# *Chapter 10*

# Representing the Drug or Medical Device Manufacturer in an Investigation

## § 10:1 Introduction

The variety of criminal statutes and theories used to prosecute drug and device manufacturers is so diverse as to defy easy summary. At one end of the spectrum are those dealing with general offenses, such as the Civil War–era statute criminalizing the submission of false claims to a department or agency of the United States,[1] or the mail[2] and wire fraud[3] statutes—each of which could be used by the government against pharmaceutical companies and medical device manufacturers and their executives. At the other end are statutes targeting more specific offenses, such as the federal misbranding statute[4] or the federal healthcare "Anti-Kickback Statute,"[5] which prohibits, among other things, "remuneration" to physicians to prescribe drugs or use medical devices that are reimbursable by a federal healthcare program. Each of these statutes exposes pharmaceutical and medical device defendants to significant criminal and civil penalties.

## § 10:2 The Statutory and Regulatory Scheme

### *§ 10:2.1 The FDCA*

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA)[6] to protect the public from deleterious, impure, and deceptive goods. FDCA violations include adulterating or misbranding food, drugs, devices, or cosmetics.[7] The U.S. Food and Drug Administration (FDA) has used the misbranding provisions of the FDCA to prosecute a wide range of actions, from failure to disclose safety information to marketing of products for off-label uses. Companies found to have violated the misbranding provisions have been subjected to criminal and civil penalties, injunctions, exclusion from federal health programs, and seizure of goods.[8]

The FDA's Office of Criminal Investigations (OCI) has primary responsibility for investigating criminal violations of the FDCA, but refers matters to the U.S. Department of Justice (DOJ) when action

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1. 18 U.S.C. § 287 (the "criminal False Claims Act").
2. *Id.* § 1341.
3. *Id.* § 1343.
4. 21 U.S.C. § 352.
5. 42 U.S.C. § 1320a-7b(b); *see also* 21 U.S.C. §§ 331(t), 333(b) (drug importation and marketing violations).
6. 21 U.S.C. §§ 301–99.
7. *Id.* § 331(a)–(b); *see also id.* § 331(e) (failure to comply with safety reporting requirements).
8. The Food and Drug Administration Amendments Act of 2007 (FDAAA) also authorized new civil penalties for a wide range of safety and advertising related activities of companies. *See* 21 U.S.C. § 333(f)(4), (g).

by a grand jury appears warranted. By regulation,[9] the Assistant Attorney General, Civil Division, through the Office of Consumer Protection Litigation (OCPL), has overall responsibility for criminal and civil litigation arising under the FDCA. Additionally, any individual U.S. attorney's office may carry out grand jury investigations and prosecute violations.

Among other "prohibited acts," misbranding or adulteration, when committed "with the intent to defraud or mislead," is a felony and, under the FDCA's penalty provisions, carries a sentence of up to three years in prison and/or a fine of not more than $10,000.[10] Misdemeanor prosecutions also carry meaningful punishment. An individual who commits a misdemeanor offense can receive up to a year in prison and/or a $1,000 fine.[11] "Because the criminal fine amounts in 18 U.S.C. § 3571 supersede the fine provisions in the FDCA, however, an individual or organization in violation of the FDCA could face much larger fines than those provided by the FDCA itself."[12] Significantly, an FDCA misdemeanor violation is also punishable as a felony if committed by an individual or organization previously convicted of an offense under the act.[13]

### § 10:2.2 The Anti-Kickback Statute

The federal Anti-Kickback Statute (AKS) prohibits any person from knowingly and willfully paying, offering, soliciting, or receiving any "remuneration," directly or indirectly, in cash or in kind, to induce the referral of business covered (in whole or in part) by a federal healthcare program, including Medicare and Medicaid.[14] Specifically, the statute makes it a crime to provide anything of value with the purpose of inducing a customer to prescribe a drug or use a medical device for a patient. Even if there are several purposes for providing remuneration to a customer, if only one of the purposes (even if not the primary purpose) is to encourage that customer to prescribe a

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9. 28 C.F.R. § 0.45(j) (2016).
10. 21 U.S.C. § 333(a)(2).
11. *Id.* § 333(a)(1). On May 1, 2008, the U.S. Sentencing Commission proposed amendments to the Sentencing Guidelines that will allow significant upward departures for misdemeanor violations that involve "a substantial risk of bodily injury or death" and will increase the base offense level for second violations of the FDCA. *See* 73 Fed. Reg. 26,923, 26,935–36 (May 9, 2008). These amendments took effect on November 1, 2008. U.S. SENTENCING GUIDELINES MANUAL § 2N2.1 application n.3(A).
12. 18 U.S.C. § 3571; *see also* section 10:2.4, *infra* (detailing fines under the Foreign Corrupt Practices Act).
13. 21 U.S.C. § 333(a)(2).
14. 42 U.S.C. § 1320a-7b(b)(2).

drug or use a device, it may violate the law. The AKS provides penalties of up to five years in prison and a $25,000 fine.[15]

Additionally, the 2010 Patient Protection and Affordable Care Act stated that claims arising out of violations of the AKS are considered false claims for the purposes of the False Claims Act (FCA).[16]

### § 10:2.3 The False Claims Act

Under the FCA, manufacturers can be prosecuted for such offenses as improper off-label promotion of drugs or devices. Penalties may include a maximum prison sentence of five years and a fine, as discussed below.[17] More frequently, however, the government has attempted to hold manufacturers liable under the civil FCA. (See chapter 11 for a more detailed discussion of the civil FCA.)

### § 10:2.4 The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) makes it illegal for any U.S. person or company or anyone acting on his or her behalf (whether a U.S. person or not) to bribe a foreign official or foreign political party for the purpose of obtaining or retaining business.[18] The DOJ and SEC enforce the FCPA through civil and criminal penalties, which include the potential for significant fines and imprisonment of up to five years.[19] The pharmaceutical and medical device industries face especially heightened FCPA risks because nearly every aspect of the approval and sale of a drug or device involves interaction with a "foreign official" within the meaning of the FCPA, such as healthcare providers employed by public hospitals or other government organizations. Indeed, the government has specifically indicated that it would focus on FCPA enforcement against pharmaceutical companies and their executives.[20] (See chapter 15 for a more detailed discussion of the FCPA.)

### § 10:2.5 Other Regulatory Tools

The government's leverage against manufacturers, however, does not come exclusively from substantive criminal statutes. Rather, drug

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15. *Id*.
16. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402, 124 Stat. 119 (2010).
17. *See generally* 18 U.S.C. § 3571, and section 10:2.5[C], *infra*.
18. 15 U.S.C. § 78dd-1 *et seq.*
19. *Id*. § 78dd-2(g).
20. *See* Lanny A. Breuer, Assistant Att'y Gen., Criminal Div., Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009), www.ehcca.com/presentations/pharmacongress10/breuer_2.pdf.

and medical device manufacturers and their executives face three additional risks in considering whether to plead guilty or take a case to trial.

### [A] Corporate Integrity Agreements

First, in connection with many plea agreements (and in civil-only settlements as well), companies have entered into corporate integrity agreements (CIAs) that require significant ongoing oversight of a wide range of activities by the government. For example, in connection with its 2009 settlement with the DOJ involving Bextra, Pfizer entered into a CIA.[21] Among other things, the agreement required Pfizer to adopt written standards addressing: the materials that sales representatives could distribute to physicians; how requests for information about off-label uses were handled; the funding of grants and educational activities; the sponsorship of clinical trials and other research; and compensation. The company was required to implement programs to monitor in detail interactions between sales representatives and physicians regarding potential off-label uses of drugs, as well as consulting arrangements, publication activities, and medical education activities. Personnel training was required to include explanations of instances in which the company did and did not meet the requirements of the compliance program. In addition, certain management personnel were required to complete a certification stating that each business unit has taken all appropriate steps to ensure compliance. Finally, the agreement required that Pfizer hire an independent review organization to conduct reviews of its systems, as well as a sample of transactions relating to many of the above-referenced activities.

In that regard, a number of recent criminal resolutions have included CIA-like provisions—including a requirement that company executives submit certifications—in the plea agreement itself.[22]

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21. Corporate Integrity Agreement Between the Office of Inspector Gen. of the Dep't of Health and Human Servs. and Pfizer, Inc. (Aug. 31, 2009), www.oig.hhs.gov/fraud/cia/agreements/pfizer_inc.pdf.

22. For example, in 2012, GlaxoSmithKline (GSK) entered into a plea agreement in connection with its settlement of a case involving allegations of off-label marketing. U.S. Dep't of Justice, Plea Agreement, United States v. GlaxoSmithKline LLC (June 27, 2012), www.justice.gov/sites/default/files/opa/legacy/2012/07/02/plea-agreement.pdf. GSK's plea agreement requires the board of directors and GSK's U.S. president to certify annually that GSK has maintained appropriate compliance measures. *Id.* The plea agreement also states that if GSK fails to maintain certain measures or to meet the reporting and certification requirements, it must pay $20,000 for each day it is in violation. *Id.* In addition, in connection with an Olympus Corp. of the Americas March 2016 settlement

### [B] Exclusion from Federal Healthcare Programs

The second is the risk that a company or executives who are convicted or plead guilty to a misbranding or kickback violation are also subject to exclusion by the Office of Investigator General (OIG), Department of Health and Human Services (HHS), from participation in the federal healthcare programs. OIG's exclusion power extends even to indirect providers, such as pharmaceutical companies, whose drugs or devices will not be eligible for federal healthcare program reimbursement—a virtual corporate death sentence. Exclusion is mandatory for a manufacturer or individual found guilty, under either federal or state law, of a felony relating to fraud "in connection with the delivery of a health care item or service."[23] Similarly, a convicted manufacturer risks debarment from certain dealings with the FDA and other government agencies. For example, debarment is mandatory for a manufacturer convicted of a felony offense relating to the development or approval of any abbreviated new drug application for a generic product.[24]

### [C] Fines

The third risk is potentially crippling fines. An organization may be fined up to $500,000 for a felony where the offense results in

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regarding allegations that it won new business and rewarded sales by paying kickbacks to doctors and hospitals, the company entered into a deferred prosecution agreement that required it to take certain remedial and compliance measures, including training and certifications. *See* Deferred Prosecution Agreement between U.S. Attorney's Office for Dist. of N.J. and Olympus Corp. of Ams. (Feb. 29, 2016), www.justice.gov/usao-nj/file/867021/download. And in connection with a November 2016 settlement regarding allegations of off-label marketing, Biocompatibles, Inc. entered into a plea agreement that attached a "Compliance Agreement" that, inter alia, required the company to maintain a compliance and ethics program and complete annual certifications and Board resolutions. U.S. Dep't of Justice, Plea Agreement, United States v. Biocompatibles, Inc. (Sept. 12, 2016).

