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Strengthen compliance to avoid management's liability for opioid diversion

» The government may turn to the Responsible Corporate Officer (RCO) doctrine to prosecute health system executives for failure to detect opioid diversion.

» Under the RCO, management can be held criminally liable for their subordinates' violations of the federal Food, Drug, and Cosmetic Act (FDCA).

» Making disclosures about individuals responsible for diversion as required to earn "cooperation credit" with the DOJ creates a dilemma for management in light of the RCO doctrine.

» In February 2017, the DOJ released compliance program guidance that provides resolution to the dilemma.

» Bolstering compliance to detect and prevent diversion should preclude charges on a RCO prosecution theory.

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Virtually no one disputes that we are in the middle of an opioid and fentanyl epidemic in the United States. Regardless of where one falls on the political spectrum, there is a recognition that prescription drug abuse is a crisis and is one of the biggest dangers to all of our communities. It leads to addiction, accidental death, and violence in our streets; and the cause of that devastation is in our medicine cabinets—and in controlled substance storage facilities at healthcare institutions.

The United States Department of Justice (DOJ) has recently announced a full-throated response to the crisis, reflecting a clear resolve to use every tool in the government's toolbox to combat prescription drug abuse. Although much of the government's efforts will target the illegal importation of fentanyl compounds manufactured in clandestine laboratories overseas, the government has stated its clear intention to prevent the illegal diversion of highly addictive drugs from healthcare institutions. Diversion is the removal of prescription drugs from intended recipients to others, typically for illicit purposes.[1]

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There is reason to believe that the government may turn to holding officers, managing employees, and even general counsel of health systems accountable for illegal diversion of opioids under the Responsible Corporate Officer (RCO) doctrine.[2] This may create a dilemma for a healthcare institution's executive staff who, in seeking to avoid prosecution of the business entity through "cooperation credit" by disclosing individual wrongdoing, may simultaneously risk criminal sanction under the RCO, because the conduct occurred under their supervision.[3] *The United States Attorney's Manual* (*USAM*) states, "cooperation is a mitigating factor,

by which a corporation… can gain credit in a case that otherwise is appropriate for… prosecution."[4]

The solution to this dilemma lies in strengthening a healthcare system's compliance program. In February 2017, the DOJ's Fraud Section issued guidance on how it evaluates compliance programs.[5] It would be prudent for healthcare systems to re-evaluate their programs in light of the government's commitment to fighting the opioid crisis with every weapon (and prosecution theory) available.

The government's announced response to the opioid crisis

Since 2016, the government has ramped up its effort to combat the growing opioid epidemic. On September 21, 2016, United States Attorney General Loretta E. Lynch directed all United States Attorneys to draft a district-specific strategy aimed at addressing the opioid crisis.[6] On June 6, 2017, Deputy Attorney General Rod J. Rosenstein addressed law enforcement safety when encountering fentanyl, particularly if it becomes aerosolized and is accidently inhaled.[7] On October 17, 2017, Rosenstein announced enforcement action to interdict deadly fentanyl and other opioids from entering the country;[8] on November 1, 2017, Attorney General Jeff Sessions announced fentanyl safety recommendations for first responders;[9] and on November 9, 2017, the DOJ announced the scheduling of all fentanyl and fentanyl-related analogues as controlled substances.[10] Most recently, on November 29, 2017, Sessions directed each U.S. Attorney to designate an "opioid coordinator" by December 15, 2017 who will: (1) facilitate the intake of opioid and fentanyl cases; (2) convene law enforcement task forces to identify opioid cases for federal prosecution; and (3) provide legal advice and training on opioid prosecutions.[11]

