

NOT GUILTY, AGAIN

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INTRODUCTION

Historically, there has been little incentive for healthcare and pharmaceutical corporations to adhere strictly to federal administrative regulations. The monetary penalties, while in the billions of dollars, have paled in comparison to the profits reaped by the unlawful marketing, off-label usages, and fraudulent billing to federal healthcare programs. In 2015, former Attorney General, Sally Yates, issued the now famous Yates Memorandum to take the first step in curbing this trend of corporate misconduct. Through this memorandum, the Department of Justice reaffirmed its commitment to prosecuting not only corporations, but to hold their executives personally liable for regulatory violations committed under their watch. On paper, this is an attainable goal. In reality, federal prosecutors have been faced with seemingly insurmountable difficulties of proving executive intent and knowledge, overcoming attorney-client corporate privilege, and ultimately, convincing juries that are reluctant to convict corporate individuals for the crimes of their company. This note will examine the history of criminal prosecution of corporate executives which gave rise to the need for the Yates Memorandum, it will analyze the Yates Memorandum and explore the expanding impact of the document, and, finally, discuss

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potential solutions to the numerous challenges faced by federal prosecutors in accomplishing the goals of the Yates Memorandum. This Note will argue that despite the mounting challenges of implementation and prosecution of corporate officers, there are viable solutions to give teeth to the original purpose of the Yates Memorandum and curb corporate misconduct.

I. FOUNDATION OF THE RESPONSIBLE CORPORATE OFFICER DOCTRINE

The “Responsible Corporate Officer” doctrine (RCO doctrine), also described as the “crime of doing nothing,”² is a procedural process that regulators and Federal prosecutors are now applying against corporate executives in administrative, civil, and even criminal actions.³ The RCO doctrine is aptly categorized as a crime of doing nothing because, at its core, the doctrine focuses on the “person’s position in an entity as the basis for imposing liability and not whether he or she had a culpable intent, was aware of any wrongdoing, or had any direct involvement whatsoever.”⁴ More recently, courts are applying the theory of liability in the public health and welfare context.⁵ It has been expanded in scope to encapsulate a wider range of regulatory violations and crimes. Along with a wider scope comes a wider range of applications that can result in harsher, criminal exposure for individuals.

Today, the Responsible Corporate Officer doctrine effects not only the top brass of the corporate suite, but reaches out to a wide range of corporate management. The RCO doctrine can impose felony criminal charges on officers and exposure for the acts of their subordinates within the corporation. This reality remains true even though the officer did not intend for the bad acts to occur or was consciously aware of the regulations that were being violated.⁶

Justice Jackson of the United States Supreme Court stated in *Morissette v. United States*, “[c]rime, as a compound concept, generally constituted only from concurrence of an evil-meaning mind with an evil-doing hand, was congenial to an intense

² Brent J. Gurney, et al., Commentary, *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA*, 22 *Andrews Litigation Reporter* 1 (West 2007), available at https://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/Files/Editorial/Publication/The%20Crime%20of%20Doing%20Nothing.pdf.

³ M.E. Clark, *The Responsible Corporate Officer Doctrine*, Duane Morris LLP (Jan. & Feb. 2012), http://www.duanemorris.com/articles/static/clark_healthcarecompliance_0112.pdf.

⁴ *Id.* at 5.

⁵ D.E. Frulla, et al., *Responsible Corporate Officer Doctrine: Strict Criminal Liability for Regulatory Violations*, Kelley Drye (Oct. 24, 2013), http://www.kelleydrye.com/publications/articles/1771/_pdf/style=pdf/articles_1771.pdf.

⁶ *Id.*

individualism and took deep and early root in American Soil.”⁷ It is important to note the deviation from the historical notion of criminal prosecution in American jurisprudence. The vast majority of criminal offenses require the unity of the bad act, *actus reus*, and bad intent, *mens rea*. Here, however, the legislature has created a discrete subset of offenses based on violation of administrative regulation relating to public health and welfare. These offenses, notably, lack the *mens rea* elements, but instead operate as strict liability offenses.⁸ The RCO doctrine is not a newcomer to American jurisprudence, but instead has been a slow build from its incipience in *United States v. Dotterweich*.

In 1943, the United States Supreme Court, in *United States v. Dotterweich*, 320 U.S. 277 (1943), granted certiorari to address whether a corporate executive had to have personal knowledge of regulatory violations to be held criminally responsible.⁹ The defendant was the president of a corporation which purchased drugs from manufacturers, repackaged them, and then shipped them out to physicians under their corporate label.¹⁰ On at least two occasions, the labels for the drugs were incorrect and thus the corporation was prosecuted for criminal violation of the Federal Food, Drug, and Cosmetic Act (FDCA) §§ 301-392. At the end of the proceedings, the jury reached their verdict in which they acquitted the corporation, but found Dotterweich guilty. He was sentenced to probation for 60-days and a fine.