23. 42 C.F.R. § 1001.101(c); *see* 42 U.S.C. § 1320a-7(a)(3). There has been some criticism that the government has not pursued debarment aggressively in its major investigations. *See* STAFF OF H. COMM. ON ENERGY AND COMMERCE, 110TH CONG., FDA'S FAULTY SAFEGUARDS AGAINST CORRUPTION: CONCERNS OVER DEBARMENT USE AND AUTHORITY (Committee Print 2008).

24. 21 U.S.C. § 335a(a)(1). *See, e.g.*, Bae v. Shalala, 44 F.3d 489, 496–97 (7th Cir. 1995) (where, after the president of a generic drug manufacturer pled guilty to one felony count of aiding and abetting interstate travel for bribing an FDA official, the FDA debarred him from participation in the generic drug industry).

pecuniary gain or loss.[25] However, "the defendant may be fined not more than the greater of twice the gross gain or twice the gross loss."[26] Application of this rule has allowed the DOJ to obtain fines dramatically higher than the maximum specified in the substantive statute.[27] For example, in a 2001 plea agreement, TAP Pharmaceuticals stipulated that the pecuniary loss from its offense was an estimated $145 million, which yielded a fine of up to $290 million.[28] In other words, the sky's the limit on the potential fine for a drug or device manufacturer.[29]

## § 10:3 Recent Developments in Enforcement Actions

### *§ 10:3.1 Enforcement Actions Against Pharmaceutical Manufacturers*

The tools available to the government have been wielded effectively. The DOJ has obtained staggeringly large settlements from pharmaceutical companies in recent years.[30] Since January 2009, the government has recovered $37.8 billion in healthcare fraud claims.[31] Prominent examples include the following:

(1) January 2017 settlement by Shire Pharmaceuticals LLC and Advanced BioHealing (acquired by Shire in 2011) in which Shire agreed to pay $350 million to resolve allegations that

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25. 18 U.S.C. § 3571(c).
26. *Id*. § 3571(d).
27. *Id*.
28. *See* Press Release No. 01-513, U.S. Dep't of Justice, TAP Pharmaceutical Products Inc. and Seven Others Charged with Health Care Crimes (Oct. 3, 2001), www.justice.gov/opa/pr/2001/October/513civ.htm.
29. *See* United States v. C.R. Bard, Inc., 848 F. Supp. 287, 289–92 (D. Mass. 1994) (approving plea agreement using company's gross sales derived from unlawful activities in assessing $30.5 million criminal fine).
30. *See generally* Stephanie Greene, *False Claims Act Liability for Off-Label Promotion of Pharmaceutical Products*, 110 PENN ST. L. REV. 41 (2005).
31. *See* Press Release No. 18-1690, U.S. Dep't of Justice, Justice Department Recovers $2.8 Billion From False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018; *see also* Press Release No. 17-1467, U.S. Dep't of Justice, Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year 2017 (Dec. 21, 2017), www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017; *see also* Press Release No. 16-1469, U.S. Dep't of Justice, Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016 (Dec. 14, 2016), www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.

Shire and Advanced BioHealing used kickbacks and other unlawful methods to induce clinics and physicians to use or overuse Dermagraft, a bioengineered human skin substitute approved for the treatment of diabetic foot ulcers;[32]

(2) An October 2015 guilty plea and settlement by Warner Chilcott U.S. Sales LLC (whose parent company had been acquired by Actavis in October 2013; Actavis was acquired by Allergan in March 2015), related to kickbacks paid to physicians, in the form of payments related to speaker programs and medical education events, in which the company agreed to pay $125 million;[33]

(3) A November 2013 guilty plea and settlement by Johnson & Johnson (and its subsidiaries Janssen Pharmaceuticals, Inc. and Scios, Inc.), related to the off-label promotion of several drugs, including Risperdal, an atypical antipsychotic, in which the company agreed to pay $2.2 billion;[34]

(4) A July 2013 guilty plea and settlement by Wyeth Pharmaceuticals, Inc. (which was acquired by Pfizer, Inc. in 2009), related to its off-label promotion of Rapamune, an immuno-suppressive approved for de novo use in kidney transplant patients, in which the company agreed to pay $491 million;[35]

(5) A December 2012 guilty plea and settlement by Amgen, Inc., related to its off-label promotion of Aranesp, an anemia treatment, and other drugs, in which the company agreed to pay $762 million;[36] and

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32. *See* Press Release No. 17-035, U.S. Dep't of Justice, Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations (Jan. 11, 2017), www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations.

33. *See* Press Release No. 15-1330, 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), www.justice.gov/opa/pr/warner-chilcott-agrees-plead-guilty-felony-health-care-fraud-scheme-and-pay-125-million.

34. Press Release No. 13-1170, U.S. Dep't of Justice, Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), www.justice.gov/opa/pr/2013/November/13-ag-1170.html.

35. Press Release No. 13-860, U.S. Dep't of Justice, Wyeth Pharmaceuticals Agrees to Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses (July 30, 2013), www.justice.gov/opa/pr/2013/July/13-civ-860.html.

36. Press Release No. 12-1523, U.S. Dep't of Justice, Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY; Pays $762 Million to Resolve

(6) A July 2012 guilty plea and settlement by GlaxoSmithKline LLC, in which the company pled guilty to three criminal counts and agreed to pay $3 billion related to its off-label marketing of a number of drugs, including Wellbutrin (an antidepressant), Paxil (an antidepressant), and Advair (an asthma drug), as well as its failure to report certain safety data on Avandia (a diabetes drug) to the FDA.[37]

It is worth noting that in the past few years, the government's enforcement efforts have been less focused on off-label marketing and more focused on kickbacks, including several novel kickback theories. Recent enforcement trends include:

*Kickbacks Paid to Distribution "Gatekeepers."* The government has entered into a number of settlements with manufacturers (including some settlements following litigation) involving alleged kickbacks paid to third parties included in the distribution of pharmaceuticals, *e.g.*, specialty and long term care pharmacies and pharmacy benefit managers (PBMs). Examples include the following:

(1) In November 2015, Novartis Pharmaceuticals Corporation agreed to pay $390 million to resolve allegations that it had paid kickbacks, in the form of patient referrals and/or rebates, to specialty pharmacies in connection with two of its drugs;[38]

(2) In February 2015, AstraZeneca LP paid $7.9 million to resolve allegations that it provided remuneration to Medco Health Solutions, a PBM, in exchange for Medco maintaining one of its product's "sole and exclusive" status on certain Medco formularies;[39] and

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Criminal Liability and False Claims Act Allegations (Dec. 19, 2012), www.justice.gov/opa/pr/2012/December/12-civ-1523.html.

37. Press Release No. 12-842, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report.

38. Press Release No. 15-300, U.S. Dep't of Justice, Manhattan U.S. Attorney Announces $370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals For Kickback Scheme Involving High-Priced Prescription Drugs, Along With $20 Million Forfeiture Of Proceeds From The Scheme (Nov. 20, 2015), www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.

39. Press Release No. 15-166, U.S. Dep't of Justice, AstraZeneca to Pay $7.9 Million to Resolve Kickback Allegations (Feb. 11, 2015), www.justice.gov/opa/pr/astrazeneca-pay-79-million-resolve-kickback-allegations.

(3) In the November 2013 Johnson & Johnson/Janssen settlement discussed above, one of the government's allegations was that the companies paid kickbacks to Omnicare Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients, by paying market share rebates conditioned upon Omnicare engaging in "active intervention programs" (*i.e.*, obtaining physician authorization to switch nursing home patients from one drug to another), data purchase agreements, grants and educational funding.[40]

Furthermore, the DOJ has recently pursued several industry-wide investigations regarding interactions between pharmaceutical companies and 501(c)(3) charitable organizations that provide financial assistance to patients.[41] As a result of one such investigation, Pfizer agreed to pay $24 million to resolve allegations that it utilized a 501(c)(3) foundation as a way to pay the copay obligations of Medicare patients taking several of its products.[42] In December 2018, Actelion Pharmaceuticals US, Inc. agreed to pay $360 million to resolve allegations that it used a foundation as a conduit to pay the copay obligations of thousands of Medicare patients taking its pulmonary arterial hypertension drugs, thereby inducing patients to purchase Actelion's drugs when the prices it had set for those drugs otherwise could have posed a barrier to purchases.[43] Similarly, in December 2017, United Therapeutics Corporation agreed to pay $210 million to resolve allegations that it used a foundation as a conduit to pay

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40. *See* Press Release No. 13-1170, *supra* note 34.
41. *See, e.g.*, Peter Loftus, *U.S. Investigates Drugmaker Contracts With Pharmacy-Benefit Managers*, WALL ST. J. (May 10, 2016, 5:47 PM), www.wsj.com/articles/u-s-investigates-drugmaker-contracts-with-pharmacy-benefit-managers-1462895700; Tracy Staton, *J&J Joins Pfizer, Celgene, Biogen and More in DOJ's Patient-assistance Dragnet*, FIERCEPHARMA (Feb. 28, 2017, 9:07 AM), www.fiercepharma.com/pharma/j-j-joins-pfizer-celgene-biogen-et-al-feds-patient-assistance-dragnet.
42. *See* Press Release No. 18-686, U.S. Dep't of Justice, Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks (May 24, 2018), https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks.
43. *See* Press Release, U.S. Dep't of Justice, Actelion Pharmaceuticals Agrees to Pay $360 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation (Dec. 6, 2018), www.justice.gov/usao-ma/pr/actelion-pharmaceuticals-agrees-pay-360-million-resolve-allegations-it-paid-kickbacks.

the copays of Medicare patients taking its own pulmonary arterial hypertension drugs.[44] Over the past year, several other companies have also entered into settlements relating to the same allegations.[45]

In addition, there have been other recent developments in relation to both manufacturers and PBMs. Most notably, a number of private plaintiffs, spurred by scrutiny in Congress and in the press about rising drug prices, have filed putative class action suits against several manufacturers and/or PBMs.[46] The complaints generally allege that over the past few years, manufacturers have raised their "benchmark" prices while simultaneously increasing the percentage rebates they are offering to the PBMs, so that the PBMs' net prices have remained consistent while their profits increase. According to the complaints, this allegedly harms insured patients, who must pay out of pocket until they meet their deductibles and whose co-insurance and co-pays have increased substantially, as well as uninsured patients, who pay

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44. *See* Press Release No. 17-1454, U.S. Dep't of Justice, Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks (Dec. 20, 2017), www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability.

