Nos. 15-1890, 15-1891

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

UNITED STATES OF AMERICA,

Appellee,

v.

AUSTIN DECOSTER,

Defendant-Appellant.

UNITED STATES OF AMERICA,

Appellee,

v.

PETER DECOSTER,

Defendant-Appellant.

On Appeals from the United States District Court
for the Northern District of Iowa, No. 14-cr-3024 (Mark W. Bennett, J.)

BRIEF FOR AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF APPELLANTS AND URGING REVERSAL

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CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1, amicus curiae Pharmaceutical Research and Manufacturers of America (PhRMA) states that it is a membership organization with no parent corporation, and no publicly held company owns 10 percent or more of its stock. PhRMA's membership, however, includes companies that have issued stock or debt securities to the public. PhRMA's member companies are listed on its website at http://www.phrma.org.

In accordance with Federal Rule of Appellate Procedure 26.1, amicus curiae Chamber of Commerce of the Unites States of America ("the Chamber") states that it is a membership organization with no parent corporation, and no publicly held company owns 10 percent or more of its stock.

TABLE OF CONTENTS

Page

CORPORATE DISCLOSURE STATEMENT

TABLE OF AUTHORITIES ii

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 3

ARGUMENT 6

I. Criminal Prosecutions Of Corporate Officers Who Lack Any Culpable State Of Mind With Respect To A Corporation's Wrongdoing Represent A Sharp Departure From Fundamental Principles In Criminal Law 6

II. The Court Should Not Extend The Responsible Corporate Officer Concept To Permit Imprisonment Without Proof Of Scienter 12

A. Imprisonment Without Scienter Raises Serious Constitutional Questions 13

B. Imprisonment Without Scienter Would Do Little To Protect The Public And May Result In Overdeterrence 18

CONCLUSION 28

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

CASES

Page(s)

Commonwealth v. Koczwara,
155 A.2d 825 (Pa. 1959).....15

Davis v. City of Peachtree City,
304 S.E.2d 701 (Ga. 1983).....15

Elonis v. United States,
135 S. Ct. 2001 (2015).....6, 8, 17

Edward J. DeBartolo Corp. v. Florida Gulf Coast Build. & Constr. Trades Council, 485 U.S. 568 (1988).....17

Friedman v. Sebelius,
686 F.3d 813 (D.C. Cir. 2012).....21

Holdridge v. United States,
282 F.2d 302 (8th Cir. 1960).....14

Lady J. Lingerie, Inc. v. City of Jacksonville,
176 F.3d 1358 (11th Cir. 1999).....4, 15, 16, 17

Morissette v. United States,
342 U.S. 246 (1952).....6, 7

People ex rel. Price v. Sheffield Farms-Slawson-Decker Co.,
121 N.E. 474 (N.Y. 1918).....14

Staples v. United States,
511 U.S. 600 (1994).....14, 15

State v. Guminga,
395 N.W.2d 344 (Minn. 1986).....15

United States v. Chavez-Alvarez,
594 F.3d 1062 (8th Cir. 2010).....9

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320 U.S. 277 (1943).....4, 5, 6, 7, 8

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421 U.S. 658 (1975).....*passim*

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495 F. Supp. 2d 569 (W.D. Va. 2007).....15

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513 U.S. 64 (1994).....6

United States v. Y. Hata & Co.,
535 F.2d 508 (9th Cir. 1976).....26

STATUTES AND REGULATIONS

21 U.S.C.
§ 331..... 24-25
§ 333.....*passim*
§ 355.....24
§ 360.....24
§ 373.....24
§ 374.....24

42 U.S.C. § 1320a-7(b)(1)(A).....21

U.S.S.G.
§ 8B2.1.....23, 25
§ 8C2.4.....25
§ 8C2.5.....25

67 Fed. Reg. 11,928 (Mar. 18, 2002).....21

DOCKETED CASES

United States v. Hermelin, No. 11-cr-85 (E.D. Mo.).....12

United States v. Norian Corp., No. 09-cr-403 (E.D. Pa.).....12

United States v. Purdue Frederick Co., No. 07-cr-29 (W.D. Va.).....12

United States v. Quality Egg, LLC, 14-cr-3024 (N.D. Iowa).....18

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Packer, Herbert L., The Limits of the Criminal Sanction (1968) 14

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STATEMENT OF INTEREST

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's member companies are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. During 2014 alone, PhRMA members invested an estimated $51.2 billion in efforts to research and develop new medicines. PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines by its members.

The Chamber of Commerce of the United States of America is the world's largest business federation, representing more than 300,000 direct members and an underlying membership of more than three million businesses and trade and professional organizations of every size and sector, and from nearly every geographic region. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts, including this Court.

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[1] This brief is filed with the consent of all parties. No counsel for any party authored this brief in whole or in part, and no entity or person, aside from amici curiae, its members, and its counsel, made any monetary contribution intended to fund preparation or submission of this brief.