The United States Supreme Court upheld his conviction and stated, “legislation dispenses with the conventional requirement for criminal conduct – an awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent, but standing in responsible relation to a public danger.”¹¹ The Supreme Court’s impact went far beyond the holding in this singular case. Their reasoning stated that “Congress could place a great burden on corporate officers to comply with regulation that directly affect public health and welfare.”¹² Criminal liability, for the violation of an administrative regulation, stretches to all those having “such a responsible share in the furtherance of the transaction which the statute outlaws.”¹³ The next stage in the development of the RCO doctrine came into being when the Supreme Court decided *Morissette v. United States*.

Justice Jackson, in *Morissette*, stated technological and society advances following the Industrial Revolution have yielded,

⁷ *Morissette v. United States*, 342 U.S. 246, 251-52 (1952).

⁸ *Id.*

⁹ *United States v. Dotterweich*, 320 U.S. 277, 284 (1943).

¹⁰ *Id.* at 281.

¹¹ *Id.*

¹² *Id.* at 284-85.

¹³ See Gurney, *supra* note 2, at 3 (citing *Dotterweich*, 320 U.S. at 284).

“dangers [that] have engendered increasingly numerous and detailed regulations which heighten the duties of those in control of particular industries, trades, properties or activities that affect public health, safety or welfare.” 342 U.S. at 253-54. “Justice Jackson further explained, ‘[m]any of those are not in the nature of positive aggression or invasions, with which the common law so often dealt, but are in the nature of neglect where a duty requires care, or inaction where it imposes a duty.’”¹⁴ However, the *Morissette* Court was prudent to limit this new category of offenses to misdemeanors, with little to no risk of incarceration, rather than more serious felony offenses.¹⁵

Finally, the Supreme Court decided the seminal case of *United States v. Park* in 1975. In *Park* the Court, as in *Dotterweich*, faced a violation of FDCA. Park was the CEO of a national food chain. Over the course of three years, FDA inspectors found repeated contamination in several of the company’s food storage warehouses. Both the company and Park were charged with five misdemeanor counts under § 301(k) for causing the adulteration of food products being stored for later sale. The company plead guilty, but Park decided to go to trial. The trial court instructed the jury that in order to find Park guilty, the jury must find that he had “a responsible relationship” to the sanitary conditions in the company’s warehouses¹⁶. Further, the trial court stated that the primary question before the jury was whether Park, “by virtue of his position in the company, had a position of authority and responsibility in the situation out of which the charges arose.”¹⁷ The jury convicted Park of all counts. Following a reversal by the Fourth Circuit Court of Appeals, the Supreme Court granted certiorari.

The Supreme Court affirmed the trial court’s jury instructions noting that the “FDCA imposes not only a positive duty to seek out and remedy violations when they occur but also and primarily, a duty to implement measures that will insure that violations will not occur.”¹⁸ The Court concluded that “the government established a prima facie case... when it introduced evidence sufficient to warrant a finding by the trier of facts that the defendant had, by reason of his position in the corporation, responsibility and authority to prevent in the first instance, or promptly correct, the violation complained of, and that he failed to do so.”¹⁹ In accordance with *Park*, and the RCO doctrine, a court could impute knowledge of administrative regulation, for strict liability offenses, and impose the corporate subordinate acts upon

¹⁴ *Dotterweich*, 320 U.S. at 256.

¹⁵ *Id.* at 273.

¹⁶ *United States v. Park*, 421 U.S. 658, 665 (1975).

¹⁷ *Id.*

¹⁸ *Id.* at 672.

¹⁹ *Id.* at 673-74.

the responsible officer. Despite the growth in scope of the RCO doctrine, the Supreme Court has held firm to *Morrisette* in that when an offense is punishable by a felony, the court should not presume knowledge on the defendant. “[T]hat because a felony carries a much harsher stigma, a court should be careful not to dispose of a felony *mens rea* requirement on the same basis as when applying the RCO doctrine.”²⁰ Currently, the federal government utilizes the RCO doctrine in an effort to change corporate culture and steer corporate conduct away from habitual regulation violations²¹. In addition to levied charges, there has been a marked increase in the scale and in the amount of financial settlements, civil penalties, and criminal charges levied against both healthcare and pharmaceutical corporations and individual executives.

II. HISTORY OF CRIMINAL AND CIVIL PENALTIES

The inability of paltry financial penalties to serve as a deterrent to further wrongdoing heightens the importance of other enforcement avenues.²² However, despite the plethora of settlements reached with the pharmaceutical industry under the False Claims Act (FCA), Department of Justice (DOJ) has, with a few exceptions, not held company heads accountable for overseeing the fraudulent activities at issue in the settlements.²³

Public Citizen reported that in the period of 1991 through 2015 there were 329 reported civil settlements, 35 civil-criminal settlements, and nine reported criminal settlements with \$28 billion in civil penalties and \$7.8 billion in criminal penalties.²⁴ All of the reported criminal penalties, from 1991 through 2015, were federal and decreased exponentially over the last two years.²⁵ When considered in totality between federal and state settlements, there was a total of 373 between 1991 through 2015. These settlements reached a total amount of roughly \$35.7 billion. In 2012-13, combined criminal penalties totaled \$7.2 billion but by 2014-15, the total had decreased 98% to just \$44 million. There were two “civil-criminal settlements” in 2014-15, down from nine in the previous year, and there have been no reported criminal settlements since 2012.²⁶

²⁰ *Staples v. United States*, 511 U.S. 600, 618 (1994).

