THE REVIVAL OF THE RESPONSIBLE CORPORATE OFFICER DOCTRINE?

Joseph F. Savage, Jr., Esq.
Maren Klawiter, Esq.
Goodwin Procter, LLP
Boston, MA

In March 2010 the Food and Drug Administration ("FDA") announced its intention to put corporate executives in prison even when they had no knowledge of or participation in criminal wrongdoing by increasing misdemeanor prosecutions of “responsible corporate officers” ("RCOs") under the Park Doctrine.1 Eleven months later, the FDA released its “Special Procedures and Considerations for Park Doctrine Prosecutions,” embracing an expansive strict liability interpretation of the RCO doctrine arguably at odds with the standards established by the United States Supreme Court and contrary explicit representations made by the Department of Justice (“DOJ”) to the Supreme Court decades earlier in U.S. v. Park.2

While the FDA pronouncements were attention-getting and concerning, there actually have been few RCO charges and convictions despite the touted policy change. The gap between the FDA’s goals and the DOJ’s track record suggests that the DOJ may not share the FDA’s enthusiasm for this strict liability misdemeanor.

However, while the number of RCO prosecutions may not have skyrocketed, there does appear to be a trend toward harsher sentences, penalties, and collateral consequences, including potentially career-ending exclusion of corporate executives from HHS-administered programs pursued under a RCO theory. If an expansive application of the RCO doctrine does materialize, the harsh consequences – jail and debarment – which were not historically a genuine risk will likely precipitate an overdue constitutional challenge to the counterintuitive notion that one can go to jail or lose his or her livelihood without proof of personal, intentional wrongdoing.

RCO Liability: Dotterweich, Park and Their Progeny

The leading cases providing that a corporate officer who stands in a “responsible relation” to misconduct may be held criminally liable even without having played a direct role in the misconduct are U.S. v. Dotterweich and U.S. v. Park.3 In Dotterweich, the Buffalo Pharmacal Company, Inc. and Dotterweich, its president and general manager, were charged with misbranding drugs. Though Dotterweich had not personally shipped the drugs, he was responsible for his firm’s system of operations. Packing and shipping employees followed established company procedures, according to a government brief. The Supreme Court approved an instruction that the jury had only to find that Dotterweich “share[d] responsibility in the business process resulting in unlawful distribution.”4

In Park, Acme Markets, Inc. and its chief executive officer ("CEO") John Park were charged with adulterating food. The Supreme Court stated:

We cannot agree with the court of Appeals that it was incumbent upon the District Court to instruct the jury that the Government had the burden of establishing ‘wrongful action’ in the sense in which the Court of Appeals used that phrase…. [T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.5

Park’s defense was that he necessarily relied on subordinates because he was responsible for more than eight hundred stores, and had no reason to suspect his subordinates were failing to ensure compliance with the Federal Food, Drug, and Cosmetic Act (“FDCA”) of 1938.6 Park admitted, however, that he had the responsibility and the power to take whatever steps were necessary to ensure that the company’s system for handling sanitation problems worked in compliance with the FDCA.7 The Government introduced rebuttal evidence demonstrating that Park had received several warnings from the FDA about warehouse conditions, was therefore on notice that his system was not working properly, and thus did not justifiably rely on his subordinates.

Importantly, however, the Supreme Court did impose limits on strict liability under the FDCA, stating:

[The FDCA], in its criminal aspect, does not require that which is objectively impossible. The theory upon which responsible corporate agents are held criminally accountable for “causing” violations of the [FDCA] permits a claim that a defendant was “powerless” to prevent or correct the violation to be raised defensively at a trial on the merits.8

The DOJ recognized the “powerlessness” defense, as well, in its Park Brief, conceding that:

While the liability created by the [FDCA] is strict, it is not vicarious. The limits of the principle appear in its articulation: the corporate officer must stand in a responsible relation to the prohibited act; a claim that he is “powerless” may be raised defensively at a trial on the merits.9
Thus, it would seem clear that the Government cannot establish a prima facie case simply by proving someone holds a particular position in the company. It must prove that the corporate agent had the power to prevent or correct the violation and failed to do so.

