

Corporate Drug Trafficking Liability— a New Legal Front in the Opioid Crisis

June 6, 2019

The [opioid epidemic](#) represents a public health crisis in the United States, with the Centers for Disease Control and Prevention [reporting](#) that overdoses on prescription and non-prescription opioids claimed a record 47,600 lives in 2017. In April 2019, the U.S. Department of Justice (DOJ) opened a new front in the struggle against the illicit distribution of prescription opioids by [indicting](#) Rochester Drug Cooperative, Inc. (Rochester Drug) and two of its executives under the [Controlled Substances Act](#) (CSA) based on the company’s sale of oxycodone and fentanyl to pharmacies that illegally distributed the drugs. Although pharmaceutical companies and their executives have previously been subject to [civil sanctions](#) and [criminal prosecution](#) related to the marketing and distribution of opioids, the Rochester Drug indictments mark the first time DOJ has brought felony charges against a pharmaceutical company under the general drug trafficking provisions of the CSA. This Sidebar contextualizes the indictments by first providing an overview of the key laws governing prescription opioids, the CSA and the [Federal Food Drug and Cosmetic Act](#) (FD&C Act). It then discusses the Rochester Drug indictments, comparing them to prior enforcement proceedings against producers and distributors of prescription opioids. Finally, the Sidebar addresses the legal significance of the indictments and considerations for Congress.

The Regulation of Prescription Opioids

Prescription opioids are subject to both the CSA and the FD&C Act. Distinct agencies administer the two statutes, and they have related but discrete goals.

Federal Food, Drug & Cosmetic Act. The [U.S. Food and Drug Administration](#) (FDA) is the agency primarily responsible for enforcing the FD&C Act, which [aims](#) to promote public health by regulating the production and sale of food, drugs, and other public health products. In relevant part, the FD&C Act [prohibits](#) the “introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded.” A drug is considered to be [misbranded](#) if, among other things, its labeling, advertising, or promotion “is false or misleading in any particular.” FDA [enforces](#) the statute through administrative means, including informal letters warning of potential compliance issues and formal

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LSB10307

administrative actions that may result in fines or temporary or permanent bans on engaging in regulated activities. FDA may also coordinate with DOJ to bring civil or criminal proceedings in court.

Unlike many crimes, criminal violations of the FD&C Act are subject to strict liability, meaning that the mere act of a violation is sufficient to support a conviction, and the accused need not have acted with a culpable mental state (such as negligence or a willful desire to do wrong). In *United States v. Dotterweich*, the Supreme Court explained that the strict liability scheme is justified by the public health purpose of the FD&C Act: individual consumers are not well-situated to protect themselves from adulterated or misbranded food and drugs; businesses are, and thus may be held liable for any risks they create by choosing to operate in those fields. In *United States v. Park*, the Supreme Court held that a corporate officer could be held liable for his company's violation of the FD&C Act without any personal "awareness of some wrongdoing" if he occupied a position in the company where he had "responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and . . . he failed to do so."

A first violation of the FD&C Act is generally a misdemeanor, but a second offense or one committed with the "intent to defraud or mislead" may constitute a felony. An individual who violates the statute faces fines plus up to a year in prison for a misdemeanor or three years for a felony. Organizations, such as corporations, face criminal fines of up to \$200,000 for a misdemeanor or \$500,000 for a felony.

Controlled Substances Act. The DOJ's [Drug Enforcement Administration](#) (DEA) is the primary agency that enforces the CSA. The CSA aims to protect public health from the dangers of highly addictive and/or dangerous controlled substances diverted into the illicit market. At the same time, the statute seeks to ensure that patients have access to pharmaceutical controlled substances for legitimate medical purposes. To accomplish these two goals, the statute creates two overlapping legal schemes: (1) a [registration system](#) to monitor and control the flow of controlled substances dispensed pursuant to legitimate prescriptions, and (2) a set of [penalties](#) for illegitimate trafficking and possession of controlled substances. Controlled substances subject to the CSA are classified on "[schedules](#)" based on their medical utility and their potential for abuse. The registration requirements and criminal penalties applicable to each controlled substance vary based on its classification, with Schedule I substances subject to the most exacting restrictions and Schedule V substances subject to the least stringent. Most prescription opioids have been placed on [Schedule II](#), reflecting a finding that they have an accepted medical use but pose a high potential for abuse, and such abuse may lead to severe psychological or physical dependence.

