

Panel: Breaking Bad, All The Time - White-Collar Crime **Problems For Business Lawyers**

Moderator: Jack Sharman Lightfoot Franklin & White (Birmingham, AL)

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Your Case | Your Public | Your Media: Costs, A. Short Course on Search Warrants **Benefits and Ethics to Public Communications**

A. The business dispute that walks and talks like a white-collar case

B. The value of public discussion

C. The danger of public discussion (with a sidebar about social media)

- D. The ethics of public discussion
- E. The ramifications of public discussion
 - 1. The board of directors
 - 2. The shareholders
 - 3. Internal counsel
 - 4. Case studies
 - a. Whitey Bulger
 - b. Richard Reid (the "Shoebomber")

c. Louise Woodward (the "British Nanny" case)

Parallel Civil and Criminal Proceedings

A. The interplay between state and/or federal investigations and prosecutions

B. Civil/criminal/guasi criminal exposure to the client.

C. Singular, Dual/Overlapping, and/or Successive investigations and/or prosecutions.

D. Parallel proceedinngs in health care

Parallel proceedings arising from political-corruption E. cases

Search Warrants | Seizing the Privilege | Witness Interviews

B. Short Course on the Fifth Amendment and Businesspeople

C. How does a Texas murder case apply to financialservices investigations?

1. Facts: Two homicides. Police recover shotgun shell casings at the scene. Agents call on Mr. Salinas, who voluntarily agrees to go to the police station. Police question him for about for an hour. (No Miranda warnings: he was free to leave, which rendered the interrogation "noncustodial," so Miranda is not implicated.)

Salinas talks until he is asked whether the casings from the scene would match his shotqun. He says nothing, looks down, shuffles his feet, bites his lip and generally acts uncomfortable.

More silence. Officers then ask more questions, which Salinas answers.

At trial, the government highlights Salinas's silence, arguing that if he were innocent, he would have answered the question.

2. Issue [supposedly]: Can the government use at trial evidence that a defendant, in a noncustodial interview, claimed his or her Fifth Amendment rights?

3. Ruling: The Supreme Court never reached the issue. Rather, it held that Salinas never invoked his Fifth Amendment rights. People can be silent for lots of reasons. He never said "Fifth Amendment" or "silence" or "lawyer" or anything else that objectively indicates an invocation of the constitutional privilege.

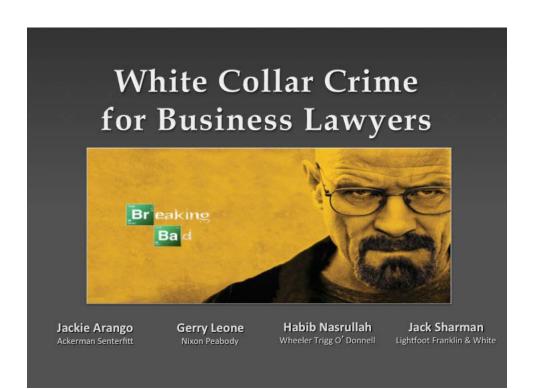
4 . What are the implications for companies and individuals?

Salinas applies to all non-custodial witness interviews by government agents.

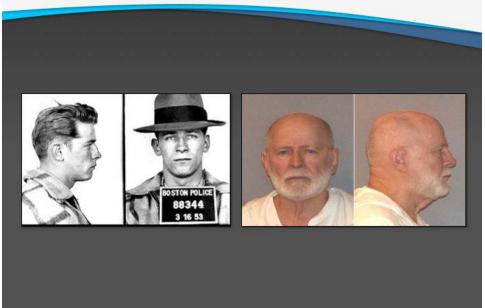
Interviews by agents are carefully-planned. If an officer or employee starts to talk, and then stops, the government at trial will probably be able to comment on the silence.

The FCPA: "I'm Not Foreign, Nor Am I Corrupt"

- A. The FCPA as a business concern
- B. The FCPA as a legal concern
- C. DOJ guidance
- D. DOJ enforcement record 2012-2013



Case | Public | Media



Search Warrants





"Search Warrants" Jack Sharman

Search Warrant

12. Based upon the factual information that I have set out in this affidavit, there is probable cause to believe that evidence of the commission of health care fraud offenses is located at the business of MedFusion Rx LLC, Specialized Pharmacy Services, 5511 highway 280, Suite 301-302, Greystone Park, Birmingham, AL 35242. Items of evidence inside the premises, including on computers and electronic storage media, are contraband, the fruits of crime, or things otherwise criminally possessed, or property which is or has been used as the means of committing the foregoing offenses. I therefore respectfully request that the court issue the attached warrant authorizing the search and seizure of the items listed in Attachment B.

The Search

LIST OF ITEMS TO BE SEIZED

 Any and all records relating to violations of the above-referenced statutes and involving the dispensing, ordering, billing, delivery, sale, claim submission, destruction/discarding, storing, payment, and/or prescription filling of any type of Factor VIII medication <u>including but not limited to</u> the following entities/companies: Lori Brill; Butch Brill; David Skowronski; Ashley Sprinkle; Rayford Goodwin; Bridget Sullivan; Helping Hearts of Hemophilia; Hemophilia Management Specialties, LLC; Alabama Clinical Therapeutics; Hemophilia Infusion Managers, LLC; Independent Management Specialties; Allied Preferred Care; ECM Home Health Services/Carl & Associates; and Brother Tim's Enterprise from January 1, 2004, to present.







Government's Opening Statement

"[T]he search warrant was done on Medfusion up in Birmingham by the FBI. And you're going to hear a lot about that. I'm not going to go into that in great depth. But listen, listen and wait. Because on one of the desks of one of the owners sitting right over there is a document open on his desk and that's going to relate to this case. It's going to show exactly what they know."

- AUSA Greg Bordenkircher (January 30, 2012)



Receipt

UNITED STATES DEPARTMENT OF JUSTICE FEDERAL BUREAU OF INVESTIGATION Receipt for frogery Received/Restered/Statesd
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On (date) 2200-15, 2009
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2 bes of Commission reports 2005-2006
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Supposed by a support of the result of th

"Wait, That's My File"



Getting Your Privileged Documents Back

5. Potentially privileged materials seized pursuant to search warrant.

In October 2009, Government agents executed a search warrant on the offices of MedfusionRx. Given what we understand to have been the scope of the materials seized, including hard drives, it is reasonable to expect that privileged materials lay within those items. We have already identified one privileged email dated May 12, 2008 from Kelli Robinson at Sirote giving advice about the HIPAA process.

Please identify what the agents did at the time of seizure and subsequently to segregate privileged materials; whether a taint attorney and taint agent have been assigned; and what the Government proposes to do about privileged materials. We demand return of all privileged items.