²¹ See Frulla, *supra* note 5.

²² Sammy Almashat, M.D., M.P.H., *et al.*, *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015*, PUBLICCITIZEN, at 25 (Mar. 31, 2016), available at <https://www.citizen.org/sites/default/files/publiccitizen-pharmasettlements1991-2015-chartbook.pdf>.

²³ *Id.* at 25.

²⁴ *Id.* at 10.

²⁵ *Id.*

²⁶ *Id.*

In the time period studied, Public Citizen totaled the amount of federal settlements at \$31.9 billion, with just \$2.4 billion in federal penalties recovered in 2014 and 2015. This amount, while substantial, is significantly reduced from the amount recovered in 2012-2013, \$8.7 billion. Likewise, the number of settlements decreased in the same time period from 22 in 2012-2013 to 19 settlements in 2014-2015, with each averaging out to \$395 million per settlement.²⁷ It is important to note that half of the recovered settlements in 2014-2015, roughly \$1.2 billion was due to one case in which the Federal Trade Commission (FTC) settled with Teva over alleged monopolistic practices²⁸. Among the reported federal settlements, the False Claims Act was the most commonly invoked law in civil settlements, while the FDCA was the most commonly invoked law in criminal prosecution. Out of all the federal prosecutions, qui tam (whistleblower) revelations amounted for 81 of 140 (58%) of all federal settlements and \$22.8 of \$31.9 billion (71%) of recovered penalties.

Through the end of 2014, the following cases resulted in guilty pleas by, or convictions of, executives of pharmaceutical companies. In 2007, three executives from Purdue Pharma pled guilty to “deceiving doctors and patients about the risks of lucrative painkiller Oxycontin” and paid a fine of \$34.5 million²⁹. In 2009, Former InterMune CEO, Scott Harkonen, was convicted for approving a press release which advertised Actimmune, one of the company’s drugs, for off-label uses. Harkonen was sentenced to six-months home confinement and forced to pay \$20,000 in fines³⁰. In the same year, Thomas Farina and Mary Holloway, both operated as sales representatives for Pfizer, were convicted for promoting the painkiller Bextra for off-label uses. Farina was sentenced to six months of home confinement and Holloway to two-years probation and a \$75,000 fine³¹. Finally, in 2011, former KV Pharmaceuticals CEO, Marc Hermelin, pled guilty to two misdemeanor charges under the FDCA and was ordered to pay the amount of \$1.9 million in fines and forfeitures and sentenced to 30-days in prison, of which

²⁷ *Id.* at 8.

²⁸ *Id.*

²⁹ Barry Meier. *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, N.Y. TIMES (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

³⁰ Greg Stohr. *Ex-InterMune CEO Harkonen’s Conviction Let Stand by Court*, BLOOMBERG BUS. (Dec. 16, 2013), <https://www.bloomberg.com/amp/news/articles/2013-12-16/ex-intermune-ceo-harkonen-s-conviction-let-stand-by-court>.

³¹ Jim Edwards, *Pfizer Exec Gets 6 Months’ Home Confinement for Off-Label Bextra Sales*, CBS. NEWS (last updated July 20, 2009.), <http://www.cbsnews.com/news/pfizer-exec-gets-6-months-home-confinement-for-off-label-bextra-sales>.

he served 15, for “failing to report that some of his company’s tablets were oversized and possibly dangerous.”³²

These reported data sets can only be considered to be the Olympics of corporate wrongdoing and settlements in the studied time period of 1991 through 2015. In that period, GlaxoSmithKline and Pfizer took gold and silver medals with \$7.9 and \$3.9 billion in settlements respectively. Johnson & Johnson, Merck, Abbott, Eli Lilly, Teva, Shering-Plough, Novartis, and AstraZeneca took home bronze and received honorable mentions with each paying penalties of at least \$1 billion in the same time period. To the average person, settlements of this magnitude would appear to be enough to curb any future corporate wrongdoing, but this is not the case. In the time period covered in this study, the total financial penalties totaled roughly \$35.7 billion. Consider that amount in comparison to the realized net profits of only the 11 largest pharmaceutical companies, \$711 billion³³. The amounts faced by corporations simply is not enough to deter the alleged regulatory violations. Consider the largest reported single settlement in the study.

