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Not Guilty, Again: Individual Corporate Liability in the Wake of the Reichel Acquittal

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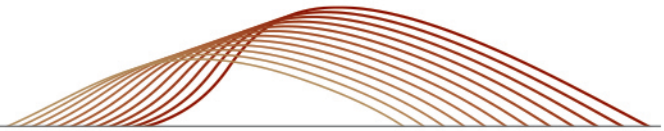
On September 9, 2015, the Department of Justice ("DOJ") issued the *Yates* Memorandum setting forth policies regarding the investigation and prosecution of individual wrongdoers in the context of corporate investigations.[1] Seven short weeks later, on October 29, 2015, the U.S. Attorney's Office for the District of Massachusetts, no stranger to the pursuit of companies and individuals alike in the pharmaceutical industry, announced the arrest of former Warner Chilcott President, W. Carl Reichel, on an indictment charging him with conspiring to violate the Anti-Kickback Statute.[2] On June 17, 2016, following a four-week trial, it took a federal jury just two days to reach the conclusion that Reichel should be acquitted of the charge against him.[3] While this acquittal is a notable loss for the government, and not its first one against individual pharmaceutical defendants, history has shown the DOJ will continue to investigate and prosecute cases of individual wrongdoing, especially in this post-*Yates* era. However, the question may now become whether the government will demand even more breadth and depth of cooperation from companies in order to meet the *Yates* requirements and to prosecute successfully its cases, or, as it has in the recent past, whether it will decline to pursue these more difficult cases of affirmative wrongdoing in lieu of the more controversial, strict criminal liability, *Park* offenses.

The Government Case Against W. Carl Reichel

Against the backdrop of certain historic criticisms that the DOJ had punished pharmaceutical companies with mammoth settlements, without holding the actual individual wrongdoers accountable, the U.S. Attorney's Office for the District of Massachusetts announced the indictment of Reichel on the same day of the Warner Chilcott agreement to pay $125 million to resolve its criminal and civil liability arising from the company's illegal marketing of certain drugs.[4] The indictment against Reichel detailed his purportedly integral role in Warner Chilcott's scheme to pay kickbacks, in the form of alleged speaker fees, dinners and other remuneration, to doctors in exchange for high volumes of prescriptions of the company's drugs.[5] In announcing the indictment and Warner Chilcott settlement, U.S. Attorney Carmen Ortiz stated that 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."[6] With the winds of *Yates* at their backs, the government team moved the criminal case forward.

At trial, the government presented the testimony of more than ten former Warner Chilcott employees and several federal agents, and introduced internal Warner Chilcott documents, and even secret recordings of meetings at which Reichel was present where Warner Chilcott employees purportedly



discussed breaking the anti-kickback law.[7] Significantly, several of the former employees had pleaded guilty to federal charges and entered into plea agreements in which they agreed to cooperate with the government in exchange for the government's recommendation that they receive a reduced sentence.[8] At least one former employee received immunity from the government in exchange for her testimony against Reichel.[9] Some of the former employees who testified at trial admitted that they had participated in a scheme to pay kickbacks to doctors in exchange for their prescription of certain Warner Chilcott products.[10] Of those former employees, some identified Reichel as having directed that scheme.[11]

The government rested its case after presenting more than three weeks of testimony.[12] Reichel then presented three witnesses in his defense, including one who recounted an instance in which Reichel told her that compliance was more important than sales.[13] Reichel did not take the stand. During closing arguments, the government asserted that there were two Warner Chilcotts, one on paper that followed the law and one which Reichel directed, that broke the law.[14] In response, Reichel's counsel told the jury that the government's witnesses "are not to be trusted," and that those witnesses were "admitted felons who said that they ignored policies."[15]