45. *See, e.g.*, Press Release, U.S. Dep't of Justice, Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations that they Paid Kickbacks Through Co-Pay Assistance Foundations (Apr. 4, 2019), www.justice.gov/usao-ma/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they (Jazz Pharmaceuticals PLC, Lundbeck LLC, and Alexion Pharmaceuticals, Inc. agreed to pay combined $122.6 million to resolve allegations they paid kickbacks to Medicare and ChampVA patients through independent charitable foundations); *see also* Press Release, U.S. Dep't of Justice, Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations that they Paid Kickbacks Through Co-Pay Assistance Foundations (Apr. 25, 2019), www.justice.gov/usao-ma/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they (Astellas Pharma US, Inc. and Amgen Inc., agreed to pay $124.75 million to resolve allegations they created two foundations and "donated" funds that functioned as kickbacks to patients); Press Release 19-448, U.S. Dep't of Justice, Pharmaceutical Company Agrees to Pay $17.5 Million to Resolve Allegations of Kickbacks to Medicare Patients and Physicians (Apr. 30, 2019), www.justice.gov/opa/pr/pharmaceutical-company-agrees-pay-175-million-resolve-allegations-kickbacks-medicare-patients (WorldMeds agreed to pay $17.5 million to resolve allegations that it paid kickbacks to patients and physicians by paying copays through a third-party foundation).

46. *See, e.g.*, Chaires v. Novo Nordisk, No. 3:17 Civ. 00699 (D.N.J. Feb. 2, 2017); *In re* EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig., No. 2:17-MD-02785 (D. Kan. 2017).

the benchmark prices that have risen so steeply. Some of the defendants in these suits have since disclosed investigations by various state Attorneys General into the pricing allegations.[47]

Similarly, in early 2018, two *qui tam* cases were unsealed after the government declined intervention.[48] The cases, filed by the same relator in the District of Rhode Island and Southern District of New York, name a number of the largest manufacturers and PBMs as defendants and allege that over the past decade, these manufacturers have paid the PBMs "kickbacks" in the form of service fees that exceeded fair market value.[49] In December 2018, the government moved to dismiss both cases.[50] In mid-2019, the Southern District of New York case was dismissed, and the District of Rhode Island case remains pending as of the date of publication of this chapter.[51]

The DOJ's decision to move to dismiss in this case and several others reflects a change in DOJ policy regarding FCA *qui tam* actions following the January 2018 publication by the DOJ of the "Granston Memo." Specifically, the Granston Memo, named after Michael Granston, the Director of the Fraud Section of the DOJ Civil Division, states that "when evaluating a recommendation to decline intervention in a *qui tam* action, attorneys should also consider whether the government's interests are served, in addition, by seeking dismissal pursuant to section 3730(c)(2)(A)," and sets forth certain factors that the DOJ should consider in determining whether to move to dismiss a case.[52]

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47. Dani Kass, *Wash., NM AGs Investigating Eli Lilly's Insulin Pricing*, LAW360 (May 3, 2017, 4:45 PM), www.law360.com/articles/919830/wash-nm-ags-investigating-eli-lilly-s-insulin-pricing; James Paton, *Novo's Legal Challenges Mount as States Query Insulin Prices*, BLOOMBERG (May 3, 2017, 4:08 AM), www.bloomberg.com/news/articles/2017-05-03/novo-s-legal-challenges-mount-as-u-s-states-query-insulin-price.

48. United States *ex rel*. v. Bayer AG, No. 14-CV-31 (WES) (D.R.I. filed Jan. 16, 2014); United States *ex rel*. Borzilleri v. AbbVie, Inc., No. 15-CV-7881(JMF) (S.D.N.Y. filed Oct. 6, 2015).

49. *Id*.

50. *Id*.

51. *Id*.

52. *See* Memorandum, U.S. Dep't of Justice, Factors for Evaluating Dismissal Pursuant to 31 U.S.C. 3730(c)(2)(A) (Jan. 10, 2018), https://assets.documentcloud.org/documents/4358602/Memo-for-Evaluating-Dismissal-Pursuant-to-31-U-S.pdf (the Department should consider moving to dismiss a *qui tam* complaint where the complaint: "is factually lacking in merit—either because a relator's legal theory is inherently defective, or the relator's factual allegations are frivolous"; "duplicates a pre-existing government investigation"; "threatens to interfere with an agency's policies or the administration of its programs"; may interfere with the "Department's litigation prerogatives"; involves "intelligence agencies

*Speaker Programs.* Another recent area of focus has been on pharmaceutical manufacturer speaker programs. Recent examples include settlements with Abiomed,[53] Forest,[54] Salix,[55] Warner Chilcott[56] and Daiichi Sankyo.[57] Most recently, in June 2019, the DOJ announced that Insys Therapeutics, Inc. had agreed to pay $225 million to settle its speaker program case, in which the government alleged that Insys used speaker programs for its drug Subsys, an opioid approved for the treatment of breakthrough cancer pain, that were actually just a vehicle to pay kickbacks to practitioners in exchange for increased prescriptions of Subsys.[58] In addition, the settlement also resolved allegations that: (i) high-prescribing physicians were paid to serve as speakers at events in which minimal or no educational component was provided; (ii) speakers were paid to speak exclusively to members of their own staff; (iii) relatives and friends of high-prescribing providers were given jobs despite their lack of qualification for the positions for which they were hired; and (iv) Insys promoted the sale and use of Subsys for unapproved uses which were not medically accepted

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or military procurement contracts"; would require the Department to expend greater resources than would be expected in gains; and would "frustrate the government's efforts to conduct a proper investigation" as a result of problems with the relator's actions.)

53. Press Release, U.S. Dep't of Justice, Abiomed, Inc. Agrees to Pay $3.1 Million to Resolve Kickback Allegations (Mar. 8, 2018), https://www.justice.gov/usao-ma/pr/abiomed-inc-agrees-pay-31-million-resolve-kickback-allegations.

54. Press Release No. 16-1477, U.S. Dep't of Justice, Forest Laboratories and Forest Pharmaceuticals to Pay $38 million to Resolve Kickback Allegations Under the False Claim Act (Dec. 15, 2016), www.justice.gov/opa/pr/forest-laboratories-and-forest-pharmaceuticals-pay-38-million-resolve-kickback-allegations.

55. Press Release No. 16-159, U.S. Dep't of Justice, Manhattan U.S. Attorney Announces $54 Million Settlement Against Salix Pharmaceuticals For Using "Speaker Programs" As Mechanism To Pay Illegal Kickbacks To Doctors To Induce Them to Prescribe Salix Products (June 9, 2016), www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-54-million-settlement-against-salix-pharmaceuticals.

56. *See* Press Release No. 15-1330, *supra* note 33.

57. Press Release No. 15-017, U.S. Dep't of Justice, Daiichi Sankyo Inc. Agrees to Pay $39 Million to Settle Kickback Allegations Under the False Claims Act (Jan. 9, 2015), www.justice.gov/opa/pr/daiichi-sankyo-inc-agrees-pay-39-million-settle-kickback-allegations-under-false-claims-act.

58. *See* Press Release No. 19-621, U.S. Dep't of Justice, Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019), www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal.

indications as defined by 42 U.S.C. § 1396r-8(k)(6).[59] In addition to the $225 million payment, Insys also entered into a five-year Corporate Integrity Agreement (CIA) and subsequently filed for bankruptcy.

*Nurse Educators and Reimbursement Support.* Another area of scrutiny by relators and some government enforcement agencies is the prevalence of nurse educators and reimbursement support personnel. In particular, a series of FCA complaints filed by the same corporate relator against a number of pharmaceutical manufacturers and vendors that provide these nurse educator and reimbursement support services allege that the value these services provide to physicians are illegal kickbacks designed to encourage physicians to prescribe higher priced medications.[60] In December 2018, the DOJ moved to dismiss eleven such *qui tam* cases pursuant to the guidance set forth in the Granston Memo.[61] Most of those cases have now been dismissed, though a handful remain pending.

*Manufacturing Practices.* The DOJ has obtained large criminal and civil fines from two pharmaceutical companies for their allegedly deficient manufacturing practices. In 2010, GlaxoSmithKline (GSK) pled guilty and agreed to pay $750 million in criminal and civil fines, including payments under the FCA, related to the manufacturing and distribution of certain adulterated products. Among other things, GSK was charged with failing to ensure that Kytril, an anti-nausea medication, and Bactroban, an ointment used to treat skin infections, were free from contamination. The charges also included allegations that defective manufacturing practices resulted in GSK selling ineffective Paxil CR, an anti-depressant.[62] In May 2013, Ranbaxy USA Inc.,

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59. *See id*.

60. *See, e.g.*, Peter Loftus, *U.S. Probes Drugmakers Over Free Services*, WALL ST. J. (Sept. 21, 2018, 3:28 PM), www.wsj.com/articles/drugmakers-free-services-spur-government-scrutiny-1537531201; Christopher Crosby, *Drug Kickback Suit Against Eli Lilly Dismissed for Now*, LAW360 (Aug. 14, 2018, 6:13 PM), www.law360.com/articles/1072394/drug-kickback-suit-against-eli-lilly-dismissed-for-now; Complaint, SMSPF, LLC v. EMD Serono, Inc., No. 2:16-cv-05594-TJS (E.D. Pa. Apr. 26, 2017); Complaint, State of California v. AbbVie Inc., No. RG18893169 (Cal. Super. Ct. Feb. 15, 2018); Ed Silverman, *AbbVie is Accused of Paying Kickbacks, Using a Stealthy Network of Nurses to Promote Humira*, STAT (Sept. 18, 2018), www.statnews.com/pharmalot/2018/09/18/abbvie-kickbacks-nurses-humira/.

61. *See* David P. Yates, *DOJ: A Company Created To File Lawsuits Has Wasted 1,500 Hours of the Government's Time*, FORBES (Dec. 19, 2018), www.forbes.com/sites/legalnewsline/2018/12/19/doj-a-company-created-to-file-lawsuits-has-wasted-1500-hours-of-the-governments-time/#7504fffa290b.

62. Press Release No. 10-1205, Dep't of Justice, GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability

a subsidiary of Indian generic pharmaceutical manufacturer Ranbaxy Laboratories Limited, agreed to pay $500 million in criminal and civil fines and to plead guilty to seven felony counts, including three felony counts under the FDCA and four felony counts of knowingly making material false statements to the FDA. The charges related to the manufacture and distribution of certain adulterated drugs made at two of Ranbaxy's manufacturing facilities in India.[63]

In another highly publicized matter, the government investigated a pharmaceutical company's deficient manufacturing practices. Specifically, the FDA investigated the manufacturing and quality control problems at Johnson & Johnson's consumer products unit, McNeil Consumer Healthcare, which resulted in multiple recalls by McNeil for numerous products, including popular over-the-counter pediatric medications such as Tylenol.[64] In May 2010, the U.S. House Committee on Oversight and Government Reform began an investigation into the circumstances of the recalls, including the accusation that McNeil conducted a "ghost recall" by hiring a third-party contractor to remove products from store shelves without notifying consumers or the FDA.[65] In May 2011, McNeil entered into a consent decree and agreed to FDA supervision of three of its Tylenol plants. The consent decree required an independent expert, paid for by Johnson & Johnson, to ensure compliance with federal quality control standards. Violation of the consent decree could cost McNeil $15,000 a day, and up to $10 million a year.[66]

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Regarding Manufacturing Deficiencies at Puerto Rico Plant (Oct. 26, 2010), www.justice.gov/opa/pr/2010/October/10-civ-1205.html.