Indeed, since Dotterweich all reported decisions convicting an individual as an RCO have involved proof beyond the defendant’s corporate position. For example, in U.S. v. Freed the Forest Service sent Freed, the incorporator and trustee of a campground, letters that the campground violated regulations; when conditions did not change, Freed was found guilty as a responsible corporate officer. Similarly, in U.S. v. Iverson, the court upheld a jury instruction that Iverson, founder, President and Chairman of the Board of CH2O, a chemical-blending company, could only be found guilty if it found that he knew pollutants were discharged, had the authority and capacity to prevent the discharge, and failed to act. Similarly, in U.S. v. Ming Hong, the Fourth Circuit affirmed the conviction of the owner of a corporation who had been involved in the purchase of an insufficient purifying system, controlled the company’s finances, and was present when discharges were made.

The U.S. Department of Health and Human Services (“HHS”) Office of Inspector General’s (“OIG”) exercise of its administrative exclusion authority has raised the stakes for executives in the healthcare industry. Recently the D.C. Circuit Court of Appeals upheld the authority of the OIG to exclude Purdue Frederick executives from HHS programs based solely on their guilty pleas to RCO charges, even in the absence of any evidence in the record – or admission by the executives – of knowledge of the wrongdoing.

One might well question the fairness of the OIG’s efforts to exclude executives in the absence of any evidence of knowledge of, or direct participation in, wrongdoing. Indeed, historically in the realm of RCO prosecutions the courts have relied on the measured discretion of the regulators, a reliance that may no longer be warranted in the politically charged world of healthcare. In Park, for example, the Supreme Court expressly decided to rely on the “good sense of prosecutors.” In its Brief for the United States, Solicitor General Robert H. Bork and attorneys from the DOJ sought to lull the court into that reliance, stating:

Officials who lack authority to prevent or correct violations, or who were totally unaware of any problem and could not have been expected to be aware of it in the reasonable exercise of their corporate duties, are not the subject of criminal action.

Further:

Even if investigation discloses the elements of liability, and indicates that an official bears a responsible relationship to them, the agency will not ordinarily recommend prosecution unless that official, after becoming aware of possible violations, often (as with Park) as a result of notification by FDA, has failed to correct them or to change his managerial system so as to prevent further violations.

If the DOJ hews to past practice and limits RCO prosecutions to cases where there is proof of something more than mere corporate position, and thereby abides by its assurance to the Supreme Court, the FDA’s aggressive position will remain simply one agency’s hope rather than the new reality of corporate executive prosecutions. On the other hand, prosecutorial discretion tends to ebb and flow. Furthermore, although the DOJ is not bound by the views of its client agencies, it is sensitive to them, so the potential problem likely will remain. Thus, an understanding of the FDA’s position is likely important preparation for any DOJ interactions.

New FDA Guidelines Embrace Strict Liability

In January 2011, the FDA released its revised regulatory procedures manual to address Park doctrine prosecutions. For the first time – largely in response to a 2010 report of the Government Accountability Office (“GAO”) criticizing the FDA’s oversight of its Office of Criminal Investigations (“OCI”) – the FDA’s regulatory procedures manual expressly affirmed the value of misdemeanor prosecutions and directed staff to consider a number of nonbinding factors to weigh in deciding whether to recommend an RCO prosecution. These factors include the individual’s position within the organization, his or her relationship to the violation and any authority the individual may have had to correct or prevent the violation, whether the public was harmed, whether the violation reflected a pattern of illegal behavior, whether the violation was widespread, and whether prosecution of the violation would constitute a prudent use of agency resources.

Importantly, with regard to mens rea, the FDA advised:

The Park Doctrine…provides that a responsible corporate official can be held liable for a first time misdemeanor…under the [FDCA] without proof that the corporate official acted with intent or even negligence, and even if such corporate official did not have any actual knowledge of, or participation in, the specific offense.

