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A NEW WORLD ORDER: THE EXPANSION OF EXECUTIVE CORPORATE
LIABILITY IN THE LIFE SCIENCES INDUSTRY.

By

Rachel M. Jones

The government has recently expanded regulation in industries where consumers have become vulnerable. The sensational betrayals of the pharmaceutical industry¹ and banking system have put government officials on high alert. The Department of Justice (DOJ) and Office of the Inspector General (OIG) have made record settlements with pharmaceutical companies based on allegations of drug misbranding, off-label promotion, false claims and kickbacks.² Similarly, we have seen the passage of the Dodd Frank Wall Street Reform and Consumer Protection Act in 2010 after the mortgage crisis revealed the banking industries abuse and indiscretions related to mortgage underwriting, predatory lending and mortgage-backed securities issuance.³ The fundamental tenant of capitalism is free market enterprise. However, the free market principle in democratic America has consistently shown that without the appropriate amount of government

¹ This writing will use the terms pharmaceutical industry and life science industry interchangeably.

² See Press Release, United States Department of Justice, *Justice Department Recovers \$3 billion in FCA Cases in Fiscal Year 2011*, (December 19, 2011). See generally, United States Department of Justice FCA Fraud Statistics, http://www.justice.gov/civil/docs_forms/C-FRAUDS_FCA_Statistics.pdf.

³ Dodd Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111-203 (2010).

regulation and oversight there can be far reaching and irreparable harm to the American consumer and economy.

The government has implemented various forms of governance and oversight over the pharmaceutical industry. There has been an attempt by the government to set standards, monitor compliance and enforce compliance on those who are in violation.⁴ Government action is not the only model of setting standards for a regulatory system. In the life science industry, monitoring of compliance with laws is done in a broader context to include self-regulation by the organization through compliance programs.⁵ A robust compliance program is a company's first line of defense in deterring violations of fraud and abuse laws.

There is also a private component of regulation of the life science industry through qui tam lawsuits under the False Claims Act ("FCA")⁶. The FCA generally prohibits individuals and entities from the filing of a false or fraudulent claim for payment by the United States.⁷ Qui tam lawsuits are brought by private individuals who are not associated with the government but have some knowledge of wrongdoing by an alleged violator under the FCA (these individuals are also known as whistleblowers or quit tam relators).⁸ Qui tam lawsuits are a powerful form of governance since there is a significant financial reward for a qui tam relator if they are successful in proving the

⁴ See generally Scott Burris, Michael Kempa, Clifford Shearing, *Changes in Governance: A Cross-Disciplinary Review of Current Scholarship*, 41 Akron L. Rev. 143 (2008).

⁵ See generally, Michael A. Cassidy, *Health Care Compliance Manual* (2001).

⁶ 31 U.S.C. 3729-3733 (1863).

⁷ Cassidy, *supra* note 5, at §11-03(6).

⁸ *Id.*

violations under the FCA.⁹ In 2011, qui tam cases accounted for 92% of all FCA recoveries. In addition, qui tam litigation recovered \$2.8 billion in 2011.¹⁰

In 1958, the life science industry formed the Pharmaceutical Research and Manufacturers of America (PhRMA), an advocacy organization representing research-based pharmaceutical and biotechnology companies. A part of the mission of the organization is to create standard procedures to better facilitate interactions with healthcare professionals. To that end, over 60 members have signed a code of ethics that governs relationships and interactions with healthcare professionals.¹¹ Governing relationships with healthcare professionals is necessary to eradicate potential healthcare fraud and abuse violations.

In general, the impact of such systems for regulation has not offered the best results, “the regulation literature has confirmed that the most powerful corporate actors have been able to hijack weak systems of accountability in service of their own ends.”¹² Based on the governments increased surveillance of the life science industry it would seem that the regulation model has not significantly deterred healthcare fraud and abuse violations. The expansion of the governments’ prosecution of corporate executives under the Park doctrine and the exclusion statute is further evidence that the regulation model is not working well in the life science industry.

⁹ *Id.*

¹⁰ Department of Justice, *supra* note 2.

