles prohibit prosecutors from considering the company's indemnification of attorney's fees for officers and employees under investigation[40] and the company's discipline or lack of discipline of culpable employees.[41] While DOJ may not consider the lack of discipline of culpable employees a factor, HHS-OIG will consider an owner, officer, or managing employee's "action in response to the misconduct"[42] when making an exclusion decision.[43] This includes whether the individual (1) acted to stop the underlying misconduct or mitigate the effects of the misconduct; (2) stopped or mitigated the misconduct before or after the individual learned of the government's investigation; and (3) disclosed the misconduct to the appropriate authorities and cooperated with investiga-

[36] *Id.*

[37] U.S.S.G. § 8C2.5(a)-(g), available at http://www.ussc.gov/Guidelines/2010_guidelines/ToC_PDF.cfm (last visited August 7, 2013).

[38] Larry D. Thompson, United States Department of Justice, *Principles of Federal Prosecution of Business Organizations*, 6 (Jan. 20, 2003) (hereinafter "Thompson Memo") available at http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf (last visited August 7, 2013).

[39] *Thompson Memo* at 7.

[40] *Id.* at 13.

[41] *But see* Ogrosky, *supra* note 16 at 8 (citing Mary Beth Buchanan, who noted that "a zero tolerance approach to employee crime is integral to the organizational culture of a good corporate citizen") (citation omitted).

[42] *Thompson Memo* at 4.

[43] *OIG Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act*, at 2 (Oct. 20, 2010) (hereinafter "OIG Permissive Exclusion Guidance") available at http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf (last visited August 7, 2013). The guidance explains that OIG will exercise a presumption in favor of exclusion under section (b)(15) for an owner, officer, or managing employee under certain circumstances. The guidance also applies to officers, general or business managers, directors, or administrators who have managerial or operational control or who have a direct or indirect role in the day-to-day operations of the entity. *See also* 42 C.F.R. § 1001.1051.

tors and prosecutors.[44] If an individual can demonstrate either that preventing the misconduct was impossible or that the individual exercised extraordinary care but still could not prevent the conduct, OIG may consider this as a factor weighing against exclusion.[45]

While the initial Principles encouraged companies to waive the attorney-client privilege, the most recent Principles prohibit prosecutors from requesting that companies disclose non-factual information or 'core' attorney-client communication protected by the attorney-client privilege or work-product doctrine.[46] Companies may still voluntarily waive such privileges, but counsel must advise officers that any improper waiver or disclosure of otherwise privileged information may constitute a breach of a fiduciary duty[47] and may expose the officers to individual liability. For example, allegations regarding illegal kickbacks or off-label promotion may originate with low or mid-level employees in violation of a company's corporate compliance policies and training. Although an internal investigation may reveal that such employees completely disregarded internal policies and were acting independent of any superior, disclosing such information may provide significant evidence that would cause DOJ, FDA, or OIG to bring an action against corporate executives under the RCO doctrine.[48]

However, when considering exclusion, OIG may consider favorably the low "level within the entity at which the misconduct occurred."[49] Moreover, if revealing such low-level misconduct demonstrates "an isolated incident," rather than a "widespread" or "larger pattern of wrongdoing," this may also weigh favorably against OIG's permissive exclusion[50] or FDA's *Park* prosecution.[51] Nevertheless, such disclosure may cause officers and other employees who have knowledge of the misconduct to be less inclined to reveal information if they have no expectation of confidentiality given the potential RCO liability. Counsel must also keep in mind that while communications regarding past crimes or frauds remain privileged, the attorney can in no way advise executives or the board how to cover-up that past crime or fraud.

Corporate counsel must closely scrutinize the language it uses to describe facts and information regarding misconduct to DOJ because DOJ may use such language in the statement of the offense. Companies that want to protect their executives from exclusion may opt to refuse agreeing to plead facts "suggesting false, misleading or deceptive promotional practices by the company"[52] because a guilty plea may have collateral consequences related to "sentenc-

[44] *Id*.

[45] *Id*.

[46] *See* Mark Filip, Deputy Attorney General, Department of Justice, *Memorandum to Heads of Department Components and United States Attorneys*, 8 (Aug. 28, 2008) (hereinafter "Filip Memo") available at http://www.justice.gov/dag/readingroom/dag-memo-08282008.pdf (last visited August 7, 2013).

[47] *See, e.g.,* Commodity Futures Trading Com'n v. Weintraub, 471 U.S. 343, 348–349 (1985).

[48] *See supra* note 10.

[49] *OIG Permissive Exclusion Guidance*, *supra* note 43 at 3 (*e.g.*, violation by one field employee of company policy versus headquarters' involvement and/or direction).

[50] *Id*.

[51] *FDA* Park *Procedures*, *supra* note 12.

[52] Dana A. Elfin, *Experts Say D.C. Circuit's Ruling May Increase Permissive Exclusion Use*, BNA Pharmaceutical Law & Industry Report, August 3, 2012, at 2, available at http://www.bassberry.com/files/Uploads/Documents/BNA-Pharma-Law-Report-8-2012.pdf (last visited August 7, 2013).

ing, business decision making, shareholder derivative actions, and Directors and Officers insurance policies."[53] Because some executives and directors may have medical licenses, counsel must advise clients about how a criminal charge or particular facts may affect the status of a medical license.[54] While licensure actions vary by state, counsel should avoid pleading to charges or agreeing to facts that suggest issues of "moral turpitude."[55] Accordingly, corporate counsel must balance these factors when conducting an investigation and interviewing employees and executives to determine what information to disclose.

A. Deferred Prosecution Agreements

The most recent Principles also describe a "third option" for prosecutors to consider. Specifically, if the impact of a conviction on innocent third parties is significant, it may be appropriate for prosecutors "to consider a non-prosecution or DPA with conditions designed, among other things, to promote compliance with applicable law and to prevent recidivism."[56] This factor is critical for companies to emphasize during government negotiations because a conviction would almost certainly force OIG to exclude a company, which would disrupt the supply of "needed drugs to patients" and harm "innocent employees, shareholders, and others."[57]

For example, in off-label cases, the government is concerned about paying for drugs that are unsafe, ineffective, or not medically necessary. If the off-label use is the standard of care (e.g., many oncology drugs),[58] DOJ may consider a DPA to avoid disrupting patient needs. Thus, counsel will need to structure their investigations of sales, marketing, and medical affairs staff accordingly to determine the level of misconduct. If employees were disseminating truthful and non-misleading information about off-label uses,[59] a DPA is easier to negotiate. On the other hand, if employees downplayed risks or marketed such uses to children or the elderly, the harm to patients may outweigh concerns for innocent third parties. In fact, information regarding "actual or potential harm to beneficiaries or financial harm to any persons or

[53] Virginia B. Evans and John S. Linehan, *Understanding the Use of Misdemeanors in Healthcare Enforcement*, Health Law Alert Newsletter, Ober Kaler (2012 Issue 3).