Ultimately, however, it is the DOJ that decides whether to bring Park prosecutions against corporate officers. With the possible exception of the Purdue Frederick executives (see below), the DOJ seems disinclined to file misdemeanor charges against corporate executives based solely on a strict liability theory of guilt without some additional aggravating factor. It is the rare – and perhaps foolhardy – prosecutor who relishes the prospect of asking a jury continued on page 34
to convict a corporate officer in the absence of proof of actual knowledge, intent, negligence, or direct participation in the underlying offense. In theory, RCO charges could be filed against corporate officers in nearly every criminal prosecution of a pharmaceutical, biotechnology, or medical device company and the DOJ clearly has not gone down that path at this point.

Harsher Sentences and Penalties For RCO Convictions

Until relatively recently, prison terms for RCO convictions were nearly unheard of. When the Purdue Frederick executives pleaded guilty to RCO charges in 2007, the judge accepted the stipulated plea and imposed a sentence of probation. A few years later, however, Synthes North America, a medical device company, and its former subsidiary Norian Corp. pleaded guilty to felony and misdemeanor corporate healthcare fraud charges (making false statements in an FDA investigation and releasing adulterated and misbranded drugs) and agreed to pay $23 million in fines. Subsequently, four Synthes executives pleaded guilty as “responsible corporate officers” to a misdemeanor misbranding violation of the FDCA for their roles in unlawful and unauthorized clinical trials. The clinical trials were designed to train surgeons in the off-label use of a bone cement compound that, injected into patients’ spines, may have caused or contributed to the deaths of three patients.

Although the government charged each Synthes executive with a single misdemeanor count under the RCO doctrine, it presented extensive evidence during sentencing of the executives’ intentionally deceiving conduct. At the sentencing hearing for Thomas B. Higgins, former President of Synthes’ Spine Division and Senior Vice President of Global Strategy, for example, Judge Legrome D. Davis of the U.S. District Court for Eastern Pennsylvania found that Higgins’ conduct demonstrated either an “intentional choice or...a knowing disregard of likely consequences.” Judge Davis added:

[T]here are two concepts here. The one is strict liability, responsible corporate official. And I think that the behavior of the subordinates is directly relevant to that issue, right? But then there’s a second issue, which we discussed; mens rea, intent, relevant circumstances. And on the relevant circumstances, relevant conduct issues...I’m not so much looking at it in terms of a corporate official being strictly liable... It’s about something far greater and more serious than that... [It’s about] a deliberate choice to circumvent the regulatory authority for purposes, as best I can discern, [of] financial motivation...And it’s a choice that is made, and it was a choice that was continued in, in spite of all of the information that was provided from multiple sources... We’re past subordinates as far as I’m concerned.

Announcing Higgins’ sentence, Judge Davis explained that Higgins “ignored the rights of patients” and “the value[] of their lives.” In a memorandum following the sentencing of another corporate officer, Michael D. Huggins, Judge Davis noted that “[a]ll of the conduct at issue in this matter was carefully planned, studiously assessed, and meticulously implemented by highly-intelligent professionals over a period of years” and that Huggins “personally participated in most of the decisions” and “committed much of the illegal conduct himself.” Further:

The scope of this behavior and the magnitude of the wrong perpetrated on unsuspecting users of the untested, and unapproved, product was extreme. No similar set of facts can be located in the universe of Park doctrine cases.

Higgins and Huggins each were sentenced to nine months in prison; a third officer received five months; and a fourth, sentenced subsequently, received eight months. The sentences were shy of the maximum one-year sentences sought by prosecutors, but they varied upward from the applicable Sentencing Guidelines range of zero to six months, the longest sentences ever imposed for misdemeanor violations of the FDCA under a strict liability theory.

Another healthcare executive went to jail in an RCO prosecution in March 2011. Marc Hermelin, the former chairman of the board and CEO of KV Pharmaceutical Company, pleaded guilty to RCO charges for misbranding and was ordered to pay a $1 million fine, forfeit $900,000, and serve a sentence of 30 days in jail. Hermelin’s conviction was based on the 2010 guilty plea of Ethex Corporation, a wholly-owned subsidiary of KV Pharmaceuticals, to two felonies in connection with the production and distribution of oversized morphine sulfate tablets.