GlaxoSmithKline paid \$3 billion for violations involving multiple of drugs. “On just the three drugs involved in the criminal plea agreement – Paxil, Wellbutrin SR, and Avandia – GlaxoSmithKline made \$28 billion in sales, or nine times the total fines for all implicated products in the settlement.”³⁴ The amount of penalties, even considering the largest monetary penalty faced, are doing little to curb regulatory violations or incentivize complete compliance with administrative regulation. Criminal prosecution of corporate executive and other employees resulting in prison sentences for the most egregious violations may be necessary and thus set the stage for Deputy Attorney General Sally Yates to issue her September 9, 2015 memorandum.

III. THE YATES MEMORANDUM

In response to the growing concerns that pure financial penalties and settlements were doing little to effectively curb wrongdoing by healthcare and pharmaceutical corporations, Deputy Attorney General Sally Quillian Yates, on September 9, 2015, issued a memorandum on Individual Accountability for Corporate

³² Press Release, U.S. Dep’t of Justice, *Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case* (last updated Sept. 15, 2014), <https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case>.

³³ See Almashat, *supra* note 22, at 23.

³⁴ *Id.* at 23-24.

Wrongdoing.³⁵ The purpose of this memorandum was simple. Yates stated “Our nation’s economy depends on effective enforcement of the civil and criminal laws that protect our financial system and, by extension, all our citizens...One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing.”³⁶ Accountability of corporate executives, those who perpetrate, or should have known to prevent such wrongdoing, is important for several reasons. First, as Yates stated, accountability deters future illegal activity. It incentivizes changes in corporate behavior. It ensures that proper parties are held responsible for their actions. Finally, and most importantly, accountability promotes the public’s confidence in our justice system.

The challenge in realizing the goals set forth in this memorandum lie in that, in large corporations, responsibility can be diffuse and decisions are made throughout the corporations and at all levels of managerial authority. In such situations, it can be, and is, difficult to determine if an individual possessed the knowledge and requisite criminal intent to establish them personally “guilty beyond a reasonable doubt.”³⁷ This challenge is particularly true in regards to high level executives, who are often well insulated from the day-to-day operations of the corporation in which many of the violations occur.

The Yates Memorandum set out the framework from which federal prosecutors may face these challenges head on. Six key steps have been formulated to “strengthen [the] pursuit of individual corporate wrongdoing.” First, in order to qualify for any cooperation credit, “typically consists of reduced fines in civil or administrative cases or potential shorter sentences in criminal cases”³⁸, corporations must provide to the Department all relevant facts relating to the individual responsible for the misconduct as criminal and civil investigations should focus on individuals from their inception. Criminal and civil attorneys handling corporate investigations should be in routine communications with one another. Absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation. Department attorneys should not resolve matters

³⁵ Sally Quillian Yates, U.S. Dep’t of Justice, Office of the Deputy Attorney General, *Individual Accountability for Corporate Wrongdoing* (Sept. 9, 2015), <http://src.bna.com/hg>.

³⁶ *Id.*

³⁷ *Id.*

³⁸ Jonathan C. Schwartz & David G. Buffa, *Cooperation Credit in Enforcement Proceedings: The Importance of Independence*, A.B.A. (Aug. 8, 2016), <http://apps.americanbar.org/litigation/committees/commercial/articles/summer2016-0816-cooperation-credit-enforcement-proceedings-importance-of-independence.html>.

with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases. Finally, civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on consideration beyond that individual's ability to pay.³⁹

The government's twin aims of this memorandum, of returning government money to the public and to hold the wrongdoers accountable and deter future violative actions, are equally important. However, the twin aims can come into apparent tension when a federal prosecutor is determining whether to levy civil charges against an individual who may not have sufficient personal resources to pay any financial penalty imposed. The goal of individual accountability supersedes the individual's ability to pay. Yates clearly stated that, "[p]ursuit of civil actions against culpable individuals should not be governed solely by those individuals' ability to pay.

In other words, the fact that an individual may not have sufficient resources to satisfy a significant judgment should not control the decision on whether to bring suit. Rather, Department attorneys should consider the following factors. First, was the individual's misconduct serious? Second, if so, is the misconduct actionable? Third, will the evidence admissible against the individual "probably be sufficient to obtain and sustain a judgment."⁴⁰ Finally, ask whether pursuing the charge reflects an important federal interest.⁴¹ Only by seeking to hold all individuals accountable, in view of the above mentioned factors, can the Department of Justice ensure that it is "doing everything in its power to minimize corporate fraud, and, over the course of time, minimize losses to the public fisc through fraud."⁴²

Under this new approach by the Department of Justice and Office of the Attorney General, corporations face increased pressure to comply with administrative regulations. Instead of the corporation and executives facing solely monetary penalties, and potential exclusion from participation in the Medicare and Medicaid, now corporate executives face potential criminal charges resulting in prison sentences. All of these measures are designed to deter future wrongdoing, incentivize long overdue changes to corporate behavior, and ensure that the proper parties are held responsible for violations. Just as Former Deputy General Yates stated, "Americans should never believe, even incorrectly, that

³⁹ Yates, *supra* note 35, at 2-3.

