Nos. 14-5772 & 14-5786

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

UNITED STATES OF AMERICA,
Plaintiff—Appellee,

v.

PATRICIA POSEY SEN AND ANINDYA KUMAR SEN,
Defendants—Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE, GREENEVILLE DIVISION
THE HONORABLE J. RONNIE GREER, DISTRICT JUDGE, CASE NO. 2:13-CR-56

BRIEF OF NATIONAL ASSOCIATION OF CRIMINAL DEFENSE LAWYERS AS *AMICUS CURIAE*

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CORPORATE DISCLOSURE STATEMENT

Pursuant to 6th Cir. R. 26.1, Amicus Curiae, National Association of Criminal Defense Lawyers (NACDL) makes the following disclosures:

1. Is said party a subsidiary or affiliate of a publicly-owned corporation?

   No. NACDL is a not-for-profit professional association. It is not a publically held company; does not have any parent corporation; and does not issue or have any stock.

2. Is there a publicly-owned corporation, not a party to the appeal, which has a financial interest in the outcome?

   No.

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STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae National Association of Criminal Defense Lawyers (NACDL) is a nonprofit voluntary professional bar association that works on behalf of criminal defense attorneys to ensure justice and due process for those accused of crime or misconduct. NACDL was founded in 1958. It has a nationwide membership of approximately 10,000, including private criminal defense lawyers, public defenders, military defense counsel, law professors, and judges. NACDL is the only nationwide professional bar association for public defenders and private criminal defense lawyers.

NACDL files numerous amicus briefs each year in the United States Supreme Court and other courts, in cases that present issues of broad importance to criminal defendants, criminal defense lawyers, and the criminal justice system as a whole. In particular, NACDL has a long-standing institutional commitment to preserving fairness and promoting a rational and humane criminal justice system that does not subject individuals to criminal prosecution and conviction unless they intentionally engage in inherently wrongful conduct or conduct that they know to be unlawful.

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[1] Pursuant to Fed. R. App. P. 29(c)(5), counsel for *amicus curiae* state that no counsel for a party authored this brief in whole or in part, and that no person other than amicus, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

ARGUMENT

I. THE CONSTITUTION PROHIBITS STRICT LIABILITY OFFENSES EXCEPT IN THE RAREST OF CIRCUMSTANCES

A. *Strict Liability Offenses Are Generally Disfavored*

The Supreme Court has repeatedly affirmed that "'*mens rea* is the rule of, rather than the exception to, the principles of Anglo-American criminal jurisprudence.'" *United States v. United States Gypsum Co.*, 438 U.S. 422, 436 (1978) (quoting *Dennis v. United States*, 341 U.S. 494, 500 (1951)); see also *Staples v. United States*, 511 U.S. 600, 605 (1994) (explaining that federal criminal statutes must be construed against the background presumption of a "requirement of some *mens rea* for a crime"). Highlighting this point, the Supreme Court explained over 70 years ago that:

> The contention that an injury can amount to a crime only when inflicted by intention is no provincial or transient notion. It is as universal and persistent in mature systems of law as belief in freedom of the human will and a consequent ability and duty of the normal individual to choose between good and evil.

Morissette v. United States, 342 U.S. 246, 250 (1952).

In short, it is a bedrock principle of American Constitutional law that "intent generally remains an indispensable element of a criminal offense." *United States Gypsum Co.*, 438 U.S. at 437.

In *United States v. X-Citement Video, Inc.*, the Supreme Court in examining the question of whether *mens rea* was a requirement of a federal criminal statute, stated that it would "not impute to Congress an intent to pass legislation that is inconsistent with the Constitution." 513 U.S. 64, 73 (1994) (citing *Yates v. United States*, 354 U.S. 298, 319 (1957) ("In [construing the statute] we should not assume that Congress chose to disregard a constitutional danger zone so clearly marked.")).

It certainly is true that in a *subset* of a certain class of cases, those involving so-called "public welfare offenses," the Supreme Court has departed from the general rule. But that is only where the "accused . . . is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from one who assumed his responsibilities" and in such cases the "penalties commonly are *relatively small*, and conviction does not [do] *grave damage* to an offender's reputation." *Morissette*, 342 U.S. at 256 (emphasis added). Thus, in both *United States v. Dotterweich*, 320 U.S. 277 (1943) and *United States v. Park*, 421 U.S. 658 (1975), the Supreme Court allowed the application of the Food and Drug and Cosmetic Act (FDCA), in particular, 21 U.S.C. § 331 to otherwise innocent persons—those without *mens rea*—who had responsibility for their corporations' compliance with the FDCA. Nothing in those cases suggests, however, that with respect to 21 U.S.C. § 331, the statute at issue

here, that the normal Constitutional presumption of *mens rea* is overcome outside that limited subset of corporate officers who have a duty and responsibility to protect society from the public dangers of adulterated foods or drugs.