[54] *Id.* (noting that medical licensure and privileging actions "frequently spring from … criminal convictions").

[55] *Id.*

[56] *Filip Memo*, *supra* note 46 at 18 (instructing prosecutors to "consider the collateral consequences of a corporate *criminal conviction or indictment*").

[57] Ed Silverman, *The OIG And Excluding Execs: Demske Explains*, PHARMALOT, (Jun. 6, 2011) (interviewing OIG's then Assistant Inspector General for Legal Affairs, Greg Demske), available at http://www.pharmalot.com/2011/06/the-oig-and-excluding-execs-demske-explains/ (hereinafter "Demske Interview") (last visited August 7, 2013).

[58] John Easton, *UChicago Researchers Establish Benchmark for Off-Label Use of Expensive Cancer Drugs*, SCIENCE LIFE, UNIV. CHICAGO MED. & BIO. SCIENCES (Feb. 22, 2013) (citing health economics researches who found that in 2010, the "ten most commonly prescribed patent-protected intravenous anticancer drugs were used off label about thirty percent of the time").

[59] *See* United States v. Caronia, 703 F.3d 149, 169 (2nd Cir. 2012) (the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.).

programs'' caused by the misconduct is a critical factor that OIG will consider for exclusions[60] and FDA will consider for *Park* prosecutions.[61] Accordingly, corporate counsel must advise companies of the potential implications that patient harm information may have on DPAs, CIAs, exclusion, product liability and tort suits, and overall corporate reputation.

Although at least eight of the world's top ten drug makers have disclosed U.S. probes under the FCPA,[62] two high-profile settlements involving DPAs are instructive into how DOJ considers using this ''third option.'' In 2011, Johnson & Johnson (J&J) paid $70 million and entered into a DPA to resolve FCPA violations for improper payments by J&J subsidiaries to government officials in Greece, Poland and Romania.[63] The DPA requires J&J to report to DOJ on implementation of its remediation and enhanced compliance efforts every six months for the duration of the agreement. The company did not have to retain a corporate monitor due to their ''pre-existing compliance and ethics programs, extensive remediation, and improvement of its compliance systems and internal controls, as well as the enhanced compliance undertakings included in the agreement.''[64] Interestingly, J&J also received a reduced punishment because the company assisted DOJ in investigating other companies.[65]

Pfizer Inc. subsidiary Pfizer H.C.P. Corporation (''Pfizer H.C.P.'') entered into a two-year DPA in August 2012 to resolve alleged criminal violations of the FCPA regarding certain relationships that employees of Pfizer and its Wyeth LLC subsidiary had with healthcare providers and government officials in Italy, China, the Czech Republic, Saudi Arabia, Indonesia, and Pakistan. Pfizer H.C.P. also agreed that the Department of Justice may file two-count Information charging the company with bribery and conspiracy to violate the FCPA.[66] Pfizer and Wyeth also settled allegations by the SEC that ''both companies made corrupt payments and

[60] *OIG Permissive Exclusion Guidance*, *supra* note 43 at 3.

[61] *FDA* Park *Procedures*, *supra* note 12.

[62] Thomas Sullivan, *Foreign Corrupt Practices Act and the Medical Products Industry Fines and Investigation Costs Increasing*, Policy & Medicine (Nov. 20, 2012) available at http://www.policymed.com/2012/11/foreign-corrupt-practices-act-and-the-medical-products-industry-fines-and-investigation-costs-increa.html (last visited August 7, 2013). In 2009 Danish insulin maker Novo Nordisk paid $9 million for FCPA violations, while medical device maker Smith & Nephew agreed to $22 million in fines and profit disgorgement. The largest FCPA penalty on record was $800 million paid in 2008 by Germany-based Siemens. *Id.*

[63] Thomas Sullivan, *FCPA: Johnson and Johnson to Pay $70 Million in Fines on International Orthopedic Subsidiary*, Policy & Medicine (May 17, 2011) available at http://www.policymed.com/2011/05/fcpa-johnson-and-johnson-to-pay-70-million-in-fines-on-international-orthopedic-subsidiary.html (last visited August 7, 2013).

[64] *Id.*

[65] Hank Bond Walther, *Former Chief Of DOJ Fraud Unit Discusses Healthcare And FCPA Enforcement*, Metropolitan Corporate Counsel (September 22, 2012) available at http://www.metrocorpcounsel.com/articles/20547/former-chief-doj-fraud-unit-discusses-healthcare-and-fcpa-enforcement (last visited August 7, 2013).

[66] Arnold & Porter, *Pfizer's FCPA Settlement Provides Important Lessons for the Medical Products Industry on Global Compliance Program Expectations for Customer Relationships* (Aug. 2012) (hereinafter ''A&P Pfizer FCPA Alert'') available at http://www.arnoldporter.com/resources/documents/Advisory-Pfizer's_FCPA_Settlement_Provides_a_Lesson_23August12.pdf (last visited August 7, 2013). Pfizer H.C.P. paid a $15 million fine and agreed to pay more than $23.6 million in disgorgement of profits; Wyeth LLC separately agreed to pay $18.8 million. *Id.*

violated the books and records and internal controls provisions of the FCPA."[67] As part of the settlement, Pfizer agreed to "provide the SEC with a written report describing its FCPA and anti-corruption remediation efforts, and two follow-up reviews documenting its monitoring efforts."[68]