63. Press Release No. 13-542, Dep't of Justice, Generic Drug Manufacturer Ranbaxy Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations and False Statements to the FDA (May 13, 2013), www.justice.gov/opa/pr/2013/May/13-civ-542.html.

64. Testimony Before the Committee on Oversight and Government Reform, U.S. House of Representatives, of FDA Principal Deputy Commissioner Joshua M. Sharfstein (May 27, 2010), www.fda.gov/Newsevents/Testimony/ucm213640.htm.

65. Press Release, Oversight & Gov't Reform, Committee on Oversight and Government Reform, Issa, Towns Ask FDA for Answers on Pediatric Medication Recall (May 6, 2010), https://oversight.house.gov/release/issa-towns-ask-fda-for-answers-on-pediatric-medication-recall/; *see also* Ransdell Pierson, *Panel Asks If FDA Knew About Secret J&J Recall*, REUTERS (Sept. 21, 2010), www.reuters.com/article/us-johnsonandjohnson-idUSTRE68K5K020100922.

66. Reed Abelson & Natasha Singer, *U.S. Regulators and J.&J. Unit Reach a Deal on Plant Oversight*, N.Y. TIMES (Mar. 10, 2011), www.nytimes.com/2011/03/11/business/11drug.html.

In light of the GSK and Ranbaxy settlements and Johnson & Johnson investigation, the government appears to be strengthening its enforcement efforts against pharmaceutical companies that are allegedly not in compliance with the FDA's current Good Manufacturing Practice (cGMP) guidelines.[67] As part of this increased focus, the FDA has set forth new initiatives designed to ensure that companies take prompt corrective action to address manufacturing deficiencies identified by the FDA through site inspections.[68] The FDA has indicated that it will move toward more serious enforcement actions following inspections at companies that have already received warning letters or conducted recalls yet failed to take corrective action.[69]

*Unapproved and Less-Than-Effective Drugs.* Another area of scrutiny is of unapproved and less-than-effective drugs.[70] As described above, the 2010 settlement by Forest Laboratories, Inc. and Forest Pharmaceuticals, Inc. involved, among other things, the sale of unapproved drugs. In another example, Schwarz Pharma, Inc. entered into a $22 million settlement with the DOJ in 2010 to resolve allegations that the company caused the submission of Medicaid reimbursement claims for an unapproved drug and a drug classified as less than effective.[71] In December 2011, KV Pharmaceutical Company agreed to pay $17 million to resolve civil allegations under the FCA that it failed to advise the Centers for Medicare & Medicaid Services that two unapproved products did not qualify for coverage under federal healthcare programs.[72]

*Foreign Payments.* In addition, pharmaceutical companies continue to be targets of FCPA investigations. Prominent examples include

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67. Testimony Before the Committee on Oversight and Government Reform, *supra* note 64; *see also* Margaret A. Hamburg, M.D., FDA Comm'r, Remarks at Food and Drug Law Institute: Effective Enforcement and Benefits to Public Health (Aug. 6, 2009), www.fda.gov/newsevents/speeches/ucm175983.htm.
68. Margaret A. Hamburg, M.D., *supra* note 67.
69. Speech by Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, at Food and Drug Law Institute, Effective Enforcement and Benefits to Public Health (Aug. 6, 2009), www.gmptrainingsys-tems.com/files/u2/pdf/Aug_6_Commish_speech.pdf.
70. Rx Compliance Report, OIG Senior Counsel puts spotlight on unapproved and less than effective drugs, Vol. IX, Issue 13, Nov. 23, 2010, at 9.
71. Press Release No. 10-499, Dep't of Justice, Schwarz Pharma Pays $22 Million to Settle False Claims Allegations Concerning Reimbursement for Unapproved Drugs (Apr. 29, 2010), www.justice.gov/opa/pr/2010/April/10-civ-499.html.
72. Press Release No. 11-1579, U.S. Dep't of Justice, St. Louis-Based KV Pharmaceutical to Pay $17 Million to Settle False Claims Allegations (Dec. 6, 2011), www.justice.gov/opa/pr/2011/December/11-civ-1579.html.

Johnson & Johnson's 2011 settlement for $77 million to resolve allegations that the company bribed doctors in several European countries and paid kickbacks to Iraq to obtain contracts under the United Nations Oil for Food Program.[73] In another example, Pfizer and two of its subsidiaries entered into a $60 million settlement in 2012 to settle charges of improper payments to public healthcare professionals and other government officials in Asia, Europe, and the Middle East.[74] In December 2016, Teva Pharmaceutical agreed to pay $519 million to settle parallel civil and criminal charges that it paid bribes to foreign government officials in Russia, Ukraine and Mexico.[75] And in September 2018, the SEC announced a settlement for which Sanofi agreed to pay more than $25 million to resolve allegations that it had made payments in multiple countries to government procurement officials and healthcare providers in order to be awarded tenders and to increase prescriptions of its medications.[76] Because international R&D typically involves, at nearly every stage, extensive interactions with individuals considered "foreign officials" under the FCPA, such as clinical trial investigators employed by government hospitals, this area presents an especially high risk area for potential FCPA violations.[77]

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73. Press Release No. 2011-87, U.S. Sec. & Exch. Comm'n, J&J to Pay $70 Million to Settle Cases Brought by SEC and Criminal Authorities (Apr. 7, 2011), www.sec.gov/news/press/2011/2011-87.htm.

74. Press Release No. 2012-152, U.S. Sec. & Exch. Comm'n, SEC Charges Pfizer with FCPA Violations (Aug. 7, 2012), www.sec.gov/News/PressRelease/Detail/PressRelease/1365171483696.

75. Press Release No. 2016-277, U.S. Sec. & Exch. Comm'n, Teva Pharmaceutical Paying $519 Million to Settle FCPA Charges (Dec. 22, 2016), www.sec.gov/news/pressrelease/2016-277.html.

76. Press Release 2018-174, U.S. Sec. & Exch. Comm'n, Sanofi Charged with FCPA Violations (Sept. 4, 2018), www.sec.gov/news/press-release/2018-174.

77. Even beyond the scope of the FCPA, companies will continue to face enforcement actions and suits in the United States stemming from relationships with foreign officials abroad. For example, in July 2018, the Justice Department instituted an investigation into various major drug and medical device companies alleged to have won contracts with the Iraqi Ministry of Health by also agreeing to provide free medical supplies and medicines. These companies, including AstraZeneca, General Electric, Johnson & Johnson, Pfizer, and Roche Holdings A.G., have also been the subjects of a lawsuit filed in federal court in October of 2017 on behalf of members of the American military who were injured or killed in Iraq between 2005 and 2009. *See* Gardiner Harris, *Justice Dept. Investigating Claims that Drug Companies Funded Terrorism in Iraq*, N.Y. TIMES (July 31, 2018), www.nytimes.com/2018/07/31/us/politics/drug-companies-iraq-terrorism.html.

### § 10:3.2 *Enforcement Actions Against Medical Device Manufacturers*

The DOJ has filed numerous proceedings against medical device manufacturers for adulterated and misbranded devices, including actions charging that manufacturers have promoted medical devices for off-label uses. Some of these actions have resulted in consent decrees, in which the manufacturer agrees to implement various remedial measures. Other actions have resulted in substantial civil and/or criminal fines or injunctions. Additionally, some actions enforcing the AKS against medical device manufacturers have resulted in substantial civil and/or criminal fines.

The relationships between medical device manufacturers and physicians require close collaboration, which can give rise to liability under the anti-kickback statute. As one federal prosecutor has pointed out, however, device manufacturers rely on physicians to "develop and test their products and report back on what works and what does not work."[78] As a result, this prosecutor acknowledged, "the interactions between device makers and physicians, to a degree, may be more appropriate than those between doctors and drugmakers," and accordingly device manufacturers may be treated differently in charging decisions.

A few prominent examples of enforcement actions include the following:

(1) In March 2019, Covidien LP, a medical device provider, agreed to pay $17.5 million to resolve allegations that it provided free or discounted practice development and market development support to physicians located in California and Florida to induce the referral or purchases of Covidien's radiofrequency vein ablation catheters;[79]

(2) A March 2018 civil settlement requiring Alere to pay $33.2 million to settle FCA allegations that the company had knowingly sold materially unreliable point-of-care diagnostic testing

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78. *BNA's Health Care Fraud Report: Federal Prosecutors Say Device Makers Face Different Issues Than Pharma Industry*, 13 Health Care Fraud Rep. (BNA) 500, at *1 (July 1, 2009) (prosecutor's remarks were in an unofficial capacity).

79. *See* Press Release No. 19-210, U.S. Dep't of Justice, Covidien to Pay Over $17 Million to the United States for Allegedly Providing Illegal Remuneration in the Form of Practice and Market Development Support to Physicians (Mar. 11, 2019), www.justice.gov/opa/pr/covidien-pay-over-17-million-united-states-allegedly-providing-illegal-remuneration-form.

devises, causing hospitals to submit false claims to Medicare, Medicaid, and other federal healthcare programs;[80]

(3) A March 2016 criminal penalties and civil settlement requiring Olympus Corp. to pay $646 million related to allegations that it won new business and rewarded sales by giving doctors and hospitals kickbacks in the form of consulting payments, foreign travel, lavish meals, grants and free equipment;[81]

(4) A December 2014 criminal penalties and civil settlement requiring OtisMed Corporation to pay more than $80 million and to be excluded from participating in all federal healthcare programs for a period of twenty years in regard to admissions that the company intentionally distributed knee replacement surgery cutting guides after their application for market clearance had been rejected by the FDA;[82]

(5) A November 2012 civil settlement involving Blackstone Medical (a subsidiary of Orthofix) to pay $30 million and enter into a CIA to resolve allegations that it paid kickbacks to spinal surgeons in a number of forms, including sham consulting agreements, sham royalty arrangements, sham research grants, travel, and entertainment;[83]

(6) A 2011 civil settlement involving Medtronic Inc. to pay $23.5 million to resolve allegations that it had violated the FCA by providing kickbacks through post-market studies and device

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80. Press Release No. 18-353, Alere to Pay U.S. $33.2 Million to Settle False Claims Act Allegations Relating to Unreliable Diagnostic Testing Devices (Mar. 23, 2018), www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic.

81. Press Release No. 16-234, U.S. Dep't of Justice, Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America (Mar. 1, 2016), www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals.

82. Press Release No. 14-428, U.S. Dep't of Justice, Otismed Corporation and Former CEO Plead Guilty to Distributing FDA-Rejected Cutting Guides for Knee Replacement Surgeries (Dec. 8, 2014), www.justice.gov/usao-nj/pr/otismed-corporation-and-former-ceo-plead-guilty-distributing-fda-rejected-cutting-guides.