Health systems diversion prosecutions

Historically, the government has prosecuted a number of cases involving diversion of opioids from healthcare systems by a myriad of healthcare professionals. In 2014, Dignity Health agreed to pay $1.55 million to resolve allegations that its compliance procedures and controls failed to prevent diversion of over 20,000 oxycodone tablets.[12] In 2015, Massachusetts General Hospital agreed to pay $2.3 million to resolve allegations that lax controls enabled its employees to divert approximately 16,000 oxycodone pills from automated dispensing machines.[13] In 2016, Appalachian Regional Healthcare, Inc. agreed to resolve allegations that its pharmacy filled improper prescriptions written by an ER physician.[14]

Provider diversions prosecutions

Consistent with the Yates Memo, the DOJ has substantially increased its prosecutions of medical personnel for opioid offenses. On November 8, 2017, the government charged a registered nurse at Abbott Northwestern Hospital, alleging that he accessed secured automated medication dispensing systems, used syringes to remove hydromorphone from vials, and subsequently injected those vials with saline solution to replace the missing hydromorphone.[15] If convicted, he faces four years' imprisonment and a $250,000 fine.[16]

On July 25, 2016, the United States charged a hospice nurse for diverting approximately 42,140 milligrams of oxycodone from Alliance Home Health Care.[17] The hospice nurse pleaded guilty and admitted that her scheme involved: (1) recommending oxycodone for patients who did not need it; (2) arranging for a courier service to hold oxycodone packages so she could pick them up; and (3) recommended hiring another registered nurse who helped the defendant divert and distribute

pills. She faces 24 years' imprisonment and a $1.25 million fine.[18]

Other schemes to divert or steal controlled substances in the hospital setting include: (1) diversion through a "Pyxsis" machine; (2) forging prescriptions; (3) stealing prescription medication from a patient's bedside; and (4) removing medications from the operating room.

The RCO: A potential weapon in the DOJ's arsenal

The RCO is a strict-liability theory of criminal prosecution for violations of the Food, Drug and Cosmetic Act (FDCA) under which the government can prosecute individuals in positions of authority at a company for their subordinates' violations of the FDCA, regardless of their knowledge of or participation in the underlying criminal activity. The seminal cases that established the doctrine are *United States v. Dotterweich*[19] and *United States v. Park*.[20]

In *Dotterweich*, the government charged the Buffalo Pharmacal Company and its president and general manager with introducing misbranded/adulterated drugs into interstate commerce, even though he had no knowledge of the shipments. The jury acquitted the company but found Dotterweich guilty. Upholding Dotterweich's conviction, the United States Supreme Court observed that the FDCA "dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[21]

In *Park*, the government charged Acme Markets, Inc. and its president and CEO with shipping adulterated food in interstate commerce.[22] The company pleaded guilty, and the jury convicted Park at trial. In upholding Park's conviction, the Supreme Court wrote that "the [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur" and that Park had the "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."[23]

Although the Supreme Court decided *Dotterweich* and *Park* in 1943 and 1975, respectively, the RCO resurfaced within the last 10 years. In 2007, the government charged Purdue Frederick Company, Inc. and its president and CEO, chief legal officer, and former chief medical officer for misbranding OxyContin®, even though the executives were not involved in and had no personal knowledge of the drug misbranding.[24] The executives pleaded guilty and were sentenced to three years' probation, 400 hours of community service, and ordered to disgorge more than $34 million. The executives were also debarred from federal healthcare programs for 12 years.[25]

In 2009, the United States charged Synthes, Inc. and its COO, former president of the Spine Division, former director of Regulatory and Clinical Affairs, and former vice president of operations with shipping adulterated and misbranded bone cement in interstate commerce.[26] The executives pleaded guilty and were sentenced to five to nine months' imprisonment and fined $100,000.

In 2011, the former chairman and CEO of KV Pharmaceutical pleaded guilty to misbranding morphine pills, even though he was unaware of the misconduct and did not intend to violate the FDCA.[27] The judge sentenced him to 30 days' imprisonment and a $1 million fine.