More recently, in United States v. Osborn, the owner, president, pharmacist-at-large, and sole director of Apothécaire, a compounding pharmacy, pleaded guilty to two counts of misdemeanor misbranding and adulteration under the RCO doctrine. The information alleged that Apothécaire sold vials of injectable colchicine that were in some cases super-potent and in other cases sub-potent. Three patients injected with the drugs died in March 2007. In all three cases, the medical examiner determined colchicine toxicity was the cause of death. The Information alleged that Osborn...
by reason of his position at Apothécure, had the responsibility and authority to prevent the misbranding” but did not allege that Mr. Osborn played a direct role in the shipment of misbranded drugs or that he possessed any knowledge or mens rea regarding the misbranded drugs. On Oct. 3, 2012 Mr. Osborn was sentenced to 90 days of in-home confinement and one year of probation, and ordered to pay the maximum fine of $100,000.

It would seem that loss of liberty is becoming a more frequent outcome of RCO prosecutions than has historically been true. This may have consequences since, as discussed below, an explicit part of the Supreme Court’s justification for the doctrine was the essentially de minimus penalties historically imposed. Mr. Park, for example, was fined a total of $250.

Collateral Consequences – HHS Exclusion

In 2007, the Purdue Frederick Company, Inc. pleaded guilty to felony “misbranding OxyContin, a prescription opioid pain medication, with the intent to defraud or mislead, a felony under the Food, Drug & Cosmetic Act.” In its plea agreement, the company stipulated that the criminal conduct involved false and misleading marketing of OxyContin for more than five years. Three Purdue executives – the former president and CEO, former executive vice president and chief legal officer, and former chief scientific officer – pleaded guilty solely to misdemeanor RCO convictions because it found that the conduct underlying the convictions lasted more than one year; the amount of financial loss was substantial; and there was a significant adverse physical or mental impact upon program beneficiaries.

Under Section 1128(b)(15) of the Social Security Act (42 U.S.C. §1320a-7(b)(15)), HHS in its discretion may exclude an owner, officer or managing employee of an entity from participation in federal healthcare programs when the entity has been convicted of certain offenses, including offenses related to fraud. The OIG is authorized to exclude an owner, or those with a controlling interest, if that person knew or should have known of the conduct that led to the sanction. Officers and managers may be excluded based solely on their position within the entity. Once a corporate officer is excluded, the corporation must terminate the officer or it will likewise be precluded from doing business with federal healthcare programs. Exclusion thus makes the corporate officer unemployable in the pharmaceutical, medical device, biotechnology, and healthcare industries. Depending on the age of the excluded individual and the length of the exclusion – ignoring entirely any damage to his or her reputation – this can be a career-ending event.

Following administrative appeals that ultimately reduced the period of exclusion to 12 years, the case came before the U.S. District Court for the District of Columbia. In December 2010 the District Court granted summary judgment for HHS, affirming the 12-year period of exclusion. On appeal to the D.C. Circuit Court of Appeals, the Purdue executives argued that Section 1320a–7(b)(1) does not authorize their exclusion because misdemeanor misbranding is not a “misdemeanor relating to fraud.” They also argued that, even if HHS was exercising its legitimate statutory authority, the HHS Secretary’s decision to exclude them for 12 years was “unsupported by substantial evidence” and was therefore “arbitrary and capricious.”

In July 2012, the United States Court of Appeals for the D.C. Circuit held that HHS was acting within its statutory authority when it excluded the Purdue executives but reversed the District Court’s judgment, holding that the 12-year period of exclusion was “arbitrary and capricious for want of a reasoned explanation for the length of the exclusion.” The Court of Appeals ordered the District Court to remand the case to HHS for further proceedings.