The Pfizer case is instructive for several reasons. When Pfizer's Corporate Compliance Division learned of the potentially improper payments made by the Croatia office, the company made a voluntary disclosure of these payments to the SEC and DOJ in October 2004 when "neither agency had been previously aware of these payments."[69] Subsequent to this disclosure, Pfizer used internal and external "Legal, Compliance, and Corporate Audit personnel to voluntarily undertake an extensive global review of its operations to analyze its relationships with government officials and government doctors in Pfizer H.C.P. markets and those of other subsidiaries."[70] After disclosing the results of this review to the government, Pfizer launched "extensive remedial actions," including: (1) implementing enhanced anti-corruption policies and procedures; (2) developing global systems to support employee compliance with those policies and procedures; (3) adding FCPA-specific reviews to its internal audits; (4) performing proactive anti-corruption compliance reviews in approximately ten markets annually, and (5) conducting extensive anti-corruption training throughout the organization.[71] In recognition of Pfizer's cooperation and the "extensive enhancements" to its global compliance program, the DPA does not require an independent corporate monitor, DOJ did not require a criminal plea, and DOJ reduced their fine by 34% off the Guidelines' recommended fine range for FCPA violations.[72]

In another recent example, Eli Lilly agreed to pay $29.4 million to settle an SEC complaint alleging that the company violated the FCPA because its subsidiaries made improper payments to foreign government officials to win millions of dollars of business in Russia, Brazil, China, and Poland.[73] To resolve the allegations, "Lilly agreed to have an independent consultant conduct a 60-day review of its internal controls and compliance program related to the anti-bribery law."[74] Although Lilly said it cooperated with the U.S. government throughout the investigation and strengthened its internal controls and compliance program globally, the SEC maintained that the company became aware of improper marketing agreements and possible FCPA violations but did not curtail the use of such agreements for more than five years.[75]

[67] *Id.* (citing, SEC Press Release, *SEC Charges Pfizer with FCPA Violations*, (Aug. 7, 2012)).

[68] *Id.*

[69] *Id.* at 2.

[70] *Id.*

[71] *Id.* Additionally, "Pfizer regularly reported to DOJ and the SEC on these activities and sought the government's input concerning their scope and focus."

[72] *Id.*

[73] Tom Schoenberg, *Lilly to pay $29.4 Million to End SEC Foreign Bribe Case*, Bloomberg (Dec. 20, 2012) available at http://www.bloomberg.com/news/2012-12-20/lilly-to-pay-29-4-million-to-end-sec-foreign-bribe-case.html (last visited August 7, 2013).

[74] *Id.*

[75] *Id.* "The SEC said an Eli Lilly subsidiary in Russia used so-called offshore marketing agreements to pay third parties chosen by government customers or distributors without knowing who these people were beyond an address or bank account information. These offshore entities were used in some instances to funnel money to government officials to obtain business for the subsidiary, the SEC alleged." *Id.*

These cases underscore the importance of voluntary internal investigations that are timely and thorough, enhancing corporate compliance, and cooperating with the federal government for DOJ to offer a DPA and other reduced sanctions or fines.

B. Parallel Government Enforcement and Civil Actions

Internal investigations also raise concerns about parallel government enforcement and civil actions that may arise from corporate disclosure and public settlement of cases with the government. Internal investigations prior to government involvement may reveal the potential need to make a voluntary disclosure under OIG's self-disclosure protocol ("SDP") or CMS's Self-Referral Disclosure Protocol. OIG's recently updated SDP outlines specific requirements for drug and device manufacturer to disclose potential anti-kickback violations, which may trigger civil monetary penalty liability.[76] While companies may avoid exclusion or a CIA and receive a lower penalty, disclosure is "expensive, time consuming and disruptive"; "may trigger a new investigation or expand an existing investigation into new territory by OIG or other agencies" and could create waiver issues that may affect subsequent civil litigation.[77]

Federal prosecutors recently alleged that four former executives of Norian Corporation conspired to conduct unauthorized clinical trials of Norian's bone cement in surgeries to treat vertebral compression fractures of the spine without an investigational new drug application.[78] The executives pleaded guilty to misdemeanor counts of shipping adulterated and misbranded bone cement into interstate commerce and were sentenced to jail for at least five months and fined. The company also pleaded guilty to felony and misdemeanor criminal charges and paid a $23.5 million fine. Parallel to this case, a plaintiff filed a civil action for wrongful death, in which the complaint is based on the same conduct in the government case.[79]

Federal prosecutors indicted the CEO of Intermune for making statements about a new lung disease drug in a press release, promoting it off-label and overstating its efficacy. The Ninth Circuit recently upheld the CEO's conviction.[80] Consequently, plaintiffs proposed a nationwide class action alleging fraud and deceptive marketing of the drug. Their complaint references the indictment, criminal fines paid by the company and charges against the CEO.[81]

[76] OIG, Updated Provider Self-Disclosure Protocol, (Apr. 17, 2013), available at https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf (last visited August 7, 2013).

[77] Ogrosky, *supra* note 16 at 10.

[78] Christiana C. Jacxsens, *The Intersection of Civil Products Liability and Government Enforcement Actions*, FDLI Enforcement, Litigation and Compliance Conference (Presentation) (Dec. 2012) (citing U.S. v. Norian Corp. et al., No. 09-403 (E.D. Pa.)) (hereinafter "Jacxxsens Presentation") available at http://www.fdli.org/docs/default-document-library/jacxsens2012.pdf?sfvrsn=0 (last visited August 7, 2013).

[79] *Id*.

[80] Thomas Sullivan, *Court Upholds InterMune Executive Conviction on Misleading Speech*, Policy & Medicine (Mar. 28, 2013) available at http://www.policymed.com/2013/03/courts-find-intermune-executive-conviction-upheld-on-misleading-speech.html (last visited August 7, 2013).

[81] Jacxsens Presentation, *supra* note 78 (citing Jarrett, et al. v. Intermune, Inc. 3:08-cv02376-MHP (N.D. Cal.)) The case was ultimately dismissed with prejudice after finding plaintiffs were unable to cure deficiencies in their pleadings. *Id*.