B. *This Case Is Not the Rare Case*

Assuming *arguendo* that Appellants' statutory construction argument fails,[2] the Appellants' case is not one of the rare cases where the Constitutional presumption of *mens rea* can be dispensed. Indeed, this case is in the heartland of cases where such *mens rea must* be presumed and applied. While the Appellants' were convicted of violations of the FDCA, they are not among that subset of persons to whom *Dotterweich* and *Park* allowed the FDCA to be applied without a *mens rea* requirement. This Court should not presume that Congress intended otherwise, especially given the Constitutional danger zone that would be implicated if the statute were construed to apply without *mens rea* to Appellants.

Here, Appellants were convicted for the mere receipt of mislabeled drugs—nothing more. Unlike the defendants in *Dotterweich* and *Park*, they were not in positions in which they were charged with the responsibility of overseeing the correct labeling of drugs or the safeguarding of the purity of food. Rather, the charges against Appellants would be akin to a consumer in *Dotterweich*, who merely received the rebranded drugs shipped by the Buffalo Pharmacal Company,

[2] NACDL joins fully in Appellants' statutory argument.

being charged with a violation of the FDCA. Likewise, with respect to *Park*, the charges against Appellants would be akin to a consumer who merely received Acme Markets, Inc.'s adulterated food being charged with a violation of the FDCA. Putting it in those terms shows how ridiculous the government's prosecution in this case is. This case is not one of those rare case where the Supreme Court has said *mens rea* is not required. Just like the hypothetical consumers in *Dotterweich* and *Park*, Appellants did not know that they were "dealing with a dangerous device . . . plac[ing] [them] in responsible relation to a public danger," such that they should have been on notice of strict liability. *Staples*, 511 U.S. at 607.

Indeed, this Court's precedent confirms the conclusion that this prosecution violated Appellants' constitutional rights. In *United States v. Wulff*, 758 F.2d 1121 (6th Cir. 1985), this Court reviewed a conviction under the Migratory Bird Treaty Act (MBTA). Defendant moved to dismiss the indictment, "arguing that because [16 U.S.C. § 707(b)(2)] does not require guilty knowledge, imposition of a felony conviction would be a violation of due process." *Wulff*, 758 F.2d at 1122. The district court granted the motion. This Court affirmed. In doing so, this Court asked "whether the absence of a requirement that the government prove some degree of scienter violates the defendant's right to due process." *Id*. at 1125. This Court articulated the test to determine whether due process was violated by the lack of a *mens rea* requirement: "The elimination of the element of criminal intent

does not violate the due process clause where (1) the penalty is relatively small, and (2) where conviction does not gravely besmirch." *Id*. There the crime carried a maximum sentence of two years imprisonment or a $2,000 fine or both. Conviction would also "irreparably damage[] one's reputation." *Id*.

Admittedly, *Wulff* involved a felony conviction, but given the facts in this case, it is directly on point. Here, someone convicted of a misdemeanor under 21 U.S.C. 331(a) faces imprisonment of up to a year or a fine of $1,000 or both. 21 U.S.C. 333(a)(1). This is not a minor penalty. It is hard to see how a difference of one year and $1,000 would render *Wulff* inapposite.

Moreover, the facts in *this* case show how a conviction under 21 U.S.C. § 331(a) imposes no small penalty and gravely besmirches the convicted. Remarkably, given that there never has been an allegation that the drugs Appellants used in their clinic posed any harm or were materially different from the name-brand drugs, *see* R. 128: Trial Tr., PID 1343, and that Mrs. Sen was acquitted of any crime the jury was instructed required *mens rea* and Dr. Sen was *not even charged* with felony offenses, the government nonetheless sought to have Mrs. Sen imprisoned for *three* years and fined $1,365,162, R. 156: Gov. Sentencing Memo., PID 2753. Ultimately, the district court sentenced Dr. Sen to three years of probation, imposed a $100,000 fine, and required him to do 100 hours of community service. With respect to Mrs. Sen, the district court sentenced

her to two days of jail time, four years of probation, imposed a $200,000 fine, and required her to do 200 hours of community service. The district court also imposed onerous probation burdens on both Appellants including requiring Dr. Sen to "hire a person" to aid the probation officer in "determining [his] compliance with the law." R. 174: Judgment, PID 3272.[3]