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It's Not Privileged, And We Didn't Read It If It Was

5. Potentially privileged materials seized pursuant to search warrant

The referenced May 12, 2008 e-mail from Kelli Robinson was one of the documents SA Kennedy discovered during his search of the Medfusion server. SA Kennedy, who is an attorney, determined that this e-mail was not privileged due to the fact that several third parties were included in the e-mail string. To the extent SA Kennedy found items while conducting his review of the Medfusion server that, based on a cursory review, appeared to be privileged, he did not thoroughly review or "book mark" them. SA Kennedy recalls only one occasion during his review of the Medfusion server in which he came across a potentially privileged e-mail. SA Kennedy provided this e-mail to another FBI agent/attorney who was not involved in this investigation. SA Kennedy did not review the e-mail further or provide it to any other agents or attorneys involved in this investigation.

Privilege Invasion = Suppression

DEFENDANT CHRIS VERNON'S OPPOSITION TO GOVERNMENT MOTION TO COMPEL PRETRIAL DISCLOSURE OF WHETHER DEFENDANTS INTEND TO ASSERT AN ADVICE OF COUNSEL DEPENSE AT TRIAL AND
DEFENDANT CHRIS VERNON'S MOTION FOR PARTIAL SUPPRESSION AND A TAINT HEARING AS TO THE GOVERNMENT'S INVASION OF PRIVILEGE
The Court should deny the Government's motion (Doc. 144) because, as the Government concedes, it has no basis in law, policy or the rules of procedure.
Further, the motion distracts the Court from the fact that the Government has invaded the privilege; failed to take steps to avoid doing so; and apparently tainted the investigation and/or prosecution teams. For that reason, Chris Vernon moves the Court (1) require the Government to cease review of all documents seized from Chris Vernon's company, Medfusion, and return potentially privileged materials; (2) establish a procedure for dealing with such documents, as set out in detail below; (3) suppress all privileged documents seized by the Government from Medfusion; (4) provide for limited waiver only, should Mr. Vernon offer the contents of a privileged cocument at trial; and (5) set a hearing to examine the Government's presumptive taint with regard to its invasion of the privilege.

Government Gives Up, Kind Of

5. Potentially privileged materials seized pursuant to search warrant

As you know, this issue is now the subject of the motion you filed on June 24, 2011, which Judge Cassady has carried over until the August 9, 2011 pre-trial conference. As the United States intends to argue in response to your motion, your client has waived any attorney-client privilege objection to the documents at issue. Further, the seizure of any arguable attorney-client privileged material during the Medfusion search was inadvertent, *de minimus*, and not in any way detrimental to your client.

Nevertheless, out of an abundance of caution, we have a established a privilege filter team. In fact, we had just finished putting this filter team together at the time you filed your motion. The filter team includes AUSA Steve Butler and FBI paralegal Melissa Watson, neither of whom are on the prosecution team. AUSA Butler will serve as the point of contact for the filter team, and he can be contacted at 251-415-7102 or subtler@usa.doj.gov.



Government Investigations & White Collar Defense Alert

A publication of Nixon Peabody LLP

FEBRUARY 15, 2013

Baksheesh, Refresco or Podmazyvat: A bribe by any other name can still get you prosecuted in the United States

By Lindsey Nelson and Grayson Yeargin

A recent district court ruling in a Foreign Corrupt Practice Act (FCPA) case could have far-reaching implications for foreign nationals. On February 8, 2013, Judge Richard Sullivan in the Southern District of New York denied a motion to dismiss in the matter of *Securities and Exchange Commission vs. Elek Straub*, 1:11-cv-09645, also known as the *Magyar* case. In so doing, the court offered a broad reading of the FCPA's jurisdiction over foreign companies and the foreign nationals who work for them, limiting common defenses—statute of limitations and jurisdiction—for foreign nationals. This decision is of particular import because of the dearth of case law on the FCPA due to the high rate of settlement of the matters and because many of the government's recent FCPA actions have targeted foreign companies and foreign nationals.

The *Magyar* case involves allegations that executives at the Hungarian telecommunications company Magyar Telekom, Plc., bribed public officials in Macedonia to limit the effects of a new law that would have opened up the Macedonia telecommunications market to another competitor. The case named three executives of Magyar as defendants. Magyar's securities were publicly traded through American Depository Receipts listed on the New York Stock Exchange and were registered with the SEC pursuant to Section 12(b) of the Exchange Act, which ostensibly brought the company under the reach of the FCPA. At issue in the motion to dismiss was (1) whether there was adequate personal jurisdiction over the defendants; (2) whether the statute of limitations had run; and (3) whether the complaint adequately stated a claim.

The court ultimately found that the SEC had established jurisdiction because the defendants' alleged conduct was "designed to violate" U.S. securities laws and thus was "directed toward the United States." The court found that Magyar's presence on the NYSE and the fact that any false statements would impact regular filings established minimum contacts because the defendants knew or had reason to know that their actions would affect "prospective American purchasers." "The Court . . . has little trouble inferring from the SEC's detailed allegations that, even if Defendants' alleged *primary* intent was not to cause a tangible injury in the United States, it was nonetheless their intent, which is sufficient to confer jurisdiction." (emphasis added).

The court also was not persuaded by the defendants' arguments that the claims against them were

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time-barred, despite the fact that more than five years had passed since the actions forming the basis for the claims. Applying the catch-all statute of limitations in 28 U.S.C. § 2462, the court considered whether the defendants' lack of physical presence in the United States kept the clock from running. The court found that the statute of limitations did not start running until the offender or the property was located within the United States. This interpretation, if it stands, could allow the SEC to bring claims against the defendants decades after allegedly corrupt conduct as long the defendants are not physically present in the United States.

Finally, while the defendants raised several arguments to support its motion to dismiss for failure to state a claim, the one that should be of most concern for foreign nationals is the court's decision regarding whether the defendants made use of U.S. interstate commerce. The FCPA requires that the government show that defendants "ma[de] use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of any offer, payment, promise to pay, or authorization of the payment of any money . . . or . . . anything of value" to "any foreign official." The government alleged that e-mails relevant to the alleged bribery were sent from foreign countries to other foreign countries, but were routed through and/or stored on network servers that were physically located in the United States. Defendants argued that the SEC failed to allege that defendants "personally knew" that the e-mails would be routed through and/or stored on network servers located in the United States. Though noting that the statute "is not a model of precision in legislative drafting," the court ultimately found that the corrupt intent requirement was not imported to the "use . . . of interstate commerce" language. Thus, defendants' lack of knowledge that their e-mails would be sent through the United States, even though both the sender and recipient of the e-mail were in foreign countries, was not fatal to the government's claims.