Importantly, the Court of Appeals expressly rejected the Purdue executives’ argument that exclusion requires mens rea and explicitly held that exclusion can be premised on strict liability. The Court upheld the exclusions because it found that the conduct underlying the executives’ misdemeanor RCO convictions was factually related to fraud under a “circumstance-specific approach” given that their convictions:

continued on page 36
The Revival of the Responsible Corporate Officer Doctrine?

continued from page 35

were predicated upon the company they led having pleaded guilty to fraudulently misbranding a drug and they admitted having “responsible and authority either to prevent in the first instance or to promptly correct” that fraud [and] they did neither.54

During the same period of time that the Purdue executives’ exclusion case was making its way through the federal court system, the OIG released a new guidance for implementing its statutory permissive exclusion authority under 42 U.S.C. § 1320a-7(b).55 Although the OIG had long possessed permissive authority to exclude owners, officers, and managing employees of an entity that has been excluded or convicted of certain offenses, the OIG had not often exercised its permissive authority. The publication of the guidance was widely interpreted as a signal, or warning, that HHS intended to exercise its permissive authority to exclude individuals. The timing and content of the new guidance suggested that HHS was calibrating its approach with the FDA’s recently announced commitment to holding individuals accountable for corporate violations.56

In November 2010, shortly after publication of its new guidance on permissive exclusion but just before the District Court granted summary judgment to HHS on the exclusion of the Purdue executives, the OIG used its permissive exclusion authority to exclude Marc Hermelin, the former CEO and chairman of the board of KV Pharmaceuticals. In the case of Hermelin, the OIG acted preemptively, initiating proceedings prior to any criminal charges being filed against Hermelin.57 Ultimately, however, Hermelin pleaded guilty to two RCO charges based on KV Pharmaceutical’s guilty plea to felony misbranding.58

More aggressively still, in April 2011 the OIG notified Forest Laboratories, Inc. executive Howard Solomon that it intended to exclude him from doing business with federal healthcare programs. Solomon was never charged with a crime. Instead, the potential exclusion was based on Solomon’s association with Forest Pharmaceuticals, which pled guilty in September 2010 to charges of off-label marketing of three drugs, submission of false data to the FDA, and obstruction of the government’s investigation.59 As part of the settlement of criminal and civil charges, Forest Pharmaceuticals agreed to pay $313 million, including $164 million in criminal penalties, and signed a Corporate Integrity Agreement (“CIA”) negotiated by the OIG.60

The settlement included no finding of knowledge or wrongdoing by Mr. Solomon; the OIG made no mention of its intention to exclude Solomon during its CIA negotiations with the pharmaceutical company; and Forest Pharmaceuticals was never accused of violating the CIA.61 In August 2011, following a public uproar over the attempted exclusion of a corporate officer accused of no wrongdoing, and after Solomon’s intention to fight the exclusion became clear, the OIG reversed course and notified Solomon that after reviewing its file, and “in consideration of the information that your attorneys provided and an in-person meeting,” it had decided to close the case.62

The growing aggressiveness of both the FDA and the OIG may be part of a broader effort to further expand healthcare enforcement actions. Should the DOJ actually join this bandwagon, it may very well be met with a constitutional challenge to the RCO doctrine. In light of recent Supreme Court opinions it seems, at the very least, to be an open question whether an expansive RCO doctrine would satisfy the basic tenants of due process.

Constitutional Challenges

A constitutional challenge based on the void-for-vagueness doctrine and fair notice requirement of the Fifth Amendment Due Process Clause has not been fully litigated in the RCO arena but the outlines are apparent in the context of recent RCO prosecutions. First, a constitutional due process challenge to HHS’s permissive exclusion activity was raised on appeal by the Purdue Frederick executives and their amici. They contended that because the HHS Secretary’s interpretation of the permissive exclusion statute allowed her to impose “career-ending disabilities” upon corporate officers whose criminal convictions required no mens rea, it raised a serious question of validity under the Due Process Clause of the Fifth Amendment.63