In 2015, the government charged the former CEO and former vice president of sales of Acclarent, Inc., and in July 2016, a jury convicted them of misbranding and

adulteration counts.[28] Sentencing of the defendants is pending.

On May 22, 2017, the Supreme Court denied *certiorari* (i.e., the high court refused to review a decision by a lower court) in *United States v. DeCoster,* which involved the owner and COO of Quality Egg, LLC pleading guilty as "responsible corporate officers" to introducing eggs adulterated with salmonella into interstate commerce.[29] The executives argued at sentencing that imprisonment would be unconstitutional because they had no knowledge of the egg contamination at the time of shipment. They lost. The judge sentenced them to three months' imprisonment and $100,000 fines. On appeal, the executives contended that they were "mere unaware corporate executive[s]." Citing *Park*, the Court of Appeals observed that

> [u]nder the FDCA responsible corporate officer concept, individuals who 'by reason of [their] position in the corporation [have the] responsibility and authority' to take necessary measures to prevent or remedy violations of the FDCA and fail to do so, may be held criminally liable as 'responsible corporate agents,' regardless of whether they were aware of or intended to cause the violation.[30]

The defendants sought review by the Supreme Court. The government successfully opposed the defendants' *certiorari* petition, contending that:

> [1] the duty… on responsible corporate agents is… one that requires the highest standard of foresight and vigilance, [2] the FDCA permits convictions of responsible corporate officials who… have the power to prevent or correct violations of its provisions, and [3] [o]n multiple occasions, Congress has considered whether to amend the FDCA to narrow the scope of liability for responsible corporate agents… but each time opted against any change.[31]

Notably, the government's litigating position regarding the RCO would have been approved at the highest levels in the DOJ.

The government clearly views the RCO as an attractive prosecution theory and could use it to charge health system executives in diversion cases. This may be because the only real defense to the RCO is objective impossibility (e.g., if one was "powerless to prevent or correct the violation"). Indeed, incarcerating management for failing to detect diversion would serve the goal of general deterrence and incentivize health systems to prevent diversion, cutting off at least one source of supply for the illegal drug trade. The FDA's *Regulatory Procedures Manual* states, "prosecutions… against responsible corporate officials, can have a strong deterrent effect on the defendants and other regulated entities."[32]

Prosecutors, however, do not have unfettered discretion to charge individuals under a RCO theory and must first notify and consult with the DOJ's Consumer Protection Branch.[33]

The dilemma for healthcare management

If the government turns to the RCO to fight the opioid crisis, health systems management faces a significant Catch-22. On the one hand, management *must* provide the DOJ all relevant facts relating to the individuals responsible for diversion to qualify for any "cooperation credit" under the Yates Memo, and on the other hand, management could unwittingly point the finger at themselves, given the tenants of the RCO.

Topics prosecutors consider

How, then, can health systems managers resolve this tension? The government has suggested the answer in the DOJ Fraud Section's

February 2017 guidance. That document explains how the DOJ evaluates the effectiveness of compliance programs and remedial efforts to implement or improve one. Although it is not a rigid checklist or formula, it summarizes the topics prosecutors typically consider when evaluating such programs and identifies the questions prosecutors ask for those evaluations. A health system would be wise to evaluate its compliance program against the topics and questions in the guidance.

Analysis and remediation of underlying misconduct
Has the company undertaken a root-cause analysis of the underlying misconduct? What has that analysis shown? If there were prior opportunities to ferret out the misconduct, why were those opportunities missed? Have changes been implemented to reduce risk of reoccurrence?

Senior and middle management
Is there truly a culture of compliance throughout the organization? Do senior leaders and management model proper behavior?

Autonomy and resources
Does the compliance function act independently within the organization? Does it receive adequate resources in funding and personnel?

Policies and procedures
Who designed and implemented the policies and procedures? How does the company communicate them? How accessible are they? Have they been operationally integrated?