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BNA's Health Care Fraud Report[™]

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Enforcement Trends Related to Executive Liability in Health Care Investigations











BY ASHLEY BAYNHAM, DEVON HAFT LITTLE, SEAN HARAN, MICHELE MASUCCI, AND DAVID FELDMAN

Bloomberg

n fiscal year (FY) 2012,¹ the Department of Justice recovered more than \$3 billion from prosecutions of health care fraud under the False Claims Act and, with the assistance of various U.S. Attorneys, obtained 14 criminal convictions and \$1.5 billion in criminal fines

¹ The DOJ's fiscal year runs from October to September. These figures are based on the fiscal year ending September 30, 2012.

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and forfeitures under the Food, Drug and Cosmetic Act (FDCA).²

This represents the second straight year in which the DOJ has set a new record for such recoveries, with some of the biggest awards coming as a result of enforcement actions involving the pharmaceutical and medical device industries.³ These numbers indicate that the government's current focus on health care is likely to continue.

In addition, during this past year and a half, the government also demonstrated a renewed commitment to prosecuting health care executives and/or holding them personally accountable for their companies' continued compliance with the law.

2012 and early 2013 saw the government increasingly using corporate settlements to place heightened compliance responsibilities on executives and board members. On several occasions, the DOJ mandated that executives personally certify their companies' compliance with Corporate Integrity Agreements signed as part of the companies' settlement agreements with the government.

In two such instances, including the government's March 2013 settlement agreement with Par Pharmaceutical Companies Inc., the CIAs signed by these companies include an additional recoupment provision that requires the companies to recover bonuses paid to certain executives if these executives or their subordinates subsequently violate the agreements (17 HFRA 260, 3/20/13).

² Press Release, Department of Justice, Justice Department Recovers Nearly \$5 Billion in False Claims Act Cases in Fiscal Year 2012 (Dec. 4, 2012), available at http://www.justice.gov/ opa/pr/2012/December/12-ag-1439.html. ³ Id.

Although the government has only recently included recoupment provisions in its enforcement arsenal, industry groups have already taken notice. In April 2013, a working group of investors and pharmaceutical companies reportedly developed a set of corporate governance principles—*Principal Elements of a Leading Recoupment Policy*—aimed at "deter[ing] unethical and inappropriate behavior."⁴ This policy document identifies certain key principles of a successful recoupment policy, such as:

> (1) Full discretion of the board compensation committee to determine if a material violation of company policy related to the sale, manufacture or marketing of health care services, has caused significant financial harm to the company and should therefore trigger consideration of a possible recoupment of incentive compensation; (2) Application of the principles extending beyond the individuals responsible for the compliance failures to potentially include supervisors who failed to appropriately manage or monitor the risk; (3) Decisions by the board compensation committee including whether to "clawback" incentive-based compensation already paid or otherwise recoup or reduce compensation that has not yet vested or has not yet been paid; and (4) Public disclosure concerning decisions to recoup compensation in compliance with SEC rules and, where appropriate, board compensation committees may choose to provide additional information.⁵

The industry's proactive response to a relatively new enforcement tool reflects that these companies are developing compliance programs designed to stay ahead of or in line with the Government's enforcement actions.

This article provides a brief background on the law underlying some of those recent actions, as well as an overview of the notable trends seen in 2012 and early 2013, and advice on how corporate executives can best address this new enforcement focus.

Prosecution of Individuals in the Pharmaceutical Industry

The Park Doctrine

The U.S. Food and Drug Administration and Department of Health and Human Services, through letters and official guidance, have indicated a renewed interest in having the DOJ prosecute individuals for misdemeanor FDCA violations under the Park doctrine related to the health care industry's marketing practices.

Based on the Supreme Court's decisions in United States v. Dotterweich⁶ and United States v. Park,⁷ the

Park doctrine (also known as the responsible corporate officer doctrine) permits the misdemeanor prosecution of the "responsible corporate officers" of a corporation that has violated the FDCA.⁸

The doctrine is based on the theory that executives of businesses subject to the FDCA have "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."⁹

The FDA has interpreted the Park doctrine as permitting prosecution of strict liability offenses, stating:

The Park Doctrine, as established by Supreme Court case law, provides that a responsible corporate official can be held liable for a first time misdemeanor (and possible subsequent felony) under the [FDCA] without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense.

In other words, executives can be subject to misdemeanor convictions under this doctrine solely based on their position as responsible corporate officers and a finding that they did not exercise "the highest standard of foresight and vigilance."¹¹

Under the Park doctrine, it is enough to secure a conviction if: (a) a prohibited act under the FDCA took place somewhere within the company, and (b) the defendant's position in the company was one that gave him or her responsibility and authority either to prevent the violation or to correct it.

Successful prosecutions may not only lead to fines and/or jail time but also possible exclusion from participating in federal health care programs.

Renewed Interest in the Park Doctrine

Recent action by the DOJ, FDA and HHS indicates a renewed interest in the Park doctrine. For example, in April 2012, Gary Osborn, the founder of ApothéCure Inc., pleaded guilty to misdemeanor misbranding, admitting that as "the owner, registered agent, President, sole Director . . . and pharmacist-in-charge at Apothé-Cure," he "had the responsibility and authority to pre-

⁹ Park, 421 U.S. at 672.

¹⁰ FDA Regulatory Procedures Manual, Ch. 6, Sec. 5-3, "Special Procedures and Considerations for Park Doctrine Prosecutions" (2011) (hereinafter "FDA Regulatory Procedures Manual 6-5-3"). See also Richard A. Samp and Cory L. Andrews, Restraining Park Doctrine Prosecutions Against Corporate Officials Under the FDCA, 13 ENGAGE: THE JOURNAL OF THE FEDERALIST SOCIETY PRACTICE GROUPS 19 (Oct. 2012), available at http://www.fed-soc.org/doclib/20130201_ParkDoctrine.pdf.

¹¹ Park, 421 U.S. at 673.

⁴ Press Release, UAW Retiree Medical Benefits Trust, Pharmaceutical Companies, Investor Coalition Develop Industry Standard-Setting Principles for Recoupment Policies Covering Major Compliance Failures (Apr. 4, 2013) (hereinafter "UAW Press Release"), *available at* http://op.bna.com/hl.nsf/r? Open=wpiy-98jj7k.

⁵ Id.

⁶ 320 U.S. 277 (1943). In *Dotterweich*, the president of a drug company was convicted of a misdemeanor under the FDCA. The Supreme Court upheld the conviction even though the president had no prior knowledge of the unlawful conduct and was found guilty "solely on the basis of his authority and responsibility as president and general manager of the corporation." *Id.* at 280. Upholding the conviction, the Court stated that the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing." *Id.* at 281.

⁷ 421 U.S. 658 (1975). In *Park*, the president and chief executive officer of a national retail food chain was convicted of a violation of the FDCA following the discovery that food had been stored in a rodent-infested warehouse. The U.S. Supreme Court upheld Park's misdemeanor conviction even though he had delegated responsibility of the warehouse to others and was unaware of the infestation. The Supreme Court stated that the FDCA "imposes [on executives of FDA-regulated businesses] 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." *Id.* at 672.