⁴⁰ *Id.* at 7.

⁴¹ *Id.*

⁴² *Id.*

one's criminal activity will go unpunished simply because it was committed on behalf of a corporation."⁴³ The impact of the memorandum was almost immediate with the first prosecution coming a short seven weeks after the publication of the memorandum.

IV. THE IMPACT OF THE YATES MEMORANDUM

The Yates memorandum serves an important purpose in helping shape the future of corporate conduct, and specifically the future compliance with administrative regulation. As Eric Holder, Former Attorney General of the United States, stated, "few things discourage criminal activity at a firm – or incentivize changes in corporate behavior – like the prospect of individual decision makers being held accountable."⁴⁴ While corporations can plead guilty and have their stock prices return to profitable levels in a matter of time, executives that plead guilty can face years of incarceration. The Yates Memorandum marks a notable shift in policy. Executives can no longer protect themselves behind the veil of corporate limited liability, but instead face the full force of punishment both their personal and their corporation's wrongdoing.⁴⁵ The impact of the Yates memo, and challenges faced by federal prosecutors, will be examined in four notable cases.

Historically, the Department of Justice punished healthcare and pharmaceutical companies with mammoth financial settlements, without actually holding the individuals charged with responsibility of such companies accountable. This was true until October, 29, 2015. The U.S. Attorney's Office for the District of Massachusetts announced that they had formally arrested the former president of Warner Chilcott, W. Carl Reichel on an indictment of conspiring to violate the Anti-Kickback Statute.⁴⁶ The indictment charged Reichel with an allegedly integral role in Warner Chilcott's

⁴³ Sally Quillian Yates, *Deputy Attorney General Sally Quillian Yates Delivers Remarks at New York University School of Law Announcing New Policy on Individual Liberty in Matters of Corporate Wrongdoing*, U.S. Dep't of Justice (Sept. 10, 2015), <https://www.justice.gov/opa/speech/deputy-attorney-general-sally-quillian-yates-delivers-remarks-new-york-university-school>.

⁴⁴ Eric Holder, *Attorney General Holder Remarks on Financial Fraud Prosecutions at NYU School of Law*, U.S. Dep't of Justice (Sept. 17, 2014), <https://www.justice.gov/opa/speech/attorney-general-holder-remarks-financial-fraud-prosecutions-nyu-school-law>.

⁴⁵ Dustin Aponte, *et al.*, *The Yates Memo and Big Pharma: Individual Prosecutions for Corporate Misconduct*, ABA (Sept. 12, 2016), <http://apps.americanbar.org/litigation/committees/health/articles/summer2016-0916-yates-memo-big-pharma-individual-prosecutions-corporate-misconduct.html>.

⁴⁶ Gary Giampetruzzi, *Not Guilty, Again: Individual Corporate Liability in the Wake of the Reichel Acquittal*, PAUL HASTINGS LLP (June 22, 2016), <https://www.paulhastings.com/publications-items/details/?id=6cc9e969-2334-6428-811c-ff00004cbded>.

scheme to pay kickbacks, in the form of speaker fees, dinners, and other remunerations, for high volume of prescription of the company's drugs.⁴⁷ However, on the same day that the U.S. Attorney's Office announced the arrest of Reichel, the office also announced that Warner Chilcott would pay a reported \$125 million to settle both the civil claims and criminal charges levied against them.⁴⁸

The impact of the Yates memorandum is clear. In this instance, the corporation has formally settled the charges against it for a monetary penalty, but the U.S. Attorney's Office continues to pursue independent criminal charges against the executive for his personal role in the wrongdoings. In announcing such an independent indictment, U.S. Attorney Carmen Ortiz stated the indictment "demonstrate[s] that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."⁴⁹

At trial, the government asserted that there were two Warner Chilcott corporation, "one on paper that followed the law, and one which Reichel directed, that broke the law."⁵⁰ The government offered the testimony of ten former Warner Chilcott employees, several had pled guilty to federal charges and entered into plea agreements to cooperate with the government in exchange for the government's recommendation that they receive lighter sentences.⁵¹ Several of the witnesses testified to providing kickbacks to prescribing physicians and that it was Reichel who truly directed the operation.⁵² Additionally, the government stated that they wished to have the jury instructed on willful blindness in that "would have allowed [the jury] to find that Reichel knew a fact if he 'deliberately closed his eyes to a fact that otherwise would have been obvious to him.'"⁵³ Reichel objected and the court sustained in favor of jury instructions that read:

Since an essential element of the offense is that it be undertaken "knowingly" and "willfully," it follows

⁴⁷ Indictment ¶ 9, *United States v. Reichel*, No. 1:15cr10324 (D. Mass. 2016).

⁴⁸ U.S. Dep't of Justice, *Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme*, (Oct. 29, 2015), <http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million>.) [hereinafter "Warner Chilcott Pleads"].