¹¹ Pharmaceutical Research and Manufacturers of America, <http://www.phrma.org/about/phrma>.

¹² Burris, *supra* note 4 at 148.

This writing will discuss specifically the different forms of governance being utilized to enforce the healthcare laws in the life science industry. This will include specific cases enforcing the Park doctrine¹³ and corporate responsibility on pharmaceutical executives, the FDA's non-binding prosecution procedures for Park doctrine cases, the Department of Health and Human Services (DHHS) restriction of an individual's ability to do business with the government, and mandatory compliance programs for healthcare entities.

The government has publicly made several comments by top officials indicating their desire to prosecute executives under the Park doctrine. Commissioner Margaret Hamburg wrote in a letter to Senator Charles Grassley on March 4, 2010, that the Office of Criminal Investigations ("OCI") of the FDA recommends increasing misdemeanor violations as an enforcement tool under the Act. The letter specifically indicates the desire to increase prosecution under the responsible corporate officer doctrine.¹⁴ The following month, Eric Blumberg, the FDA's deputy chief counsel for litigation also confirmed at the Food Drug and Law Institute Annual Conference, the FDA's desire to increase prosecution under the Park doctrine.¹⁵ With the current state of increased regulation and oversight, the government is pushing the legal boundary for liability of companies within the life science industry.

¹³ This paper will use the terms Park doctrine and Responsible Corporate Officer (RCO) doctrine interchangeably.

¹⁴ Letter from Margaret Hamburg, Commissioner of the Food and Drug Administration to Senator Charles Grassley (March 4, 2010), <http://www.grassley.senate.gov/about/upload/FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCI.pdf>.

¹⁵ Food Drug and Law Institute Annual Conference, April 22, 2010, *See also, infra* note p. Washington Business Information, Inc.,

The government has begun to explore and effectively prosecute pharmaceutical executives under the Park doctrine. The Park doctrine was established in the 1975 Supreme Court case, *United States v. Park*.¹⁶ In this case, Acme Markets, Inc., a national retail grocery chain and the chief executive officer of the chain were charged with violating 21 USCS § 301(k) of the Federal Food, Drug and Cosmetic Act (FDCA or Act).¹⁷ This section of the Act refers to the alteration of a food, drug, device, tobacco product or cosmetic when held for sale and placed in interstate commerce and results in such article being adulterated or misbranded.¹⁸ The government alleged that the company and CEO caused interstate food shipments to be exposed to rodent contamination in their warehouse.¹⁹ The Act imposes a misdemeanor penalty on anyone who violates §301.²⁰ The strict liability interpretation of this statute as it relates to corporate executives is controversial.

The Supreme Court in *Park* reversed the Appeals Court decision because the Court held that a corporate officer could be found guilty under the Act if there is a responsible relation to the situation.²¹ The Court further looked at *United States v. Dotterweich*, where they determined that the Act imposes upon persons exercising authority and supervisory responsibility in an organization not only a positive duty to seek out and remedy violations but also, a duty to implement measures that will insure

¹⁶ 421 U.S.C. 658 (1975).

¹⁷ *Id.* at 660.

¹⁸ 21 U.S.C. 301(k).

¹⁹ 421 U.S.C. 662 (1975).

²⁰ 21 U.S.C. 303(a).

²¹ 421 U.S.C. 667 (1975).

that violations will not occur.²² The *Park* court continued to follow *Dotterweich*, in that a person found in violation of the Act does not have to be aware of some wrongdoing. A wrongful action might be “gross negligence and inattention in discharging corporate duties and obligations or any of a host of other acts of commission or omission which would cause the contamination of food.”²³ However, the Supreme Court specifically reviewed whether the government has to make a prima facie case of some “wrongful action”.²⁴ The Supreme Court reasoned that the Act imposes a strict liability on responsible corporate agents who deal with products that affect the health of consumers.²⁵ The Supreme Court in *Park* noted that the penal sanctions were rigorous, however a defendant can pursue an affirmative defense that they were “powerless” to prevent or correct the violation.²⁶ The strict liability implication of the statute is a very serious concern of executives of pharmaceutical companies that may have responsibility under the Act.