Quoting from Morissette v. United States, a case the Supreme Court relied upon in Park, Appellants and their amici noted that in Morissette the Supreme Court upheld the constitutionality of strict liability crimes “in part, because their associated penalties ‘commonly are relatively small, and conviction does not do grave damage to an offender’s reputation.’”64 The D.C. Circuit Court of Appeals rejected Appellants’ argument, explaining in dicta that exclusion simply barred the excluded individual from working for a government contractor or supplier and stating, further, that the Due Process Clause was not implicated where the exercise of HHS’s exclusionary authority was not based on a criminal statute, and that “although exclusion may indeed have serious consequences, we do not think excluding an individual [from federal healthcare programs] … on the basis of his conviction for a strict liability offense raises any significant concern with due process.”65

There is a substantial body of case law holding that strict liability
offenses implicate constitutional due process concerns unless the penalty is relatively small and the reputational effects relatively light. Given that the OIG relied solely on the Appellants’ misdemeanor pleas as the basis for excluding them, however, the civil exclusion order could be deemed an additional sanction for Appellants’ RCO offense. This is the argument made by the Washington Legal Foundation in its amicus brief in support of Appellants. In addition, amici argued that exclusion implicates a constitutional liberty interest by stripping the Purdue executives of their ability to pursue their careers. This argument has not been addressed by the Court. In refusing to recognize the potentially reputation-destroying and career-ending implications of an exclusion based on an underlying strict liability offense, the Court may have opened the door to further constitutional challenges based on the very real harms the Court was perhaps too quick to dismiss.

Second, the Supreme Court’s limitation of the scope of the “honest-services” fraud concept in Skilling v. United States suggests that the RCO statutes could be found void for vagueness. Skilling involved the prosecution of former Enron CEO Jeffrey Skilling for conspiracy to commit “honest-services” wire fraud by “depriving [Enron and its shareholders] of the intangible right of [its] honest-services.” On appeal, the Supreme Court disagreed with the Fifth Circuit’s honest-services ruling, focusing its analysis on the right of citizens to fair notice of what constitutes criminal activity. To avoid invalidating the statute in its entirety, the Court held that the honest-services fraud statute, which prohibits “a scheme or artifice to deprive another of the intangible right of honest-services,” covers only bribes and kickback schemes, not the broader interpretation favored by prosecutors, who used it to target conduct that may have been morally wrong or unethical but did not include proof of participation in a bribery or kickback scheme for personal gain.

In Skilling, the Supreme Court held that a “limiting interpretation” should be applied to avoid striking the federal statute for being unconstitutionally vague. In reviewing honest-services fraud case law, the Court concluded that “[t]he vast majority of the honest-services cases involved offenders who, in violation of a fiduciary duty, participated in bribery or kickback schemes” and held that the statute clearly was intended to reach “at least” this type of conduct. The Court rejected the government’s argument that conflict of interest cases such as Skilling’s fell within the parameters of the statute. Invoking the rule of lenity, the Court concluded that a “reasonable limiting construction…must exclude this ‘amorphous category of cases.’” Concurring in part and concurring in the judgment, Justices Scalia, Thomas and Kennedy concluded that the honest-services fraud statute could not be saved by a limiting construction but rather “is vague and therefore violates the Due Process Clause of the Fifth Amendment.”

The adequacy of notice is something that has divided the Supreme Court in its RCO cases, with a bare majority permitting the doctrine in Dotterweich (5-4) and a significant number dissenting, as well, in Park (6-3). But it would seem that the Court as a whole has shifted in the decades since Dotterweich and Park. It is hard to imagine that the present Court, after Skilling, could say, as the Dotterweich majority did, that it would be “too treacherous to define or even to indicate by way of illustration the class of employees which stands in such a responsible relation,” and it seems highly unlikely that the present Supreme Court would simply conclude that “the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted.” None of that was enough to save the honest-services fraud concept – at least not in the form used by prosecutors, judges and juries to convict corporate executives.

Rather, like the four Dotterweich dissenting justices, today’s Court might hold that:

reliance on the legislature to define crimes and criminals distinguishes our form of jurisprudence from certain less desirable ones. The legislative power to restrain the liberty and to imperil the good reputation of citizens must not rest upon the variable attitudes and opinions of those charged with the duties of interpreting and enforcing the mandates of the law.

