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EXPERT ANALYSIS

Prior Conviction, Present Danger: Felony Liability Under the Food, Drug And Cosmetic Act

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Imagine you're the head of a venerable and successful drug company that develops, promotes and sells pharmaceuticals to medical providers across the country. You know that the Food and Drug Administration is scrutinizing your company's promotional activities, and you make every effort to comply with the agency's requirements. The government, however, takes a different view, and you find yourself the target of a criminal investigation into some of your company's promotional efforts.

This is worrisome, you think, but as you mount your defense you take some small solace in the fact that, at worst, you're facing a misdemeanor charge under the federal Food, Drug and Cosmetic Act.[1] Although serious, a misdemeanor conviction does not carry with it the risk of mandatory debarment from all federal programs. That penalty would effectively destroy your career and severely harm your company, which sells many of its products through Medicare.

Then you remember something. Twenty years ago, you and your company were charged with and pleaded to a misdemeanor violation of the FDCA. It was about conduct completely unrelated to the pending investigation. Many of the executives in charge at that time have long since moved on, and your company doesn't even sell the drug that was at issue anymore. An unfortunate incident in the company's otherwise sterling history, the plea and conviction now serve primarily as a cautionary tale handed down within the legal and marketing departments.

But as William Faulkner once wrote, "The past is never dead. It's not even past."[2] That is certainly true when it comes to criminal enforcement of the FDCA. The act authorizes federal prosecutors to transform a strict liability misdemeanor violation into a felony charge on the basis of any prior FDCA conviction — no matter how old or factually dissimilar the prior conviction was from the conduct now at issue.

This robust enforcement power, which carries with it the threat of mandatory debarment from federal health care programs, raises significant due process concerns that have never been litigated.

FROM STRICT LIABILITY MISDEMEANOR TO FELONY

The statutory background is as follows. Among other things, the FDCA prohibits individuals from "causing" the "adulteration" or "misbranding" of any drug in interstate commerce, or from causing such an adulterated or misbranded product to be introduced into interstate commerce.[3] The government's criminal enforcement powers are set forth in FDCA Section 333. That provision provides two tiers of liability for FDCA offenses: misdemeanor and felony.

This robust enforcement power, which carries with it the threat of mandatory debarment from federal health care programs, raises significant due process concerns.

Section 333(a)(1): Misdemeanor liability

Section 333(a)(1) allows the government to charge violators with a misdemeanor, stating that any person who violates the FDCA "shall be imprisoned for not more than one year or fined not more than $1,000, or both." This provision creates a strict liability offense as the 9th U.S. Circuit Court of Appeals has held a charge may be brought and sustained "pursuant to the misdemeanor provision 'without any conscious fraud at all,' thus creating a form of strict criminal liability."[4]

The lack of any mens rea requirement makes this provision a potent prosecutorial weapon. And under the so-called *Park* doctrine, a company executive can be held vicariously liable for the acts of others within the company, even if he or she knew nothing of the alleged conduct, so long as the executive was in the position to prevent or correct the violation.[5]

Accordingly, executives can be convicted and imprisoned for crimes they personally knew nothing about and played no role in committing.[6] A recent legal challenge to the imposition of such a penalty on due process grounds failed in federal district court.[7]

Section 333(a)(2): Felony liability

FDCA Section 333(a)(2) permits the government to seek a felony conviction, but only in two specific circumstances. The first concerns *scienter* — if the violation was committed "with the intent to defraud or mislead," the violation can be ratcheted up to a felony. This intent requirement forms the basis for most felony charges under the FDCA.

But the second, less frequently invoked circumstance may implicate a decades-old conviction. Section 333(a)(2) also provides that the government may bring a felony charge against anyone who "commits ... a violation after a conviction of him under this section has become final." The statute includes no restriction on how recent the conviction must be; any conviction will do, no matter how old or factually unrelated. Like the misdemeanor charge, this prosecutorial option requires no proof of *scienter* — it remains essentially a strict liability offense.

In other words, if a company has been previously convicted of an FDCA violation, no matter how long ago or for what, that company could be charged with a felony the next time the government places the company in its sights. And federal prosecutors could sidestep the heavy burden of proving to a jury beyond a reasonable doubt that someone at the company acted with the affirmative intent to defraud or mislead.