Many of amici's members are subject to the comprehensive and strict regulations of the Federal Food, Drug, and Cosmetic Act (FDCA), which protect the public by ensuring that food and drugs introduced or delivered into interstate commerce are free of adulterating substances and are not misbranded. *See* pp.7-9, *infra*. Entities that introduce or deliver food and drugs in interstate commerce—including many of amici's members—are also subject to potential prosecution for criminal violations of the FDCA under 21 U.S.C. § 333, providing an additional measure of security to the public. In addition, and directly at issue here, under the "responsible corporate officer" (RCO) concept, officers of amici's members are *individually* subject to potential prosecution under 21 U.S.C. § 333(a), which, under current precedent, does not require a culpable mental state for conviction.

Amici have a vital interest in ensuring that the "responsible corporate officer" concept is given a fair and rational construction, consistent with fundamental precepts of the Anglo-American legal tradition. Allowing imprisonment of a corporate officer based only on his position within a company, without proof that the officer had a criminal state of mind or any culpable connection to a violation of the FDCA, will not advance public health or safety, is fundamentally unfair, and will likely result in overdeterrence, impairing the public's access to pharmaceuticals and other products that extend or improve lives. The government's recent determination to seek imprisonment of corporate officers

who had neither knowledge of nor intent to commit violations of the FDCA raises substantial constitutional doubts about the responsible corporate officer concept. Those constitutional doubts had previously been avoided by decades of restraint in the government's use of strict criminal liability theories under the FDCA, but now have been brought to the fore by the government's decision to seek imprisonment of an individual for violation of a strict-liability misdemeanor. This Court can avoid those profound constitutional questions by holding that imprisonment is not a permissible form of punishment under § 333(a) when the government proceeds solely under the theory that the defendant is liable as a responsible corporate officer. In the alternative, if the Court concludes that § 333(a) does permit imprisonment in such cases, the Court should rule that such punishment is unconstitutional.

SUMMARY OF ARGUMENT

1. Scienter is a bedrock principle of criminal law. A fundamental precept of Anglo-American criminal law, as opposed to civil or administrative provisions, has long been that individuals should be punished not merely because they committed a wrong but because they also did so with a culpable state of mind. The Supreme Court has recognized a narrow exception to that longstanding rule, by which responsible corporate officers of entities that commit violations of the FDCA may be found criminally liable without proof of criminal intent, a failure to exercise

reasonable care, or even knowledge of the violations, if those infractions fall within the officers' ultimate area of supervision. *See United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Park*, 421 U.S. 658 (1975). But the violations in those cases were misdemeanor offenses in which the government was seeking small financial penalties; the Supreme Court has never condoned imposing imprisonment on a strict liability basis. Recognizing the hardship that may result from proceeding under this anomalous concept, the government until recently followed a policy of prosecuting FDCA violations only against corporate officers who had demonstrated some kind of personal culpability.

2. The sentences of imprisonment here represent an unwarranted extension of this strict-liability regime of *Dotterweich* and *Park*. Imprisonment, even for a few months, is a punishment different in kind from a mere conviction or fine—beyond property or reputation, it deprives the individual of liberty. Imprisoning a blameless individual for the actions of another creates serious constitutional concerns; indeed, the Eleventh Circuit has correctly held that an individual may not be imprisoned for an offense solely based on the individual's "responsible relation" to the wrongdoer. *Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358, 1367-1368 (11th Cir. 1999) (discussing *Park*). This Court should hold that, in light of these constitutional concerns, § 333 does not permit imprisonment for a strict liability, vicarious violation of the FDCA.

3. Imprisonment for strict-liability violations of the FDCA is neither necessary nor appropriate to advance the purposes of the FDCA. To the contrary, extending the *Dotterweich* and *Park* decisions to permit imprisonment of non-culpable individuals would be useless (at best) or affirmatively harmful (at worst). With or without imprisonment, allowing convictions of people even if they have exercised due care, based on the actions of others of which they were unaware, is unlikely to deter violations of the FDCA. Actual deterrence would be better achieved by rigorously enforcing a compliance program to root out and prevent violations of the FDCA, and punishing individuals personally responsible for the violations. Even if one purpose of strict liability for corporate officers is to promote effective compliance systems, little in the way of deterrence is accomplished by imprisoning individuals who use their best efforts to maintain and enforce such systems and who themselves act in entirely appropriate ways merely because a violation happens on their watch. Because strict liability under the responsible corporate officer concept does not recognize mitigation, it cannot be effectively calibrated. Moreover, that rigid enforcement, coupled with the risk of imprisonment, may provide individual officers with a perverse incentive to protect their own interests at the risk of their employer company and the public at large. Since reasonable precautions do not insulate them from liability, they may exercise *more* than reasonable precautions, steering their company away from socially

beneficial conduct out of a concern for their own best interests. There is therefore no need or reason to extend *Dotterweich* and *Park* to allow imprisonment of individuals based on violations for which they had no personal culpability.