⁴⁹ Indictment ¶ 9, *United States v. Reichel*, No. 1:15cr10324 (D. Mass. 2016).

⁵⁰ See Giampetruzzi, *supra* note 46 (citing Brian Amaral, *Bribery Case Against Ex-Warner Chilcott Exec Heads to Jury*, LAW 360 (June 16, 2016), <https://www.law360.com/articles/807929/bribery-case-against-ex-warner-chilcott-exec-heads-to-jury>).

⁵¹ See Warner Chilcott Pleads, *supra* note 48.

⁵² See Giampetruzzi, *supra* note 46.

⁵³ Government's Proposed Instructions No. 21, *United States v. Reichel*, No 1:15cr10324 (D. Mass. 2016)).

that good faith on the defendant is a complete defense. It is for you to decide whether or not the defendant acted in good faith, but if you decide that at all relevant times he acted in good faith, it is your duty to acquit him.⁵⁴

Over the next two days, the jury deliberated and ultimately acquitted Reichel of all charges.⁵⁵ As one commentator pointed out, “Had he been convicted, Reichel faced up to five years’ imprisonment and mandatory exclusion from all federal healthcare benefit programs, such as Medicare and Medicaid.”⁵⁶ He further stated, “In a case that everyone seemed to be watching, and had a *Yates* imprint all over it, the government had come up short against an individual.”⁵⁷ This case is a clear demonstration of the challenged faced by federal prosecutors in charging corporate individuals as they bear the burden of proof to establish both the executive’s knowledge and his or her intent to break the law. Despite this setback, the Department of Justice will not forgo prosecution of corporate executives, but will instead work to improve the quality of their evidence and sources of information, primarily the mandated corporate cooperation.⁵⁸

In a similar case, GeneScience Pharmaceutical was investigated for a period of three years and ultimately was charged, along with the founder, Lei Jin.⁵⁹ GeneScience pled guilty to a felony charge of illegally distributing human growth hormone in the United States.⁶⁰ GeneScience was sentenced to pay a settlement of \$3 million towards a clean competition fund, which supports drug-free sports, and \$7.2 million in criminal forfeitures.⁶¹ However, Lei Jin entered a guilty plea and was sentenced to 5 years’ probation.⁶²

Another challenge faced by the Department of Justice when prosecuting corporate executives is not only the burden of proof, but also overcoming the hurdle of the attorney-client privilege. In 2011, GlaxoSmithKline made headlines when they agreed to plead guilty and pay a record \$3 billion to resolve fraud allegations and failure to report safety data.⁶³ In addition to corporate responsibility,

⁵⁴ Final Jury Instructions at 6, *United States v. Reichel*, No. 1:15cr10324 (D. Mass. 2016).

⁵⁵ Docket at No. 245, *United States v. Reichel*, No. 1:15cr10324 (D. Mass. 2016)).

⁵⁶ Giampetruzzi, *supra* note 46 (citing 18 U.S.C.S. § 371; 42 U.S.C.S. § 1320(a)).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Duff Wilson, *Drug Maker From China Pleads Guilty*, N.Y. TIMES (Oct. 6, 2010), available at <http://www.nytimes.com/2010/10/07/business/07drug.html>.

⁶⁰ *U.S. v. Lei Jin*, No. 10CR00144 2010 WL 3936987 (D.R.I. Oct. 1, 2010).

⁶¹ *Id.*

⁶² Jesse C. Vivian, *New FDA Strategy: Criminal Charges Against Pharma Executives*, U.S. PHARMACIST (June 20, 2011), <https://www.uspharmacist.com/article/new-fda-strategy-criminal-charges-against-pharma-executives>.

⁶³ Duff Wilson, *Glaxo Settles Cases With U.S. for \$3 Billion*, N.Y. TIMES, (Nov. 3, 2011).

prosecutors alleged that a high-ranking attorney obstructed an FDA investigation into whether the company marketed one of their anti-depressant drugs, Wellbutrin SR, for the off-label use of weight loss.⁶⁴ Prosecution alleged that the attorney made false statements during an investigation in which she denied having any knowledge that the company was promoting the drug for such uses.⁶⁵ The difficulty arises when prosecutors are attempting to prosecute an attorney representing a client for a criminal offense because the bulk of the communications between the attorney and client are privileged and cannot be compelled for disclosure. “While there have been a few drug company executives who have pled guilty to criminal and/or civil charges relating to the unlawful marketing of a product, this strategy of suing corporate executives, who almost always rely on the advice of their attorneys, is very problematic.”⁶⁶