The Supreme Court first addressed the doctrine of criminal liability for “responsible corporate officers” in *United States v. Dotterweich*.²⁷ Joseph Dotterweich served as the President of the Buffalo Pharmacal Company. This company distributed manufactured drugs, which were repackaged under their own label and resold to the public. The government charged both the company and Mr. Dotterweich with shipping a

²² *Id.* at 672.

²³ Christopher Hall and Gregory Schwab, *Counseling Responsible Corporate Officers in a New Age of Government Food and Drug Enforcement*, 34 *Champion* 41 (2010).

²⁴ *Id.*

²⁵ *Id.* at 42.

²⁶ *Id.*

²⁷ 320 U.S. 277 (1943).

misbranded drug and shipping and adulterated drug under Section 301(a) of the Act.²⁸

The trial court convicted Mr. Dotterweich on all counts charged but disagreed as to the company's culpability.

The Second Circuit reversed the lower courts decision on the ground that Congress did not intend to have Section 301(a) of the Act apply to individuals based on their interpretation of a "good faith" exception set forth in Section 303(c).²⁹ The "good faith" exception applied to individuals who received a guaranty from the manufacturers that the drugs were approved by the FDA and not misbranded or adulterated in any way.³⁰ The Second Circuit inferred that Congressional intent was not to apply the misdemeanor provisions of the Act to individuals because individual employees do not obtain guarantes.³¹ The Second Circuit reasoned that it would be unfair to hold individual employees accountable based on their company's failure to obtain a guaranty. The Supreme Court disagreed with the Second Circuit's interpretation of the Act. The Supreme Court reasoned that Congress passed the Act to keep adulterated and misbranded drugs out of the channels of commerce and created severe penalties for disobedience.³² "The purposes of this legislation thus touch phases of the lives and health of people which, in circumstances of modern industrialism, are largely beyond

²⁸ *Id.* at 278.

²⁹ *Id.* at 284. *See also*, Christopher Hall and Gregory Schwab, *Counseling Responsible Corporate Officers in a New Age of Government Food and Drug Enforcement*, 34 *Champion* 41 (2010).

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

self-protection”.³³ The penalties serve as an “effective means of regulation” and “dispensed with the conventional requirement for criminal conduct-awareness of some wrongdoing”.³⁴ The Supreme Court stated that “in the interest of the larger good [the legislation] puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger”.³⁵

The Supreme Court recognized the hardship imposed on corporate officers with the imposition of such a strict liability. “Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting.”³⁶ Congress, however, “has preferred to place [the hardship] upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless”.³⁷

Section 303 of the Act, imposes a penalty for violations of Section 301. A person who violates the Act may be imprisoned for not more than a year or fined not more than \$1,000 or both.³⁸ In *Park*, the respondent was sentenced to pay a mere fine of \$250. As we have seen in more recent pharmaceutical cases where the Park doctrine is imposed, the government is requesting the maximum fine and prison terms.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ 21 U.S.C.S. §303(a).

In addition, the government has become increasingly vigilant in their prosecutions, such that they have begun to piggy-back with an application to exclude those who were found guilty under the Park doctrine from participation in federal health care programs. This exclusion can have severe repercussions for corporate executives with careers focused in the healthcare field. “When an individual is excluded, federal health care programs like Medicare and Medicaid will not pay for any item or service furnished, ordered, or prescribed by that individual. Entities that employ an excluded individual for providing items or services to federal program beneficiaries are subject to monetary penalties, making exclusion a de facto ban on working in the health care industry.”³⁹

The Social Security Act allows for exclusion from participation in federal healthcare programs.⁴⁰ The Secretary of the DHHS is required to exclude individuals or entities from participation under certain circumstances and has discretion to exclude individuals or entities under other circumstances.⁴¹ Felony offenses relating to fraud and felony offenses relating to the unlawful distribution of a controlled substance require exclusion. Misdemeanor convictions, however, fall within the permissive category.⁴² The secretary may exclude individuals convicted of misdemeanors relating to fraud or relating to the unlawful distribution of a controlled substance.

³⁹ Letter from Washington Legal Foundation to Eric Blumberg, deputy chief counsel of litigation, FDA (October 26, 2010).