ARGUMENT

I. CRIMINAL PROSECUTIONS OF CORPORATE OFFICERS WHO LACK ANY CULPABLE STATE OF MIND WITH RESPECT TO A CORPORATION'S WRONGDOING REPRESENT A SHARP DEPARTURE FROM FUNDAMENTAL PRINCIPLES IN CRIMINAL LAW

"Historically, our substantive criminal law is based upon a theory of punishing the vicious will. It postulates a free agent confronted with a choice between doing right and doing wrong and choosing freely to do wrong." *Morissette v. United States*, 342 U.S. 246, 250 n.4 (1952) (internal quotation marks omitted). Because this precept of our criminal law—that criminal punishment is inappropriate without a culpable state of mind—is so fundamental, courts strive to interpret criminal statutes to require a criminal mental state as a prerequisite to punishment. *See, e.g., Elonis v. United States*, 135 S. Ct. 2001, 2009 (2015); LaFave, *Substantive Criminal Law* § 5.1 (2d Ed. 2015) ("An act does not make one guilty unless his mind is guilty."). That is true "even where the statute by its terms does not contain" any element of intent. *United States v. X–Citement Video, Inc.*, 513 U.S. 64, 70 (1994). Whether one calls it "*mens rea*, scienter, [or] malice aforethought," *Elonis*, 135 S. Ct. at 2009, a guilty mindset is a natural element of criminal liability, and removing any scienter requirement is contrary to deep-seated

notions of justice and fairness. For the most basic reasons, including bedrock concerns about fairness and peace of mind in the conduct of daily affairs, our society does not lightly embrace the notion that one can be criminally punished without acting even negligently, much less recklessly or intentionally.[2]

Yet prosecution of individuals merely because they are "responsible corporate officers" does just that: It permits an individual to be criminally punished without any proof of blameworthiness or personal participation in the facts that form the basis of criminal liability (or, indeed, knowledge of those facts). Although 21 U.S.C. § 333(a) does not expressly dispense with a scienter requirement, the Supreme Court has twice read it to do so. *United States v. Dotterweich*, 320 U.S. 277, 285 (1943); *United States v. Park*, 421 U.S. 658 (1975). In *Dotterweich*, the Court concluded that it was "[i]n the interest of the larger good" that a person "otherwise innocent" should be criminally punished if an FDCA violation occurs within his area of responsibility, even without

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[2] *See* Holmes, The Common Law 50 (1909) ("[A] law which punished conduct which would not be blameworthy in the average member of the community would be too severe for that community to bear."); *Morissette*, 342 U.S. at 254 n.14 ("To inflict substantial punishment upon one who is morally entirely innocent, who cause injury through reasonable mistake or pure accident, would so outrage the feelings of the community as to nullify its own enforcement.") (quoting Sayre, *Public Welfare Offenses*, 33 Colum. L. Rev. 55, 56 (1933)).

"conscious fraud." *Dotterweich*, 320 U.S. at 281.[3] Accordingly, Dotterweich was fined $1,500 (with all but $500 suspended) for his offense, even though he lacked scienter. U.S. *Dotterweich* Br. 3, 1943 WL 54821 (Aug. 1943). In *Dotterweich* the Court acknowledged that its strict-liability standard could reach anyone with a "responsible relation" to the violation, 320 U.S. at 285, and that "[h]ardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting," *id.* at 284. But the Court concluded that it could entrust responsibility for avoiding such unfairness to juries, the "wise guidance of trial judges," and "the good sense of prosecutors." *Id.* at 285.

In *Park*, the United States offered the Supreme Court a "good sense" approach to the potentially sweeping scope of criminal liability under *Dotterweich*. A scienter requirement, the government submitted, would be an "impractical burden of proof" when prosecuting a corporate officer because he will likely know "in general terms[] about a problem … [but] he is unlikely to know about any of the details, and thus may not knowingly or willfully have caused the specific

[3] *Dotterweich*'s approach and holding are in tension with the Supreme Court's recent case law on criminal scienter, which makes clear that scienter should be read into a criminal statute to "separate wrongful conduct from otherwise innocent conduct." *Elonis v. United States*, 135 S. Ct. 2001, 2010 (2015).

violations involved." U.S. *Park* Br. 38 (Jan. 1975).[4] But in asking the Court to dispense with a *mens rea* requirement for individuals, the government assured the Court that it would exercise restraint and prosecutorial discretion to avoid needlessly harsh outcomes in the application of the FDCA: It pledged not to prosecute officers who were "totally unaware of any problem" and who "could not have been expected to be aware of it." *Id.* at 31. Likewise, the government assured the Supreme Court that the FDA would "not ordinarily recommend prosecution unless" the defendant actually learned about violations and "failed to correct them or to change his managerial system so as to prevent further violations." *Id.* at 32. According to the government, the defendant in *Park* was an appropriate target for criminal prosecution under 21 U.S.C. § 333(a) because he had "had actual notice from FDA of the problem and failed to correct it." U.S. *Park* Br. 17.