⁸ The FDCA imposes misdemeanor liability for "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U.S.C. § 331(a).

vent the misbranding" of the products that ApothéCure handled. Osborn, however, did not admit to having any knowledge of the quality control issues that led to the charges against himself or ApothéCure.¹²

¹³ The U.S. District Court for the Northern District of Texas subsequently sentenced Osborn to one year of probation and ordered that he pay a \$100,000 fine and complete 200 hours of community service.

Given the government's statements about prosecuting individuals and the usefulness of the Park doctrine, the health care industry should expect such cases to continue.

On March 4, 2010, FDA Commissioner Margaret Hamburg wrote a letter to Sen. Charles Grassley (R-Iowa), then ranking member on the Senate Finance Committee, outlining recommendations made by an FDA committee on how to "enhance coordination and strategic alignment between [the FDA's Office of Criminal Investigations] and other [FDA] components."¹⁵

One such recommendation was to "increase the appropriate use of misdemeanor prosecutions, a valuable enforcement tool, to hold responsible officials accountable."¹⁶ In response to this recommendation, Hamburg noted: "[c]riteria have now been developed for consideration in selection of misdemeanor prosecution cases and will be incorporated into the revised policies and procedures that cover appropriate use of misdemeanor prosecutions."¹⁷

The following year, in February 2011, the FDA issued new guidelines concerning prosecutions under the Park doctrine. Those guidelines highlighted that: "[m]isdemeanor prosecution under the [FDCA] can be a valuable enforcement tool" and stated:

> When considering whether to recommend a misdemeanor prosecution against a corporate official, consider the individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation. *Knowledge of and actual participation in the violation are not a prerequisite to a misdemeanor prosecution* but are factors that may be relevant when deciding whether to recommend charging a misdemeanor violation.¹⁸

Interestingly however, the FDA purposefully declined to provide examples of actions that may lead to liability under the Park doctrine.¹⁹

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Exclusion

In addition to fines and jail time, executives convicted of a misdemeanor under the Park doctrine may be subject to exclusion from federal health care programs such as Medicare. As discussed below, recent guidance from the HHS Office of Inspector General makes clear that executives who knew or should have known of conduct leading to their entity's conviction or exclusion from federal health care programs, may themselves be subject to exclusion.

In April 2011, the OIG took this one-step further, announcing that it "will operate with a *presumption in favor of exclusion*" in cases where "there is evidence that an executive knew or should have known of the underlying criminal misconduct of the organization...."²¹

It is important to note, however, that the OIG's exclusion analysis differs based on whether the individual to be excluded is an owner or an officer/managing employee. The OIG can only exclude owners if it can prove that they *knew or should have known* of the underlying conduct.²² Officers and managing employees, however, may be excluded "based solely on their position within the entity."²³

Thus, while an organization's guilty plea alone²⁴ may be insufficient to support exclusion of the company's owner, it is sufficient to support exclusion of an officer and/or managing employee.

Moreover, in July 2012, the D.C. Circuit held that a misdemeanor conviction for, or guilty plea to misbranding under the FDCA, is a "health care-related crime" for the purposes of determining whether a corporation is a "sanctioned entity."²⁵

 22 42 U.S.C. 1230a-7(b)(15)(i) ("The Secretary may exclude ... [a]ny individual ... who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know ... of the action constituting the basis for the conviction or exclusion...."); OIG GUIDANCE, *supra* note 20, at §§ IV.B.3-4.

²³ OIG GUIDANCE, supra note 20, at §§ IV.B.3-4; accord 42 U.S.C. 1230a-7(b) (15) (ii). See also Friedman v. Sebelius, 686 F.3d 813, 823 (D.C. Cir. 2012) (upholding exclusion of "an individual under 42 U.S.C. § 1320a-7(b) on the basis of his conviction for a strict liability offense").

²⁴ If OIG seeks exclusion pursuant to its authority to exclude *individuals* who *pleaded guilty* to health care-related crimes, it *does not* need to prove the individual's guilt. The individual's conviction or guilty plea is sufficient.

²⁵ Friedman, 686 F.3d at 818-26. In 2007, Purdue Pharma settled claims that it had unlawfully misbranded the drug Oxy-Contin for \$600 million, and pled guilty to a felony misbranding charge. Three former senior executives also pleaded guilty to misdemeanor misbranding under the Park doctrine in connection with this matter. After their guilty pleas, HHS excluded all three executives for 12 years. On appeal, in July 2012, the U.S. Court of Appeals for the D.C. Circuit ruled that the executives' guilty pleas provided sufficient grounds for exclusion, but remanded the matter back to HHS to better explain the specific duration of the exclusion.

¹² Factual Resume at 2, 4, *United States v. Gary D. Osborn*, No. 3:12-cr-047-M (N.D. Tex. Apr. 18, 2012) (hereinafter "Osborn Factual Resume").

¹³ See *Id*.

 ¹⁴ Transcript of Sentencing at 38-41, Osborn, No. 3:12-cr-047-M (N.D. Tex. Oct. 3, 2012) (hereinafter "Osborn Sentencing Transcript").
 ¹⁵ Letter from Margaret Hamburg, M.D., Commissioner of Margaret Hamburg, Margaret Hamburg, M.D., Commissioner of Margaret Hamburg, Ma

¹⁵ Letter from Margaret Hamburg, M.D., Commissioner of Food and Drugs, to Senator Charles E. Grassley (Mar. 4, 2010), *available at* http://www.grassley.senate.gov/about/upload/ FDA-3-4-10-Hamburg-letter-to-Grassley-re-GAO-report-on-OCL pdf

OCI.pdf. ¹⁶ Id. at 2.

¹⁷ Id.

¹⁸ FDA Regulatory Procedures Manual 6-5-3, *supra* note 10 (emphasis added).

¹⁹ *Id.* ("As the Supreme Court has recognized, it would be futile to attempt to define or indicate by way of illustration either the categories of persons that may bear a responsible relationship to a violation or the types of conduct that may be viewed as causing or contributing to a violation of the Act.")

²⁰ OFFICE OF INSPECTOR GENERAL, GUIDANCE FOR IMPLEMENTING PER-MISSIVE EXCLUSION AUTHORITY UNDER SECTION 1128(B)(15) OF THE SO-CIAL SECURITY ACT §§ IV.B.3-4 (2010) (hereinafter "OIG GUID-ANCE"), available at http://oig.hhs.gov/fraud/ exclusions/files/ permissive_excl_under_1128b15_10192010.pdf.

 ²¹ Gerald T. Roy, Deputy Inspector General for Investigations, Office of Inspector General, U.S. Department of Health & Human Services, A Perspective on Fraud, Waste, and Abuse Within The Medicare and Medicaid Programs 11 (Apr. 5, 2011), available at http://oig.hhs.gov/testimony/docs/2011/Roy Testimony_04052011.pdf.
 ²² 42 U.S.C. 1230a-7(b) (15) (i) ("The Secretary may exclude the secretary may exclude

As such, executives of FDA-regulated companies who plead guilty to or are convicted of misdemeanor misbranding may be subject to exclusion by the OIG if they should have been aware of their companies' violation.