⁴⁰ 42 U.S.C. 1320a-7(a) – 7(b)(1)-(16).

⁴¹ *Id.*

⁴² *Id.*

Based on the *Purdue* case discussed below, the Secretary has taken the position that an RCO conviction based on the promotion of a misbranded drug is a misdemeanor conviction relating to both fraud and a controlled substance.⁴³ The government also intends to exclude individuals who fail to act when they are under a duty to act and the inaction relates to any acts referred to in the exclusion statute.⁴⁴ The exclusion statute creates a presumptive exclusion period of three years for misdemeanor convictions relating to fraud or controlled substances.⁴⁵ The Secretary has discretion to apply a different period in accordance with published regulations if mitigating or aggravating circumstances apply. Aggravating circumstances for individuals convicted of a misdemeanor relating to fraud include (1) acts that caused, or reasonably could have caused a governmental program to incur a loss of \$5,000 or more, (2) acts committed over a period of one or more years, (3) acts that had a significant adverse effect on physical or mental well-being of individuals or other program beneficiaries. Mitigating circumstances for this class of misdemeanor violations include, (1) conviction of three or fewer offenses and less than \$1500 in financial loss, (2) cooperation. There are similar aggravating and mitigating circumstances promulgated by the secretary for misdemeanor convictions relating to controlled substances.⁴⁶

Now that the government is expanding corporate executive liability to include exclusion from the federal healthcare programs, executives must consider how to protect themselves under the exclusion statute. Executives should consider implementing the

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *See Hall, infra* note 23, at 44.

compliance and quality control measures. In addition, executives should develop processes within their company that will combat the exclusion statutes aggravating factors. When considering the aggravating factor of long duration, an executive can implement annual audits of specific risk areas. In monitoring patient impact, an executive should allocate resources to compliance based on the safety issues. In assessing the financial impact, an executive should also consider allocating resources to compliance based on the revenue that a product generates from government programs. In preventing second violations, an executive should implement root cause analysis for all significant compliance violations. Lastly, a robust compliance program whereby the executives are actively engaged will help in protecting against an RCO prosecution where there is an underlying felony charge.⁴⁷ These types of best practices are necessary in protecting executives against the extensive reach of the Park doctrine.

The OIG also intends to expand the application of the exclusion statute as it relates to executives of large complex organizations.⁴⁸ One of the permissive exclusions is based on individuals who control a sanctioned entity. If an individual owns or has ownership control in a sanctioned entity or is an officer or managing employee then the secretary can exclude them based on the sanctioned company.⁴⁹ The individual does not have to be convicted of any civil or criminal statute in order for this exclusion to apply.⁵⁰ During Congressional testimony, Inspector General Daniel Levinson, stated the OIG has

⁴⁷ *Id.* at 60.

⁴⁸ *Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges, Hearing Before the United States Senate Committee on Finance (2010)* (testimony of Inspector General Daniel Levinson).

⁴⁹ 42 USC 1320a-7(b)(15).

⁵⁰ *Id.*

historically only applied this exclusion to small companies but will now start to apply it more broadly to larger organizations.⁵¹ For example, the OIG excluded the owner of Ethex Corporation for 20 years based on the exclusion of the company. Ethex plead guilty to felony criminal charges after it failed to inform the FDA that it was manufacturing oversized tablets of two prescription drugs.⁵² However, the most controversial case involving exclusion from government programs and the Park doctrine is the Purdue Frederick Company case.

Purdue Case

In May 2007, Purdue Frederick, a subsidiary of Purdue Pharma L.P., (“Purdue”) pled guilty to felony misbranding of Oxycontin as part of a settlement with federal prosecutors.⁵³ Misbranding is when a product’s label is incomplete, false or misleading.⁵⁴ A product’s label can include written, printed, or graphic matter that appears on the product or its container. It also includes information that accompanies the product, such as advertisements for the product.⁵⁵ Purdue falsely marketed Oxycontin as posing a lower risk of abuse and addiction than non-time released painkillers.⁵⁶

⁵¹ *Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges, Hearing Before the United States Senate Committee on Finance (2011)* (testimony of Inspector General Daniel Levinson).