With the benefit of the government's assurances, the Court in *Park* held that an individual could be convicted under § 333(a) without any criminal intent, as long as he had "responsibility and authority" to prevent or correct an FDCA violation. *Park*, 421 U.S. at 673-674; *see also* Greenberg & Brotman, *Strict*

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[4] The government did not explain why these problems could not be avoided by applying the settled rule that one who willfully blinds himself to a fact or act is deemed to have had knowledge of it. *See United States v. Chavez-Alvarez*, 594 F.3d 1062, 1067 (8th Cir. 2010).

Vicarious Criminal Liability for Corporations and Corporate Executives, 51 Am. Crim. L. Rev. 79, 90 (2014). The Court therefore affirmed the $250 fine imposed on Park. *Id.* at 666.

Until recently, the government appeared to stay true to its word that it would not proceed against defendants who lacked any culpable scienter. For the first few decades, "the overwhelming majority (if not all)" of the prosecutions brought under *Park* "involved a defendant who was aware of the conduct giving rise to the violation but failed to correct it—as was the situation in *Park* itself." *Id.*; *see* Bragg et al., *Onus of Responsibility: The Changing Responsible Corporate Officer Doctrine*, 65 Food & Drug L.J. 525, 529 (2010) ("[T]he defendant has nearly always been alleged to have either had knowledge of the underlying violation, participated to some extent in the wrongdoing, or both.").[5]

Recent years have seen a dramatic change in the government's approach to using the "responsible corporate officer" concept as a basis for criminal prosecution. Whereas previously the government generally pursued only corporate officers who had knowledge of the facts that formed the basis of the criminal violation, and even then usually sought only fines and not imprisonment as a sanction, the government recently has moved to prosecute corporate officers solely

[5] Based on this general practice of prosecutorial restraint, some commentators have suggested that *Park* actually requires "strict liability *plus*" or another heightened standard. Bragg, 65 Food & Drug L.J. at 529 (emphasis added).

because their role in the corporation included ultimate responsibility to supervise the persons or entities that violated the FDCA, and has sought imprisonment in those cases. In consequence, the government's use of the "responsible corporate officer" concept today looks very different than it looked when the government assured the Supreme Court in *Park* that it would exercise restraint when invoking that basis for criminal liability.

In response to a 2010 Government Accountability Office report urging the FDA to intensify its investigations of criminal misconduct, the FDA Commissioner stated that the government would seek to "hold responsible corporate officers accountable." Breen & Retzinger, *The Resurgence of the Park Doctrine and the Collateral Consequences of Exclusion*, 6 J. Health & Life Sci. L. 90, 101 (2013) (note). In a similar vein, a high-ranking official of the Justice Department stated in 2011 that individuals ought, in the right circumstances, to be "held strictly liable for criminal violations of the Food, Drug, and Cosmetic Act." Speech at the 12th Annual Pharmaceutical Regulatory and Compliance Congress (Nov. 2, 2011), available at www.justice.gov/iso/opa/civil/speeches/2011/civ-speech-111102.html.

Following this apparent change in government enforcement policy, the Department of Justice has aggressively used the responsible corporate officer

concept to charge individuals with criminal violations of the FDCA.[6] That change in policy includes seeking a term of incarceration in cases like this one, where the defendant was charged with an offense that does not require proof of scienter. Likewise, in January 2011 the FDA significantly revised its guidelines for referring cases to the Justice Department for prosecution. The FDA eliminated its previous guideline that "ordinarily" required proof that the individual was on notice of a violation but had failed to correct a "continuous course of violative conduct." FDA, *Regulatory Procedures Manual* § 6-5-1 (Mar. 2004). Under the 2011 guidelines, the FDA expressly disavows "[k]nowledge of and actual participation in the violation" as a necessary conditions for prosecution. FDA, *Regulatory Procedures Manual* § 6-5-3 (Jan. 2011). Nor does it require a continuous course of violations by the defendant—one infraction is apparently enough and any subsequent violation is a felony. *Id.*

II. THE COURT SHOULD NOT EXTEND THE RESPONSIBLE CORPORATE OFFICER CONCEPT TO PERMIT IMPRISONMENT WITHOUT PROOF OF SCIENTER

This Court should not join the government's effort to push scienter to the side and thereby overturn a fundamental element of the criminal law. First,

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[6] *See, e.g.*, Information, *United States v. Purdue Frederick Co.*, No. 07-cr-29 (W.D. Va. 2007) (charging three officers with criminal liability as responsible corporate officers); Indictment, *United States v. Norian Corp.*, No. 09-cr-403 (E.D. Pa. June 16, 2009) (charging four officers); Information, *United States v. Hermelin*, No. 11-cr-85 (E.D. Mo. Mar. 10, 2011) (charging officer).

imposition of a sentence of imprisonment without any culpable mental state—even negligence—raises grave constitutional questions, and the Court should not discern in § 333(a) a legislative intent to authorize such punishment without guilty knowledge absent a most clear expression of that purpose by Congress—which is surely lacking in the statute. Second, punishment by imprisonment of those without personal culpability does not advance the central purpose of the FDCA: It does nothing to ensure the safety of food and drugs marketed to the public, and it may result in overdeterrence, harming the public by impairing their access to needed and desirable pharmaceuticals, medical devices, food products, and other products in the sectors regulated by the FDCA.