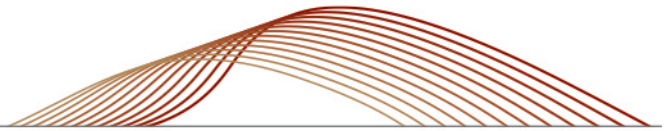
Perhaps sensing weakness in its case, or feeling the ghosts of failed individual prosecutions of the past, the government sought to have the District Court provide the jury with an instruction on willful blindness, which would have allowed them to find that Reichel knew a fact if he "deliberately closed his eyes to a fact that otherwise would have been obvious to him."[16] Reichel objected arguing that such an instruction was improper given the government's theory that he had actually directed the sales force to pay kickbacks.[17] Reichel further argued the government had presented no evidence that he "ever purposefully closed his eyes or deliberately avoided learning the facts about how Warner Chilcott employees were allegedly paying kickbacks."[18] The Court sustained Reichel's objection and, on Thursday, June 16, 2016, instructed the jury, in part, that "[k]knowingly means an act that was done voluntarily and intelligently and not because of ignorance or misunderstanding."[19] The Court further instructed the jury:

> Since an essential element of the offense is that it be undertaken 'knowingly' and 'willfully,' it follows 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.[20]

After deliberating several hours over two days, on Friday, June 17, 2016, the jury returned with its verdict acquitting Reichel of the charge against him.[21] Had he been convicted, Reichel would have faced up to five years in prison, among other criminal penalties, and mandatory exclusion from federal health care benefit programs.[22] In a case that everybody seemed to be watching, and had a *Yates* imprint all over it, the government had come up short against an individual.

What Comes Next? The *Park* Doctrine?

This high-profile acquittal, where the government failed to prove that the individual defendant acted knowingly and intentionally, conjures up memories of the alternative *Park* Doctrine charges upon which the government has chosen to pursue individual pharmaceutical defendants. In *United States v. Park*, which was decided back in 1975, the Supreme Court provided the foundation for modern-day "responsible corporate officer" ("RCO") doctrine liability.[23] The Court explained that "the [FDCA] imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions."[24] The Court found that a RCO's culpability for a misdemeanor violation of the FDCA arises not from his or



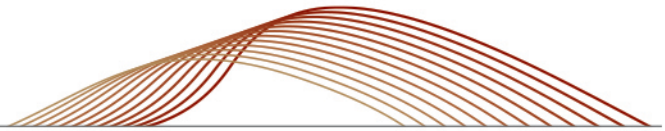
her knowing and intentional violation of the law, but from his or her position at the company.[25] The Court explained that the government can establish a RCO's guilty of a misdemeanor violation of the FDCA where it introduces evidence "to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so."[26]

In the decade following the Court's decision in *Park*, the DOJ brought a range of *Park* Doctrine cases against corporate executives. Beginning in the mid-1980s, though, the DOJ began using the *Park* Doctrine less often. Misdemeanor violations of the FDCA are punishable by a term of imprisonment of no more than one year, and a limited fine. In practice, however, most of the *Park* Doctrine cases brought by the DOJ between 1975 and 1985 resulted in no jail time.[27] By the late 1990s into the early 2000s, for a variety of reasons, the DOJ appeared to have shifted its focus away from the *Park* Doctrine to bringing more serious felony criminal charges against individual corporate executives, as evidenced by the charges in the seminal TAP case.[28]

Over 10 years ago, the U.S. Attorney's Office for the District of Massachusetts suffered a setback similar to that in the *Reichel* case when, on July 14, 2004, following a three-month trial, a federal jury in Boston acquitted eight sales executives and personnel from TAP Pharmaceuticals of having conspired to pay physicians kickbacks in the form of gifts, dinners, trips, and cash in exchange for those physicians' prescriptions of TAP's cancer drug Lupron.[29] Counsel for the sales executives and personnel argued at trial that, in part, their clients did not know or intend to break the law.[30] The DOJ's prosecution of the TAP sales executives and personnel came after the government had extracted from the company a then-record sum of $875 million to resolve civil and criminal claims.[31] The individual prosecutions nonetheless failed.