Following the Warner Chilcott case, federal prosecutors filed suit in a Massachusetts federal court against William Facteau, former CEO of Acclarent, and Patrick Fabian, former Vice President of Sales. Like many others, this case arose out of a qui tam suit filed under the federal False Claims Act by a former sales representative who worked for Acclarent from 2007 to 2011.⁶⁷ The relator alleges that Acclarent received FCA clearance for its “Relieva Stratus MicroFlow Spacer” (Stratus) device, a device which utilized saline to open a patient’s sinuses following surgery.⁶⁸ However, allegedly, this was not the true purpose of this device. Following FDA clearance, Facteau and Fabian intended to use Stratus as a drug-delivery device and marketed Stratus for that purpose even after, in 2007, when the FDA rejected the request to promote Stratus for such purposes.⁶⁹ Following this rejection, the relator alleged that between 2008 and 2011, Facteau and Fabian engaged in a scheme to develop and market Stratus rapidly in order to generate sales and make the company, Acclarent, an overall desirable target for acquisition or an IPO.⁷⁰

The relator further alleged that, as part of the scheme, sales employees were praised promotion and trained only in the off-label

⁶⁴ Indictment ¶ 25-26, *United States v. Stevens*, No. RWT 10 CR 0694 2010 WL 4530135 (D. Md. 2010).

⁶⁵ *Id.*

⁶⁶ Vivian, *supra* note 62.

⁶⁷ Laurence Freedman, *Another Jury Acquits in One of the First Few Prosecutions of Health Care Executives Following DOJ’s Yates Memo*, MINTZ LEVIN, (July 27, 2016) <https://www.healthlawpolicymatters.com/2016/07/27/another-jury-acquits-one-first-prosecutions-health-care-executives-following-doj-yates-memo/>.

⁶⁸ U.S. Attys Off., U.S. Dep’t of Justice, *Former Acclarent, Inc. Executives Convicted of Crimes Related to the Sale of Medical Devices* (Jul. 20, 2016), <https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-convicted-crimes-related-sale-medical-devices>.

⁶⁹ Freedman, *supra* note 67.

⁷⁰ Indictment ¶ 15, *United States v. Facteau*, No. 1:15-cr-10076-ADB (D. Mass. 2015).

use of the Stratus device and were encouraged to discuss with physicians the benefits of the off-label uses of the device with steroids.⁷¹ Their efforts paid off and made them a desirable target for acquisition when in 2010, Johnson & Johnson acquired Acclarent for \$785 million.⁷² Despite being told to discontinue the promotion of the Stratus device for off-label uses, Acclarent continued to promote the device and ultimately allegedly caused several doctors and other health care providers to bill federal health care programs for unapproved uses of the device. In May 2013, Acclarent made the decision to discontinue the use of the Stratus device.

Despite discontinuing the device, both Facticeau and Fabian were indicted for “felony wire fraud and conspiracy, as well as a number of misdemeanor counts related to introducing a misbranded and adulterated device into interstate commerce.”⁷³ The prosecution argued, at trial, that the two parties hid the truth of their device’s purpose from the FDA. The defense countered, and jury agreed, that they had not hid the truth, but had rather applied for several years to have the off-label use cleared by the FDA, but had not received any approval beyond the initial saline use. The jury agreed and acquitted them of the singular felony charge. “Facteau and Fabian did not escape trial unscathed, however, and were convicted on 10 misdemeanor counts of introducing a misbranded and adulterated device into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act.”⁷⁴ Johnson & Johnson agreed to pay \$18 million to resolve any civil allegations that it caused health care providers to submit false claims to the federal health care programs.

In the most recent, and ongoing, development of the Yates memorandum, a former senior executive of Tenet Healthcare Corp, John Holland, has been indicted on charges of participation in a scheme to bribe physicians for patient referrals, enabling the healthcare corporation to fraudulently bill Medicaid programs in excess of \$400 million.⁷⁵ Holland was senior vice president for Tenet’s southern states between 2006 and 2013 and has been accused by federal prosecutors of paying \$12 million in kickbacks to Clinica de la Mama, a clinic serving predominately undocumented pregnant women in Georgia and South Carolina. In these states, the clinic referred expecting mothers to local Tenet

⁷¹ Freedman, *supra* note 67.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ U.S. Dep’t of Justice, Office of Public Affairs, *Former Executive of Tenet Healthcare Corporation for Alleged Role in \$400 Million Scheme to Defraud* (Feb. 1, 2017), <https://www.justice.gov/opa/pr/former-executive-tenet-healthcare-corporation-charged-alleged-role-400-million-scheme-defraud>.

hospitals. In return, Tenet would bill Medicaid, and in some cases, Medicare, for the total of \$149 million in reimbursement from the referrals.⁷⁶ The indictment also alleges that Holland falsified compliance reports to the Department of Health and Human Services, violating Tenet's previous 2006 settlement agreement in which Tenet agreed to pay \$900 million for over-inflating charges to Medicaid. Holland, facing four charges of mail fraud, health care fraud, and major fraud against the United States, pled not guilty in federal court in Miami.