Similarly, Stryker Biotech pleaded guilty to a misdemeanor misbranding charge for its promotion of Calstrux, a bone void filler and paid a $15 million fine. Prosecutors dismissed all charges against all executives after documents showed they acted in good faith. Nevertheless, plaintiffs brought a case against Stryker alleging negligence, breach of express and implied warranty and fraud in their complaint, with references to the indictments.[82]

State attorneys general are increasingly hiring plaintiffs' attorneys on a contingent-fee basis to bring civil actions against life science companies on behalf of the State itself in *parens patriae* actions.[83] Arkansas, Louisiana and South Carolina have each hired plaintiffs' contingency fee attorneys to file lawsuits against Johnson & Johnson and Janssen Pharmaceuticals for the off-label promotion of Risperdal. Trial courts in these states entered judgments totaling nearly $2 billion against Janssen asserting consumer protection laws,[84] which states are increasingly using to sue drug and device companies.[85] A federal court also admitted evidence of Bayer Pharmaceutical's CIA at trial, finding it relevant and admissible to show intent and lack of mistake.[86]

Last, the United States Court of Appeals for the First Circuit[87] recently issued an opinion that may allow third-party payers to bring "class-action racketeering claims" against Pfizer for its illegal off-label marketing of Neurontin.[88] Similar to the actions brought by the federal government under the False Claims Act (FCA) and state-related false claims statutes, private insurers may be able to allege—using predicate federal or state settlements, convictions, pleas or disclosures—that their payment for off-label or unapproved uses was improper due to the off-label marketing. These cases underscore the importance of corporate counsel taking a global approach to resolving alleged misconduct and any secondary causes of action or potential liability that may arise from government enforcement.

C. Increasing Transparency of Industry Interactions

Corporate counsel also face new and unique challenges for internal investigations because the nature of relationships and interactions between life science companies and physicians, hospitals, charities, the government, and various entities are becoming increasingly transparent. In 2008, Eli Lilly announced that it would voluntarily post the names and payments the company made to physicians on a public website.[89] Shortly thereafter, companies

[82] *Id.* (citing Cabana v. Stryker Biotech, LLC, et al, No. BC 465313 (Ca. Sup. Ct. L.A., Cent. Dist.)).

[83] *Id.*

[84] *Id.*

[85] Peter Loftus, *States Take Drug Makers to Court Over Marketing*, THE WALL STREET JOURNAL (Apr. 22, 2013) (listing at least eight states that have separate lawsuits against drug makers). Cases under state consumer protection law are easier to prove because only evidence of ''deceptive marketing,'' not patient injury or harm, is needed.

[86] Jacxsens Presentation, *supra* note 78 (citing *In re* Yasmin & Yaz (Drospirenon) Mktg., 3:09-md-2100-DRH-MDL, 2011 WL 6740391, at *4 (S.D. Ill. Dec. 22, 2011)).

[87] *In re Neurontin Marketing and Sales Practices Litigation*, 11-1806; and *Kaiser Foundation Health Plan et al v. Pfizer Inc et al.* 11-1904 and 11-2096 (1st Cir. 2013).

[88] Jef Feeley and Janelle Lawrence, *Pfizer Neurontin Class Improperly Denied, Court Says*, BLOOMBERGBUSINESSWEEK (Apr. 4, 2013).

[89] Thomas Sullivan, *Physician Payment Sunshine: Eli Lilly Acts*, Policy & Medicine (Sept. 24, 2008) available at http://www.policymed.com/2008/09/physician-payment-sunshine-lilly-acts.html (last visited August 7, 2013).

began publishing payments regarding clinical research, meals, travel, consulting, and educational grants as a requirement of CIAs.[90] In 2010, an investigative organization known as ProPublica launched a campaign known as "Dollars for Docs," in which the group aggregated the payments life science companies had published—either voluntarily or because of a CIA—and created a searchable database that aggregated payments to physicians and hospitals across approximately fifteen companies.[91] This increased transparency has led to various Congressional, state and federal investigations into improper payments for research, speaking, consulting, education, and promotion.[92] Such increased scrutiny eventually led to Congress passing the Physician Payments Sunshine Act, as part of the Affordable Care Act (ACA).[93]

The Sunshine Act requires applicable manufacturers of drugs, devices, biologicals, or medical supplies (AMs) covered under Medicare, Medicaid or the Children's Health Insurance Plan (CHIP) to report annually to CMS certain payments or other transfers of value ("payment") to physicians and teaching hospitals.[94] CMS will aggregate all payments and publish them on a searchable website with certain information. The Sunshine Act website will be a powerful new tool for state and federal prosecutors and a number of other government agencies. Payments to physicians for speaking, travel, meals, research, consulting, and other services may violate the Anti-Kickback Statute (AKS) if any one purpose of the payment is to induce physicians to prescribe medication or refer patients for goods or services paid for by CMS. Under the ACA, violations of the AKS can serve as the basis for FCA violations for all claims submitted that resulted from illegal remuneration. Public disclosure of physician investment or ownership interests in a manufacturer will also raise issues under the Stark Law and AMs will need to ensure compliance with a growing number of international transparency laws and foreign industry guidelines.[95]

Government officials may also use a physician's reported specialty to determine if payments are being made to a physician for an off-label use (e.g., a psychiatrist receives a payment related to an anti-epileptic drug). Federal and state prosecutors may also use payment data to call into question the medical necessity of treatment provided and to analyze claims tied to

[90] Copeland, *supra* note 3 at 1056 (citing Pfizer's CIA).

[91] Thomas Sullivan, *Physician Payment Sunshine: ProPublica Updates Dollars for Doctors Database for 2013*, Policy & Medicine (Mar. 12, 2013) available at http://www.policymed.com/2013/03/physician-payment-sunshine-propublica-updates-dollars-for-doctors-database-for-2013.html (last visited August 7, 2013).

[92] *See e.g.,* Gardiner Harris, *Researchers Fail to Reveal Full Drug Pay*, New York Times, (Jun. 8, 2008). Dr. Joseph Biederman, a renowned child psychiatrist at Harvard Medical School, and a colleague, Dr. Timothy E. Wilens, reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000 to 2007 when in fact they had earned at least $1.6 million each.

[93] H.R. 3590, section 6002.

[94] *Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests*, 78 Fed. Reg. 9458 (Feb. 8, 2013) (hereinafter "Final Sunshine Rule").

[95] This includes France, the Netherlands, Slovakia, Australia, China, Croatia, Denmark, Japan, the Association of the British Pharmaceutical Industry, the International Federation of Pharmaceutical Manufacturers & Associations, and the European Federation of Pharmaceutical Industries & Associations.

physicians, "including the number of surgeries conducted, and prescriptions for off-label use of medications or high cost drugs," which could lead to FCA investigations.[96]

Private insurers or third-party payers may use the Sunshine database to deny or delay claims from physicians that they see receive payments from companies if they determine that such payments are influencing improper off-label prescribing or are not medically necessary.