It was perhaps with the TAP acquittals in mind that the DOJ once again turned to the *Park* Doctrine, just a few years later, when investigating individual corporate wrongdoing at Purdue Pharma. On May 10, 2007, Purdue Pharma and three of its former executives, Michael Friedman, its former president, Howard R. Udell, its former General Counsel and Chief Legal Officer, and Dr. Paul D. Goldenheim, its former Medical Director, pleaded guilty in U.S. District Court in the Western District of Virginia to a misdemeanor charge of misbranding OxyContin.[32] Under the terms of their plea agreements, the three former Purdue executives agreed to pay the government $34.5 million in fines, penalties, and forfeitures.[33] Purdue's plea agreement was part of its broader settlement with the government under which it agreed to pay $600 million in criminal and civil fines, penalties, and forfeitures.[34] On July 20, 2007, the three former Purdue executives were each sentenced to a term of three years' probation and 400 hours of community service in drug treatment programs.[35] Following their sentencing, the Department of Health and Human Services, Office of the Inspector General ("HHS OIG") excluded each of the men from doing business with federal health care programs for a term of 20 years, a ban that was later reduced to 12 years.[36] In 2012, the Court of Appeals for the District of Columbia agreed that the executives' misdemeanor convictions could result in their exclusion, but found that the 12-year length was a significant departure from precedent and was "arbitrary and capricious."[37]

Then, in 2009, facing numerous felony counts alleging that they conducted clinical trials of a bone cement without FDA approval, medical device maker Synthes Inc., and its subsidiary Norian Corp. pleaded guilty to criminal charges and agreed to pay a total of $24.3 million in fines and forfeitures.[38] In what the government said were the maximum criminal monetary penalties allowed by law, under the terms of the settlement, Norian paid $22.5 million and Synthes paid $669,800.[39] In 2011, following that settlement, four Synthes executives pled guilty to one misdemeanor count of shipping adulterated and misbranded bone cement in interstate commerce in the District Court for the Eastern



District of Pennsylvania. The District Court sentenced the executives to terms of imprisonment ranging from five to nine months.[40] As had been the case in *Purdue*, the government never had to make its case of affirmative wrongdoing against these executives, as they each pleaded guilty under the *Park* Doctrine. HHS OIG also excluded the four executives from doing business with federal health care programs.[41]

The government secured another notable *Park* Doctrine conviction in March 2011 when Marc Hermelin, the former CEO of KV Pharmaceuticals and an officer of Ethex Corporation, a KV subsidiary, pleaded guilty to two misdemeanor violations of the FDCA related to the misbranding of morphine sulfate tablets that contained more of the active drug than was specified in its labeling.[42] Hermelin was sentenced to one month in prison, ordered to pay a fine of $1 million and forfeit $900,000.[43] The case against Hermelin followed a March 2010 criminal case against Ethex, which pleaded guilty to two felony counts resulting from the company's failure to report the issue with the oversized morphine tablets to the FDA, and agreed to pay $27.6 million in fines, forfeiture and restitution.[44] Later that same month, KV Pharmaceuticals closed Ethex down.[45] In November 2010, HHS OIG excluded Hermelin from federal health care benefit programs based on the Ethex criminal conviction.[46]

From there, the application of the *Park* Doctrine, and all of the controversy and uproar within the pharmaceutical industry that followed it, arguably seemed to subside somewhat for those corporate executives who might find themselves in the government's crosshairs. However, with the *Yates* mandate now in place, the DOJ may have returned its focus to prosecuting individual corporate wrongdoers with felony offenses requiring the government to prove their knowledge and intent to break the law. In light of the *Reichel* outcome, what might come next?

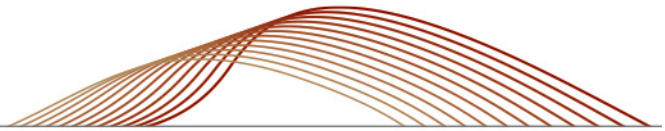
Three Key Takeaways from the Reichel Acquittal

1. The DOJ Will Continue to Focus on Individual Corporate Wrongdoing

While the Reichel acquittal is undoubtedly a disappointing loss for the DOJ, history dictates that it will not cause the government to abandon its focus on investigating and prosecuting individual corporate wrongdoers. The question is not whether the government will continue to investigate and prosecute individual corporate wrongdoers, but rather how the government will go about it.

