No. 16-877

In the Supreme Court of the United States

AUSTIN DECOSTER, AKA JACK DECOSTER, AND PETER DECOSTER, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

JEFFREY B. WALL Acting Solicitor General Counsel of Record CHAD A. READLER Acting Assistant Attorney General DOUGLAS N. LETTER SCOTT R. MCINTOSH JEFFREY E. SANDBERG Attorneys

Department of Justice Washington, D.C. 20530-0001 SupremeCtBriefs@usdoj.gov (202) 514-2217

QUESTIONS PRESENTED

The Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, prohibits the introduction of adulterated food into interstate commerce, subject to criminal penalties. 21 U.S.C. 331(a). Petitioners each entered unconditional guilty pleas to misdemeanor violations of the FDCA, which are punishable by (*inter alia*) imprisonment of up to one year. 21 U.S.C. 333(a)(1). After finding that petitioners knew or should have known of unsanitary conditions at their company's egg-production facilities and of the health risks posed by those conditions, but that they failed to remedy those conditions, the district court sentenced each petitioner to three months of imprisonment. The questions presented are:

1. Whether petitioners' three-month prison sentences for violations of the FDCA's prohibition on introducing adulterated food into interstate commerce violate the Fifth Amendment's Due Process Clause.

2. Whether petitioners, having entered unconditional guilty pleas and not having challenged the legal basis for their convictions below, may seek review of those convictions in this Court; and if so, whether this Court's decisions in *United States* v. *Park*, 421 U.S. 658 (1975), and *United States* v. *Dotterweich*, 320 U.S. 277 (1943), construing the FDCA to impose liability on "responsible corporate agents" who have the "responsibility and authority" to ensure their organization's compliance with the FDCA, *Park*, 421 U.S. at 673-674, should be overruled.

(I)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-31a) is reported at 828 F.3d 626. The sentencing opinion of the district court (Pet. App. 32a-108a) is reported at 99 F. Supp. 3d 920.

JURISDICTION

The judgment of the court of appeals was entered on July 6, 2016. A petition for rehearing was denied on September 30, 2016 (Pet. App. 109a-110a). On November 29, 2016, Justice Alito extended the time within which to file a petition for a writ of certiorari to and including January 10, 2017, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

(1)

STATEMENT

This case arises from a massive, nationwide outbreak of food poisoning caused by the interstate distribution of Salmonella-contaminated eggs by the company of which petitioners Austin (Jack) DeCoster and Peter De-Coster were the owner and chief operating officer, respectively. Pet. App. 35a-36a. Following unconditional guilty pleas in the United States District Court for the Northern District of Iowa, petitioners were each convicted on one count of introducing adulterated food into interstate commerce in violation of 21 U.S.C. 331(a). Pet. App. 153a, 155a-186a. Each petitioner was sentenced based on facts the district court found at sentencing to three months of imprisonment, to be followed by one year of supervised release, and ordered to pay restitution and a fine. Id. at 108a; Pet. C.A. Br. Add. 69-80. Petitioners appealed only their three-month jail sentences, which the court of appeals affirmed. Pet. App. 1a-31a.

1. For more than a century, federal law has regulated commerce involving adulterated or misbranded food to "protect consumers from dangerous products," *United States* v. *Sullivan*, 332 U.S. 689, 696 (1948), and to ensure "the health and safety of the public at large," *POM Wonderful LLC* v. *Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014). In the Federal Food and Drugs Act of 1906, ch. 3915, §§ 1-2, 34 Stat. 768, Congress sought to "keep impure and adulterated food and drugs out of the channels of commerce" by imposing criminal penalties —including imprisonment and fines—on those who manufacture such adulterated or misbranded food or introduce it into interstate commerce. *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). In 1938, concerned that even these sanctions could be treated as merely a "license fee for the conduct of an illegitimate business," Congress "extended the range of its control over illicit and noxious articles and stiffened the penalties" for those who introduce them into commerce, *id.* at 280, 282-283 (citation omitted), by enacting the Federal Food, Drug, and Cosmetic Act (FDCA or Act), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*

The FDCA, as amended, establishes a comprehensive framework regulating the interstate distribution of food, drugs, and various other products. Among other conduct, the FDCA prohibits the introduction or delivery for introduction into interstate commerce of adulterated food. 21 U.S.C. 331(a). A food is adulterated if, among other things, it "bears or contains any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. 342(a)(1). The FDCA imposes an affirmative obligation on market participants and persons responsible for their operation to comply with these requirements. See United States v. Park, 421 U.S. 658, 676 (1975). "[T]he Act imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions." Ibid.