Thus, in this case the penalties Appellants received were anything but small. Moreover, their reputations have been gravely besmirched. As explained in Dr. Sen's sentencing memorandum, upon filing of the first indictment, the government issued a press release detailing the various felonies with which the Dr. Sen was being charged. While the felony charges were ultimately dropped, the effects were immediate and deleterious to Dr. Sen. Insurance companies terminated their contracts with him and a number of hospitals revoked his privileges. These effects were felt even before the Sens elected to exercise their constitutional right to a trial by jury. *See* R.158: Dr. Sen Sentencing Memo., PID 2767.

After trial and conviction, the besmirching of the Sens' reputations has continued. While Dr. Sen can continue to practice medicine, he is subject to onerous conditions imposed by the Court. Mrs. Sen cannot work with Dr. Sen or

[3] The irony that Dr. Sen may have to pay an expert to determine his compliance with the FDCA seems to have been lost on the district court and the government. It certainly underscores the absurdity of making the receipt of mislabeled drugs a strict liability offense.

other medical providers unless her probation officer grants prior approval and even then is limited in what she can do. R 172: Judgment, PID 3265. Whether this bell can ever be unrung is unclear. What is clear, however, is that the Sens should never have faced such consequences. Applying Section 331 to them without a *mens rea* requirement violated their Constitutional right to due process.

II. THE EXPANSION OF STRICT LIABILITY CRIMES STRETCHES PROSECUTORIAL DISCRETION TO THE BREAKING POINT

A. *There Has Been An Unwarranted Expansion of Federal Criminal Liability And, In Particular, Strict Liability Crimes*

Given the above discussion of how the Constitution clearly disfavors strict liability criminal offenses, Congress' expansion of Federal crimes and, in particular, strict liability crimes, is deeply troubling.

The Supreme Court has recognized that "[a]ll are entitled to be informed as to what the State commands or forbids." *Lanzetta v. New Jersey*, 306 U.S. 451, 453 (1939). "Historically, it was presumed that the law, and especially the criminal law, was 'definite and knowable,' even by the average person." Brian Walsh and Tiffany Joslyn, *Without Intent: How Congress Is Eroding the Criminal Intent Requirement in Federal Law*, The Heritage Found. & NACDL, April 2010, 4. While that may have been true when criminal laws were primarily directed to prohibiting *malum in se*—"evil in itself"—conduct, it is no longer so.

> Whatever its plausibility centuries ago, the "definite and knowable" claim cannot withstand modern analysis. There has been a "profusion of legislation making otherwise lawful conduct criminal (*malum prohibitum*)." Therefore, even a person with a clear moral compass is frequently unable to determine accurately whether particular conduct is prohibited.... In today's complex society, therefore, a person can reasonably be mistaken about the law.

Joshua Dressler, *Understanding Criminal Law* 166 (3d ed. 2001) (internal quotation marks and citations omitted).

Today, there is no list of all of the federal criminal statutes and regulations currently on the books. Walsh & Joslyn, at 6. Indeed, it may be impossible to compile such a list. *Id*. at 2-4. In the late 1980s, the Department of Justice suggested there were more than 3,000 federal criminal laws. *See* James A. Strazzella, *The Federalization of Criminal Law*, Criminal Justice Section, American Bar Association, 1998, at 94. In 1998, an American Bar Association Task Force on the Federalization of Crime concluded that it was virtually impossible to get an accurate count of all of the federal crimes because the statutes are complex, there are so many, their location in the United States Code and Code of Federal Regulations is so scattered, and there are nearly 10,000 regulations that are nearly impossible to categorize because they mention some sort of criminal or criminal-type sanction. *Id*. at 10. That same ABA Task Force study found that, "of the federal criminal provisions passed into law during the 132-year period from

the end of the Civil War to 1996, fully 40 percent were enacted in the years from 1970 to 1996." *Id*. at 7-8.