The *Reichel* case demonstrates the difficulty in proving a corporate executive's knowledge and intent to break the law. The government's evidence against Reichel included the testimony of numerous former Warner Chilcott employees, many of whom were testifying pursuant to a plea agreement or grant of immunity provided years after Reichel purportedly engaged in the charged conduct.[47] Reichel's counsel argued, not surprisingly, that these witnesses lied about his role in the kickback scheme in an effort to obtain a break from the government for their own illegal conduct.[48] The government also presented secret recordings of Warner Chilcott employees discussing violating the anti-kickback law, and Reichel was present for these meetings. Reichel's counsel, however, argued that the message from their client to Warner Chilcott employees had been consistent: "Don't do anything illegal. It's not worth your job."[49] The jury considered the government's evidence, and acquitted Reichel.

The Reichel acquittal was preceded by the less closely followed defense verdict in the case against Vascular Solutions, Inc., a medical device company, and its CEO, Howard Root. On November 13, 2014, the DOJ announced the indictment of Vascular Solutions and Root on charges of having conspired to sell misbranded devices and having sold misbranded and adulterated devices.[50] The indictment alleged that Root had instructed the sales force to sell the Vari-Lase Short Kit to treat veins



deep in the leg, even though the Food and Drug Administration ("FDA") had only approved the treatment for veins near the skin's surface.[51] The charges against Vascular Solutions and Root followed the company's July 28, 2014 civil settlement with the DOJ under which it agreed to pay $520,000 to resolve allegations that it caused false claims to be submitted to federal health care benefit programs by marketing the Vari-Lase Short Kit for off-label uses.[52] On February 26, 2016, following a several week trial, a jury in San Antonio, Texas acquitted Vascular Solutions and Root on all charges.[53] Another tough government loss.

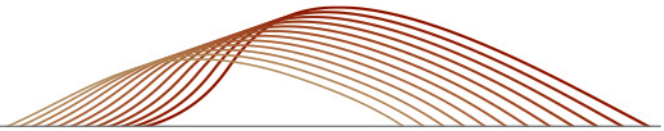
However, rather than abandoning felony prosecutions of corporate executives altogether, in future cases the government will undoubtedly seek to improve the quality of its evidence through all available investigative techniques, including consensual recordings and wiretaps, and sources of information, including highly placed cooperating individuals and cooperating corporations. Ultimately, of course, for those felony cases against corporate executives that proceed to trial, the trier of fact will judge whether the government's evidence proves any individual corporate executive's guilt beyond a reasonable doubt. In light of the very recent arrival of the *Yates* policy statement, however, the government can be expected to continue pursuing these cases.

Indeed, the U.S. Attorney's Office for the District of Massachusetts, the same office responsible for the case against Reichel, is currently on trial against the former CEO, William Facteau, and former Vice President of Sales, Patrick Fabian, of Acclarent, Inc., a device company, on conspiracy, securities fraud, wire fraud and Food Drug and Cosmetic Act ("FDCA") violations.[54] The government's case against Facteau and Fabian stems from allegations that they misled the FDA into believing that a device called the Stratus would be used with saline to open sinuses, when the true intended use of the device was to deliver drugs, in particular steroids, to the sinuses.[55] The government alleges that Facteau and Fabian lied regarding the actual off-label use of the Stratus during the sale of Acclarent to Ethicon in 2010, a sale which made both men millionaires.[56] The trial of Facteau and Fabian began in Boston on June 6, 2016 and is ongoing.[57]

2. The Yates Memorandum Will Continue to Guide Corporate Cooperation

The acquittal of this one executive also does not change the *Yates* Memorandum's directive that companies under government investigation and seeking cooperation credit "must identify all individuals involved in or responsible for the misconduct at issue, regardless of their position, status or seniority, and provide to the D[OJ] all facts relating to that misconduct."[58]

In Warner Chilcott's case, the company's "prior, ongoing, and future cooperation" was an "important" and "material factor underlying the decision by the United States" to enter into a criminal plea agreement with the company.[59] Pursuant to the terms that agreement, Warner Chilcott agreed to "continue to cooperate fully and actively" with the government "regarding any matter about which Warner Chilcott has knowledge or information in any ongoing investigation, trial, or other proceedings arising out of any federal investigation of its current and former officers, agents, and employees."[60] Warner Chilcott continues to receive the benefit of its plea agreement with the government because of its full and active cooperation regardless of the outcome of the trial against Reichel. As such, company counsel should continue to work to ensure that they have a common understanding with the government around what that means and how that bears on the nature and scope of the internal investigation. The government's loss in the Reichel case will likely strengthen the resolve of the government to secure truly meaningful corporate cooperation in the hopes that such cooperation will help it more successfully identify, investigate, and prosecute individual corporate wrongdoers.