Persons who cause the introduction of adulterated food into interstate commerce are subject to criminal prosecution. 21 U.S.C. 331(a), 333(a)(1). As relevant here, an individual who violates Section 331(a) may be imprisoned for up to one year, fined up to \$100,000, or both. 21 U.S.C. 333(a)(1); 18 U.S.C. 3571(b)(5).¹

¹ A person who has a prior conviction for violating Section 331 or who violates that provision with intent to defraud or mislead may be subject to enhanced penalties. See 21 U.S.C. 333(a)(2).

2. During the spring and summer of 2010, an estimated 56,000 persons throughout the United States fell ill after eating eggs contaminated with *Salmonella* Enteritidis.² Pet. App. 4a, 13a-14a, 41a n.7. Federal and state officials traced the outbreak to eggs distributed by petitioners' business, Quality Egg, LLC. *Id.* at 4a. Quality Egg operated a feed mill and farms in Iowa that collectively housed approximately five million hens. *Id.* at 2a. Jack DeCoster was the owner and principal operator of Quality Egg, and his son, Peter, was its chief operating officer. *Id.* at 2a, 9a, 35a-36a, 158a, 174a. Together they "exercised significant control" over the business's operations, including food safety. *Id.* at 36a.

In August 2010, U.S. Food and Drug Administration (FDA) officials inspected Quality Egg's Iowa operations. Pet. App. 4a. They found that "the company's eggs tested positive for salmonella at a rate of contamination approximately 39 times higher than the current national rate," and "contamination had spread throughout all of the [company's] facilities." *Ibid.* The FDA's inspection also discovered other, widespread "insanitary conditions," such as "live and dead rodents and frogs in the laying areas, feed areas, conveyer belts, and outside the buildings," and "manure * * * piled to the rafters." *Id.* at 4a, 9a; see *id.* at 21a, 64a. They "concluded that Quality Egg had failed to comply with its

² As petitioners note (Pet. 7), *Salmonella* Enteritidis is a "particularly harmful" strain of *Salmonella* bacteria that may cause moderate-to-severe illness in humans. Most persons infected with the bacteria develop diarrhea, fever, and cramps within days. Pet. App. 41a n.6. Hundreds of Americans die each year from *Salmonella* poisoning, while others may suffer long-term complications, such as chronic joint pain or arthritis. See 74 Fed. Reg. 33,031 (July 9, 2009).

written plans for biosecurity and salmonella prevention." *Id.* at 4a.

Based partly on these findings and the massive, foodborne-illness outbreak, the FDA commenced a criminal investigation into Quality Egg's food-safety practices. Pet. App. 5a. Petitioners, the investigators discovered, knew of but "ignored the positive salmonella environmental test results" throughout their company's facilities, which "increased in frequency" from 2006 through fall 2010. *Id.* at 3a, 6a, 80a. Petitioners also understood that these positive test results signaled an "increased risk" of *Salmonella* contamination in the eggs themselves. *Id.* at 64a, 65a n.17, 77a. Yet petitioners chose not to implement the measures set forth in their company's *Salmonella*-prevention and biosecurity plans. *Id.* at 3a, 15a, 42a, 45a-46a, 61a, 80a, 141a-142a.