The collection of NPI numbers[97] will raise concerns for AMs because it will permit researchers to link information on providers' financial relationships to Medicare claims data (Part D drugs) to evaluate the impact of these interactions on prescribing practices. Transparency will also bring scrutiny to physicians on hospital Pharmacy and Therapeutics Committees that make or influence purchasing decisions, as well as senior officials, deans and department chairs at hospitals that may influence utilization of products or services.[98] This increased transparency will add new complexity for corporate counsel when investigating improper conduct and gathering facts about various relationships and transactions.

III. Recommendations

A. Internal Investigation Interviews: Practical Considerations

Even when there may be uncertainty as to whether corporate constituents may assert the attorney-client privilege, corporate counsel should always give *Upjohn* warnings to employees and third parties during investigation interviews.[99] Clarifying this role is particularly important in life science companies because in-house or outside counsel may have pre-existing relationships with employees. In-house may provide compliance training for sales, marketing and various other staff, or employ outside contractors to perform such training. Counsel may also answer legal or compliance questions throughout day-to-day operations for low-level staff or even mid-level managers. Each of these interactions may suggest to employees a pre-existing attorney-client relationship that may jeopardize an attorney's role in a future interview.

Counsel may also want to warn employees of the criminal consequences for tampering with or destroying evidence and that lying to investigators during internal investigations could have criminal consequences.[100] This is

[96] Tracy E. Miller, *The Payment Sunshine Act: Assessing the Compliance Risks for Healthcare Providers*, AHLA CONNECTIONS (Aug. 2011) at 26.

[97] *Final Sunshine Rule* at 9468–9469.

[98] Miller, *supra* note 96.

[99] *See* AMERICAN BAR ASSOCIATION MODEL RULE OF PROFESSIONAL CONDUCT 1.13(f). *See also* ABA's White Collar Crime Committee Working Group example *Upjohn* warning. Such a warning must indicate that while the interview is covered by the attorney-client privilege, the privilege belongs to, and is controlled solely by, the company not the employee; the content of the interview must be kept confidential in order to maintain attorney-client privilege, and therefore the employee cannot discuss the interview with others; and the company may decide to waive the privilege in the future and may disclose certain information obtained from the employee in the interview to third parties and/or government investigators or prosecutors.

[100] *See* Sehyung D. Lee, *The Benefits of a Miranda-Type Approach to* Upjohn *Warnings*, SECTION OF LITIGATION, COMMERCIAL & BUSINESS LITIGATION, (Apr. 30, 2012) available at http://apps.americanbar.org/litigation/committees/commercial/articles/spring2012-0412-benefits-miranda-warning-upjohn-warnings.html (last visited August 7, 2013) (suggesting that including language in counsel's *Upjohn* warning, regarding the potential criminal risks may be beneficial for the following reasons: "first, as [a] matter of fairness to inform employees that they could be committing a crime; and, second, to prevent employees from muddying investigations by providing misinformation").

particularly important because low- or mid-level employees, such as sales reps, often have key information pertaining to the alleged misconduct like records from which physicians or hospitals received payments and notes pertaining to any interactions. Such advice should also indicate that the employee might choose to secure counsel, particularly employees that might face exclusion or loss of licensure. Although counsel should memorialize interviews in fact-based summaries or memorandums, they should "refrain from including mental impressions and strategy in their notes of witness interviews" to avoid any disclosure of attorney work product or privileged materials.[101]

Counsel must also recognize when third parties have an established working relationship with the corporate client that is similar to that of regular employees to determine if the attorney-client privilege applies. Such analysis is important given the number of third party consultants life science companies hire for compliance training, aggregate spend, manufacturing or distribution, marketing, accounting and reimbursement, and numerous other areas. Counsel must also use this analysis to determine if the privilege applies to "agents" whose communications are reasonably necessary for adequate legal assistance. This decision is critical given the various and frequent consulting arrangements life science companies engage in (e.g., ensuring FDA approval or CMS reimbursement). To retain this privilege, engagement letters should clearly indicate that the expert or consultant is retained to help the attorney provide legal assistance to the client and that the expert or consultant will work under the attorney.

Corporate counsel should obtain information during interviews about any employee disciplinary action taken by management or higher-level officials. If a company terminates an employee for misconduct, counsel must locate and interview the former employee, particularly to avoid any allegations of improper termination under whistleblower protections.[102] In off-label promotion or kickback cases such information is critical to determine whether an employee's termination was for engaging in misconduct at the direction of their superior. This information would allow corporate counsel and corporate boards to find which employees are truly culpable for misconduct.[103] Counsel and boards may also want to locate improperly disciplined or terminated employees immediately because such individuals have a high likelihood of becoming relators.

When interviewing former employees, counsel must determine whether and to what extent communications are priv-

[101] Ogrosky, *supra* note 16 at 8 (citing former director of the Exec. Office of U.S. Attorneys Mary Beth Buchanan).

[102] Companies are prohibited from retaliating against whistleblowers. *See* 18 U.S.C. § 1514A(a)(1) ("No company … may discharge, demote, suspend, threaten, harass, or in any other manner discriminate against an employee … [who] provide[s] information, cause[s] information to be provided, or otherwise assist[s] in an investigation regarding any conduct which the employee reasonably believes constitutes a violation of section 1341, 1343, 1344, or 1348, any rule or regulation of the SEC, or any provision of Federal law").

[103] This information is also critical for determining whether the action taken by the employee at the direction of a supervisor can be attributed to the company and lead to the company being held vicariously liable if the "individuals involved possessed the requisite knowledge and intent." Ogrosky, *supra* note 16 at 8.

ileged. Most courts extend the privilege if the communication relates to the former employee's conduct and knowledge or communication with counsel during his or her employment. Counsel should modify an *Upjohn* warning to emphasize that the interview will cover facts and information relating to the former employee's time at the company.[104] If former employees have retained independent counsel, attorneys must be aware of the ethical rules regarding communications with represented parties.

Given the inordinately high number of government "touches," or points of contact with government agencies and officials that life sciences companies have, global compliance and training programs are critical to prevent FCPA or other violations that may lead to an internal investigation.[105] Companies must assess FCPA risks by identifying where their business directly or indirectly interacts with government or "foreign" officials, which includes anyone employed by a state-owned or state-run enterprise."[106] To begin making such assessments, companies may train their employees based on the recently published resource guide by DOJ and the SEC.[107] This comprehensive guidance provides critical clarity to important FCPA definitions, such as "foreign official,"[108] "instrumentality,"[109] "public international organizations,"[110] and third parties or intermediaries.[111] The guide also frames critical factors DOJ and the SEC will consider in applying these definitions to foreign transactions and relationships. Given the increased scrutiny[112] that other countries are placing on industry relationships, companies must demonstrate thoughtful and effective FCPA and healthcare compliance programs, employee training, and periodic testing to minimize the impact of an enforcement action.