Enforcement Trends From 2012–2013

The following is a brief overview of two notable trends found in settlements in 2012 and early 2013 involving medical device and pharmaceutical companies:

 (1) Resolutions that require executives to certify their companies' compliance with relevant laws and/or institute recoupment programs; and

■ (2) Co-Prosecutions of companies and their executives. These settlements highlight the DOJ's increasing focus on executive accountability, through its use of both individual prosecutions and Corporate Integrity Agreements.

Resolutions that Require Executives to Certify Compliance and/or Institute Recoupment Programs

Corporate Integrity Agreements (CIA) are enforcement tools routinely used by the OIG to ensure that the settling company institutes compliance programs aimed at preventing future wrongdoing.

Many CIAs in the pharmaceutical and medical device space include common provisions meant to correct industry-wide practices.

For example, one provision commonly found in CIAs entered into by pharmaceutical and medical device companies requires these entities to change their sales representative compensation structure to prevent rewarding unlawful behavior.

Both the CIAs signed by Abbott Laboratories Inc. in 2012 and Par Pharmaceutical Companies Inc. in 2013 require that the companies make significant alterations to their compensation plans to avoid rewarding behavior such as improper off-label promotion.²⁶

In cases settled in 2012 and early 2013, the government has taken this idea one-step further, requiring that entities not only sign a CIA, but also mandating that their executives personally certify the companies' compliance with the CIA and, in some cases, that the company institute a program to recoup bonus compensation from executives in the event of misconduct by the executives or their subordinates.

In at least four settlements with major pharmaceutical and/or medical device companies in 2012 and 2013, the government included a provision in the companies' CIAs that requires top executives to annually review their companies' compliance programs and personally certify their companies' adherence to these programs.²⁷ Individuals from whom certification is required under these CIAs include the CEO, president, and members of the Board of Directors.²⁸ In several of the CIAs, failure to complete the personal certifications explicitly subjects the company to exclusion from federal health care programs such as Medicare and Medicaid.²⁹

Even more noteworthy, in two settlements that occurred, respectively, in late 2012 and early 2013, the CIAs include a recoupment provision under which companies must reclaim up to three years' worth of annual performance pay from certain executives in the event of misconduct by the executive or an employee for whom the executive is responsible.³⁰

Employees covered by these recoupment programs include, for example, "all senior [] executives at the level of Vice President or above," who currently work for the company or did at the time the misconduct oc-curred.³¹

The fact that this provision has now appeared in two different settlements indicates that the government may increasingly request similar provisions in the future.

Co-Prosecutions of Companies and their Executives

DOJ also prosecuted several cases against both companies and their executives in 2012. In the majority of these cases, such as that against WellCare Health Plans Inc., the charges against the individual executives stemmed from allegations that the executives had personally engaged in misconduct.³²

²⁹ Amgen Press Release, supra note 27; Abbott Press Release, supra note 27.
 ³⁰ See e.g., Par Press Release, supra note 27; Par CIA, su-

³⁰ See e.g., Par Press Release, supra note 27; Par CIA, supra note 27, at § III(H).

³¹ See e.g., Par CIA, supra note 27, at Appendix D.

²⁶ Many of the cases settled in 2012 arose under the False Claims Act or were a result of a company promoting a product "off-label." Under the provisions of the FDCA, a drug's application to the FDA must stipulate its intended uses. After the FDA approves the product as safe and effective for the specified uses, the company can only promote the product for those approved uses. The FDA considers promotion for any other use to be "off-label" promotion, which constitutes misbranding under the FDCA.

ing under the FDCA. ²⁷ Press Release, Department of Justice, Par Pharmaceuticals Pleads Guilty and Agrees to Pay \$45 Million to Resolve Civil and Criminal Allegations Related to Off-Label Marketing (Mar. 5, 2013) (hereinafter "Par Press Release"), available at

http://www.justice.gov /opa/pr/2013/March/13-civ-270.html; Corporate Integrity Agreement, Office of Inspector General, U.S. Department of Health and Human Services, and Par Pharmaceutical Companies, Inc. § III(A) (4) (Mar. 4, 2013) (hereinafter "Par CIA"), available at https://oig.hhs.gov/fraud/cia/ agreements/Par_Pharmaceutical_03042013.pdf; Press Release, Department of Justice, Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY; Pays \$762 Million to Resolve Criminal Liability and False Claims Act Allegations (Dec. 19, 2012) (hereinafter "Amgen Press Release"), available at http:// www.justice.gov/opa/pr/2012/December/12-civ-1523.html; Press Release, Department of Justice, Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-label Promotion of Depakote (May 7, 2012) (hereinafter "Abbott

Promotion of Depakote (May 7, 2012) (hereinafter "Abbott Press Release"), available at http://www.justice.gov/opa/pr/ 2012/May/12-civ-585.html.

²⁸ Par Press Release, *supra* note 27; Par CIA, *supra* note 27, at § III(A)(4); Amgen Press Release, *supra* note 27; Abbott Press Release, *supra* note 27.

³² Press Release, Department of Justice, Mississippi Pharmaceutical Firm and CEO to Pay \$2.8 Million to Resolve Allegations of Illegal Marketing of Unapproved Drugs (Mar. 28, 2012) (hereinafter "Cypress Press Release"), *available at* http://www.justice.gov/opa/pr/2012/ March/12-civ-389.html; Press Release, Department of Justice, Florida-Based WellCare Health Plans Agrees to Pay \$137.5 Million to Resolve False Claims Act Allegations (Apr. 3, 2012) (hereinafter "WellCare Press Release"), *available at* http://www.justice.gov/opa/pr/ 2012/April/12-civ-425.html; Press Release, Department of Justice, Pacific Health Corporation and Related Entities Agree to Pay \$16.5 Million for Allegedly Engaging in an Illegal Kickback Scheme in Los Angeles (Aug. 24, 2012) (hereinafter "Pacific Health Corp. Press Release"), *available at* http:// www.justice.gov/opa/pr/2012/August/12-civ-1046.html; Press

Examples of charges brought against executives in these types of cases include conspiracy, making false statements, health care fraud, and violations of the antikickback statute and False Claims Act.³³ Sanctions include fines, jail time and exclusion.³⁴

Release, Department of Justice, South Carolina-based Harmony Care Hospice Inc. and CEO/Owner Daniel J. Burton to Pay U.S. \$1.286 Million to Resolve False Claims Act Allegations (Nov. 20, 2012) (hereinafter "Harmony Press Release"), *available at* http://www.justice.gov/opa/pr/2012/November/12civ-1401.html; Press Release, Department of Justice, Orthofix Subsidiary, Blackstone Medical, Pays U.S. \$30 Million to Settle False Claims Act Allegations (Nov. 2, 2012) (hereinafter "Orthofix Press Release"), *available at* http://www.justice.gov/opa/ pr/2012/November/12-civ-1309.html. ³³ Cypress Press Release, *supra* note 32 (violations of the

³³ Cypress Press Release, *supra* note 32 (violations of the False Claims Act); WellCare Press Release, *supra* note 32 (conspiracy, making false statements and health care fraud); Pacific Health Corp. Press Release, *supra* note 32 (violations of the Anti-Kickback statute and the False Claims Act); Harmony Press Release, *supra* note 32 (violations of the False Claims Act); Orthofix Press Release, *supra* note 32 (violations of the Anti-Kickback statute).