A. Imprisonment Without Scienter Raises Serious Constitutional Questions

Under the government's approach to prosecution of responsible corporate officers, an individual could be sentenced to a year in prison for a single violation of the FDCA and to three additional years in prison for any subsequent violation. *See* 21 U.S.C. § 333(a); *Park*, 421 U.S. at 682-683 (Stewart, J., dissenting). As the government sees it, such grave punishments are permissible even if the individual did not know about the facts underlying the violation and was not even negligent in allowing their occurrence; rather, the individual faces incarceration because he is ultimately responsible for some corporate functions and another person happens to commit a violation within his area of responsibility.

That kind of grave punishment extends the "theory of the public welfare offense" that underlies the responsible corporate officer concept far beyond the cases in which it has been approved by the courts. *See Staples v. United States*, 511 U.S. 600, 618 (1994). Although this Court has previously held that a strict liability crime does not violate due process "where the penalty is relatively small," and "where [the] conviction does not gravely besmirch" the defendant (among other criteria), *Holdridge v. United States*, 282 F.2d 302, 310 (8th Cir. 1960), those supportive factors fade quickly when one examines the consequences of a conviction and potential for imprisonment under § 333(a).

Imprisonment is "apart from anything else the law imposes." Packer, The Limits of the Criminal Sanction 131 (1968); *see People ex rel. Price v. Sheffield Farms-Slawson-Decker Co.*, 121 N.E. 474, 477 (N.Y. 1918) (Cardozo, J.) ("the power to fine" is not "the power to imprison"). Given the gravity of the sanction of imprisonment, courts have traditionally subjected any attempt to impose the penalty of incarceration on a defendant who has not been proven to possess a guilty mind or other culpable involvement to close scrutiny. As Judge Crane explained in his concurring opinion in *Price*, a sentence of imprisonment for an infraction lacking any element of scienter would "stretch[] the law regarding acts *mala prohibita* beyond its legal limitation." *Id.* at 478.

Several courts have agreed with Judge Crane that imprisonment should not be an available punishment for a strict-liability offense in which the defendant was not proven to play any personal role in the facts underlying the violation. The Georgia Supreme Court concluded that it violates due process to send a defendant to jail when his conviction is based on the "actions of his employees which are taken without his knowledge, consent, or authorization and which are not the result of negligence attributable to him." *Davis v. City of Peachtree City*, 304 S.E.2d 701, 702 (Ga. 1983). The Minnesota Supreme Court likewise concluded that it would violate due process to criminally punish a person "for an act which [he] did not commit or ratify." *State v. Guminga*, 395 N.W.2d 344, 346-347 (Minn. 1986). And the Pennsylvania Supreme Court determined that, although a defendant could be fined for an offense that required neither *mens rea* nor his personal involvement, it violated due process to imprison him for that offense. *Commonwealth v. Koczwara*, 155 A.2d 825, 829-831 (Pa. 1959).

The Eleventh Circuit has similarly held that "due process *at least* requires individualized proof of intent or act" before "sending someone to prison." *Lady J. Lingerie, Inc. v. City of Jacksonville*, 176 F.3d 1358, 1367-1368 (11th Cir. 1999).[7]

[7] *See also United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569, 576 (W.D. Va. 2007) (without "proof of knowledge by the individual defendants of the wrongdoing, prison sentences are not appropriate"); *Staples*, 511 U.S. at 617 ("imposing severe punishments for offenses that require no *mens rea* would seem incongruous").

The statute at issue in *Lady J.* held the owner of certain regulated property criminally liable for act committed by his employees "within … [an] employee's scope of authority under the owner." *Id.* at 1367. Like § 333(a), the statute contained no scienter requirement and also did not require proof of the defendant's personal involvement in the facts underlying the employees' violation of law. And like § 333(a), the statute appeared to authorize incarceration even for a strict-liability offense; a defendant's first five convictions under the statute could be punished by a fine or ten days in jail, and subsequent offenses were punished by a mandatory 90 days in jail. *Id.*

The Eleventh Circuit did not question that the owner of the property could be subject to some criminal sanctions based on a theory of strict and vicarious liability, such as criminal fines, but it concluded that incarceration, even for ten days, would violate the Due Process Clause. As the Eleventh Circuit explained, "due process prohibits the state from imprisoning a person without proof of some form of personal blameworthiness more than a 'responsible relation.'" *Lady J.*, 176 F.3d at 1367. The court further noted that its holding was consistent with *Park*, for in *Park* the defendant's "only punishment was a fine; incarceration is a different matter." *Id.* Indeed, consistent with *Park*, the Eleventh Circuit held that "criminal liability based on *respondeat superior* is acceptable if the defendant is in

a 'responsible relation' to the unlawful conduct or omission, *but only if the penalty does not involve imprisonment*." *Id.* (emphasis added).