Instead, the criminal investigation showed, petitioners and the company concealed these facts. Pet. App. 5a. For example, the company "falsified records about food safety measures"; it "lied to auditors for several years about pest control measures and sanitation practices"; an employee "bribed a USDA inspector" to release defective eggs for sale; and the company "misled state regulators and retail customers" by selling eggs with intentionally false date labels. *Ibid.*; see *id.* at 42a-57a. Moreover, Peter DeCoster himself "made inaccurate statements to Walmart about Quality Egg's food safety and sanitation practices," and the FDA obtained evidence that Jack DeCoster reprimanded an employee for failing to hide defective eggs from federal inspectors. *Id.* at 5a; see *id.* at 16a, 82a, 144a, 146a.

3. Petitioners were charged as "responsible corporate officers" with introducing adulterated food into interstate commerce in violation of 21 U.S.C. 331(a) and

333(a)(1). Pet. App. 36a. Petitioners pleaded guilty, "stipulat[ing] that they were in positions of sufficient authority to detect, prevent, and correct the sale of contaminated eggs." *Id.* at 6a. They further "agreed to be sentenced based on facts the sentencing judge found by a preponderance of the evidence." *Ibid.*; see *id.* at 159a, 174a-175a. The government agreed to leave to the district court's discretion whether to impose a sentence of incarceration, home confinement, or probation. See *id.* at 162a, 177a-178a.

After considering petitioners' roles in causing distribution of the contaminated eggs, the district court sentenced each petitioner to three months of imprisonment. Pet. App. 108a. It found petitioners' conduct blameworthy because they personally "had knowledge of the insanitary conditions at Quality Egg and the increased risk that their shell eggs were contaminated with [Salmonella]." Id. at 65a n.17; see id. at 64a, 77a. Petitioners, the court found, knew based on their experience "how to effectively deal with [Salmonella] contamination." Id. at 77a. Yet they "did not minimize [Salmonella] contamination in their plants." Ibid.; see id. at 60a-61a, 141a. Although "nothing in the record indicate[d] that [petitioners] had actual knowledge that the eggs sold by Quality Egg were infected," the "insanitary conditions" at their facilities were "egregious"; petitioners ignored positive Salmonella environmental test results by not testing their eggs; there was evidence they knew of efforts to deceive and bribe a USDA inspector; and the record was "replete with evidence" of petitioners' "misrepresentations regarding [the company's] food safety and sanitation practices and procedures and independent audits." Id. at 80a-83a; see id.

at 61a. Petitioners, moreover, "created a work environment where employees not only felt comfortable disregarding regulations and bribing USDA officials, but may have even felt pressure to do so." *Id.* at 81a.³

4. Petitioners appealed, arguing (as relevant) that their sentences were disproportionate to their conduct in violation of the Eighth Amendment and also "violate[d] substantive due process." Pet. App. 8a. Petitioners did not challenge their convictions. The court of appeals affirmed. *Id.* at 2a; see *id.* at 1a-31a.

a. The panel majority rejected petitioners' Eighth Amendment and due process challenges. Pet. App. 7a-14 (opinion of Murphy, J.); *id.* at 17a-22a (Gruender, J., concurring in part and concurring in the judgment).

i. The lead opinion, authored by Judge Murphy, held that petitioners' three-month sentences did not violate the Eighth Amendment because they were "not grossly disproportionate" to their offenses. Pet. App. 13a. It further rejected petitioners' claim that "incarceration of any length" violates due process because petitioners "did not personally commit wrongful acts," and due process prohibits incarceration based on "vicarious liability crimes." Id. at 8a. Petitioners, the opinion explained, were sentenced not based on the acts of others, but for their own wrongdoing. Id. at 9a. "Under the FDCA, * * * a corporate officer is held accountable not for the acts or omissions of others, but rather for his own failure to prevent or remedy 'the conditions which gave rise to the charges against him." Ibid. (citation omitted). Here, "the district court reasonably found

³ Petitioners dispute (Pet. 9) that they knew of the bribes, but they stipulated below that two employees were prepared to testify that petitioners were notified of the bribes after the fact. Pet. App. 146a.