[104] CORPORATE COUNSEL'S GUIDE TO LEGAL AUDITS AND INVESTIGATIONS, § 5:6 *Attorney-Client Privilege and Confidentiality*, (West 2011) (citations omitted).

[105] Walther, *supra* note 65.

[106] *Id.*

[107] *See* Dep't. of Just. and Enforc. Div. SEC, *Resource Guide to the U.S. Foreign Corrupt Practices Act* (Nov. 14, 2012) (hereinafter "DOJ-SEC FCPA Guidance") available at http://www.justice.gov/criminal/fraud/fcpa/guide.pdf (last visited August 7, 2013).

[108] *Id.* at 19–20. The term "foreign official" generally refers to an individual falling within three categories: any officer or employee of a foreign government or any department, agency, or instrumentality thereof or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization.

[109] *Id.* at 20–21.

[110] *Id.* at 21.

[111] *Id.* at 21–23. The FCPA expressly prohibits corrupt payments made through third parties or intermediaries.

[112] *A&P Pfizer FCPA Alert*, *supra* note 66 (noting that "regulators in the United Kingdom, Germany, Italy, and other jurisdictions are scrutinizing industry relationships under their local anti-bribery laws"). *See also* Aruna Viswanatha, *India Drugs Inquiry Could Prompt New U.S. Scrutiny*, REUTERS (May 10, 2012) available at http://www.reuters.com/article/2012/05/10/us-drugs-india-bribery-idUSBRE8491IP20120510 (last visited August 7, 2013) (noting that DOJ and the SEC have begun to conduct "extensive inquiries into nearly every major drug and medical device manufacturer for potential violations" of the FCPA, including China and Latin America).

B. The Challenges of Transparency and Internal Investigations

Increased transparency creates new challenges for counsel during internal investigations and interviews. Given the Sunshine Act penalties companies may face and the additional government and public scrutiny transparency brings, counsel must determine whether reporting or tracking failures took place and the nature and extent of such failures. Gathering facts surrounding such failures is also crucial because improper reporting will likely raise concerns from CMS, OIG, DOJ and FDA, particularly for consulting, marketing, education, and research. For example, improper or suspect payments could call into question the sufficiency of research data or journal articles used to support the safety and efficacy of off-label uses, causing FDA to reject a new indication. Such payments could also raise concerns about the data submitted to CMS to obtain listings in the medical compendia to establish that off-label uses are medically accepted and thereby eligible for federal reimbursement, as was recently alleged in the recent Amgen settlement.[113]

Counsel will need to identify any discrepancies that Sunshine Act regulations may have with other reporting obligations required by NIH and FDA regulations. For research payments to be granted delayed publication on the Sunshine database, counsel will need to determine if research agreements are in writing. Counsel must also determine whether activities segregable from the research, like travel or meals, were included in the research contract, as such payments must be reported separately.[114] Counsel will need to determine if employees only included appropriate costs when reporting the "total amount of research payment."[115]

Corporate counsel face unique challenges interviewing corporate executives and employees responsible for attesting that the submitted payment information was accurate.[116] Due to the tremendous amount of payments that companies will track and report, responsible executives may have no way of knowing if mistakes occur or the company omitted payments.[117] Consequently, interviewing executives responsible for reporting may uncover facts that implicate the OIG's exclusion statute. Since CMS is implementing the Sunshine Act, OIG may interpret a knowing failure to report or correct a payment as a program related crime that would subject the executive to a mandatory exclusion.[118] OIG may also consider a reporting violation as a failure to supply payment information[119] or an

[113] *See supra* note 2.

[114] *Final Sunshine Rule* at 9484.

[115] *Id.* This includes costs associated with patient care such as diagnostics, exams, laboratory expenses, time spent by healthcare professionals treating the patient and managing the study, and the provision of study products or other in-kind items.

[116] *Final Sunshine Rule* at 9497–9498; 42 C.F.R. §403.908(e).

[117] *See e.g.*, Thomas Sullivan, *CMS Open Door Dorum on Transparency Reports Recap*, Policy & Medicine (Mar. 28, 2011) available at http://www.policymed.com/2011/03/cms-open-door-forum-on-transparency-reports-recap.html (last visited August 7, 2013) (noting that in a mid-sized pharmaceutical company, there could be more than 1 million transactions with over 300,000 physicians).

[118] 42 U.S.C. § 1327a-7(a)(1).

[119] 42 U.S.C. § 1327a-7(b)(11).

offense "relating to fraud … or other financial misconduct,"[120] which could result in a permissive exclusion. Counsel must advise employees and executives of the potential implications that may arise if facts reveal mistakes or errors in Sunshine reporting.

Counsel will also face challenges dealing with third parties or agents during interviews. Under the Sunshine Act, physicians and hospitals have a 45-day review period to resolve any discrepancy in a reported payment.[121] Because data collection and reporting is happening year-round, an internal investigation involving a physician expert or consultant may occur during the review period. Counsel should ensure that the resolution of any discrepancy does not occur within the context of an interview unless the disputed payment is related to the investigation. Counsel should maintain an amicable exchange with third parties or agents regarding payment disputes to avoid creating an uncooperative interviewee and ensure valuable relationships with the company continue.

C. Considerations for Executives and Boards

Although boards and directors may fulfill their fiduciary obligations to be informed about misconduct[122] by initiating an investigation,[123] the repeated nature of misconduct in the life sciences industry strongly suggests that such actions are not enough. In fact, repeated violations may indicate that the laws governing "directors' exercise of their fiduciary duties to impel boards to pursue their company's strict adherence to the law"[124] are failing. Moreover, while fully informed board decisions may have protections under the business judgment rule,[125] repeated and similar misconduct in the life sciences industry may suggest that such decisions are *not* made in good faith or on a fully informed basis. For example, an internal investigation may reveal that a company's board meeting does not include reports or updates from a chief compliance officer or compliance staff. Such investigations may also reveal that compliance officers and staff have infrequent interactions with the board or executives and that compliance decisions regarding training, resources, risk-analysis, internal reporting or hotlines, and preventative measures are undervalued or nonexistent.