Indeed, it would seem that, at minimum, today’s Court would follow the dissenting justices in Park, three decades after Dotterweich, where the dissenters found the statute troubling because the predicate for conviction – “responsibility” – had “whatever meaning the jury in its unsaged discretion chose to give it,” what it means to be “responsible” is so ambiguous that the jury was, in essence, told: “You must find the defendant guilty if you conclude that he is guilty.” In much the way the Skilling Court narrowly construed the honest-services doctrine, the Park dissenters concluded that the way to cure the statute’s ambiguity was to require that “before a person can be convicted of a criminal violation of this Act, a jury must find...evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence.”

**Conclusion**

There is no question that addressing healthcare fraud remains one of the highest priorities of the federal government, and given its importance to the economy, that is not changing anytime soon. Pressure will continue to mount on the DOJ – from the agencies, Congress and the public – to pursue prosecutions of the highest ranking corporate executives. Ultimately, if the

continued on page 38
DOJ succumbs to that impulse by pressing the RCO theory to its outer limits, it is hard to imagine that courts will not circumscribe the scope of the amorphous and potentially dangerous RCO doctrine.

Joseph F. Savage, Jr. is a partner in the Boston office of Goodwin Procter LLP where he is a member of the firm’s White Collar and Government Investigations Group. He represents companies and individuals in a variety of criminal cases, especially in the areas of healthcare fraud and securities and financial fraud. He is also Chairman of the Board of the New England Innocence Project and represents indigent criminal defendants by court appointment in Massachusetts. Mr. Savage was an Assistant United States Attorney in Boston, New York, West Virginia and Missouri and was also Senior Trial Counsel in the Office of Independent Counsel. He may be reached at jsavage@goodwinprocter.com.

Maren Klawiter, J.D., Ph.D. is a litigation associate in the Boston office of Goodwin Procter LLP and a former Special Assistant District Attorney in the Suffolk County District Attorney’s Office. Prior to entering law practice, Ms. Klawiter was a medical sociologist, a health policy professor, and the author of numerous publications, including The Biopolitics of Breast Cancer (2008). She may be reached at mklawiter@goodwinprocter.com.

Endnotes


4 Dotterweich, 320 U.S. at 285.

5 Park, 421 U.S. at 673-74.


8 Park, 421 U.S. at 673. The Supreme Court did not reach the issue of whether Park “would have been entitled to an instruction as to his lack of power” since such an instruction was never requested. Id. at 677.


10 Although the RCO doctrine originated in the context of the FDCA and FDA-regulated industries, it has a much broader reach, including environmental law and EPA-regulated industries.


12 U.S. v. Iverson, 162 F.3d 1015 (9th Cir. 1998).

13 U.S. v. Ming Hong, 242 F.3d 528 (4th Cir. 2001).

14 421 U.S. at 669, quoting Dotterweich, 320 U.S. at 285.


16 Id. at 31-32.


19 Id.

20 Id. (emphasis added).


22 Id.

23 Id.


25 Id. at 45-47.

26 Id. at 75.


28 Id. at 20.


32 Id.


37 U.S. v. Park, 499 F.2d 839, 840 (4th Cir. 1974).


39 Id. at 571. Pursuant to the plea agreement, the district court put Purdue on probation for five years, fined it $500,000, and imposed other monetary sanctions totaling approximately
$600 million, approximately $160 million of which was earmarked for restitution to federal and state healthcare agencies, which had been large buyers of the misbranded drug. Id. at 572.

Id. at 570-71.

Id. at 571.


Purdue Frederick, 495 F.Supp. 2d at 571.

See 42 C.F.R. § 1001.201(b)(2)(i)-(iii); id. § 1001.401(c)(2)(i)-(ii).


Id. at 1.

Id. at 2.


Id. at 817.

Id. at 813.

Id. at 823-24.

Id. at 824.


The FDA is an operating division of the HHS. See www.hhs.gov/about/orgchart (last accessed Aug. 13, 2013).


$600 million, approximately $160 million of which was earmarked for restitution to federal and state healthcare agencies, which had been large buyers of the misbranded drug. Id. at 572.