⁵² *Id.*

⁵³ Michael Friedman, et al. v. Kathleen Sebelius, Secretary, Department of Health and Human Services, et al., No. 09-2028 (December 13, 2010).

⁵⁴ 21 U.S.C. 501.

⁵⁵ 21 U.S.C. 301(k).

⁵⁶ Friedman, *supra* note 53.

There were also three executives of the company that pled guilty to misdemeanor misbranding under the Park doctrine for their failure to prevent Purdue's fraudulent marketing of Oxycontin. The corporate executives included Michael Friedman, the president, Howard Udell, general counsel and Dr. Paul Goldenheim, the medical director. In their plea agreements, the executives disclaimed any actual knowledge of fraudulent marketing of Oxycontin but admitted to failing to discharge their "responsibility and authority to prevent in the first instance or to promptly correct the misrepresentations certain unnamed Purdue employees made regarding Oxycontin."⁵⁷

Several months after the executives pled guilty, the OIG, the main enforcement agency for the FFDCA determined that the executives "should be excluded from participation in Federal health care programs for 20 years, pursuant to 42 USC §1320a-7(b)(1) which permits the DHHS to exclude an individual convicted of a misdemeanor related to fraud."⁵⁸ This restriction period was later reduced to 12 years, however the executives appealed the exclusion based on the interpretation of whether failure to act as "responsible corporate officers" (RCO) and making a plea for misdemeanor misbranding constituted a "misdemeanor relating to fraud".⁵⁹ The executives further argued that their pleas under the Park doctrine do not reflect any personal wrongdoing and that excluding them from participation in all federal health care programs is inconsistent with the law.

⁵⁷ Ropes and Gray, *DC Circuit Holds That Former Purdue Pharma Executives Who Pleaded Guilty to Misdemeanor Misbranding May Be Excluded From Participation in Federal Health Care Programs*, (August 1, 2012).

⁵⁸ *D.C. Circuit Affirms HHS Power to Disqualify Corporate Officials Convicted of Misdemeanors Under the "Responsible Corporate Official (RCO) Doctrine*, Mondaq, (April 14, 2012).

⁵⁹ *Id.*

After years of litigation, on July 27, 2012, the Court of Appeals upheld the DHHS exclusion of the Purdue executives.⁶⁰ The DC circuit judges were not dissuaded by the argument of the professional careers of these men. The court realized that the plaintiffs are free to seek private employment at a company that does not rely on federal or state funds.⁶¹ This case is a first of its kind and based on the public remarks by the FDA, there is a significant push to “criminally charge individuals at all levels in the company”⁶² because even the large monetary settlements from the drug companies for FDA violations has not adequately deterred off-label promotion and misbranding.

Synthes Case

In November 2011, four key executives of Synthes North America (“Synthes”), a medical device company based in West Chester, PA were sentenced to prison for charges related to health care fraud.⁶³ The government charged the company with unlawful clinical trials and the executives were charged under the RCO doctrine.⁶⁴ Synthes is the first case where the court has sentenced the executives of the company to jail time. The court felt that the egregious actions and disregard for human life shown by the company and executives was indicative to prison time.⁶⁵ According to the prosecution, Synthes officials wanted to beat their competitors to market without going through the rigorous FDA new drug approval process for their bone cement product. Instead, the Synthes

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Supra* note 39.

⁶³ Press Release, Food and Drug Administration, *Former Executives of International Medical Device Maker Sentenced to Prison in Unlawful Clinical Trials Case* (November 21, 2011).