The CSA's registration regime applies to "every person who manufactures or distributes" or "dispenses" any controlled substance; it exempts from registration "ultimate users," such as patients, who possess controlled substances for personal use. Entities required to register—including organizations such as pharmaceutical manufacturers and distributors, hospitals, and pharmacies, and individuals such as doctors, pharmacists, and researchers—must obtain DEA registration for each category of controlled substances they plan to work with. Registrants are required to [track](#) inventory of controlled substances and [report](#) to DEA any orders that appear suspicious. Registered medical practitioners and pharmacists may not dispense controlled substances without a valid [prescription](#). Failure of a registrant to meet the applicable requirements can trigger [enforcement](#) actions including warning letters, suspension of registration, and fines. However, a violation of the registration requirements generally does not constitute a criminal offense unless it is committed [knowingly](#). A first criminal violation of the registration requirements by an individual is punishable by a [fine](#) or up to a year in prison; a criminal violation by a "registered manufacturer or distributor of opioids" may be punished by a fine of up to \$500,000.

By contrast, the CSA's trafficking provisions prohibit activities such as illicitly [possessing](#), [manufacturing](#), and [distributing](#) controlled substances. Violations of the trafficking provisions are criminal offenses that may give rise to larger fines and significant jail time. Penalties vary based on the type and amount of the controlled substance at issue. As an example, a first time drug trafficking offense involving a Schedule II controlled substance (such as oxycodone or prescription fentanyl) is [punishable](#) by a prison term of up to 20 years and a fine of up to \$1,000,000. If death or serious bodily injury results from the use of the Schedule II controlled substance, the CSA imposes a mandatory prison sentence of 20 years to life.

The CSA's registration system and its trafficking regime are not mutually exclusive, and participation in the registration system does not insulate registrants from the statute's trafficking penalties. In [United States v. Moore](#), the Supreme Court rejected a claim that the CSA "must be interpreted in light of a congressional intent to set up two separate and distinct penalty systems," one for registrants and one for persons not registered under the Act. Faced with the case of a registered doctor who distributed large amounts of methadone with inadequate patient exams and no precautions against misuse or diversion, the Court in [Moore](#) [held](#) that physicians registered under the CSA can be prosecuted under the general drug trafficking provision "when their activities fall outside the usual course of professional practice."

The Rochester Drug Indictments in Context

On April 23, 2019, DOJ and DEA [announced](#) criminal charges against Rochester Drug, former Rochester Drug CEO Laurence F. Doud III, and former chief compliance officer William Pietruszewski. Rochester Drug and Pietruszewski were [each charged](#) with conspiracy to distribute controlled substances, a violation of the CSA's [trafficking provision](#); [conspiracy to defraud the United States](#); and willfully failing to file suspicious order reports, a criminal violation of the CSA's [reporting requirements](#). Pietruszewski pled guilty and is currently awaiting sentencing. The company entered into a five-year deferred prosecution [agreement](#) with DOJ, under which it will accept responsibility for its conduct, pay a \$20 million penalty, update its CSA compliance program, and submit to independent supervision. Doud was [charged](#) with one count of conspiracy to distribute controlled substances and one count of conspiracy to defraud the United States. He has pled not guilty.

The Rochester Drug indictments represent the first time the government has brought felony charges against a pharmaceutical company under the *general drug trafficking* provisions of the CSA. When DOJ has previously brought criminal trafficking charges against CSA registrants, it has targeted individual [doctors](#) and [pharmacies](#) who improperly prescribed or dispensed opioids directly to patients, rather than drug companies. By contrast, [prior DEA enforcement actions against pharmaceutical companies](#) have generally proceeded under the CSA's *registration* provisions, rather than the trafficking provisions, and have involved only civil and administrative penalties, such as suspension of registration and fines.

Nonetheless, the Rochester Drug indictments are not wholly novel in exposing a pharmaceutical company and its officers to felony liability for activities undertaken in the scope of their business. Drug companies and executives have previously faced criminal charges related to the marketing of prescription drugs under the FD&C Act and other statutes. For example, in 2007 the [Purdue Frederick Company](#) pled guilty to felony charges under the FD&C Act based on its misbranding of OxyContin; three Purdue executives pled guilty to misdemeanor misbranding. In 2013, [ISTA Pharmaceuticals, Inc.](#) pled guilty to felony charges including conspiracy to introduce a misbranded drug into interstate commerce in violation of the FD&C Act. (Other criminal statutes unrelated to the regulation of public health, such as [bribery](#) and [racketeering](#) laws, have also been used to prosecute drug companies.) Similarly, the Rochester Drug indictments do not appear unusual in terms of the immediate practical consequences for the company—

the \$20 million penalty Rochester Drug will pay is significantly lower than some of the penalties in the civil and criminal proceedings discussed above, which have ranged as high as **\$600 million**.

However, the current indictments do appear novel in terms of individual executives' exposure to punishment. The Purdue executives convicted of misdemeanor misbranding were **sentenced** to fines of \$5,000, probation, and community service. The Rochester Drug executives each **face** large fines and a mandatory minimum sentence of ten years in prison and a maximum of life in prison if convicted of conspiracy to distribute controlled substances, plus the possibility of five or six years in prison on the remaining charges.