Ten years after the ABA Task Force report, Professor John S. Baker, Jr., while acknowledging many of the same difficulties as the ABA Task Force in trying to count accurately the total number of federal criminal laws, concluded that by the end of 2007, the United States Code contained at least 4,450 federal criminal laws. John S. Baker, Jr., *Revisiting the Explosive Growth of Federal Crimes*, Heritage Foundation Legal Memo. No. 26, June 16, 2008, at 5. Of those 4,450 federal criminal laws, approximately 452—a full ten percent—had been added in the eight years from 2000 through 2007, an average rate of 56.5 new criminal laws per year—i.e., more than one per week. *Id*. at 1-2. Professor Baker commented that this rate is

> roughly the same rate at which Congress created new crimes in the 1980s and 1990s. So for the past twenty-five years, a period over which the growth of federal criminal law has come under increasing scrutiny, Congress has been creating over 500 new crimes per decade.

Id.

This hyper-federalization of criminal law has been especially acute in the area of strict liability crimes. Despite the recognized importance of a *mens rea* requirement and the Constitutional implications where such a requirement is not

present, a joint Heritage Foundation and NACDL study that looked only at the 109th Congress, concluded that of the thirty-six non-violent offenses introduced during that congressional session, a full one-quarter had no *mens rea* requirements whatsoever and almost forty percent had only "weak" *mens rea* requirements. Walsh & Joslyn, at 11-15.[4]

B. *Expansion of Federal Criminal Law Especially in the Area of Strict Liability Crimes Dangerously Grants Prosecutors Too Much Discretion*

In light of the expansion of Federal crimes and, in particular, strict liability crimes, prosecutorial discretion becomes especially problematic. As the Supreme Court noted in *Morissette*, the "purpose and obvious effect of doing away with the requirement of a guilty intent is to ease the prosecution's path to conviction." 342 U.S. at 263. In such an environment, it is not a question if, but when prosecutors will overstep their bounds and rashly and improperly exercise their discretion.

Nor is it enough for the government to promise that it will exercise its discretion to prosecute strict liability crimes carefully and sparingly. As the Supreme Court has stated, the Constitution "does not leave us at the mercy of *noblesse oblige*." *United States v. Stevens*, 559 U.S. 460, 480 (2010). Indeed, a

[4] The Heritage/NACDL report put offenses in the "weak" category if the statute's "language is reasonably likely to protect from conviction at least some defendants who did not intend to violate a law and did not have knowledge that their conduct was unlawful or sufficiently wrongful to put them on notice of possible criminal responsibility." Walsh & Joslyn, at 15.

court should "not uphold an unconstitutional statute merely because the Government promised to use it responsibly." *Id*. As Justice Breyer explained in his concurring opinion in *Chicago v. Morales*, a law "is unconstitutional . . . [when] the [prosecutor] enjoys too much discretion in *every* case. And if every application of the [statute] represents an exercise of unlimited discretion, then the ordinance is invalid in all its applications." 527 U.S. 41, 71 (1999) (Breyer, J., concurring) (emphasis in original).[5]

C. *This Case Is the Poster Child for Prosecutorial Overreach*

While the Supreme Court in *Dotterweich* declined to set "a formula" by which to determine who could be liable for violating the FDCA without *mens rea*,

[5] The concerns about prosecutorial discretion in an age of expanding Federal criminal liability are hardly abstract. For instance, a retired logger and his son in Idaho were convicted of violating the Archaeological Resources Protection Act of 1979 for attempting to dig for arrowheads near their favorite campground. Though the two men did not discover any arrowheads and there was no evidence that they either intended to break the law or knew it existed, they were convicted of violating the Act. Gary Fields and John R. Emshwiller, *As Criminal Laws Proliferate, More Are Ensnared*, Wall St. J., July 23, 2011, http://online.wsj.com/news/articles/SB10001424052748703749504576172714184601654; *see also* Edwin Meese III, Paul J. Larkin, Jr., *Reconsidering the Mistake of Law Defense*, 102 J. Crim. L. & Criminology 725, 784 n.115 (2012) (listing a series of dubious criminal charges and convictions including a defendant who "spent sixty-nine months in federal prison for importing marginally small lobsters and for bulk packing them in plastic, rather than bin boxes, in violation of Honduran law," and a man "charged . . . with freeing a whale caught in his fishing net, rather than reporting the ensnarement to federal authorities so that they could free the whale instead, in violation of the Marine Mammal Protection Act of 1972, 16 U.S.C. §§1371-1423 (2006)").

it expressed confidence that going forward its application could be entrusted to the "good sense" and "conscience and circumspection" of prosecutors. 320 U.S. at 285 (internal quotation marks omitted). This case demonstrates that confidence was misplaced and clearly shows the perils inherent in expanding the reach of strict liability crimes. This case *is* the definition of prosecutorial overreach and demonstrates that prosecutors will in fact push the outer bound of criminal liability to unprecedented and novel situations.