⁶⁴ *Id.*

⁶⁵ Peter Loftus, *Former Synthes Officers Receive Prison Sentences*, Wall Street Journal (2011).

officials conspired to train select surgeons in its off-label use and then have the physicians publish their findings.⁶⁶ Off-label promotion of a drug is promoting a drug for a purpose, which has not been approved by the Food and Drug Administration.⁶⁷ Before a pharmaceutical company can market a drug in the United States they must go through a rigorous application and clinical trial process to test the safety and efficacy of the drug they wish to market. Due to the cost and length of time to bring a new drug to market, most drug manufacturers will only seek approval for one type of use of the drug.⁶⁸ If alternative uses are discovered during clinical trials or once the drug is being widely used by the public then the drug manufacturer must begin the drug approval process again for this new use. Historically, drug manufacturers have been charged with illegally promoting and misbranding a drug because they employed marketing and sales tactics, which suggested to physicians that they could use a particular drug for non-approved medical purposes. In the United States, physicians are generally allowed to prescribe a drug or a combination of drugs for off-label purposes to their patient if they believe it is their best course of treatment.

In the Synthes case, this illegal promotion program continued even after patients died in surgery in Texas and California.⁶⁹ The patients suffered shard drops in blood pressure after the bone cement compound was injected into their spines.⁷⁰ The program was not halted until a third death occurred in California. These deaths were never

⁶⁶ *Id.*

⁶⁷ *Infra* note 73.

⁶⁸ *Id.*

⁶⁹ Loftus, *supra* note 65.

⁷⁰ Thomas Sullivan, *The Park Doctrine and FDCA Violations: Holding Corporate Executives Accountable*, Policy and Medicine (2011).

reported to the FDA.⁷¹ Although Synthes used the bone cement in 200 patients, surgeons could not rule out the bone cement as a factor one way or the other in the deaths of the patients.⁷² The patient deaths involving the off-label marketing scheme spurred the district court judge to immediately sentence the former president Michael Huggins and the former senior vice president Thomas Higgins to nine months in prison.⁷³ The former director of regulatory and clinical affairs also received a five-month sentence. All four executives have irreparably damaged their careers and agreed to pay fines of \$100,000 a piece.⁷⁴

Glaxo-Smith Kline Case

In July 2012, GlaxoSmithKline (“GSK”) entered into a settlement agreement with the Department of Justice for \$3 billion dollars, the largest health care fraud settlement in the history of the life science industry⁷⁵. GSK was charged with civil and criminal violation under the Act and civil violations under the False Claim Act. GSK’s liability stemmed from their failure to report safety data, false price reporting and their illegal marketing activities for several drugs, including Paxil, Avandia and Welbutrin.⁷⁶ The government alleged that GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. GSK

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ See John E. Kelly and Sarah K. Bogni, *Government Expands Settlement Requirements, Entices Whistleblowers with \$3 Billion GlaxoSmithKline Settlement*, BNA’s Health Care Fraud Report (2012).

⁷⁶ Press Release, United States Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

also allegedly promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. Additionally, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA. The FDA must have true and accurate safety information regarding an approved drug on the market because it is essential to ensuring the public's safety.⁷⁷ This case is unique in that the government did not bring an RCO action against company executives but did put in place a Corporate Integrity Agreement ("CIA") that provides financial disincentives for company executives when there is misconduct. Strangely, the government brought other non-RCO related charges against company executives, including the company's general counsel. The charges against the general counsel were dismissed by the circuit court judge because the government's evidence was unsubstantiated.⁷⁸ This case emphasized the problems the government may encounter when working across several agencies in their prosecutions.

Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified

⁷⁷ *Id.*

⁷⁸ See Susan Kohn Ross, *Case Against Former GSK Lawyer Dies-Park Doctrine Lives* (June 10, 2011).

policies in its contracts with various health care payors. “Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives,” said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. “For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets.”⁷⁹

The government is focusing on individual accountability by requiring certifications of compliance by company boards, individual presidents, as well as key executives and managers of the company. By incorporating such widespread accountability across an organization, the government seems to believe the compliance certification will affect the way individuals do business in the company.⁸⁰ We have seen similar measures implemented through Sarbanes Oxley Act. These settlement provisions may also be a way for the government to lay the groundwork for pursuing a future RCO claim. Whether the government treats CIA’s as a framework for future RCO claims or solely as an internal oversight tool of the company, the life sciences industry should expect to see more of these types of provisions in CIA’s as another means for the government to enforce individual liability of corporate executives.⁸¹

⁷⁹ *Supra* note 76.

⁸⁰ *Id.*

⁸¹ *Supra* note 75.