In seeking more severe criminal penalties under the CSA, prosecutors shoulder a correspondingly more exacting burden of proof. As discussed above, most violations of the FD&C Act are strict liability offenses, requiring no proof of culpable intent or even knowledge of an offense. A violation of the CSA's recordkeeping and reporting requirements **requires** only a showing of negligence. By contrast, a violation of the CSA's drug trafficking provision must be committed "**knowingly or intentionally**," with **corporations** subject to liability "based on the 'knowledge and intent' of their employees." Prosecutors bringing these charges would thus need to show that employees of a pharmaceutical company **knew or reasonably should have known** that opioids the corporation distributed were being dispensed **outside the usual course** of professional practice.

Considerations for Congress

The more stringent mental state requirement applicable to the CSA's trafficking provisions may make it difficult to secure convictions, particularly as to pharmaceutical companies and executives who are not directly involved in day-to-day distribution decisions. However, it appears recently proposed legislation would alter the legal framework for corporate and executive liability for opioid distribution. For example, the Opioid Crisis Accountability Act of 2019, introduced in the **Senate** on May 21, 2019, and in the **House** on May 22, would amend the FD&C Act to render it "unlawful for any person who manufactures or distributes an opioid to engage in [a] dubious marketing or distribution practice with respect to an opioid." Covered unlawful practices would include promotional statements that misrepresent the addictiveness of opioids, "supplying States or communities with a quantity of opioids that is not medically reasonable," and failing to report orders for opioids "that the person knows are not being dispensed in a medically reasonable manner." The bill would also, among other things, provide for assessment of fees against each company that manufactured or distributed any opioid between 1993 and the present, requiring that the total amount assessed equal \$20 billion. Companies that fail to pay the fee would lose FDA approval to market the opioid. In addition, the bill would terminate or reduce the period of **market exclusivity** enjoyed by companies that violate the proposed statute.

The bill would provide for both direct and vicarious liability. Individuals who directly violate the proposed statute would be subject to fines and prison terms of up to ten years. Corporations would be subject to a civil penalty of 75 percent of the profits from their legal U.S. sales of opioids during the period when the violation occurred. As for vicarious liability, the bill provides that if a company violates the statute, certain of its executives would be subject to fines "without regard to the participation of such individuals in, or knowledge of such individuals of, the violation."

The Opioid Crisis Accountability Act is one of several recent proposals developed in response to the opioid crisis that would **shift costs** and **expand liability** for pharmaceutical companies and executives. Such an approach could raise legal questions. For example, there may be constitutional limits on the extent to which substantial penalties can be imposed on a strict liability basis. Imposing strict liability for vicarious offenses, including for executives employed at the time a judgment is entered against a company (who may not have been employed at the time the violation occurred), would expand the holding in *Park* and expose pharmaceutical executives to sanctions regardless of their knowledge, intent,

or ability to prevent a violation. The Supreme Court has not directly addressed whether the Fifth Amendment's Due Process Clause limits the magnitude of penalties that can be imposed under the *Park* doctrine, and federal appeals courts [have split](#) on the issue. However, in *Staples v. United States*, the Court noted that for most strict liability offenses “penalties commonly are relatively small” and that “imposing severe punishments for offenses that require no *mens rea* [culpable mental state] would seem incongruous.” Moreover, although the Court in *Park* upheld the imposition of strict liability on the facts before it, it [rejected](#) the proposition that “a finding of guilt could be predicated solely on respondent’s corporate position,” instead requiring a finding that the executive had the “authority and responsibility” to address his company’s violation.

In addition, increasing penalties for corporate entities and officers could raise separate questions, including whether such penalties would qualify as excessive fines barred by the [Eighth Amendment](#). The relevant question for a reviewing court would be whether any payment styled as a “fee” or “civil penalty” in fact constitutes a punishment that is “[grossly disproportional](#)” to the gravity of the offense. Finally, with some proposals suggesting that drug manufacturers should not only be assessed for conduct in the future but also for past conduct, the [Ex Post Facto Clause](#) of the Constitution may be implicated. The ban on ex post facto laws generally [applies](#) only to penal laws, and thus may not implicate proposals such as the Opioid Crisis Accountability Act, which appears only to impose fees retroactively. However, the Supreme Court has [held](#) that “the ex post facto effect of a law cannot be evaded by giving a civil form to that which is essentially criminal.” The fees could be considered punitive measures subject to the Ex Post Facto Clause if they were “[so punitive either in purpose or effect](#)” that they could not be deemed civil in nature. In sum, the issue of expanding corporate liability raises a number of points for Congress to consider as it works to combat the opioid crisis.

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