These cases show that, at a minimum, imposition of a sentence of imprisonment where the government has not proven that the defendant acted with a culpable state of mind (even negligence) or personally participated in the facts underlying the violation raises grave constitutional questions. This Court should avoid those constitutional doubts by holding that a sentence of imprisonment is not authorized under § 333(a) for a violation of the FDCA predicated solely on a responsible corporate officer theory. Such a statutory reading is well-supported given the failure of § 333(a) to expressly authorize imprisonment in the absence of a culpable mental state coupled with the longstanding presumption of Anglo-American criminal law that imprisonment requires "*mens rea*, scienter, [or] malice aforethought." *Elonis*, 135 S. Ct. at 2009. And "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress." *Edward J. DeBartolo Corp. v. Florida Gulf Coast Build. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

If, however, the Court concludes that imprisonment is so authorized under § 333(a), then it should rule that imprisonment for an offense that does not require

proof that the defendant acted with culpable intent or personally participated in the facts forming the basis of the violation is unconstitutional.

B. Imprisonment Without Scienter Would Do Little To Protect The Public And May Result In Overdeterrence

The government contends that the threat of imprisonment for responsible corporate officers under § 333(a) is necessary to deter violations of the FDCA and to safeguard the public from health violations. As the government would have it, corporate officers are in the best position to prevent violations throughout their companies, and the potential for strict criminal liability encourages those officers to "investigate further and take appropriate ameliorative action." U.S. Resistance to Mot. that Sentence of Incarceration or Confinement Is Unconstitutional 10, *United States v. Quality Egg, LLC*, 14-cr-3024 (Oct. 23, 2014, Dkt. 74). But the government's support for strict criminal liability in this context is thin at best, and excessive deterrence is not without cost as well.

It is highly doubtful that imposing strict criminal liability on corporate officers based on their corporate positions will effectively deter violations of the FDCA.[8] The only individuals punished by a strict-liability regime, beyond those who would be punished under a traditional criminal law regime requiring at least

[8] That is doubly true under § 333(a), because the corporate officer is held strictly liable for another employee's violation, and that violation itself is subject to punishment based on the employee's strict liability rather than his personal blameworthiness.

negligence, are those who exercised reasonable care in their duties. By definition, those who have exercised reasonable care cannot avoid further risks without taking *unreasonable* and excessive precautions. And when, as in this context, the liability is not only strict but vicarious—that is, the defendant is being punished for offenses committed by others under his ultimate supervision—the chance that a defendant could have prevented an injury through additional precautions is even further attenuated. *See* O'Leary, *Credible Deterrence: FDA and the* Park *Doctrine in the 21st Century*, 68 Food & Drug L.J. 137, 148 (2013) ("[U]sing corporate officer liability to deter non-negligent conduct is pointless because harms resulting from truly non-negligent behavior are not subject to deterrence."); *see generally* Demougin & Fluet, *A Further Justification for the Negligence Rule*, 19 Int'l Rev. L. & Econ. 33, 33 (1999) ("[T]he negligence rule is shown to Pareto dominate the strict liability rule" when seeking the optimal level of care a pre-determined level of activity).

In that circumstance, the officer may be punished, not for something that he might have anticipated and prevented, but for something that he could *not* have anticipated, even if he had acted with due care. In other words, in the government's view, even if the corporate officer had done everything he reasonably could have done to prevent a violation of the FDCA, but a violation nonetheless resulted as a consequence of others' actions, the officer may still be

sent to prison. It is difficult to see how such an approach to criminal liability effectively advances deterrence. *See* Copeland, *The Crime of Being in Charge: Executive Culpability and Collateral Consequences*, 51 Am. Crim. L. Rev. 799, 802 (2014) ("[T]he FDA is pursuing misdemeanor criminal charges against executives for the criminal conduct of their subordinates.").[9]

Moreover, even if some criminal punishment under a strict-liability regime might be justified on the basis of deterrence, *imprisonment* is unnecessary to accomplish the optimal level of compliance with the FDCA. Even without the imposition of a prison sentence, convictions under § 333(a) have severe consequences for individuals employed in industries covered by the FDCA. Such convictions are highly publicized in the pharmaceutical and medical-device sectors and inflict incalculable damage to reputation and career. *See, e.g.*, Barry Meier, *Narcotic Maker Guilty of Deceit over Marketing*, N.Y. Times, May 11, 2007; Peter

[9] Officers of companies regulated by the FDA are not bound to their corporate position. They can pursue employment elsewhere, in industries that are not susceptible to prosecutions with the threat of imprisonment based solely on the individual's status as a corporate officer. That is not necessarily desirable. The government's enforcement of truly strict liability prosecutions under *Park* is still new, *supra* pp.10-12, and its long-term effects are not yet known, but the consequences for food, pharmaceutical, and medical-device companies could be truly grave if, as a consequence of the increased threat of prosecutions of corporate officers under a strict-liability theory, they could not attract or retain highly qualified individuals. Nor would it be beneficial for those companies—or for the public—for these positions to be filled by individuals who were willing to accept the risk of a prison sentence in order to climb the corporate ladder.