The difference between a misdemeanor charge and a felony charge has massive strategic implications. Not only does a felony conviction risk a longer prison sentence, but it also leads to mandatory and permanent debarment of an individual under 21 U.S.C. § 335a(a). It also dramatically increases the possibility of debarment for the entire company under Section 333a(b) as well. Because federally funded programs like Medicare and Medicaid make the government the largest payor for pharmaceuticals and medical devices, "[d]ebarment means losing the company's largest customer."[8]

Because even the threat of debarment can be catastrophic, defendants often choose to settle with the government rather than risk a felony conviction. As a result, legal arguments challenging the FDCA's felony provision often go unmade and remain untested.[9]

DUE PROCESS ISSUES

An FDCA felony charge predicated on a stale and factually dissimilar prior conviction would raise serious due process concerns. When the FDCA is read alongside the *Park* doctrine, it arguably grants prosecutors the power to charge an executive or company with a strict liability felony

— one that could destroy the executive's career and drive the company out of business — based solely on old and factually dissimilar conduct.

Challenging such a felony FDCA conviction on due process grounds would be an uphill battle. The U.S. Supreme Court has held that a convicted defendant "is eligible for, and the court may impose, whatever punishment is authorized by statute for his offense, so long as that penalty is not cruel and unusual, and so long as the penalty is not based on an arbitrary distinction that would violate the Due Process Clause of the Fifth Amendment."[10] In practice, that means Congress must have had a "rational basis for its choice of penalties" in the FDCA.[11]

That's a high hurdle for a defendant to surmount. And in fact, other criminal statutes — such as the "three strikes" statute, 18 U.S.C. § 3559(c), and the Armed Career Criminal Act, 18 U.S.C. § 924(e) — allow for severe penalties based on prior convictions, yet include no temporal limitation. When defendants have challenged harsh sentences handed down under these laws, courts have refused to infer a temporal limit on prior convictions and have let the sentences stand.[12]

But a corporate executive with no actual complicity in the charged illegal conduct is a far cry from a violent recidivist or career criminal. Although Congress may impose severe penalties based on old and unrelated convictions to protect society from further violence, that rationale holds less weight in the FDCA context. The defendant would have to argue that imposing such a draconian penalty for old and unrelated conduct is arbitrary and irrational, or that it "shocks the conscience."[13] Although that sets an admittedly high bar, one could imagine an egregious abuse of prosecutorial discretion in the FDCA context that violates due process.

Ratcheting up a strict liability misdemeanor FDCA violation to a felony based solely on a very old and unrelated prior FDCA conviction may well cross the line.

A defendant facing a felony conviction based solely on a prior conviction could also argue that the penalties that flow from the conviction are too harsh for a crime committed without mens rea. In *Staples v. United States*, 511 U.S. 600 (1994), the Supreme Court considered a criminal statute prohibiting the possession of unregistered automatic weapons. The statute lacked any intent requirement, making it a strict liability offense. Noting that strict liability criminal offenses are generally disfavored, the court reversed a conviction, effectively reading an intent requirement into the statute. In reaching this conclusion, however, the court emphasized that its decision was a "narrow one" and that in general, "public welfare or regulatory offenses" had been deemed acceptable without a mens rea requirement. The FDCA arguably falls into that category.

That said, the court also observed that historically, "the cases that first defined the concept of the public-welfare offense almost uniformly involved statutes that provided for only light penalties such as fines or short jail sentences, not imprisonment in the state penitentiary."

The court continued: "[T]he small penalties attached to such offenses logically complemented the absence of a mens rea requirement: In a system that generally requires a 'vicious will' to establish a crime, imposing severe punishments for offenses that require no mens rea would seem incongruous." Analyzing its own cases on the subject, the court noted that "we, too, have included in our consideration the punishments imposed and have noted that 'penalties commonly are relatively small, and conviction does no grave damage to an offender's reputation.'"

Dicta though it may be, that language suggests an opening to argue that an FDCA felony charge based on nothing more than a prior conviction would be improper. "After all," the court stated, "'felony' is ... as bad a word as you can give a man or thing." And prison time plus mandatory debarment are hardly "small penalties" that leave a person's or company's reputation intact.[14]

Because even the threat of debarment can be catastrophic, defendants often choose to settle with the government rather than risk a felony conviction.

Any argument challenging a recidivism-based FDCA felony charge would appear to be novel; there seems to be no precedent upholding such a prosecution and conviction, nor any precedent prohibiting it. But the only cases that discuss recidivism-based FDCA charges concern prior convictions that were both very close in time to the second charge and based on identical illegal conduct.