Risk assessment
What methodology has the company used to identify and analyze risk? Did the information and metrics detect or miss the underlying wrongful conduct? If the latter, what steps has the company taken to mitigate risk?

Training and communications
Have high-risk and control employees received training that addresses the risk where the misconduct occurred? Have senior management made the company's position clear on misconduct and made resources available for employees to consult on compliance policies?

Confidential reporting and investigation
Has the company collected, analyzed, and used information from its reporting mechanisms and assessed the seriousness of the allegations received? Was the ensuing investigation conducted independently and objectively by qualified personnel with full access to the reporting function? How high within the company is reporting and investigation escalated?

Incentives and disciplinary measures
What discipline did the company impose in response to the misconduct and when did it do so? Are managers held accountable for misconduct that occurred under their supervision? Who participates in the disciplinary decisions? Is discipline imposed fairly and consistently across the organization?

Continuous improvement, periodic testing and review
Has the company learned from its mistakes? Has it periodically tested its vulnerabilities, reviewed the results, and made systemic improvements in its controls?

Third party management
Has the company appropriately managed its third parties to mitigate risk as part of its compliance program?

Mergers and acquisitions
Was the misconduct or risk of misconduct identified during the due diligence process? Has the compliance function been

consolidated into the merger, acquisition, and integration process?

Resolution: Evaluation/strengthening of compliance program

With the foregoing topics as a backdrop, a health system can take several steps to establish or enhance its compliance program to mitigate opioid diversion, such as conducting comprehensive background checks and investigations of its employee candidates. Concomitantly, health systems should report individual employee's obvious wrongful conduct to state and local law enforcement and to an employee's future employer. Doing so will prevent diverters from taking advantage of an industry that naturally resists disclosure, given HIPAA and privacy concerns, which otherwise results in diverters freely moving from employer to employer, undetected, and simultaneously putting the institution and community at risk. Moreover, concealing diversion from the authorities invariably will result in far-worse consequences.

A health system should impose pre-employment drug testing for candidates and random, periodic drug testing for all employees. The company should also order testing for specific opioids in addition to common street drugs. Although specific tests cost more, a prosecutor will distinguish between the company that tests to mitigate specific risks and the company that skimps in an effort to save a few extra dollars.

Health systems must regularly audit opioid dispensing mechanisms and storage facilities and address head-on the audit's findings. The company should determine why dosage/unit counts are off and how the controlled substances went missing. The company should also test vials/ampules of liquid opioids to see whether they have been surreptitiously replaced with saline or water.

A health system should also carefully consider the placement of its opioid dispensers/machines. Diverters easily take advantage of machines placed in isolated rooms, out of public view, or near bathrooms where the diverter can quickly hide after stealing the medication. Placement that increases the risk of detection is best. Security cameras installed near the dispensers will also have a strong deterrent effect.

Finally, management should train all employees and third parties about diversion and prevention. Senior leaders likewise should instill a zero-tolerance culture against diversion, and, if misconduct is uncovered, permit an independent and objective investigation by qualified personnel.