83. Press Release No. 12-1309, U.S. Dep't of Justice, Orthofix Subsidiary, Blackstone Medical, Pays U.S. $30 Million to Settle False Claims Act Allegations (Nov. 2, 2012), www.justice.gov/opa/pr/2012/November/12-civ-1309.html.

registries to physicians so that they would implant its pacemakers and defibrillators;[84]

(7) A 2011 conviction of Guidant LLC, a wholly owned subsidiary of Boston Scientific Corporation, relating to its withholding of information from the FDA about failures of three models of implantable cardioverter defibrillators, for which the company was required to pay more than $296 million in fines and forfeiture and was sentenced to three years of probation;[85] and

(8) A 2010 settlement by Synthes, Inc. and Norian Corporation to resolve criminal and civil charges relating to claims that the companies conducted unauthorized clinical trials involving a bone cement, in which the companies paid $23.6 million.[86] In connection with the settlement, Synthes was required to sell Norian's assets pursuant to a divestiture agreement to avoid having Norian excluded by the OIG.[87]

Just as pharmaceutical companies have become frequent targets of FCPA enforcement actions, so too have medical device companies. For example, in 2012, Biomet, Inc. paid $22 million to settle charges

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84. Press Release No. 11-1623, U.S. Dep't of Justice, Minnesota-Based Medtronic Inc. Pays US $23.5 Million to Settle Claims That Company Paid Kickbacks to Physicians (Dec. 12, 2011), www.justice.gov/opa/pr/2011/December/11-civ-1623.html.

85. Press Release No. 11-035, U.S. Dep't of Justice, Medical Device Manufacturer Guidant Sentenced for Failure to Report Defibrillator Safety Problems to FDA (Jan. 12, 2011), www.justice.gov/opa/pr/2011/January/11-civ-035.html.

86. Press Release, U.S. Attorney's Office, E. Dist. of Pa., International Medical Device Maker Agrees to Plead Guilty in Connection with Shipments of Adulterated and Misbranded Bone Cement Products As Part of Unlawful Clinical Trial (Oct. 4, 2010), www.justice.gov/archive/usao/pae/News/2010/Oct/synthes,norian_release.pdf.

87. Other settlements involving medical device companies include: Press Release No. 09-350, U.S. Dep't of Justice, Quest Diagnostics to Pay U.S. $302 Million to Resolve Allegations That a Subsidiary Sold Misbranded Test Kits (Apr. 15, 2009), www.justice.gov/opa/pr/2009/April/09-civ-350.html (2009 settlement totaling $302 million in fines against Quest Diagnostics and its subsidiary); Press Release No. 08-1050, U.S. Dep't of Justice, Bayer Healthcare to Pay U.S. $97.5 Million to Settle Allegations of Paying Kickbacks to Diabetic Suppliers (Nov. 25, 2008), www.usdoj.gov/opa/pr/2008/November/08-civ-1050.html ($97.5 million in civil fines against Bayer HealthCare LLC in 2008); Maureen A. Ruane, Michael T.G. Long & Syrion A. Jack, *An Ounce of Prevention: Lessons Learned from Recent Enforcement Actions in the Pharmaceutical and Medical Device Industry*, 14-7 MEALEY'S EMERG. DRUGS & DEVICES 28 (Apr. 2, 2009) ($311 million in civil and criminal fines in 2006 against manufacturers of hip and knee surgical implants).

that it bribed doctors in Argentina, Brazil, and China.[88] As another example, in 2013, Stryker Corporation entered into a $13 million settlement to resolve allegations that its subsidiaries bribed healthcare professions and other government-employed officials in Argentina, Greece, Mexico, Poland, and Romania.[89]

### § 10:3.3 Individual Accountability

In connection with its enforcement efforts against companies, the government has increasingly targeted individuals at various corporate levels for violations ranging from misbranding under the FDCA to wire fraud and obstruction of justice. For instance, in 2008, the former CEO of InterMune, W. Scott Harkonen, M.D., was indicted on two felony counts, under the federal wire fraud statute[90] and the FDCA's misbranding statute,[91] for his role in the creation and dissemination of an allegedly false and misleading press release about the efficacy of InterMune's drug Actimmune for an off-label use. In 2009, Harkonen was convicted on the felony wire fraud count but acquitted on the misbranding count.[92] In 2010, a former vice president and associate general counsel at GSK was indicted on charges of obstructing an official proceeding, concealing and falsifying documents, and making false statements to the FDA, in connection with the FDA's investigation of GSK's alleged off-label promotional practices. The indictment alleged that the former GSK lawyer falsely denied to the FDA that the company had promoted a GSK drug for off-label uses, despite her knowledge of company-sponsored programs in which the drug was promoted for unapproved uses. The indictment also alleged that she failed to disclose to the FDA certain materials that showed the company had engaged in off-label promotional practices, despite the FDA's request for such materials.[93] In May 2011, at the conclusion

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88. Press Release No. 2012-50, U.S. Sec. & Exch. Comm'n, SEC Charges Medical Device Company Biomet with Foreign Bribery (Mar. 26, 2012), www.sec.gov/News/PressRelease/Detail/PressRelease/1365171487958#.UumLn_vhJ8E.
89. Press Release No. 2012-50, U.S. Sec. & Exch. Comm'n, SEC Charges Stryker Corporation with FCPA Violations (Oct. 24, 2013), www.sec.gov/News/PressRelease/Detail/PressRelease/1370540044262#.UumMbvvhJ8E.
90. 18 U.S.C. § 1343.
91. 21 U.S.C. § 352.
92. Press Release No. 08-164, Dep't of Justice, W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud (Sept. 29, 2009), www.fbi.gov/sanfrancisco/press-releases/2009/sf092909.htm.
93. Press Release No. 10-1266, Dep't of Justice, Pharmaceutical Company Lawyer Charged with Obstruction and Making False Statements (Nov. 9, 2010), www.justice.gov/opa/pr/pharmaceutical-company-lawyer-charged-obstruction-and-making-false-statements.

of the government's case in chief, a federal judge dismissed the case, finding that, among other things, the GSK attorney had relied on the advice of outside counsel.[94]

Under the FDCA, a misdemeanor charge requires no proof of "the conventional requirement for criminal conduct—awareness of some wrongdoing."[95] In 2007, the DOJ began to utilize this provision, also known as the *Park* or "Responsible Corporate Officer" doctrine, because it permits a responsible corporate officer to be found liable for a misbranding violation under the FDCA if he "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."[96] That year, the DOJ obtained plea agreements from three top executives of Purdue Frederick Company for misdemeanor misbranding violations of the FDCA relating to the marketing of the company's drug OxyContin. The executives agreed to pay criminal fines and civil penalties of over $34.5 million and were also sentenced to a period of probation.[97] In an agreed-upon statement of facts relating to the plea, the government conceded that the three executives were not involved with the violations at issue and had no knowledge of the misconduct.[98] Additionally, in 2009, four senior executives of Synthes, Inc., a medical device company, and its subsidiary, Norian Corporation, pled guilty to charges under the FDCA for their alleged involvement in conducting clinical trials of an unapproved use of a medical device without the authorization of the FDA and in spite of a warning on the product's label against this use and serious concerns about the safety of the product for that unapproved use.[99] Each of the executives was subsequently sentenced to

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94. David Voreacos & Jef Feeley, *Ex-Glaxo Lawyer Wins Acquittal from Federal Judge at Obstruction Trial*, BLOOMBERG (May 10, 2011), www.bloomberg.com/news/2011-05-10/former-glaxo-lawyer-wins-acquittal-by-judge-at-maryland-obstruction-trial.html.
95. United States v. Dotterweich, 320 U.S. 277, 281 (1943); *see also* United States v. Park, 421 U.S. 658 (1975).
96. United States v. Park, 421 U.S. 658, 673–74 (1975).
97. *The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding OxyContin; Will Pay over $600 Million*, PR NEWSWIRE (May 10, 2007), www.prnewswire.com/news-releases/the-purdue-frederick-company-inc-and-top-executives-plead-guilty-to-misbranding-oxycontin-will-pay-over-600-million-58092727.html.
98. Plea Agreement, at Attachment B, "Agreed Statement of Facts" ¶ 46, United States v. Purdue Frederick Co., No. 07CR00029, 2007 WL 1423895 (W.D. Va. May 9, 2007).
99. Indictment, United States v. Norian Corp., Synthes, Inc., Michael D. Huggins, Thomas B. Higgins, Richard E. Bohner & John J. Walsh, No. 09CR00403, 2009 WL 1850315 (E.D. Pa. June 16, 2009).

time in prison.[100] Similarly, in 2011, KV Pharmaceuticals' CEO and Chairman of the Board pled guilty to two misdemeanor violations of the FDCA under the Responsible Corporate Officer doctrine in connection with the company's shipping interstate oversized tablets of a pain killer containing more active ingredients than indicated in the label. He was ordered to pay a $1 million fine, forfeit $900,000, and serve a thirty-day jail sentence.[101]

The government's decision to pursue and obtain criminal pleas from individuals for strict liability offenses represents a substantial expansion of risk in FDCA criminal investigations. Indeed, the FDA announced in 2010 that an internal committee had recommended that the FDA and OCI "increase the appropriate use of misdemeanor prosecutions, which allows responsible corporate officials to be held accountable and is a valuable enforcement tool."[102] However, since this time, the government, apart from a few notable exceptions, has not pursued many cases against individuals under a *Park* theory of liability.

The FDA has also issued guidance on when it will recommend a misdemeanor prosecution against a corporate official under the *Park* doctrine.[103] Among the factors that it will consider are "the

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100. Two Synthes executives were sentenced to nine months' imprisonment, another to eight months' imprisonment, and the fourth to five months' imprisonment. Peter Loftus, *Former Synthes Officers Receive Prison Sentences*, WALL ST. J. (Nov. 22, 2011), http://online.wsj.com/article/SB10001424052970204443404577052173679627572.html; Peter Loftus, *Fourth Ex-Synthes Officer Sentenced*, WALL ST. J. (Dec. 14, 2011), http://online.wsj.com/article/SB10001424052970203518404577096753820444484.html.

101. Press Release No. 11-306, U.S. Dep't of Justice, Former Drug Company Executive Pleads Guilty in Oversized Drug Tablets Case (Mar. 10, 2011), www.justice.gov/opa/pr/former-drug-company-executive-pleads-guilty-oversized-drug-tablets-case. A subsidiary of KV Pharmaceutical, Ethex Corporation, also "pleaded guilty to two felony offenses as a result of its failure to file required reports with the FDA concerning certain oversized drug tablets." *Id.* The court ordered Ethex to pay Medicare $1,762,368 in restitution, Medicaid $573,000, and the subsidiary was fined $23,437,382. It also forfeited $1,796,171. *See* March 10, 2011: *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*, U.S. FOOD & DRUG ADMIN. (Jan. 28, 2015), www.fda.gov/ICECI/CriminalInvestigations/ucm246881.htm.