Id. at 570-71.

Id. at 571.


Purdue Frederick, 495 F.Supp. 2d at 571.

See 42 C.F.R. § 1001.201(b)(2)(i)-(iii); id. § 1001.401(c)(2)(i)-(ii).


Id. at 1.

Id. at 2.


Id. at 817.

Id. at 813.

Id. at 823-24.

Id. at 824.


The FDA is an operating division of the HHS. See www.hhs.gov/about/orgchart (last accessed Aug. 13, 2013).


Id.

Id. at 824 (quoting Morissette v. United States, 342 U.S. 246 (1952)).

Id. at 824.

In addition to Morissette, see United States v. Keller, 579 F.2d 990, 994 (6th Cir. 1978) (“if Congress attempted to define a Mala prohibi

tur offense that placed an onerous stigma on an offender’s reputation and that carried a severe penalty, the Constitution would be offended”); Holdridge v. United States, 282 F.2d 302, 310 (8th Cir. 1960) (concluding that the elimination of a mens rea requirement did not violate due process where, among other things, “the penalty is relatively small” and the “conviction does not gravely besmirch”); United States v. Unser, 165 F.3d 755, 762-64 (10th Cir. 1999) (applying Holdridge); Tart v. Commonwealth of Massachusetts, 949 F.2d 490, 502-03 (1st Cir. 1991) (same); United States v. Wulff, 758 F.2d 1121,1125 (6th Cir. 1985) (same).


Id. at 23 (citing O’Donnell v. Barry, 148 F.3d 1126, 1141 (D.C. Cir. 1998) (“Government action that has the effect of ‘seriously affecting,’ if not destroying[ing] a plaintiff’s ability to pursue his chosen profession” infringes a liberty interest) (quoting Greene v. McElroy, 360 U.S. 474, 492 (1959)).


Id. at 2908. The mail- and wire-fraud statutes criminalize the use of the mails or wires in furtherance of “any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. 18 U.S.C. §§ 1341 (mail) 1343 (wire). The honest-services statute defines the term “scheme or artifice to defraud” in these provisions to include “a scheme or artifice to deprive another of the intangible right of honest-services.” 18 U.S.C. § 1346.

Id. at 2896, 2932-34.

Id. at 2929-30.

Id. at 2930.

Id. at 2931 (emphasis in original).

Id. at 2932.

Id. at 2935.

Id. at 2935.

Dotterweich, 320 U.S. at 285.

Id. at 292-93 (Murphy, J., dissenting, joined by Justices Roberts, Reed, and Rutledge).

Park, 421 U.S. at 679 (Stewart, J., dissenting, joined by Justices Marshall and Powell).

Id. at 683.

Health Law Section Offers Publishing Opportunities

The Health Law Section is always interested in publishing material from our members and others. We strive to produce top quality, relevant and interesting articles, books, toolkits, and the like for the health law bar. Opportunities include:

**The Health Lawyer** – This prestigious national magazine is the flagship publication of the Section. For more than 30 years The Health Lawyer has covered cutting edge, topical and timely health law-related issues that not only spark discussion but also provide practical advice and help readers in their daily work. A full index of topics covered can be found at The Health Lawyer webpage (http://www.americanbar.org/publications/health_lawyer_home.html). For more information or to receive our Publication Guidelines, contact Marla Durben Hirsch, Esq., Editor at mdhirsch@comcast.net or at 301/299-6155.

**ABA Health eSource** – Our electronic monthly newsletter is a perfect place to find and publish succinct, timely articles. Generally the articles for this monthly publication are not as long as the articles in The Health Lawyer but are every bit as important. Simeon Carson is the staff person in charge of the ABA Health eSource and can be reached at 312/988-5824 or at simeon.carson@americanbar.org.

**Practical Guide Series** – Do you have a good idea for a single topic book? Contact Simeon Carson to discuss your book project. Generally these are soft covered books of 200 to 300 pages. Simeon can be reached at 312/988-5824 or at simeon.carson@americanbar.org.