Corporate executives should be weary in the first instance mentioned above since CIA's are entered into with the company.⁸² The individual employee may not be offered a Deferred Prosecution Agreement ("DPA"). A DPA is when the government decides to decline further prosecution of a case based on certain requirements of the defendant, i.e. entering into a CIA. The corporate executive should evaluate the potential consequences of their company entering into a CIA and their possible liability under RCO theory.

The government has focused on other enforcement methods to complement its prosecution of corporate executives. The government issued a release of non-binding Park doctrine criteria to determine whether to recommend a misdemeanor prosecution of a corporate official.⁸³ There are seven factors that are enumerated:

1. Whether the violation involves actual or potential harm to the public;
 2. Whether the violation is obvious;
 3. Whether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings;
 4. Whether the violation is widespread;
 5. Whether the violation is serious;
 6. The quality of the legal and factual support for the proposed prosecution;
- and
7. Whether the proposed prosecution is a prudent use of agency resources.

⁸² Press Release, United States Department of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012).

⁸³ Regulatory Procedures Manual, Special Procedures and Considerations for Park Doctrine Prosecutions, 6-5-3 (2011).

This release can be interpreted as good or bad news for pharmaceutical executives. On the one hand, there is clarification by the government on what types of situations are going to cause them to seek exclusion of a corporate executive. On the other hand, the release reiterated the government's position and dedication to prosecuting RCO cases. Corporate executives can now be targeted as part of an investigation of their companies alleged misconduct. In fact in the Purdue case discussed previously, the parent company was able to limit the allegations of misbranding to the subsidiary and escaped exclusion from federal health care programs. The parent company paid the large fine of \$634.5 million in penalties but did not suffer the long-term consequence of exclusion.⁸⁴ Executives can be prosecuted for a misdemeanor violation of the Act and not have any knowledge of the alleged bad acts of the company. The executives who may or may not have had any direct knowledge of wrongdoing became the face of the companies' wrongdoing. Pharmaceutical company executives must ensure some protection from their employers against possible prosecution under the RCO doctrine. The interpretation of the Park doctrine as a strict liability statute creates a significant risk of liability for these executives.

The pharmaceutical industry is going to have difficulty fulfilling corporate executive positions, compliance positions and even legal positions because of the implications of the Park doctrine. There is no specific boundary as to who can be held liable. Even legal counsel can be subject to these prosecutions.⁸⁵ One area an executive can seek protection is in negotiating RCO protections into their employment agreements.

⁸⁴ *Supra* note 82.

⁸⁵ *Id.*

An executive can seek indemnification from their employer if prosecuted under the Park doctrine. This indemnification should survive an employment termination. An executive should consult their director and officer liability policies and seek coverage for RCO liabilities. Lastly, and most importantly an executive should ensure that the companies compliance program is closely monitored and audited.

The OIG believes that a robust compliance program is going to prevent many of the potential illegal activities associated with healthcare fraud and abuse. In 2003, DHHS issued the first release of “OIG Compliance Program Guidance for Pharmaceutical Manufacturers”.⁸⁶ The compliance program guidance provides an initial step for pharmaceutical companies to adhere to the applicable statutes, rules and regulations related to the healthcare industry.

There are seven elements that are fundamental to an effective compliance program for pharmaceutical manufacturers. There must be (a) written policies and procedures, (b) a designated compliance officer and compliance committee, (c) an effective training and education component, (d) an effective communication program, (e) an internal auditing and monitoring program, (f) enforcement of standards through well publicized disciplinary guidelines and (g) a program that responds promptly and resolves detected problems.⁸⁷ In many instances, when the OIG is investigating a pharmaceutical company for healthcare fraud and abuse, they will first evaluate the type of compliance

⁸⁶ OIG Compliance Program Guidance for Pharmaceutical Manufacturers, Federal Register Vol.68, No. 86 (May 5, 2003).

⁸⁷ *Id.*

program in place within the company.⁸⁸ It is imperative that the life science industry commits significant resources to developing and maintaining a robust compliance program. A meaningful compliance program will deter fraud and abuse practices within a company as well as protect senior executives from potential liability under the Park doctrine.