One such case, *United States v. Stella D'Oro Biscuit Co.*, 143 F. Supp. 275 (S.D.N.Y. 1956), is a Southern District of New York opinion from 1956 concerning a biscuit distributor that had been convicted of the exact same offense five years before being tried and convicted a second time, for the same conduct, in the same court. Challenging the felony conviction, the company argued that the earlier conviction hadn't been alleged in the indictment. The court dismissed this argument, finding that the FDCA required no such procedure and that "[d]ue process ha[d] been fully observed."

Similarly, in *United States v. Roma Macaroni Factory*, 75 F. Supp. 663 (N.D. Cal. 1947), a macaroni factory was convicted of shipping food tainted with "insect fragments, rodent hair fragments, hair resembling rodent hair and unidentified hair." As "revolting" as the court found that conduct, more troubling was the fact that the same defendant had been convicted in the same court, for the same conduct, a mere six months before being indicted again. Based on those facts, the court found a felony charge appropriate, explaining that "very little if anything had been done" to correct the problems between the first and second indictments. "Congress," the court observed, "had in mind the imposition of that rather severe criminal penalty to avoid the consequences of that type of conduct which we have presently reviewed."

Although both of these cases upheld a felony conviction based on a prior offense, neither concerned a stale or unrelated prior conviction. If what Congress had in mind with Section 333(a)(2) was preventing true recidivism — *i.e.,* a company continuing to violate the FDCA in an ongoing fashion, in a similar way, and despite a previous conviction — threatening a felony conviction and mandatory debarment based on stale and unrelated conduct may push congressional intent beyond the breaking point.

CONCLUSION

The FDCA grants robust enforcement powers to federal prosecutors, and one weapon in their arsenal is the threat of elevating a misdemeanor charge into a felony charge based on any prior FDCA conviction. Seldom litigated, this prosecutorial option raises significant due process concerns given the draconian nature of the penalties associated with a felony conviction under the FDCA, and the lack of any mens rea requirement in the statute.

Whether a court would be receptive to a due process challenge is an open question and may well remain so. With the stakes so high, the threat of a felony conviction may be enough to prevent any defendant from litigating this question to judgment and appeal. In any event, corporate executives and legal advisers would do well to remember that a prior FDCA conviction, no matter how old, carries with it a unique peril in the context of a subsequent criminal investigation under the FDCA.

NOTES

[1] 21 U.S.C. § 301.

[2] William Faulkner, Requiem for a Nun 73 (First Vintage Int'l ed., Vintage Books 2011) (1950).

[3] 21 U.S.C. § 331(a), (b) and (k).

[4] *United States v. Watkins,* 278 F.3d 961, 964 (9th Cir. 2002) (quoting *United States v. Dotterweich,* 320 U.S. 277, 281 (1943)).

[5] *See United States v. Park,* 421 U.S. 658, 673-74 (1975).

[6] *See* generally, Brent J. Gurney et al., *The Crime of Doing Nothing: Strict Liability for Corporate Officers Under the FDCA* (2007), *available at* http://www.wilmerhale.com/uploadedFiles/WilmerHale_Shared_Content/Files/Editorial/Publication/The_Crime_of_Doing_Nothing.pdf.

[7] *See United States v. Quality Egg LLC,* 2015 WL 1769042, at *30 (N.D. Iowa Apr. 14, 2015).

[8] Ralph F. Hall & Robert J. Berlin, *When You Have A Hammer Everything Looks Like A Nail: Misapplication of the False Claims Act to Off-Label Promotion*, 61 Food & Drug L.J. 653, 676 (2006).

[9] A handful of defendants have argued that the debarment provision is unconstitutionally vague or that it is a criminal sanction that violates the double jeopardy or *ex post facto* clauses. Courts have rejected these arguments, finding that debarment is a civil remedy, not a criminal penalty, and that its terms are clear enough. *See Bhutani v. FDA*, 161 F. App'x 589 (7th Cir. 2006); *DiCola v. FDA*, 77 F.3d 504 (D.C. Cir. 1996).

[10] *Chapman v. United States,* 500 U.S. 453, 465 (1991).

[11] *Id.*

[12] *See e.g., United States v. Rich,* 708 F.3d 1135, 1139 (10th Cir. 2013) (Armed Career Criminal Act); *United States v. Bredy,* 209 F.3d 1193, 1198 (10th Cir. 2000) (three-strikes statute).

[13] *United States v. Salerno,* 481 U.S. 739, 746 (1987) (citation and quotations omitted).

[14] The argument may turn on whether the FDCA reflects "a clear statement from Congress that *mens rea* is not required" to convict someone of a felony under Section 333(a)(2)'s prior-conviction prong. *Staples v. United States,* 511 U.S. 600, 618 (1994).

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