Any evidence of this nature may have significant implications on the government's willingness to enter into a DPA or CIA, may increase penalties and fines, and increases the likelihood of actions under the RCO doctrine. For example, because

[120] 42 U.S.C. § 1327a-7(b)(1)(B).

[121] *Final Sunshine Rule* at 9501–9503; 42 C.F.R. §403.908(g).

[122] *See, e.g.*, Norlin Corp. v. Rooney, Pace Inc., 744 F.2d 255, 264 (2d Cir. 1984) (duty of care "refers to the responsibility of a corporate fiduciary to exercise, in the performance of his tasks, the care that a reasonably prudent person in a similar position would use under similar circumstances").

[123] *See, e.g.*, Quan v. Computer Sciences Corp., 623 F.3d 870, 885 (9th Cir. 2010) (the duty to investigate arises when there is "'something akin to a "red flag" of misconduct'") (citation omitted).

[124] Kathleen M. Boozang, *Responsible Corporate Officer Doctrine: When is Falling Down on the Job a Crime?* 6 St. Louis University Journal of Health Law & Policy 77, 81 (2012).

[125] "The business judgment rule is a presumption that board decisions are made in good faith and on a fully informed basis, and thus generally serves to shield directors from liability based on second-guessing of good faith decision-making." Robert L. Haig, et al. Business and Commercial Litigation in Federal Courts, 1 Bus. & Com. Litig. Fed. Cts. § 5:2 (3d ed. 2012).

most life science companies have a "prior history of criminal misconduct,"[126] DOJ and OIG may view gaps in compliance reporting to the board and executives unfavorably. In addition, evidence that a company's board or executives do not take compliance seriously will significantly reduce the chances that DOJ or OIG will consider the company to have an *effective* compliance and ethics program.[127] For example, HHS-OIG Chief Counsel Greg Demske recently emphasized that effective healthcare boards are "active," "raise questions," "stay informed on risk areas"; "learn of *all* significant compliance issues," and "attend compliance training and speak to staff about compliance."[128]

Directors that fail to stay informed and, where appropriate, conduct an internal investigation could subject themselves to civil liability via shareholder derivative suits.[129] OIG may also permissively exclude any individual "who has a direct or indirect ownership or control interest in a sanctioned entity"[130] and "who knows or should know of the action constituting the basis for the [sanction]; or who is an officer or managing employee of such an entity."[131] Corporate counsel should advise his or her board and executives about the affect compliance lapses may have and how they could affect the information boards provide to the public, shareholders, and regulators to explain questionable conduct, mitigate any reputational harm to the company, and better manage the company's public disclosures. Corporate counsel may also be able to advise executives and board members to leave the company to avoid exclusion since OIG can "only pursue [exclusion of] a person who is in office of a convicted entity." The agency cannot "reach the former CEO."[132]

Corporate boards and executives must also scrutinize assurances provided by employees, distributors, or customers. When it conducted third-party due diligence in evaluating marketing payments in foreign countries, "Eli Lilly and its subsidiaries possessed a 'check the box' mentality" instead of looking at the surrounding circumstances of any payment to adequately assess whether it could wind up in a government official's pocket."[133] Corporate executives and boards increasingly need new systems and measures to guarantee compliance with a wide set of regulations and laws. In light of the growing globalization of drug supply chains, manufacturers are now responsible for "the implementation of oversight and controls over the manufacture of drugs to ensure

[126] U.S.S.G. § 8C2.5(g).

[127] *Id*.

[128] Thomas Sullivan, *OIG Offers Compliance Tips for Healthcare Boards, Executives*, Policy & Medicine (Mar. 28, 2013) available at http://www.policymed.com/2013/03/oig-offers-compliance-tips-for-healthcare-boards-executives.html (last visited August 7, 2013).

[129] *See* Pan Pacific Retail Properties, Inc. v. Gulf Ins. Co., 471 F.3d 961, 967–968 (9th Cir. 2006) ("A shareholder's derivative suit seeks to recover for the benefit of the corporation and its whole body of shareholders when injury is caused to the corporation that may not otherwise be redressed because of failure of the corporation to act") (citations omitted).

[130] A "sanctioned entity" is defined as an entity that has been: (a) convicted of any offense under 1320a-7(a) (*i.e.*, offenses that require mandatory exclusion); (b) convicted of an offense described in 1320a-7(b)(1), (2), or (3) (*i.e.*, the first three offenses that can lead to permissive exclusion listed above); or (c) excluded from participation under a Medicare program or a state healthcare program. 42 U.S.C. § 1320a-7(b)(15)(B).

[131] 42 U.S.C. § 1320a-7(b)(15).

[132] Demske Interview, *supra* note 57.

[133] Schoenberg, *supra* note 73 (quoting Kara Novaco Brockmeyer, head of the SEC's foreign bribery unit).

quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products."[134] This provision further highlights the importance of gaining assurances from suppliers and other drug supply chain entities because FDA will hold manufacturers accountable for any contractors or subcontractors they use.

Publicly-traded life science companies also raise unique challenges for dealing with shareholders. While boards may elect to provide counsel to defend executives implicated in any internal investigation or alleged misconduct, the threat of conviction or exclusion may cause shareholders, particularly those with significant holdings, to question the board's decisions. In the case of OIG's proposed exclusion of Forest CEO Howard Solomon, Carl Icahn—who had acquired about 7 percent of Forest stock—nominated four directors to the Forest board.[135] In addition, the AFL-CIO, which also controlled a significant number of shares in Forest Labs,[136] called for Solomon's resignation and urged shareholders to "withhold" their vote for him.[137] Corporate counsel should work with their board to determine which executives may face exclusion or conviction to determine whether the company will represent those individuals and how to deal with their status and responsibilities on the board. This decision must comply with state or federal rules regarding an employer's payment for representing one of its employees and counsel should properly terminate representation if any conflicts arise.[138] Counsel should take a flexible approach in making these decisions as new facts or information obtained during an investigation may change this strategy.

When communicating to executives or the board in writing, counsel must separate legal advice from other advice, particularly business advice, so that they may allow legal advice to be deleted or otherwise protected if the communication must be disclosed.[139] This is particularly important because executives or the board may ask for advice regarding how the misconduct or internal investigation may affect business or other non-legal concerns of the company, and such advice is generally not

[134] Food and Drug Administration Safety and Innovation Act, Pub. L. 112–144, 126 Stat. 993 (2012) § 711.