Executives should have an intimate understanding of the potential liabilities for fraud and abuse in the operations of their company. Monitoring specific risk areas associated with company operations should be the cornerstone of a compliance program. A prudent pharmaceutical manufacturer will assess the risk areas of their operations with regard to the various healthcare fraud and abuse laws.⁸⁹ The compliance officer should directly monitor these specific risk areas. Any executive that could potentially prevent fraud and abuse in a risk area should require a weekly risk assessment report from the compliance officer. If an executive is directly involved in the compliance monitoring there is a better chance of detecting and correcting illegal activities.

In addition to a sophisticated compliance program, a life science company should also employ a quality control program that is supervised by upper management. Senior executives should consider implementing the following quality control measures:

1. “Regular meetings with subordinates involved in quality issues to review existing and new quality problems.

⁸⁸ *Id.*

⁸⁹ *Id.*

2. Carefully-crafted procedures requiring written notification and periodic updates on quality problems.
3. Insuring the firm has a robust CAPA – Corrective and Preventive Action-program that features stringent timelines for conducting investigations and taking corrective actions.
4. A well-conceived and regularly occurring internal audit program designed to identify suspect operations and controls before they blossom into actual issues.
5. Use of outside auditors to review operations even absent problems identified in internal audits.”⁹⁰

Although many of the day-to-day activities, of quality control and compliance are done by subordinates, executives should at least receive at least weekly monitoring updates. Delegation of responsibility will not insulate executives from liability under the Park doctrine. In fact, the one affirmative defense that an executive can assert is to show that they were powerless to prevent the violation from occurring.⁹¹

The government has mandated under the Patient Protection and Affordable Care Act (“PPACA”) that all healthcare providers and suppliers implement compliance programs as a condition of Medicare enrollment.⁹² Until this new statutory provision, compliance programs were entirely voluntary. The Centers for Medicare and Medicaid Services (“CMS”) is conducting a comment period on defining core elements for the

⁹⁰ *Trend Three: Executives Can Be Held Accountable for Quality*, The Food and Drug Letter, (2012).

⁹¹ *Id.*

⁹² Patient Protection and Affordable Care Act of 2010, §6401.

mandated compliance program.⁹³ It is likely CMS will build on the seven core compliance guidelines promoted by the OIG. Any variations may be determined by the responses submitted during the comment period for the new regulation. Perhaps the government will attempt to institute a provision whereby executive compensation packages are aligned with performance and compliance with healthcare laws.

Conclusion

The government has broadly interpreted the Park doctrine in commencing enforcement actions under the Act. The Park doctrine has been recently tested in several cases, including the Purdue case, the Synthes case and the Glaxo-Smith Kline case. It appears that the government has been successful in applying the Park doctrine to corporate executives under a strict liability theory. The government has also been successful in applying the exclusion statute to Park doctrine cases in order to emphasize the importance of protecting consumer safety. The government will continue to attribute resources and increase enforcement in this area as long as the monetary recoveries continue to rise. We have seen with the GlaxoSmithKline case that recoveries are reaching \$3 billion.

Executives in the life science industry face substantial challenges in exerting control over areas of risk for fraud and abuse violations. These executives must preserve protections for themselves through negotiating additional liability insurance and

⁹³ See, Beth Rosenbaum and Ari Markenson, *The Patient Protection and Affordable Care Act of 2010 ("PPACA") Includes Mandatory Compliance and Ethics Program Requirements for Nursing Home Providers*. ABA Health source, April 2011 Volume 7 Number 8.

indemnification provisions in their employment contracts. Executives should also maintain direct oversight of their quality control and compliance programs. Executives should be prepared to negotiate compensation based on performance. The government has already required some companies through CIA's to allow reduction of bonuses from executives when there is significant misconduct.

The amount of healthcare fraud and abuse violations still remains staggering. The government is utilizing many different types of governance tools to enforce the laws. In addition, the life science industry is also utilizing governance tools of self-regulation and robust compliance programs to dissuade fraud and abuse violations. These various governance tactics should continue to be used and with continued vigilance until individuals and corporations have met their threshold and are adequately deterred.