Loftus, *Former Synthes Officers Receive Prison Sentences*, Wall Street J., Nov. 22, 2011. In addition, a misdemeanor conviction under § 333(a) can serve as the basis for an order by the Secretary of Health and Human Services to exclude the individual from participation under all federal health care programs. 42 U.S.C. § 1320a-7(b)(1)(A); *Friedman v. Sebelius*, 686 F.3d 813, 824 (D.C. Cir. 2012).[10] An order of exclusion effectively bans the individual from working in any health-care field, as almost all health-care providers participate in Medicare, Medicaid, or other federal health-care programs.[11] Individuals working in the sectors regulated by the FDCA are therefore well aware that violations that occur under their watch can have severe consequences for them personally, even if they had no culpable intent or involvement in the violations.

The government presumably believes that the possibility of imprisonment is necessary because the corporate officer, facing the prospect of incarceration, will

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[10] Amici have serious concerns about the interpretation of § 1320a-7(b)(1)(A) adopted by the Secretary and upheld in *Friedman*, as allowing exclusion based on a conviction for a strict-liability misdemeanor. Exclusion from the health care system is supposed to protect the public from "untrustworthy health care providers." 67 Fed. Reg. 11,928, 11,928 (Mar. 18, 2002). Excluding someone based on his position of responsibility, rather than any culpable act of his part, does little to advance the public safety goals that are at the heart of the FDCA.

[11] HHS OIG, *Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs* (Sept. 1999) ("[T]he practical effect of an … exclusion is to preclude employment of an excluded individual in any capacity by a health care provider that receives reimbursement, indirectly or directly, from any Federal health care program."), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm.

send a message to others under his supervision that such violations will not be tolerated and will establish internal controls to ferret out such violations and prevent them from occurring. It is true that compliance programs can deter and prevent violations of law. The officer and other managers at the corporation can install a compliance program (if one does not already exist) so that the organization's employees can be trained against violations, put monitoring and checklists in place, ensure quality control, and establish procedures to ensure compliance with the FDCA. Effective compliance programs can provide significant benefits to the company, the public, and the government. *See Oversight of the False Claims Act: Hearing Before the H. Comm. On the Judiciary*, 113th Cong. (2014) (statement of Patricia J. Harned, President, Ethics Resource Center).

But there is no reason why an effective compliance program must be spurred by threatening blameless individuals with incarceration. In the first place, the failure to maintain a reasonable compliance program or other reasonable internal controls in a company that operates in a sector where violations of law are a serious problem could be viewed as negligence on the part of responsible officers. Strict liability, however, operates to impose punishment even when the company *does* have reasonable internal controls, or even state-of-the-art controls targeted at the particular offense. No organization—whether private or governmental—can

guarantee perfect compliance with the law, particularly highly technical provisions like the FDCA; infractions are inevitable.

Moreover, the government can and does impose incentives directly on companies to establish and operate effective compliance programs. The federal sentencing guidelines, for example, offer incentives for installing and maintaining an effective compliance program. *See* U.S.S.G. § 8B2.1 (prescribing similar elements of an effective compliance program). The government often requires a version of a compliance plan (a Corporate Integrity Agreement) as a condition of settling contested matters with pharmaceutical and medical device manufacturers. *See* Office of Inspector General, Corporate Integrity Agreement Documents, https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp (collecting Corporate Integrity Agreements). An effective compliance program significantly minimizes the company's risk of civil and criminal liability.

Under the government's view, however, an officer at a company that has an effective compliance program can still face strict criminal liability under § 333(a) and be imprisoned for a violation that he could not reasonably have anticipated. But no corporation or manager (indeed, no governmental manager) can absolutely guarantee that his subordinates will never commit a violation. Even the very best compliance programs cannot guarantee that no violations will ever occur. *See* Posner, Economic Analysis of Law 178 (6th ed. 2003) (accidents still occur in a

strict liability regime when the defendant exercises due care). And that is particularly true under the FDCA, which pervasively reaches every aspect of the sectors that it regulates. Under the FDCA, a responsible corporate officer may be prosecuted (and, in the government's view, imprisoned) if any employee of the company under his ultimate supervision commits any one of numerous offenses under the FDCA:

- Introducing, delivering, or receiving any drug or device that is "adulterated or misbranded." § 331(a), (c).
- "[A]dulterating or misbranding" any drug or device. § 331(b).
- Introducing an unapproved drug. § 331(d).
- Failing to allow the government to inspect and copy records showing a drug's movement in interstate commerce. §§ 331(e), 373.
- Failing to allow the government to inspect a vehicle carrying drugs. §§ 331(f), 374.
- Failing to keep or maintain records relating to a drug's clinical experience. §§ 331(e), 355(k)(1).
- Disclosing trade secrets learned while seeking a new drug application. §§ 331(j), 355.
- Failing to provide a licensed practitioner, upon request, with all printed material that is included in the drug's packaging. § 331(o).
- Failing to complete an annual registration. §§ 331(p), 360.
- Failing to report or reporting misleading clinical trial data. § 331(jj).
- Failing to notify the government that a significant amount of the drug has been stolen. §§ 331(bbb), 360bbb-7.