3. Companies Should Take Steps To "Park Proof" Their Executives

In those cases where the government may have insufficient evidence to prove an executive's knowledge and intent, it could also seek to hold that executive accountable for violations under the FDCA pursuant to the *Park* Doctrine. While the criminal penalties for a misdemeanor offense under the FDCA are relatively minor, the practical consequences of such a conviction, including the exclusion from doing business with federal health care programs, are extremely serious, as evidenced by exclusions imposed against a number of pharmaceutical executives. In light of this most recent high-profile acquittal, one could see prosecutors dipping back into their prosecutorial tool kits, and pursuing these less challenging, if not less controversial, cases.

However, under *Park,* while corporate executives can be held strictly liable for misdemeanor violations of the FDCA, responsibility does not extend to violations that executives were "powerless" to prevent or correct.[61] Some courts have interpreted this statement to create an affirmative defense of objective impossibility for those executives who demonstrated "extraordinary care," but were nonetheless unable to prevent violations of the FDCA.[62] While this affirmative defense has been raised unsuccessfully by only a few defendants, companies should nonetheless implement and maintain compliance programs that reflect the "extraordinary care" taken to prevent and remediate FDCA violations. [63] Taking such steps will address some of the factors FDA personnel might consider when deciding whether to recommend prosecution for FDCA violations, including "[w]hether the violation reflects a pattern of illegal behavior and/or failure to heed prior warnings" and "whether the violation is widespread."[64]

Companies can also consider taking more affirmative and proactive steps to create demonstrable evidentiary records for their key executive and management personnel in the event that the government comes knocking, and brings along the risk of *Park* prosecution. While companies typically go to great lengths to develop effective corporate compliance programs, and create records of having done so, there has not been as much of an emphasis on how individual executives and management fit into those records. In light of the potential for renewed interest in prosecutions under the *Park* Doctrine, companies might consider so-called *Park* proofing their key executive and management personnel by keeping a documentary record showing the "extraordinary care" that those individuals are taking to prevent compliance violations.

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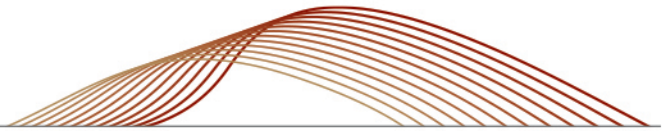

[1] U.S. Dep't of Justice, Yates Memorandum, Sept. 9, 2015 http://www.justice.gov/dag/file/769063/download.

[2] U.S. Dep't of Justice, Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations, Oct. 29, 2015, http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.

[3] Docket at No. 245, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[4] U.S. Dep't of Justice, Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations, Oct. 29, 2015, http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.

[5] Indictment at ¶ 9, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[6] U.S. Dep't of Justice, Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay $125 Million to Resolve Criminal Liability and False Claims Act Allegations, Oct. 29, 2015, http://www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.

[7] Docket at No. 222-238, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[8] *Id.* at No. 218, 226; Letter from Carmen M. Ortiz, United States Attorney District of Massachusetts, to Mark W. Pearlstein, Attorney for Jeffrey Podolsky (May 14, 2015); U.S. Dep't of Justice, Warner Chilcott Agrees to Plead Guilty to Health Care Fraud Scheme and Pay $125 Million, Oct. 29, 2015, https://www.justice.gov/usao-ma/pr/warner-chilcott-agrees-plead-guilty-health-care-fraud-scheme-and-pay-125-million.

[9] Docket at No. 222, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016); Government's List of Exhibits No. 163, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[10] Brian Amaral, *Bribery Case Against Ex-Warner Chilcott Exec Heads to Jury*, Law 360, Jun. 16, 2016 http://www.law360.com/articles/807929/bribery-case-against-ex-warner-chilcott-exec-heads-to-jury.

[11] *Id*.