1. *United States v. Moore*, 423 U.S. 122, 135 (1975).
2. *United States v. Park*, 421 U.S. 658 (1975).
3. Memorandum from Sally Quillian Yates, Deputy Attorney General: "Individual Accountability for Corporate Wrongdoing" September 9, 2015. Available at http://bit.ly/2tSoJh8
4. *United States Attorneys Manual*, §§ 9-28.210; 9-28-300; 9-28-700
5. U.S. Department of Justice Criminal Division, Fraud Section: Evaluation of Corporate Compliance Programs. 2017. Available at http://bit.ly/2o03nZ5
6. Memorandum from Loretta E. Lynch, Attorney General: "Department of Justice Strategy to Combat Opioid Epidemic" September 21, 2016. Available at http://bit.ly/2EChSKr
7. DOJ: Justice News press release: "Deputy Attorney General Rod J. Rosenstein Delivers Remarks on DEA Fentanyl Guidance" June 6, 2017. Available at http://bit.ly/2EHlpLG
8. DOJ: Justice News press release: "Deputy Attorney General Rod J. Rosenstein Delivers Remarks on Enforcement Actions to Stop Deadly Fentanyl and Other Opiate Substances from Entering the United States" October 17, 2017. Available at http://bit.ly/2oib6Tb
9. DOJ: Justice News press release: "Statement by Attorney General Sessions on Fentanyl Safety Recommendations for First Responders" November 1, 2017. Available at http://bit.ly/2GsEnC0
10. Drug Enforcement Administration, press release: "Department of Justice Announces Significant Tool in Prosecuting Opioid Traffickers in Emergency Scheduling of All Fentanyls" November 9, 2017. Available at http://bit.ly/2FhgBcI
11. Memorandum from Attorney General Jeff Sessions: Designation of Opioid Coordinators. November 29, 2017. Available at http://bit.ly/2EPrZij
12. United States Attorney's Office, Eastern District of California, press release: "Dignity Health Agrees to Pay $1.55 Million in Civil Penalties to Resolve Controlled Substances Act Claims" July 16, 2014. Available at http://bit.ly/2oj1Myt
13. Settlement Agreement between United States and Massachusetts General Hospital. Sept. 28, 2015 at 8, Attachment 2, Statement of Relevant Conduct. Available at http://bit.ly/2EDvSHN
14. *United States v. Appalachian Regional Healthcare*, Inc., Civ. No. 5:16-cv-00132-JMH, (E.D. Ky. May 2, 2016), Complaint, at Docket Entry No. 1.
15. See *United States v. Amundson*, Crim. No. 17-283-SRN-DTS, (D. Minn. Nov. 8, 2017), Indictment, Docket Entry 1.
16. See 21 U.S.C. §§ 843(a)(3) and (d)(1).
17. *United States v. Ulibarri*, Crim. No. 16-cr-03486-JB, (D.N.M. Jul. 25, 2016), Criminal Compl., Docket Entry 1.
18. See 21 U.S.C. §§ 846, 841(a)(1) and (b)(1)(C), 843(a)(3) and (d)(1).
19. *United States v. Dotterweich*, 320 U.S. 277 (1943).
20. *United States v. Park*, 421 U.S. 658 (1975).
21. Dotterweich, 320 U.S. at 278, 286.
22. Park, 421 U.S. at 658.
23. Id. at 658, 674.
24. *United States v. Purdue Frederick Co., Inc.*, 495 F. Supp.2d 569 (W.D. Va. 2007).
25. *Friedman v. Sebelius*, 686 F.3d 813, 828 (D.C. Cir. 2012).
26. *United States v. Norian Corp., et al.*, Crim. No. 09-cr-403-LDD, (E.D. Pa. Jun. 16, 2009), Indictment, at 54, Docket Entry 1.
27. *United States v. Hermelin*, Crim. No. 4:11-CR-85-ERW, (E.D. Mo. Mar. 10, 2011), Information, at 7,8, Docket Entry 1..
28. *United States v. Facteau*, et al., Crim. No. 15-cr-10076-ADB, (D. Mass. Apr. 8, 2015), Indictment, Docket Entries 1, 432.
29. *United States v. DeCoster*, 828 F.3d 626 (8th Cir. 2016, cert. denied, ___ U.S. ___, 137 S. Ct. 2160 (2017).
30. Id. at 632 (citing Park, 421 U.S. at 673-74).
31. Brief for the United States in Opposition, *DeCoster v. United States*, at 10 (filed Apr. 12, 2017) at 10-11, 23, 24 (citing S. Rep. No. 684, 94th Cong., 2d Sess. 30 (1976).
32. FDA's *Regulatory Procedures Manual* at §6-5-3. Available at http://bit.ly/2C98AYU.
33. See *USAM* §4-8.200.