- Possessing colored margarine without prescribed labeling. § 331(m).

The prospect of imprisonment based on strict and vicarious liability for such violations, regardless of the individual defendant's culpability, is particularly striking given that the government is often willing to take into account the circumstances of the case when arriving at the *corporation's* punishment. Under the Sentencing Guidelines, the sentencing court may examine whether an "effective compliance and ethics program" was in place and operating, U.S.S.G. § 8B2.1(a), whether senior officers "exercise[d] reasonable oversight" of the compliance efforts, *id.* § 8B2.1(b)(2)(A), and whether the corporation took "reasonable steps to prevent or detect criminal conduct," *id.* § 8B2.1(b)(6). Those considerations reflect the fact that the organization is less morally culpable, *id.* § 8C2.5(f)(1), when it does its best to prevent violations, self-reports any discovered violations, and cooperates with the government's investigation, *id.* § 8C2.5(g)(1). As such, a reduced monetary penalty will be recommended. *Id.* §§ 8C2.4, 8C2.5.

The *Park* doctrine allows none of this flexibility. *Park* recognizes only "objective[] impossib[ility]" as a potential defense to criminal liability as a responsible corporate officer, *see* 421 U.S. at 673, and it is unclear how impossibility would be proven. Soon after *Park*, the government took the position that impossibility is not a defense if the officer has the option of shuttering the

manufacturing facility. *United States v. Y. Hata & Co.*, 535 F.2d 508, 511 (9th Cir. 1976). Even if some lower standard for impossibility applies, an individual still faces the prospect of conviction—and imprisonment under the government's view—even if he can prove that he took effective compliance measures in good faith. Further, a responsible corporate officer who discovers a violation faces a moral hazard. Unlike a regime that operates based on negligence, under which the officer can avoid liability by moving to remedy the violation, in a strict-liability regime, such an officer has likely *already* committed a crime, and taking remedial action is only likely to bring the violation to light and thereby increase the possibility of prosecution. As the doctrine stands, it "furthers none of the goals of the criminal law" and instead only sends the message "that no good deed will go unpunished." Andrew Weissman, *A New Approach to Corporate Criminal Liability*, 44 Am. Crim. L. Rev. 1319, 1326 (2007).

Such an officer might decide to heed the government's position in *Y. Hata* and suspend or cease operations to avoid criminal liability. Such drastic action would come at high cost to the general public. The effects of this kind of deterrence have been seen before. In 2009, the oncology drug Leucovorin was produced at two plants operated by Bedford Laboratories and Teva Pharmaceuticals. Roman, *The FDA and The Pharmaceutical Industry: Is Regulation Contributing to Drug Shortages?*, 77 Alb. L. Rev. 539, 557-558 (2013-

2014). At the time, there was an ongoing shortage of Leucovorin. Hayes et al., *Lessons from the Leucovorin Shortages Between 2009 and 2012 in a Medicare Advantage Population: Where Do We Go From Here?*, 7(5) Am. Health Drug Benefits 264, 266 (2014). When warned by the FDA that it had committed thirteen regulatory violations, Teva closed its plant that "produce[d] all of the company's sterile injectable drugs" for more than a year. Roman, *supra* at 559. When the plant reopened in 2011, at a cost of $375 million, it operated at "significantly reduced production capacity." *Id.* Also in 2011, Bedford's plant received dozens of warnings of regulatory violations that primarily "related to aseptic processing weaknesses that affect the sterility of the injectables produced at the facility, rather than life-threatening deficiencies." *Id.* at 560. When those violations were found again later in the year, Bedford too shut down its plant. *Id.* at 561. The plant remained closed for more than a year, undergoing a $300 million overhaul; it was reopened with limited production so that Bedford could "produce the most needed sterile injectable drugs." *Id.* These are not singular events, and officers of the manufacturing companies must choose how to respond to seen and unseen FDCA violations.

In some circumstances, it may be appropriate for the government to shut down operations that present a threat to public health or safety. But the shuttering of facilities should not occur because individual officers, troubled by the

possibility of a prison sentence if they choose wrongly, choose to avoid otherwise socially beneficial conduct out of fear of imprisonment under a strict liability legal regime. Neither the public nor the company should suffer because an individual officer is influenced by a perverse incentive to protect his own interests by adopting *unreasonable* precautions. The deterrence the government seeks can and ought to be achieved through regulation, fines and penalties where appropriate, civil liability, and compliance systems. The prospect of imprisonment adds little to the protection of the public and is counterproductive as well.

CONCLUSION

The sentence of incarceration against appellants should be reversed.

Respectfully submitted.

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(d).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B)(iii), the brief contains 6,542 words.

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Pursuant to Eighth Circuit Rule 28A(h)(2), the undersigned further certifies that this brief has been scanned for viruses and is virus-free.

/s/ David W. Ogden
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July 27, 2015

CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of July, 2015, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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