102. Alicia Mundy, *FDA Criminal Division to Increase Prosecutions*, WALL ST. J. (Mar. 4, 2010), http://online.wsj.com/news/articles/SB10001424052748703862704575099942109582112.

103. FDA, REGULATORY PROCEDURES MANUAL § 6-5-3 (Jan. 2011), www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm.

individual's position in the company and relationship to the violation, and whether the official had the authority to correct or prevent the violation."[104] In addition, "[k]nowledge 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."[105]

The government's emphasis on individual liability continued with the issuance of the "Yates Memo" in September 2015 as well as its modifications announced in November 2018. The memorandum, formally titled "Individual Accountability for Corporate Wrongdoing," was authored by former Deputy Attorney General Sally Quillian Yates.[106] It provides guidance to federal prosecutors as to "steps that should be taken in any investigation of corporate misconduct" to "identify culpable individuals at all levels in corporate cases."[107] The memo focuses on individual accountability in order to "deter[ ] future illegal activity," "incentivize[ ] changes in corporate behavior," "ensure[ ] that the proper parties are held responsible for their actions" and "promote[ ] the public's confidence in our justice system."[108] Notably, the memo reflects a desire to hold individuals accountable in both civil and criminal investigations of corporate wrongdoing.[109] Although the DOJ recognizes the "substantial challenges" in pursuing cases against individuals, especially in establishing knowledge and criminal intent of high-level executives who may be insulated from day-to-day activities, the memo exhorts both civil and criminal prosecutors to think early and often about identifying culpable individuals and bringing cases.[110] The memo warns that a corporation that fails to provide all relevant facts about individuals involved in misconduct will be ineligible for any cooperation credit.[111]

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104. *Id*.
105. *Id*.
106. Memorandum from Sally Quillian Yates, Deputy Att'y Gen., U.S. Dep't of Justice, Individual Accountability for Corporate Wrongdoing (Sept. 9, 2015) [hereinafter Yates Memo], www.justice.gov/dag/file/769036/download. Modifications to the Yates Memo were announced by former Deputy Attorney General Rod Rosenstein in November 2018. See Press Release, U.S. Dep't of Justice, Deputy Attorney General Rod J. Rosenstein Delivers Remarks at the American Conference Institute's 35th International Conference on the Foreign Corrupt Practices Act (Nov. 29, 2018), www.justice.gov/opa/speech/deputy-attorney-general-rod-j-rosenstein-delivers-remarks-american-conference-institute-0.
107. Yates Memo at 2.
108. *Id*.
109. *See generally id.*
110. *See id*. at 2.
111. *Id*. at 3. Similarly, in May 2019, the DOJ released guidance explaining the manner in which it awards credit to defendants who cooperate

As the Yates Memo acknowledges, pursuing these cases can prove difficult.[112] For example, in 2014, a company called Vascular Solutions Inc. (VSI) and its founder and CEO, Howard Root, were each charged with one count of conspiracy and four counts of misbranding in connection with the alleged off-label promotion of a medical device made by the company.[113] In February 2016, after a trial, the jury found both the company and Root not guilty on all charges.[114]

Finally, in July 2016, a jury in Massachusetts found two former executives of medical device company Acclarent Inc.—the former CEO, William Facteau, and Vice President of Sales, Patrick Fabian—not guilty of ten felony counts under the misbranding and adulteration provisions of the FDCA.[115] They were, however, convicted on ten misdemeanor FDCA violations for misbranding and adulteration under the *Park* doctrine.[116] Thus, although *Facteau* illustrates the difficulties of obtaining individual accountability for corporate wrongdoing (particularly for a felony conviction that requires proof of the defendant's intent), its greater significance arises from the misdemeanor convictions premised on *Park* liability, as they suggest that *Park* remains a potential backstop for government prosecutors to secure convictions of pharmaceutical and medical device executives even where that executive had no direct involvement in the conduct at issue and there was no evidence of criminal intent.

Outside of the *Park* context, the government has also pursued individuals associated with companies that have reached settlements with the government under other legal theories. For example, in connection with the October 2015 Warner Chilcott settlement (discussed above), the company's former president, W. Carl Reichel, was indicted

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with the DOJ during a False Claims Act investigation and setting forth a number of factors that it would consider in determining whether to give a defendant cooperation credit. *See* Press Release No. 19-478, U.S. Dep't of Justice, Department of Justice Issues Guidance on False Claims Act Matters and Updates Justice Manual (May 7, 2019), www.justice.gov/opa/pr/department-justice-issues-guidance-false-claims-act-matters-and-updates-justice-manual.

112. *Id*. at 2.

113. *See* USA v. Vascular Sols., Inc., No. 5:14CR00926, 2014 WL 13307688 (W.D. Tex. Nov. 13, 2014).

114. *See* USA v. Vascular Sols., Inc., No. 5:14CR00926, 2016 WL 80265 (W.D. Tex. Feb. 26, 2016).

115. United States v. Facteau, No. 1:15-cr-10076, Dkt. No. 432 (D. Mass. July 20, 2016).

116. *Id*.

on one count of conspiracy to violate the AKS related to the company's speaker programs and medical education events.[117] Although three of the company's sales managers pled guilty to various criminal violations,[118] Reichel went to trial. In June 2016, after a one-month trial, he was acquitted after less than one day of jury deliberations.[119]

In addition, in the Insys settlement described above, the government prosecuted company executives, employees and healthcare providers for, among other things, paying and receiving kickbacks to prescribe Subsys, and has obtained numerous guilty pleas and convictions of these individuals.[120]

### § 10:3.4 Sorrell, Caronia, *and First Amendment Challenges*

Although the breadth of the prohibitions on off-label promotion has long been attacked as unconstitutional,[121] these challenges picked up speed with the Supreme Court's decision in *Sorrell v. IMS Health*.[122] In *Sorrell*, the Supreme Court held that a state prohibition on the sale, use, and disclosure of pharmacy data identifying prescribers, which pharmaceutical companies have traditionally used for marketing purposes, should be scrutinized under the heightened scrutiny standard and, under that standard, failed to pass constitutional muster. The

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117. *See* United States v. W. Carl Reichel, No. 1:15CR10324, 2015 WL 6759909 (D. Mass. Oct. 28, 2015).

118. *See* Press Release, U.S. Attorney's Office. Dist. Mass., Former Pharma Company Manager Pleads Guilty to Criminal HIPAA Violation (Nov. 12, 2015), www.justice.gov/usao-ma/pr/former-pharma-company-manager-pleads-guilty-criminal-hipaa-violation.

119. *See* United States v. Reichel, No. 1:15CR10324 (D. Mass. June 17, 2016).

120. *See* Press Release, U.S. Dep't of Justice, Insys Therapeutics Agrees to Enter into $225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019), www.justice.gov/usao-ma/pr/insys-therapeutics-agrees-enter-225-million-global-resolution-criminal-and-civil.

121. *See* Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) (First Amendment), *vacated on procedural grounds sub nom.* Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Allergan, Inc. v. United States, No. 09-1879 (D.D.C. Oct. 1, 2009) (alleging violation of Allergan's First Amendment right to provide truthful information to the medical community about off-label Botox® uses). As part of its settlement with the government in September 2010, Allergan agreed not to pursue its First Amendment challenge. Press Release No. 10-988, U.S. Dep't of Justice, Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion of Botox® (Sept. 1, 2010), www.justice.gov/opa/pr/2010/September/10-civ-988.html.

122. Sorrell v. IMS Health, Inc., 564 U.S. 552 (2011).

*Sorrell* decision sparked a number of challenges[123] that the prohibitions on off-label promotion, including felony misbranding, similarly impinge on First Amendment rights.

In December 2012, in *United States v. Caronia*, the Second Circuit ruled on one such challenge. The court vacated the conviction of Alfred Caronia, a pharmaceutical sales representative for Orphan Medical, Inc. (later acquired by Jazz Pharmaceutical) who had been found guilty of conspiring to introduce a misbranded drug in violation of the FDCA. The court held that his conviction, premised solely on his promotion of the drug Xyrem for off-label use, violated his free speech rights under the First Amendment.[124] In assessing Caronia's conviction under the First Amendment, the Second Circuit relied on *Sorrell*, applying the same analysis.[125] Significantly, the Second Circuit stated: "We construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs."[126] The court concluded that the government "cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the

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123. *See, e.g.*, United States v. Higgins, No. 09-403-4, 2011 WL 6088576, at *12–13 (E.D. Pa. Dec. 7, 2011) (rejecting *Sorrell* arguments as untimely and finding that First Amendment protections do not attach where a defendant "personally participated in an elaborate, carefully implemented, scheme to deliver adulterated and misbranded medical devices to physicians for ultimate use on unknowing, and completely uninformed, medically frail patients"); Brief for Defendant-Appellant at 43–44, United States v. Harkonen, No. 11-10209 (9th Cir. Oct. 28, 2011) (arguing that *Sorrell* bars prosecutions and convictions arising from restrictions of scientific or commercial opinions); Complaint, Par Pharm., Inc. v. United States, No. 11-01820 (D.D.C. Oct. 14, 2011) (alleging violation of Par Pharmaceutical's First Amendment right to provide truthful information to the medical community about on-label uses of its anorexia and unexplained weight-loss drug Megace® ES). In March 2013, it was announced that Par Pharmaceutical had pled guilty to charges related to the promotion of its prescription drug Megace ES and had agreed to criminal and civil forfeitures totaling $45 million. Press Release No. 13-270, U.S. Dep't 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), www.justice.gov/opa/pr/par-pharmaceuticals-pleads-guilty-and-agrees-pay-45-million-resolve-civil-and-criminal. As part of this settlement, Par Pharmaceutical agreed to dismiss its First Amendment claims. U.S. Dep't of Justice, Plea Agreement, Par Pharm., Inc. v. United States (Jan. 3, 2013), http://pharmarisc.com/wp-content/uploads/2013/03/Par-Pharmaceutical-Plea%20Agreement-1.pdf.

124. United States v. Caronia, 703 F.3d 149 (2d Cir. 2012).

125. *Id*. at 161–62.

126. *Id*. at 168.

lawful, off-label use of an FDA-approved drug."[127] The majority holding sparked a strong dissenting opinion, which argued that if pharmaceutical manufacturers were permitted to promote their products off-label, they would have little incentive to obtain FDA approval for those uses.[128]

Following the decision, the government decided not to seek rehearing en banc, and the FDA issued a statement explaining that it did not believe the decision would affect its enforcement of the misbranding provisions of the FDCA.[129]

In that regard, the government appears to view the *Caronia* decision as one of limited relevance, primarily because the holding explicitly places off-label promotion marked by non-truthful or misleading statements as outside its ambit. Accordingly, in future off-label investigations, in contrast to how it tried the *Caronia* case, the government could focus on evidence showing that false and misleading statements were made in the course of the promotional campaign (by overstating efficacy or minimizing safety issues, for example) that render *Caronia* inapplicable.