Here, there is no dispute that Dr. Sen and his wife provided exceptional care. Nor is there any claim that the mislabeled drugs they received were dangerous because of that mislabeling or materially different from the equivalent brand name drugs. This was a case in which Mrs. Sen began ordering drugs from Clinical Care after she received a solicitation from the company offering medications at a lower price than other distributors. R. 141: Trial Tr., PID 1556; R. 144: Trial Tr., PID 2159-70. The Sens were unaware that Clinical Care was being investigated by the FDA as a "criminal enterprise." R. 144: Trial Tr., PID 2216. When Mrs. Sen learned of this, she voluntarily assisted the FDA in its investigation. Despite all of this and despite the fact that the FDA Agent driving the investigation was, himself, ignorant of the FDA regulations governing labeling, *see* R. 144: Trial Tr., PID 2235-37, the government chose to prosecute the Sens. Indeed, even the FDA's labeling expert admitted at trial that he was unaware of the labeling regulations

during his 18 years as a practicing physician. R. 128: Trial Tr., PID 1372-73, 1376. Nevertheless, the government pushed forward with its prosecution. After conviction, the government continued its overreach, remarkably seeking a three-year prison term for Mrs. Sen—all for receiving mislabeled drugs.

One other aspect of this prosecution illustrates the perverse distortions created by strict liability crimes. As Appellants explain, the allegedly misbranded labels were suppressed at trial because they were the product of an unconstitutional search. *See* Appellants' Br. at 18-19. This left the prosecution with very little to prove its case. The slender reed that it used to make its case was the collection of invoices and packing slips sent by Clinical Care, the very organization the FDA considered to be a "criminal enterprise." Appellants effectively show that these records were inadmissible as hearsay as they clearly were not business records of Dr. Sen's clinic. *See* Appellants' Br. at 50-56. But, more broadly, their use and admission show the perils of strict liability offenses. Because under the government's unconstitutional theory, it needed to prove only that the Sens' received mislabeled drugs, it could reach for the weakest of possible evidence to prove its case. Such are the perverse incentives placed on prosecutors when they are given the hammer of strict liability crimes.

Thus, this demonstrates the distortions that strict liability crimes create with respect to prosecutorial discretion. Good sense and reasonableness fly out the

window when the government must do nothing more than prove that a defendant received something mislabeled or adulterated. Even the weakest of evidence is marshalled to attempt to secure a conviction.

III. STRICT LIABILITY CRIMES DISTORT THE PLEA BARGAINING PROCESS

A final argument against the expansion of strict liability offenses is that they distort the plea bargaining process. If the government must not prove intent, it is given a huge cudgel with which to beat a defendant into submission: take this plea because we do not need to prove much at trial. This gives the government, which already has a significant advantage, *all* the cards in plea negotiations. Furthermore, where the government has a strict liability felony with which it can plausibly charge a defendant in addition to misdemeanor charges—as it did here—that advantage is further enhanced.

Again, the FDCA provides the emblematic example. The government can threaten someone who has merely received mislabeled drugs or adulterated food with a felony charge effectively to force her to accept a misdemeanor charge even though the person had no criminal intent. The threat of a felony charge is a massive hammer that assuredly distorts the plea bargaining process in the context of strict liability crimes.

Indeed, here the district court questioned why the Sens would even have proceeded to trial given that the government, *in its view*, did not need to prove criminal intent. See R. 171: Sentencing Tr., PID 3178-79. If the judgments in this case are not reversed and remanded with an order to enter judgments of acquittal, the distortive dynamic described above will only be accentuated. In light of the Appellants' conviction, the next innocent doctor charged with merely receiving mislabeled drugs will have to think long and hard whether she is willing to roll the dice at trial even though she has received those drugs innocently. This is all the more reason for this Court to reverse.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgments and remand for entry of judgments of acquittal.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME, TYPEFACE, AND STYLE REQUIREMENTS

This brief contains complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), because it contains 3,881 words according to the Microsoft Word word processing program, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been prepared in Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that I served this brief on all counsel of record through the Court's CM/ECF system on October 6, 2014.

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AMICUS CURIAE'S DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Amicus Curiae, NACDL, pursuant to 6th Circuit Rules 28(c) and 30(b), hereby designates the following relevant District Court documents in the electronic record:

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141	Trial Transcript	1544
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156	Government Sentencing Memorandum	2739
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174	Judgment	3270

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