³⁴ Cypress Press Release, *supra* note 32 (company and CEO settled for \$2.8 million); Pacific Health Corp. Press Release, *supra* note 32 (jail sentence of three years and one month, and two years, respectively); Harmony Press Release, *supra* note 32 (CEO individually liable for \$200,000 of \$1.3 million settlement with company); Orthofix Press Release, *supra* note 32 (vice president sentenced to eight months in prison and ordered to pay a \$20,000 fine and to forfeit \$30,000 in assets).

One notable case involving exclusion is that against Dr. Scott Harkonen, former CEO of InterMune Inc. In 2009, Harkonen was convicted him of felony wire fraud in connection with his approval of a press release promoting the drug Actimmune for an unapproved use, and sentenced to probation for three years, a \$20,000 fine, community service, and home detention for six months. Compliant at 11-12, Harkonen v. Sebelius et al., No. 4:13-cv-00071 (N.D. Cal. Jan. 7, 2013) (hereinafter "Harkonen Complaint") (the same jury acquitted Harkonen of introducing a misbranded drug into interstate commerce in violation of the FDCA). On March 4, 2013, the Court of Appeals for the Ninth Circuit affirmed Harkonen's conviction, concluding that there was "sufficient evidence" to support the jury's findings that "the Press Release was misleading, that Harkonen knew it was misleading, and that Harkonen had the specific intent to defraud." United States v. Harkonen, Nos. 11-10209, -10242, 2013 U.S. App. LEXIS 4472, *7 (9th Cir. Mar. 4, 2013)

Previously, on Aug. 31, 2011, the OIG alerted Harkonen that it considered the grounds upon which his felony wire fraud conviction was based to have occurred "in connection with the delivery of a health care item or service," and as such, was imposing a five-year exclusion from federal health care programs under Section 1320a-7(a)(3). Harkonen Compliant, *supra*, at 15. Both an administrative law judge and HHS's Departmental Appeals Board subsequently upheld Harkonen's exclusion. *Id.* at 2-3.

On Jan. 7, 2013, Harkonen sued HHS in California federal court, alleging that the agency had misinterpreted the Social Security Act and had ignored the fact that HHS must base participation bans on offenses connected to the "delivery" of health care. *Id.* Harkonen claims that, as the government had failed to prove that the press release caused, or was intended to cause harm or financial loss to patients or payors, there is no such connection. *Id.* at 4. Harkonen also alleged that the "career-debilitating" ban had subjected him to a second and excessive punishment for his conduct, in violation of the Fifth and Eighth Amendments. *Id.* As of June 4, 2013, Harkonen has

However, in some cases, such as ApothéCure Inc. (discussed below), where the government appears to have charged the company's CEO under the Park doctrine, courts have handed down severe sanctions even though the executives never admit engaging in or having any knowledge of wrongdoing.

In addition, while most DOJ prosecutions end in settlements favoring the government, one notable case in 2012, Stryker Biotech LLC, ended in a victory for both the company and its management.

ApothéCure Inc.

On April 24, 2012, ApothéCure Inc. and its CEO, Gary Osborn, pleaded guilty to misdemeanor misbranding under the FDCA "in connection with ApothéCure's interstate shipment of two lots of misbranded colchicine injectable solution that led to the deaths of three people."³⁵

As part of his plea, Osborn admitted that as "the owner, registered agent, President, sole Director ... and pharmacist-in-charge at ApothéCure," he "had the responsibility and authority to prevent the misbrand-ing" of the products at issue.³⁶ Osborn, however, did not admit to having any knowledge of the quality control issues that led to the charges against himself and ApothéCure.³⁷

On Oct. 3, 2012, the U.S. District Court for the Northern District of Texas sentenced Osborn to one year of probation, with the first 90 days to be served under house arrest, and ordered that he pay a \$100,000 fine and completed 200 hours of community service.³⁸ The court sentenced ApothéCure to five years of probation and ordered that it pay a \$100,000 fine.³⁹

The court's essentially mirror sentencing of Osborn and ApothéCure is indicative of increasing emphasis on individual liability for health care violations. Although Osborn did not admit having any prior knowledge of the underlying events, as a corporate officer, the court found him responsible for their consequences.

Stryker Biotech LLC

The trial of Stryker Biotech LLC (Stryker) and its executives was one notable bright spot for pharmaceutical and medical device companies and executives in 2012.

³⁵ Press Release, Department of Justice, Dallas Compounding Pharmacy Owner Pleads Guilty in Connection with Misbranded Drug Shipment (Apr. 24, 2012), *available at* http:// www.justice.gov/opa/pr/2012/April/12-civ-526.html. The FDA subsequently tested samples from the lethal shipment and discovered "that some of the vials were super-potent, containing 640 percent of the level of colchicine declared on the label. Other vials were determined to be sub-potent, and contained less than 62 percent of the declared levels on the labels." *Id*.

filed a Motion for Summary Judgment in this matter, but no legal rulings had been made.

InterMune had previously resolved its civil and criminal liability relating to this matter in 2006 by entering into a deferred prosecution agreement, signing a five-year CIA with OIG-HHS, and paying a \$37 million penalty. Press Release, Department of Justice, Former InterMune CEO Sentenced for False & Misleading Statements Related to Pulmonary Fibrosis Drug's Clinical Tests (Apr. 14, 2011), available at http:// www.justice.gov/opa/pr/2011/April/11-civ-475.html.

³⁶ Osborn Factual Resume, *supra* note 12, at 2, 4.

³⁷ See Id.

 $^{^{38}}$ Osborn Sentencing Transcript, supra note 14, at 38-41. 39 Id. at 29.

On Jan. 17, 2012, Stryker pleaded guilty to one count of misbranding a medical device in violation of the FDCA and agreed to pay a \$15 million fine (16 HFRA 62, 1/25/12).⁴⁰ The government had originally charged Stryker and four of its executives with "wire fraud, conspiracy to defraud the federal government, conspiracy to distribute misbranded medical devices and making false statements."41 Stryker also faced possible mandatory exclusion from federal health care programs.