Thus, although *Caronia* is a significant decision, it has not significantly deterred the government from bringing future off-label cases. One signal that DOJ's off-label enforcement activities did not "radically chang[e]" as a result of *Caronia*, as one DOJ official put it, is that just sixteen days after the *Caronia* decision was announced, biotechnology company Amgen pled guilty—in the Eastern District of New York, which had also prosecuted Caronia—and agreed to pay $762 million to resolve DOJ's investigation relating to Amgen's alleged off-label promotion of Aranesp.

In addition, the government has taken the position that *Caronia* is inapplicable to cases litigated under the civil FCA.[130] In a statement of interest it filed in *United States ex rel. Cestra v. Cephalon*, a case in which it had declined to intervene, the United States asserted that *Caronia* "does not preclude a cause of action under the False Claims Act based on a manufacturer's off-label marketing of a prescription drug causing the submission of false claims to federal health care programs."[131] The United States distinguished the FDCA from the FCA, arguing that the latter prohibits any *conduct* that causes the

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127. *Id*. at 169.
128. *Id*. at 178.
129. Ed Silverman, *FDA Declines to Pursue Hearing in Free Speech Case*, PHARMALOT PHARMA BLOG (Jan. 22, 2013), www.investorvillage.com/smbd.asp?mb=2885&mn=73903&pt=msg&mid=12490063.
130. Statement of Interest of U.S.A., United States *ex rel.* Cestra v. Cephalon, Inc., No. 1:10-cv-06457 (S.D.N.Y. Nov. 7, 2013).
131. *Id*. at 1.

submission of false claims to the government, which include any claim for a use not approved by the FDA or supported by a compendium listing.[132] According to the government, even if that conduct is carried out through truthful speech—the same speech that *Caronia* holds may be constitutionally protected under the FDCA—FCA liability could still attach.[133]

In 2015, however, two pharmaceutical companies sued the FDA over the FDA's off-label marketing restrictions—and both companies achieved a successful result. In May 2015, Amarin Pharma sued the FDA, alleging that the FDA's restrictions on promoting drugs for unapproved uses violates the company's First Amendment rights, and arguing that it should be able to promote a product for uses for which it has not been approved so long as that promotion is truthful and non-misleading.[134] In connection with its complaint, Amarin filed a motion seeking a preliminary injunction. In August 2015, a judge in the district court for the Southern District of New York granted a preliminary injunction for Amarin precluding the FDA from prosecuting Amarin for truthful and non-misleading off-label promotion.[135] Of most significance, the judge rejected the government's argument that the Second Circuit's holding in *Caronia* was a "fact-bound" decision limited to the issues in that case. Instead, the judge held that *Caronia* stands for the proposition that the government "may *not* bring such an action based on truthful promotional speech alone, consistent with the First Amendment."[136] Following that decision, the case was stayed while the parties discussed a settlement. In March 2016, the case was settled, with the FDA agreeing to be bound by the Court's decision allowing Amarin to engage in truthful and non-misleading off-label speech and agreeing that "under *Caronia*, such speech may not form the basis of a prosecution for misbranding."[137]

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132. *Id*. at 2, 5–6.
133. *Id*. at 6–7. In June 2015, the Eastern District of Pennsylvania denied Cephalon's motion to dismiss. With respect to Cephalon's First Amendment argument, the court found that because the relator had alleged that Cephalon's off-label promotion was false and misleading, the question of First Amendment protection could not properly be disposed of at the motion to dismiss stage. *See* Memorandum of Decision, United States *ex rel.* Cestra v. Cephalon, Inc., No. 14-1842, 2015 WL 3498761, at *12 (E.D. Pa. June 3, 2015).
134. Complaint, Amarin Pharma, Inc. v. U.S. Food & Drug Admin., No. 1:15-cv-03588 (S.D.N.Y. May 7, 2015).
135. Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196 (S.D.N.Y. 2015).
136. *Id*. at 224.
137. *Id*. at 237.

Following in the wake of Amarin's successful preliminary injunction against the FDA, in September 2015, Pacira Pharmaceuticals, Inc. filed a case against the FDA, also in the Southern District of New York, seeking a preliminary injunction.[138] Pacira sought to resume promotion of its drug Exparel, which was approved to treat post-surgical pain, as it did before it received a 2014 FDA Warning Letter that it argued attempted to limit Exparel's indication to use in two specific types of surgery. Citing *Caronia* and *Amarin*, Pacira argued that the First Amendment protects the dissemination of truthful and non-misleading information concerning uses of Exparel in patients who have undergone surgeries other than the two types of surgery for which the company conducted studies to get the drug approved, even if off-label.[139] In October 2015, the FDA quietly "unpublished" the Warning Letter at issue.[140] The case was stayed while the parties engaged in settlement discussions, and in December 2015, the case was settled, with the FDA "confirming" that Pacira's view of Exparel's indication was correct and supplementing Exparel's label to make that clear.[141]

In addition, in the case against VSI and its CEO, discussed above, the *Caronia* and *Amarin* decisions were at issue, with pretrial briefing focusing on how the First Amendment and the decisions that extended its protections to include truthful, non-misleading speech about off-label uses applied to the allegations regarding off-label promotion against VSI and Root.[142] The court instructed the jury that if it found that "VSI's promotional speech to doctors was solely truthful and not misleading," that could not form the basis for a misbranding conviction.[143] As noted above, both VSI and Root were acquitted,

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138. *See* Pacira Pharm., Inc. v. U.S. Food & Drug Admin., No. 1:15-cv-07055, 2015 WL 5256628 (S.D.N.Y. Sept. 8, 2015).

139. *See generally* Pacira Pharm., Inc. v. U.S. Food & Drug Admin., No. 1:15-cv-07055-RA, 2015 WL 6865944 (S.D.N.Y. Sept. 9, 2015).

140. Jeff Overley, *FDA Removes Pacira Warning Letter Amid Free Speech Suit*, LAW360 (Oct. 16, 2015, 8:40 PM ET), www.law360.com/articles/714740/fda-removes-pacira-warning-letter-amid-free-speech-suit.

141. *See generally* Pacira Pharm., Inc. v. U.S. Food & Drug Admin., No. 1:15-cv-07055, 2015 WL 9499516 (S.D.N.Y. Dec. 15, 2015).

142. *See generally* USA v. Vascular Sols., Inc., No. SA-14-CR-926, 2016 WL 806240 (W.D. Tex. Jan. 12, 2016); 2016 WL 806257 (W.D. Tex. Jan. 15, 2016); 2016 WL 806233 (W.D. Tex. Jan. 18, 2016); 2016 WL 806255 (W.D. Tex. Jan. 19, 2016); 2016 WL 806242 (W.D. Tex. Jan. 19, 2016); 2016 WL 806239 (W.D. Tex. Jan. 19, 2016); 2016 WL 806243 (W.D. Tex. Jan. 25, 2016).

143. *See* Final Jury Instructions, USA v. Vascular Sols., Inc., No. 5:14-CR-00926, 2016 WL 1743175 (W.D. Tex. Feb. 25, 2016).

providing yet another victory to pharmaceutical and medical device manufacturers in these types of cases.[144]

A similar First Amendment argument was made in *Facteau*, discussed above, by defendants' lawyers, resulting in the issuance of a similar jury instruction.[145] The court also cautioned the jury, however, that "[t]ruthful, non-misleading speech . . . can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent."[146] This instruction is significant as it addressed a question that the *Caronia* court did not have to resolve, namely, whether a misbranding conviction could be premised on truthful off-label speech if that speech is used to evidence intent to misbrand.

In addition, for several years, the FDA has been suggesting it would issue guidance regarding the permissible scope of manufacturer discussions of off-label uses, but to date it has not done so. In November 2016, the FDA held a hearing on "Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products."[147] During the two-day hearing, the FDA heard from nearly sixty speakers, with slightly over half generally in favor of providing additional clarity and flexibility for manufacturers to engage in off-label scientific and medical communications and slightly less than half generally in support of status quo or more rigid restrictions. In January 2017, the FDA issued a memorandum regarding "Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products," essentially defending its current position with respect to manufacturer communications of off-label information.[148]

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144. *See* Jury Verdict, USA v. Vascular Sols., Inc., No. 5:14-CR-00926 (W.D. Tex. Feb. 26, 2016).
145. United States v. Facteau, No. 1:15-cr-10076, Dkt. No. 436 (D. Mass. July 15, 2016).
146. *Id*.
147. U.S. FOOD & DRUG ADMIN., Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, www.fda.gov/newsevents/meetingsconferencesworkshops/ucm489499.htm (last visited June 26, 2017).
148. Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, 82 Fed. Reg. 6367 (proposed Jan. 19, 2017) (to be codified at 21 C.F.R. pt. 15).

## § 10:4 FDA Warning and Untitled Letters to Pharmaceutical Companies Regarding Promotional Materials

The FDCA requires that any promotional material produced by or on behalf of a drug company that makes claims for a product also present the important risks and limitations of that product.[149] Promotional materials include, among other things, television and print advertisements, brochures, detailing pieces, exhibits at conventions, Internet websites, and even oral statements by company representatives.[150] Promotional claims that are inconsistent with and contrary to the FDA-approved product label are considered false and/or misleading.

The FDA's Office of Prescription Drug Promotion (OPDP), formerly known as the Division of Drug Marketing, Advertising, and Communications (DDMAC), is responsible for reviewing promotional materials to ensure that both broad promotional themes and individual promotional statements are not false or misleading and are consistent with the drug's label.[151] Drug companies are required to submit each new promotional piece to OPDP, accompanied by FDA Form 2253, at the time of the piece's initial public dissemination.[152]

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149. *See* section 502(n) of the FDCA (codified at 21 U.S.C. § 352(n)) and the FDA's implementing regulation, 21 C.F.R. § 202.1.

150. *See* U.S. Food & Drug Admin., Guidance for Industry: Presenting Risk Information in Prescription Drug and Medical Device Promotion (May 2009) [hereinafter Guidance for Industry], at 3 n.9, www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf.

151. *See About FDA: The Office of Prescription Drug Promotion (OPDP)*, U.S. FOOD & DRUG ADMIN. (July 7, 2014), www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090142.htm.