Holland is likely the first of several managers and executives at Tenet Healthcare to be charged. In the past year, Tenet Healthcare reached a \$514 million settlement to resolve the criminal and civil claims that came from a whistle-blower lawsuit filed more than 10 years ago. Richard Deane, attorney for Holland, stated that "[t]he allegations relate to contracts from more than 10 years ago that were openly reviewed and approved at multiple levels of the company, including by their lawyers, was released on a \$3 million bond late Wednesday."⁷⁷ If convicted, John Holland could face up to 50 years in prison with his homes in Dallas and Park City also facing seizure. However, Holland's attorney believes that his client is innocent, that the jury will find him so, and "the company's resolution", of the issue, "should have ended the matter."⁷⁸ Acting Assistant Attorney General, Blanco said that the "charges underscore our continued commitment to holding both individuals and corporations accountable for the fraudulent conduct. We will follow the evidence where it takes us, including to the corporate executive ranks."⁷⁹ Although juries have not entirely sided against corporate executives in the various cases and charges levied against them, considered together, they raise questions about the willingness of juries to hold individuals personally accountable for the actions or wrongdoings of their companies, despite the government's "recommitment to prosecuting individuals as professed in the Yates Memo."⁸⁰

V. CONSIDERATIONS TO COMBAT THE INEFFECTIVENESS OF THE YATES MEMORANDUM

Laws without teeth are merely words. Historically, monetary penalties have done little to effectively curb the trend of corporate violation of federal administrative regulation from the Federal Food, Drug, and Cosmetics Act to the Anti-Kickback Statute. The billions

⁷⁶ *Id.*

⁷⁷ *Former Tenet Vice President Faces Prison Time for Role in \$400 Million Scheme*, MODERN HEALTHCARE (Feb. 1, 2017), <http://www.modernhealthcare.com/article/20170201/NEWS/170209987>.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

imposed as federal sanctions are written off as insignificant means to reach the end of realized exponential profits. The Yates Memorandum is sound in both idea and scope, but the goals and language have not been effectuated in the most efficient ways. The number of corporate senior executives that have been charged individually following the memo has grown. However, the number of convictions of criminal charges is small. It is more likely that a middle manager or sales representative will face the full force of criminal charges, and even jail sentences, than the majority of charged senior executives.

The state of American healthcare and regulation is always in flux, but that has never been truer than now. While we are in the early stages of a new administration, it will be interesting, as time goes on, to see the impacts that will be made on the prosecution of corporate executives. The following are considerations on what might be done to remedy the ineffectiveness found in the application of the Yates Memorandum. Time will tell whether future administrations will continue to pursue accountability by using the same methods or if they will make changes, from minor to major, to potentially empower prosecutors to fully perform all of the goals set forth in the memorandum.

The first potential solution to accomplish the goals set forth by the Yates memo is to further empower federal prosecutors. In doing so, it would be necessary to call for further cooperation by corporations involved in investigations. In order to qualify currently for the cooperation credit, a corporation must disclose to the Department of Justice all relevant facts about an individual's misconduct. "The company must identify any individuals involved or otherwise responsible for the misconduct at issue, regardless of their position, status, or seniority, and provide to the Department all facts relating to that misconduct."⁸¹ The revision should include further calls for corporate transparency and full disclosure. Federal prosecutors face the burden of often having to prove individual *mens rea* and *actus reus* without all of the necessary facts and as their cases have suffered as a result. By fully disclosing all relevant information to the misconduct at hand, and employees who are connected to such misconduct, federal prosecutors might be able to build stronger cases reinforced by this additional evidence which might be able to prove the intent and knowledge of corporate executives.

By revising the current or issuing a new memorandum to reflect this first proposal, federal prosecutors might be empowered to overcome the challenges of acquiring sufficient evidence to hold individual corporate executives accountable. With more access to evidence, federal prosecutors will not only be able to better show

⁸¹ See Yates, *supra* note 35, at 3.

the knowledge of misconduct or intent of the corporate executive, but will also be able to better advocate their cause to the jury. As it has been noted previously, juries have shown a hesitancy to convict individuals for the wrongs of their companies. However, with enough information, stemming from full and transparent cooperation by corporations, juries will be better able to understand the role that executives play in the misconduct or why they should be held vicariously liable for the acts of the corporation that they knew, or should have known, were illegal.

Finally, a more immediate proposal would be to revise the Department of Justice's approach to monetary penalties. If the profits that can be made by the sale of pharmaceuticals or services billable to federal healthcare programs can justify the financial penalties imposed on the means utilized to realize them, as the cost of doing business, then it would be wise for the Department of Justice to seek, and impose, higher monetary settlement and sanctions against these violative corporations. If evidence fails to show cause or juries are too hesitant to hold individuals accountable for the wrongdoings of the corporation, then, perhaps, it is best left to the shareholders to rectify noncompliance. If the Department is able to advocate for and impose far higher monetary penalties, then it would be wise for shareholders, acting in the best interest of their investments, to remove habitually offending executives and managers who are threatening their return on investment by continually incurring billions of dollars in settlements for regulatory violations.