The prosecution of Stryker and its executives has been described as "the first bona fide off-label case against a pharmaceutical or medical device company to go to trial since the government's enforcement initiative in those two sectors started in earnest roughly a decade ago."43

The government had accused Stryker of deliberate misleading doctors and endangering patients by promoting the unapproved mixture of two Stryker products.⁴⁴ At trial however, Stryker's attorneys revealed that while the government had not interviewed any of the doctors whom it claimed the Stryker's sales representatives misled, defense counsel had, and these doctors were prepared to testify that they were not misled by Stryker or its sales representatives.45 Further, the government's first witness corroborated Stryker's claim that doctors mixed the two Stryker products at issue as a standard practice, and not as a result of Stryker's marketing efforts.46

The government subsequently dismissed all of the charges against the executives and settled its case against Stryker.47

The Stryker trial stands out because of the outcome and the fact that four Stryker sales representatives had previously pled guilty to charges of felony misbranding.⁴⁸ While this fact would seemingly bolster the government's case against Stryker and its executives, the impact of this fact was mitigated by Stryker's actions

⁴² Thomas Sullivan, Stryker Biotech: Case Dismissed Charges Dropped, Policy and Medicine (Mar. 15, 2012), http:// www.policymed.com/2012/03/stryker-biotech-case-dismissedcharges-dropped.html.

^{43`}Id.

⁴⁴ Id.

⁴⁵ Id.

⁴⁶ Id. In an earlier case connected to these products, four Stryker sales representatives had pled guilty to charges of felony misbranding. Id. While this fact would seemingly bolster the government's case against Stryker and its executives, the impact of this fact was mitigated by Stryker's actions at the time. Upon discovery, Stryker not only fired the four sales representatives, but also made several reports to the FDA about the matter at the time. Id.

⁴⁷ Id.

⁴⁸ Id.

upon discovery, including terminating the sales representatives and making several contemporaneous reports to the FDA about the matter.49

What should Corporate Executives Do in Light of These Enforcement Trends?

This past year, the government demonstrated a commitment to prosecute health care executives and/or hold them personally accountable for their companies' continued compliance with the law. This trend, in conjunction with the government's renewed interest in the Park doctrine, will continue to place additional scrutiny on the conduct of health care executives.

In particular, should the government investigate or question a pharmaceutical or medical device manufacturer's conduct, an executive should expect that his or her individual efforts to implement, enforce, and/or supervise the company's compliance efforts will face a much closer investigation than previously may have occurred.

In other words, the (in)ability to demonstrate and document a commitment to compliance may be determinative in persuading the government whether or not to pursue a case.

Instituting and enforcing an effective compliance program can help identify potential problems before they lead to an investigation. Key in accomplishing this task is instituting not only a strong compliance program but also complementing it with the necessary training on how to market and/or price products in a way that complies with the relevant legal requirements.

One particularly helpful resource for executives creating or reviewing their company's compliance program is the section of the federal sentencing guidelines that relates to effective compliance and ethics programs.50

The U.S. Sentencing Guidelines dictate that an effective compliance program requires not only written standards and procedures intended to "prevent and detect criminal conduct" but also "due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law."51

The Principal Elements of a Leading Recoupment Policy,⁵² mentioned above, is likely another helpful resource. These principles also indicate that pharmaceutical and medical device companies have quickly taken notice of the government's latest enforcement tool.

In sum, although the industry must wait and see whether enforcement tools that increasingly target executives become the norm in DOJ prosecutions of medical device and pharmaceutical companies, both companies and their executives can best protect themselves now by ensuring that the company has a strong compliance program in place, as well as a firmwide commitment to ethics.

⁴⁰ Tom Moylan, Stryker Biotech Pleads Guilty, Will Pay \$15 Million For Promoting Bone Repair Products, LEXISNEXIS LITIGA-BLOG (Jan. 18, 2012), http://www.lexisnexis.com/ TION community/litigationresourcecenter

[/]blogs/litigationblog/archive/2012/01/18/stryker-biotech-pleads -guilty-will-pay-15-million-for-promoting-bone-repairproducts.aspx.

⁴¹ Id.

⁴⁹ Id.

⁵⁰ See U.S. Sentencing Guidelines Manual § 8B2.1.

 $^{^{51}\,}See$ id.

⁵² UAW Press Release, supra note 4.



Government Investigations & White Collar Defense Alert

A publication of Nixon Peabody LLP

JULY 22, 2013

Diving into E-Data, Second Circuit provides guidance regarding searches of computers

By: D. Grayson Yeargin and Emily C. Harlan

A recent Second Circuit ruling concerning search warrants for computer hard drives and other digital devices could have significant implications for companies and individuals facing government investigations involving electronically stored data. Recognizing the potential for overbroad searches in the digital realm, the court called for heightened particularity in warrants seeking digital data, which can contain vast amounts of private information susceptible to over-intrusive and even unconstitutional searches.

In <u>United States v. Galpin</u>, No. 11-4808-cr (June 25, 2013), the Second Circuit vacated a district court's ruling refusing to suppress evidence that led to new charges against the defendant and his subsequent conviction. The defendant had challenged the admissibility of evidence gathered pursuant to a search warrant for his computer hard drive and other electronic devices that specified only a sex offender registration offense. The warrant did not authorize searches for evidence supporting child pornography or sexual abuse offenses. Despite this, the government seized evidence relating to those offenses and ultimately charged and convicted the defendant of those offenses.

The Second Circuit affirmed the district court's determination that portions of the warrant were unconstitutional because they were not supported by probable cause. It vacated the denial of the suppression motion, however, because the district court had not gathered facts sufficient to show that the unconstitutional provisions could be severed from the rest of the warrant or that the evidence in question was in plain view when it was seized. The court remanded the case for consideration of these issues.

Most importantly for future matters, in assessing the scope of the warrant, the court focused on the particularity requirement in the Fourth Amendment, which states that warrants must "particularly describ[e] the place to be searched, and the persons or things to be seized." The court outlined the three elements of the particularity requirement, all of which must be present for a warrant to be deemed constitutional: (1) identification of the specific offense(s) for which probable cause has been established, (2) a description of the place(s) to be searched, and (3) a description of the evidence sought by its relation to the specified crimes.

The court noted that when the property to be searched is a computer hard drive, the particularity requirement is of heightened importance. Comparing a hard drive to a residence in terms of the amount and scope of private information it can reveal, the court noted that "[t]he potential for privacy violations occasioned by an unbridled exploratory search of a hard drive is enormous."

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Further, where officers searching a residence are necessarily constrained in their search by the dimensions of the evidence sought (meaning, an officer can only search in locations and containers that are physically capable of housing the evidence), there are no such limitations on the search of a digital drive. Because the outer characteristics of a digital file, such as the file's name and size, can be entirely unrelated to its contents, the only way to uncover the contents may be to open the file. The court cautioned that this could lead to over-assertion of admissibility by the government under the "plain view" doctrine, which creates even further need to carefully apply the particularity requirement in scrutinizing warrant applications from the outset.