152. *See* 21 C.F.R. § 314.81(b)(3). A Draft Guidance recently issued by the FDA creates an exception to this rule for "interactive promotional media," such as blogs and social networking sites. For the "interactive promotional media" component of a promotional piece, companies may submit an updated listing on Form 2253 once a month, instead of at the time of each real-time communication. *See* U.S. Food & Drug Admin., Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics (Jan. 2014), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf [hereinafter Draft Guidance: Interactive Promotional Media]. Drug companies also may voluntarily submit materials prior to initial dissemination for review and comment by OPDP. Letters from OPDP to the drug company providing pre-dissemination comments are "advisory" letters and do not assure the company that

OPDP can identify a violation through either its review processes or its monitoring and surveillance activities.[153] If OPDP identifies a violation, it decides whether to issue an "Untitled Letter" (also known as a "Notice of Violation Letter") or a "Warning Letter" to the drug company as a way to achieve voluntary compliance with the FDCA and the applicable regulations.[154] A Warning Letter is issued only for those violations deemed "significant" by the FDA, which "are those violations that may lead to enforcement action if not promptly and adequately corrected."[155] By contrast, an Untitled Letter is issued for violations that are not considered by OPDP to rise to that level.[156] Both Untitled Letters and Warning Letters cite the violation identified by OPDP and request that the drug company cease dissemination of the promotional materials at issue.[157] In a Warning Letter, however, OPDP usually takes the additional step of requesting corrective action that, if complied with by the drug company, should satisfactorily address the impact of the purportedly misleading communication.[158]

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its proposed piece is in compliance with the FDCA. Some direct-to-consumer TV ads are required to be submitted to FDA for review prior to the ad being disseminated. *See* U.S. Food & Drug Admin., Draft Guidance: Guidance for Industry Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program (Mar. 2012), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM295554.pdf.

153. Additionally, in 2010, the FDA announced its new "Bad Ad Campaign," which encourages healthcare professionals to report potentially misleading promotion. OPDP has issued several letters resulting from complaints filed through the program, including complaints about statements made by sales representatives to doctors, which had not usually been addressed by past letters.

154. *See* FDA, REGULATORY PROCEDURES MANUAL (Mar. 2010) [hereinafter REGULATORY PROCEDURES MANUAL], ch. 4, "Advisory Actions," § 4-1-1.5, www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf; *see also* U.S. GOV'T ACCOUNTABILITY OFFICE, Rep. No. GAO-08-835, PRESCRIPTION DRUGS: FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES, at 11, n.20 (July 2008) [hereinafter GAO Report], www.gao.gov/new.items/d08835.pdf.

155. REGULATORY PROCEDURES MANUAL, *supra* note 154, § 4-1-1; *see also id.* § 4-1-5 ("Centers should issue Warning Letters, not Untitled Letters, for promotional activities if the nature of the activity is such that the center would support further regulatory action.").

156. *Id.*; *see also* GAO Report, *supra* note 154, at 11.

157. *See id.* Typically, Warning Letters and Untitled Letters state that the company's promotional material "misbrands" the drug, in violation of the misbranding provisions of the FDCA, 21 U.S.C. § 352(f)(1) & (n), and applicable regulations, *e.g.*, 21 C.F.R. §§ 201.128, 202.1(e).

158. *Id*.

The issuance of an Untitled Letter or Warning Letter is not, by itself, considered an "enforcement action" by the FDA.[159] Rather, "it is [the FDA's] practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action," and "Warning Letters are issued to achieve voluntary compliance and to establish prior notice."[160] If, however, a drug company does not comply with the Warning Letter's request to take corrective action, then the FDA may bring an enforcement action against the company, which could lead to, for example, civil money penalties and/or a prosecution to achieve correction.[161]

Among the issues most frequently raised by OPDP in its recent Untitled Letters and Warning Letters are:

(1) omitting or minimizing risk information;

(2) overstating efficacy;

(3) misleading or unsubstantiated claims;

(4) broadening the indication;

(5) making unsubstantiated claims of superiority; and

(6) misbranding of an investigational drug.

In assessing whether all material information has been included in a promotional piece, OPDP looks at the four corners of the label and does not limit its analysis to any specific section. Instances in which OPDP may find even truthful statements to be problematic include when the promotional piece omits other material information needed to make the claims not misleading, the information provided is not clinically relevant, or statements about a patient's personal positive experience with the drug is not consistent with the product's label. When reviewing promotional materials, OPDP considers not only the textual claims, but also the inferences that might be drawn from the images.[162] OPDP generally finds it insufficient simply to state that a certain population has not been studied or to warn against a certain type of use, without also disclosing the consequences that may result from such use.

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159. *See* REGULATORY PROCEDURES MANUAL § 4-1-1, *supra* note 154.

160. *Id*.

161. *Id*. Even if a company takes corrective action in response to an Untitled Letter or Warning Letter that is sufficient to satisfy the FDA, the company's receipt of the letter may nevertheless result in other adverse consequences for the company, such as having the letter used as evidence against it in a products liability or False Claims Act suit.

162. *See generally* Guidance for Industry, *supra* note 150.

Many of the Warning Letters and Untitled Letters issued by OPDP in the last couple of years have involved promotional materials found on the Internet, such as websites, online banners, and sponsored links on Internet search engines. OPDP appears to impose the same requirements for online promotional materials as it does for traditional print materials insofar as it generally has not made special exceptions for Internet-based promotional materials despite the unique nature of the Internet and space limitations inherent in certain forms of Internet promotion. For example, OPDP has concluded that a sponsored link (which is the text of the hyperlink and the lines of accompanying text that appear when the name of a drug is run through an online search engine) that included statements about the product's indication must also include risk information, even though the sponsored link was a hyperlink to the product's website where the complete risk information could be found. As evidenced by several letters OPDP has issued regarding promotional materials on the Internet, OPDP has rejected a one-click rule (that is, it is not sufficient for all risk information to be even one click away from efficacy statements).

In 2014, FDA issued some of this much-anticipated "social media" guidance, addressing a drug company's responsibility for content on third-party websites and "user generated content" on its own website, which depends on the company's level of control over the content.[163]

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163. *See* Draft Guidance: Interactive Promotional Media, *supra* note 152. In particular, the draft guidance provides that if a company collaborates on or has the ability to edit or review content on a third-party site, the company is responsible for promotion on the site. If the company provides only financial support and has no other control or influence, it is not responsible for information posted on the third-party site. With respect to its own website, a company is responsible for content generated by its employees or agents acting on its behalf in promoting a product. Conversely, the company is generally not responsible for user-generated content that is truly independent of the company, even if posted on a company-owned or -controlled venue, as long as the user has no affiliation with the company and the company had no influence on the content. In June 2014, FDA issued draft guidance that permits a company, if it chooses to do so, to correct misinformation posted by an independent third party on social media, but requires that any such corrections be made to both negative and positive misinformation about the product in a particular forum. U.S. Food & Drug Admin., Draft Guidance for Industry: Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices (June 2014), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401079.pdf.

In June 2014, the FDA issued guidance on how to fulfill regulatory requirements when using tools associated with space limitations.[164]

In June 2018, the FDA issued two final guidance documents[165] that expand the scope of permissible communications by manufacturers with respect to: (i) communications "consistent with" a drug's label;[166] and (ii) communications of healthcare economic information (HCEI) to payors.[167] With respect to the latter, in December 2016, Congress passed the "21st Century Cures Act" which, inter alia, amends section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (21 U.S.C. § 352(a)) to help clarify and facilitate the dissemination of HCEI to payors, formulary committees and other similar entities and, in essence, broadens the definition of HCEI as well as the permissible audience that can receive this information.[168]

## § 10:5 Compliance Strategies

In the current climate of increased prosecution for healthcare fraud, the best defense is a good offense. Pharmaceutical companies

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164. *See* U.S. Food & Drug Admin., Draft Guidance for Industry: Internet/Social Media Platforms with Character Space Limitations—Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices (June 2014), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM401087.pdf. In that guidance, FDA sets forth guidelines for companies that choose to use social media platforms such as Twitter or "sponsored links" such as those on Google. In short, FDA will expect that companies that use these platforms present both benefit and risk information, with risk information being comparable in content and prominence to benefit information. Benefit information should be accurate, non-misleading and reveal material facts. Risk information should include the most serious risks associated with a product and should include a link to a more complete discussion of risk information (that is, a non-promotional website dedicated only to providing risk information).

165. The FDA issued these documents as draft guidance in June of 2017 before they were finalized in June 2018.

166. *See* U.S. Food & Drug Admin., Guidance for Industry: Medical Product Communications That Are Consistent with the FDA-Required Labeling—Questions and Answers (June 2018), www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537130.pdf.

167. *See* U.S. Food & Drug Admin., Guidance for Industry: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers (June 2018), www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf.

168. 21st Century Cures Act, Pub. L. No. 114-255, § 3037, 130 Stat. 1033, 1105 (2016).

now must have highly structured compliance programs to help prevent problematic conduct and put them in as good a position as possible to persuade prosecutors that any violations uncovered in an investigation are not systemic. The OIG has identified seven elements of a comprehensive compliance plan to thwart criminal activity:

- designation of a compliance officer;
- development and distribution of written standards of conduct, policies and procedures reflecting the company's commitment to compliance;
- development and implementation of regular, effective education and training;
- creation and maintenance of effective lines of communication between the compliance officer and all employees;
- use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;
- effective disciplinary action for those who have violated company policies and procedures; and
- development of policies and procedures for the investigation of identified instances of noncompliance or misconduct.[169]

In addition, companies should establish a protocol for handling possible wrongdoing, including disclosure to government agencies, if appropriate. The OIG has published a protocol on self-disclosure by healthcare providers.[170] The OIG emphasizes that, if a healthcare provider uncovers an "ongoing fraud scheme," the provider should contact the OIG instead of performing its own assessment because of the potential that an internal investigation may compromise the government's investigation.[171] Of course, the promptness and quality of a company's disclosure is a key element in DOJ's assessment under the Principles of Federal Prosecution of Business Organizations

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169. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (Jan. 29, 2014).

170. *See* Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,399–403 (Oct. 30, 1998); *see also* Office of Inspector Gen., An Open Letter to Health Care Providers (Apr. 15, 2008), http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf; Office of Inspector Gen., An Open Letter to Health Care Providers (Mar. 24, 2009), www.oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf.

171. Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. at 58,400.

(the "Principles") of whether to bring charges.[172] So too are the existence and adequacy of the corporation's compliance program and any other remedial actions taken by the corporation.

## § 10:6 Conclusion

The risk-reward calculus generally favors a negotiated disposition of criminal charges and civil claims against a drug or device manufacturer—provided, of course, that the manufacturer will not be excluded and the fines and penalties are not crippling.

Drug and medical device manufacturers are caught in criminal, regulatory, and civil crosshairs. Their options are few, if any, once a serious violation occurs and an investigation begins. Their best hope is to cooperate with the government and implement aggressive compliance measures.

In order to limit exposure, any target of an investigation should consider the directive that the Principles provides prosecutors determining whether to bring charges or negotiate plea or deferred prosecution agreements. In particular, the Principles look favorably on "the corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents." Similarly, "any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies" will weigh in the corporation's favor.[173]

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172. *See* U.S. Dep't of Justice, Principles of Federal Prosecution of Business Organizations, § 9-28.000-1300.

173. *Id*. For a detailed discussion of the Principles, see *supra* chapters 1 and 2.