[12] Docket at No. 238, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[13] *Id.* at No. 242, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016); Brian Amaral, *Ex-Warner Chilcott Exec Acquitted in Doctor Bribery Scheme*, Law 360, Jun. 17, 2016 http://www.law360.com/articles/807944/breaking-ex-warner-chilcott-exec-acquitted-in-doctor-bribery-scheme.

[14] Brian Amaral, *Bribery Case Against Ex-Warner Chilcott Exec Heads to Jury*, Law 360, Jun. 16, 2016 http://www.law360.com/articles/807929/bribery-case-against-ex-warner-chilcott-exec-heads-to-jury.

[15] *Id*.

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

[17] Docket at No. 237, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016); Defendant's Mem. of Law in Support of Objection to Government's Proposed Instruction on Willful Blindness at 1, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

[18] Docket at No. 237, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016); Defendant's Mem. of Law in Support of Objection to Government's Proposed Instruction on Willful Blindness at 1, United States v. Reichel, No. 1:15cr10324 (D. Mass. 2016).

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

[20] *Id.* at 6-7.

[21] Docket at No. 246, United States v. Reichel, No 1:15cr10324 (D. Mass. 2016).

[22] 18 U.S.C.S. § 371; 42 U.S.C.S. § 1320(a).

[23] *United States v. Park*, 421 U.S. 658 (1975).

[24] *Id.* at 676.

[25] *Id*. at 668; *see* 21 U.S.C. § 333(a)(1) ("Any person who violates a provision of [21 U.S.C. § 331 ("prohibited acts")] shall be imprisoned for not more than one year or fined . . . or both."); *compare* 21 U.S.C. § 333(a)(2) "if any person . . . commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined . . . or both."

[26] *Park*, 421 U.S. at 673.

[27] John R. Felder, "*The Park Criminal Liability Doctrine: Is it Dead or is it Awakening?*," Food and Drug Law Institute, September/October 2009, at 48 (http://www.hpm.com/pdf/FLEDERPARK.PDF).

[28] *Id.*

[29] Indictment at ¶ 2, United States v. Mackenzie, et al., No. 1:01cr10350 (D. Mass. 2004); Docket at No. 705-11, United States v. Mackenzie, et al., No. 1:01cr10350 (D. Mass. 2004).

[30] Bruce Jaspen, *8 Execs Acquitted of Bribing Doctors*, Chi. Tribune, July 15, 2004, http://articles.chicagotribune.com/2004-07-15/news/0407150283_1_prostate-cancer-drug-tap-sales; Shelley Murphy and Alice Dembner, *All acquitted in drug kickbacks case*, Bos. Globe, July 15, 2004, http://www.boston.com/news/local/articles/2004/07/15/all_acquitted_in_drug_kickbacks_case/?page=full.

[31] U.S. Dep't of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes; Company Agrees to Pay 875 Million to Settle Charges, Oct. 3, 2001, https://www.justice.gov/archive/opa/pr/2001/October/513civ.htm.

[32] Op. and Order, United States v. Purdue Inc., et al., No. 1:07cr00029 (W.D. Va. 2007).

[33] *Id.*at 6.

[34] *Id.* at 5-6.).

[35] Docket No. 76, United States v. Purdue Inc., et al., No. 1:07cr00029 (W.D. Va. 2007).

[36] *Friedman v. Sebelius*, 686 F.3d 813, 816 (D.C. Cir. 2012).

[37] *Id*. at 828. The Court thus reversed the grant of summary judgment and asked the District Court to remand to DHHS.[37] It does not appear that DHHS subsequently entered into new exclusions against the individual defendants, and none of them currently appear on DHHS' exclusion list. *See* http://oig.hhs.gov/exclusions/.

[38] Ryan Davis, *Synthes to Pay $24M for Illegal Bone Cement Tests*, Law 360, Oct. 4, 2010, http://www.law360.com/articles/198836/synthes-to-pay-24m-for-illegal-bone-cement-tests.

[39] *Id.*

[40] Docket, United States v. Norian Corporation et al., No. 2:09cr403 (E.D. Pa. 2016); Former Synthes President Michael Huggins, and former Synthes Senior Vice President Thomas B. Higgins, were each sentenced to nine months in prison, former Synthes Vice President of Operations was sentenced to eight months in prison, while John J. Walsh, the former Director of Regulatory and Clinical Affairs received a sentence of five months in prison.