Under the court's reasoning in *Galpin*, warrants for electronically stored data that do not contain sufficient particularity—notably, a greater particularity than warrants for other, more necessarily limited containers—will not pass constitutional muster. Companies and individuals that face searches and seizures of their electronic data would be well-served to examine closely the warrants presented to them, mindful of the *Galpin* court's statements about the heightened importance of the Fourth Amendment's particularity requirement in the context of digital searches.

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Government Investigations & White Collar Defense Alert

A publication of Nixon Peabody LLP

IXON PEABODY

AUGUST 21, 2013

Second Circuit ruling narrows double jeopardy protections in honest services prosecutions

By D. Grayson Yeargin and Anthony Chavez

On August 6, 2013, the Second Circuit Court of Appeals gave the government a second chance to prosecute a New York state politician for honest services fraud. In doing so, the court delivered two weapons to the government to use in fighting double jeopardy arguments. The first is that the government's decision not to prosecute a defendant under a particular theory does not mean that the government cannot later use this theory on re-trial, even if the theory is under the same statute used in the original trial. The second is that convictions that are subsequently overturned can be considered as evidence that a defendant possessed criminal intent. While the surprisingly brief Second Circuit decision is a "summary order" that does not have precedential effect on its own, there is no doubt that its reasoning will be used by future litigants.

In United States v. Bruno,¹ the court considered an appeal brought by Joseph L. Bruno, a former Republican New York State Senator. In 2009, Mr. Bruno was indicted on eight charges of honest services fraud for failing to disclose conflicts of interest involving \$3 million worth of payments he received from companies seeking contracts and grants from the state and contracts to manage pension fund investments. Later that year, a jury convicted Mr. Bruno of two counts of honest services fraud for failing to disclose payments from Jared Abbruzzese, a friend with whom he had business ties. Mr. Bruno was found not guilty of five other counts and the jury was unable to reach a verdict on one count. The government's convictions were based on evidence introduced at trial that Mr. Bruno failed to disclose \$200,000 paid to him by consulting firms run by Mr. Abbruzzese and failing to disclose \$80,000 in payments from Mr. Abbruzzese for forged debt and a "virtually worthless" horse.

Mere weeks after Mr. Bruno's sentencing in May 2010, the Supreme Court issued its landmark holding in *Skilling v. United States*² in which the Court limited the honest services fraud statute to bribery and kickback schemes. As part of this ruling, the Court held that failure to disclose conflicts,

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¹ Second Circuit No. 13-152

² 130 S. Ct. 2896 (2010)

the theory used to convict Mr. Bruno, could not support a conviction. The Second Circuit subsequently overturned Mr. Bruno's conviction.³

On May 3, 2012, the government filed new honest services fraud charges against Mr. Bruno. This time, the indictment alleged honest services fraud based on a *quid pro quo* theory. The government alleged that Mr. Bruno solicited \$440,000 in payments from Mr. Abbruzzese, and that Mr. Abbruzzese routed them through several companies to disguise them as consulting payments and a payment toward the "virtually worthless" horse. The government alleged that in return for the payments, Mr. Abbruzzese received a number of benefits, including a recommendation that his business partner be appointed to the board of the New York Racing Association and the award of government grants to companies connected to Mr. Abbruzzese.

Mr. Bruno moved to dismiss the new indictment, arguing that the government was barred under the Double Jeopardy Clause of the Constitution. Mr. Bruno argued that the government's new charges were barred by the fact that the government abandoned them. Mr. Bruno rooted his argument in the fact that after spending four years pursuing criminal charges against him, the government failed to bring the charges they were now making. Instead, the government charged him with eight counts of honest services fraud based on an alleged failure to disclose conflicts of interest. Mr. Bruno argued that the government was trying to get a second bite at the apple by prosecuting him under a new criminal theory for the same conduct on which he was already tried. The district court denied Mr. Bruno's motion to dismiss the indictment and he filed an interlocutory appeal to the Second Circuit.

The Second Circuit affirmed the district court. First, the court rejected Mr. Bruno's argument that the government abandoned the *quid pro quo* theory when the district court did not instruct the jury on that theory in 2009. The court reasoned that the government did not originally indict Mr. Bruno on a *quid pro quo* theory and, therefore, did not abandon that theory. The court held that the new charges were not barred by collateral estoppel because Mr. Bruno was not acquitted of all the original charges by the jury. The court reasoned that even though the *Skilling* ruling required that his convictions on two counts of honest services fraud based on undisclosed conflicts be vacated, the jury still found that Mr. Bruno possessed the requisite intent to commit fraud. Therefore, collateral estoppel did not stop the government from pursuing new honest services fraud charges based on a *quid pro quo* theory.

The Second Circuit's short summary order could have far-reaching effects on how courts interpret the Double Jeopardy Clause. It may be that the impact of this decision is limited to the peculiar circumstances of an honest services conviction obtained just before the *Skilling* ruling. If other courts broadly adopt the reasoning of the Second Circuit in double jeopardy challenges, however, then the protections of that clause will be significantly weakened.

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³ United States v. Bruno, 661 F.3d 733 (2d Cir. 2011)

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"Draw your chair up close to the edge of the precipice and I'll tell you a story." — F. Scott Fitzgerald.

The place where your business or your life meets the legal system is a cliff. To not fall off the cliff requires two things.Trust. And, someone to tell your story.

Trust between lawyer and client. And a narrative that persuades, whatever the audience—judge or jury, prosecutor or regulator, adversary or ally.

I base my practice first on trust, then on persuasion. Trust gets you to a comfort level; persuasion allows us to solve problems by shaping someone else's thinking. From white-collar criminal prosecutions to toxic torts, from D&O lawsuits to professional liability claims, from electronic-discovery advice to alternative-fee arrangements— all of which I do—none of it matters unless there is trust and a narrative.

In the current economic and political climate, directors, officers and professionals—accountants, investment bankers, business consultants and lawyers—are ripe targets for blame. I've handled most types of directors' and officers' and professional liability litigation—fiduciary duty lawsuits, malpractice claims and contract disputes, claims for securities fraud and tortious interference with contractual and business relations, and recovery actions brought by trustees of bankrupt publicly-traded companies.

On the white-collar side, I have pretrial, trial and appellate experience across the federal and state landscape: corporate internal investigations, kickback cases, grand jury investigations, gaming issues, defense of criminal environmental offenses, public-corruption enforcement, due diligence issues under the Foreign Corrupt Practices Act, Congressional investigations, election contests, defense of health-care entities in civil and criminal matters, including Medicare fraud and qui tam lawsuits under the False Claims Act, and investigations by military officials.

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