[135] Ed Silverman, *AFL-CIO To Forest Investors: Send Solomon Packing*, PHARMALOT (July 29, 2011) available at http://www.pharmalive.com/afl-cio-forest-investors-send-solomon-packing (last visited August 7, 2013).

[136] *Id.* (explaining that the AFL-CIO "owns 208 shares of Forest Labs, and recently created the AFL-CIO Equity Index Fund, which holds another 11,629 shares in the drugmaker." "The AFL-CIO Office of Investment works with Taft-Hartley labor union retirement funds with over $400 billion under management and these hold more than 800,000 shares in Forest." *Id*).

[137] *Id*. *See also* Ed Silverman, *AFL-CIO Wants Forest Labs CEO To Resign*, PHARMALOT (May 16, 2011) available at http://www.pharmalive.com/afl-cio-wants-forest-labs-ceo-resign (last visited August 7, 2013).

[138] *See e.g.,* AMERICAN BAR ASSOCIATION MODEL RULES OF PROFESSIONAL RESPONSIBILITY 1.13 and 1.7.

[139] KAREN L. VALIHURA, ATTORNEY-CLIENT PRIVILEGE AND WORK PRODUCT DOCTRINE: CORPORATE APPLICATION, § A-15, 22 (BNA, 4th ed. 2012) (for example, use introductory language signaling that what follows is legal opinion (e.g. "your legal opinion is" or, "in reply to your request for legal assistance")).

privileged.[140] Counsel should also avoid including third parties in conferences, interviews, or in correspondence with clients to maintain confidentiality. If a meeting involves both legal and non-legal matters, attorneys must monitor who attends and determine whether certain people should leave if legal issues arise during the meeting.

Outside counsel must work closely with in-house counsel to ensure that responsible employees and staff respond adequately to requests or contacts from government officials, subpoenas, and search warrants. Corporate counsel should apprise their employees "of their rights and obligations should they be contacted by agents and asked to submit to an interview."[141] Although employees should meet first with counsel to "understand the government's methods and objectives," they are also free to answer questions from government agents, but such answers must be truthful. Employees must accord government agents with respect because "prosecutors who sense obstructive conduct will respond by escalating the investigation, and may open new investigations into additional criminal conduct such as obstruction of justice."[142] With the increased use of civil investigative demands, companies must prepare witnesses to avoid making statements that "contain inaccuracies that later can create credibility concerns or give rise to of perjury"; "confuse issues; or create the impression of improprieties that do not exist."[143]

With respect to administrative, civil and/or criminal subpoenas, counsel should issue a "hold notice" that explains to relevant employees "in plain English … what documents should be retained, who will be collecting the documents, and contain instructions on how to collect documents for those participating in the collection."[144] Outside counsel must also work closely with the company to evaluate the "state of its records and its ability to comply with the request," and should convey this information to the government "to discuss compliance issues."[145] While warrants may be used less frequently, responsible officials at manufacturing, packaging, labeling or storage facilities where government officials frequently inspect must be prepared.

Because warrants permit the government to seize original documents, counsel should "request copies of items seized and/or the return of critical documents" and "counsel should request an inventory and attempt to assure that the inventory fully describes the items seized."[146] Counsel or the responsible on-site official should also

[140] This paper does not address the concerns regarding the attorney-client privilege when business advice is sought. *See* John F. Brenner, *The Attorney-Client Privilege in Pharmaceutical Litigation Under Attack: Lessons from In Re Vioxx Products Liability Litigation*, Pepper Hamilton LLP (Nov. 6, 2008), available at http://www.pepperlaw.com/publications_article.aspx?ArticleKey=1279 (last visited August 7, 2013).

[141] Ogrosky, *supra* note 16 at 3. Contacted employees should request an agent's name, agency and phone number and "all contacts should be handled immediately and as confidentially as possible." *Id.*

[142] *Id.*

[143] *Id.* at 11 (noting that new rules in 2010 allowing the Attorney General to delegate authority to issue CIDs to individual U.S. Attorneys and the Assistant Attorney General for the Civil Division has greatly increased their use).

[144] *Id.* at 4.

[145] *Id.*

[146] *Id.* at 4–5. A senior person on scene should "keep track of the areas searched, questions asked and items taken."

communicate with the agent in charge of the search "to ascertain the nature of the allegations" and seek a copy of the affidavit filed in support of the warrant.[147] While sending non-essential employees home during an inspection is more difficult in a manufacturing plant than a doctor's office, counsel should ensure that employees do not "expand the scope of the search by consent" or engage in activities or behaviors that may be "misinterpreted as interfering with the search."[148]

IV. Conclusion

While internal investigations have advantages, their existence may also become disadvantageous once they are made public, and any written work product related thereto could be discoverable and "adversely affect related private or public suits by providing a road map for actions against the company by regulators or civil plaintiffs."[149] Such publicity could also negatively affect the company's reputation with potential or existing clients, customers or vendors and implicate senior executives in misconduct or indicate that such personnel failed to monitor subordinates adequately, which in turn could lead to RCO prosecutions or exclusion. Increased transparency of the interactions and relationships physicians have with life science companies and the tracking and reporting of payments associated with such relationships also brings new and unique ethical challenges for corporate counsel. Regardless of whether a company ultimately determines to conduct an internal investigation, a company must take immediate and appropriate steps to stop any illegal conduct if it exists.

The unique challenges life science companies face create significant obstacles for in-house and outside counsel when conducting internal investigations and managing ethical obligations. Coupled with the increased government expectation that upper management be actively involved in ensuring corporate compliance with federal healthcare laws and regulations, counsel must manage the overlapping and separate obligations. Given the significant weight the government places on effective compliance programs, along with recent settlements crediting compliance programs counsel must proactively work with clients to prevent, mitigate, and reduce the likelihood and occurrence of corporate misconduct that may trigger an internal investigation and related actions. Counsel for life science companies must place an emphasis on corporate compliance moving forward by providing a structural foundation for self-policing employee conduct through an effective compliance and ethics program that will reduce and ultimately eliminate criminal conduct.

[147] *Id.* at 5.

[148] *Id.* at 4.

[149] Jacxsens Presentation, *supra* note 78.