[41] David Sell, Four former Synthes executives excluded from federal health-care programs, Philly.com, Oct. 9, 2012, http://www.philly.com/philly/blogs/phillypharma/Four-former-Synthes-executives-excluded-from-federal-health-care-programs.html. Based on a search of the executives' names at https://exclusions.oig.hhs.gov/Verify.aspx, the executives appear to remain excluded.

[42] U.S. Dep't of Justice , Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case, , Mar. 10, 2011, https://www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case.

[43] Press Release, U.S. Dep't of Justice, Marc S. Hermelin, Former CEO of KV Pharmaceutical, Pleads Guilty to Misbranding Drugs and Agrees to Pay United States $1.9 Million as Fines and Forfeiture (Mar. 10, 2011) (http://www.fda.gov/ICECI/CriminalInvestigations/ucm246881.htm).

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[49] *Id.*

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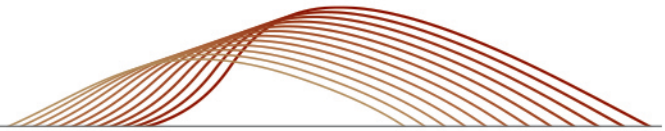
[51] Indictment at ¶ 12-19, United States v. Vascalur Solution, Inc., et al, No. 5:14cr926 (W.D. Tx. 2014). The Vari-Lase devices were approved by the FDA to be marketed for the treatment of superficial veins and the Great Saphenous Vein.



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[53] Docket at No. 286, United States v. Vascular Solutions, Inc., et al, No. 5:14cr926 (W.D. Tx. 2014). Notably, the District Court instructed the jury that "it is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device." Final Jury Instructions at 12, United States v. Vascular Solutions, Inc., et al, No. 5:14cr926 (W.D. Tx. 2014).

[54] U.S. Dep't of Justice, Former Acclarent, Inc., Executives Charged with Securities Fraud and Crimes Related to Sale and Distribution of Medical Devices, Apr. 10, 2015, https://www.justice.gov/usao-ma/pr/former-acclarent-inc-executives-charged-securities-fraud-and-crimes-related-sale-and-0.

[55] Indictment at 1-20, United States v. Facteau and Fabian, No. 1:15-cr-10076-ADB (D. Mass. 2015).

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[58] U.S. Dep't of Justice, Yates Memorandum at 3, http://www.justice.gov/dag/file/769036/download.

[59] Letter from Carmen M. Ortiz, U.S. Attorney for the District of Massachusetts, to Geoffrey E. Hobart, Attorney for Warner Chilcott Sales (U.S.) LLC, Covington & Burling LLP (Oct. 23, 2015), (https://www.justice.gov/usao-ma/file/789101/download).

[60] *Id.*

[61] *Park,* 421 U.S.at 673.

[62] *United States v. Gel Spice Co*., 601 F. Supp 1205, 1213 (E.D.N.Y. 1984) ("to establish the impossibility defense a corporate officer must introduce evidence that he exercised extraordinary care, but was nevertheless unable to prevent violations of the Act.").

[63] *United States v. Starr*, 535 F. 2d, 515-16 (9th Cir. 1976) (affirming conviction of food company executive finding that it was not impossible for the executive to control rodent infestation of company warehouses as such infestation was reasonably foreseeable to him); *United States v. Y. Hata & Co.*, 535 F.2d 508, 511-12 (1976) (finding that an executive exercising extraordinary care would have put in place a system to prevent bird access to food in a warehouse prior to the time defendant did so); and *United States v. Gel Spice Co.*, 773 F.2d 427, 429 (2d Cir. 1985) (affirming conviction of company president and rejecting impossibility defense due to the extent of filth at warehouse and failure to take possible steps to control rodent infestation).

[64] FDA Regulatory Procedures Manual, Section 6-5-3 (the other factors include: "Whether the violation involves actual or potential harm to the public;" "Whether the violation is obvious;" "Whether the violation is serious;" "The quality of the legal and factual support for the proposed prosecution;" and "Whether the proposed prosecution is a prudent use of agency resources.").