that [petitioners] 'knew or should have known'" of the "insanitary conditions" at their facilities and the "risks [they] posed," of the need for further testing, and of "proper remedial and preventative measures." *Id.* at 9a-10a (citation omitted). Petitioners, Judge Murphy noted, did not "claim to have been 'powerless' to prevent" these violations, yet they "failed to take sufficient measures" to address them. *Id.* at 9a (citation omitted).

ii. Judge Gruender concurred in part and concurred in the judgment. Pet. App. 17a-22a. He joined the lead opinion "in rejecting [petitioners'] Eighth Amendment challenge." Id. at 17a n.1. He further "join[ed] [the lead] opinion" in rejecting petitioners' due process claim "to the extent that it recognize[d] that [petitioners] were negligent." Id. at 17a. In Judge Gruender's view, a sentence of "imprisonment based on vicarious liability would raise serious due process concerns." Ibid. But as he explained, this case "does not implicate these concerns" because "the district court found [petitioners] negligent," and thus petitioners "were not held vicariously liable for violations committed by others." *Ibid.* Judge Gruender wrote separately to express his view that the FDCA itself, as construed in *Park*, *supra*, requires a finding of negligence before a sentence of imprisonment may be imposed. Pet. App. 17a-22a.

b. Judge Beam dissented. Pet. App. 23a-31a. He opined that due process forbids a sentence of imprisonment "without establishing some measure of a guilty mind," and in his view "[t]here is no proof that" petitioners acted "with a 'guilty mind' or, perhaps, even with negligence." *Id.* at 30a-31a.

5. Petitioners sought panel or en banc rehearing, which were denied, with three judges dissenting. Pet. App. 110a.

ARGUMENT

Petitioners principally urge the Court to grant review to resolve whether the Fifth Amendment's Due Process Clause prohibits imposing a sentence of imprisonment on a corporate agent who is held vicariously liable for the actions of his company and its employees. This case, however, does not present that question. As the court of appeals explained, petitioners' sentences were based not on vicarious liability for others' conduct, but rather on petitioners' own blameworthy acts and omissions, as found by the district court at sentencing. Petitioners' due process challenge to the severity of their sentences, moreover, is misdirected. Such a challenge is governed by the Eighth Amendment, but petitioners have abandoned any Eighth Amendment claim here, and in any event their sentences comply with that Amendment. Even if petitioners' due process challenge to their sentences were cognizable, it lacks merit. The court of appeals' decision affirming petitioners' sentences is correct and does not conflict with any decision of this Court or of any other court of appeals or state supreme court. Further review is not warranted.

Petitioners' belated attack upon the legal basis for their underlying convictions likewise does not warrant review. That issue is not properly before the Court because petitioners knowingly and voluntarily pleaded guilty, and they asserted no challenge to their convictions in the court of appeals. In any event, petitioners' attack on this Court's settled precedent in *United States* v. *Park*, 421 U.S. 658 (1975), and *United States* v. *Dotterweich*, 320 U.S. 277 (1943), would not warrant review even if petitioners had properly preserved it. 1. Petitioners argue (Pet. 12-26) that the court of appeals erred and created a lower-court conflict by holding that the Due Process Clause permits prison sentences for "supervisory" or "vicarious" liability offenses. The court of appeals, however, rendered no such holding. Its conclusion on the only due process question it addressed concerning petitioners' sentences is correct and does not create a conflict.

a. Petitioners' first question presented asks "[w]hether the Due Process Clause prohibits the imposition of a term of imprisonment as punishment for a supervisory liability offense," Pet. i, which petitioners treat interchangeably with "vicarious liability," *e.g.*, Pet. 2-3, 23. That issue is not implicated here because petitioners' sentences were imposed and affirmed based on petitioners' own acts and omissions.

As the court of appeals correctly held, the FDCA imposed an affirmative duty on petitioners themselves to prevent their company from violating 21 U.S.C. 331(a)'s prohibitions. Pet. App. 7a, 9a (opinion of Murphy, J.); id. at 17a-18a (Gruender, J., concurring in part and concurring in the judgment). "[I]n providing sanctions which reach and touch the individuals who execute the corporate mission," this Court has explained, the FDCA "imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." Park, 421 U.S. at 672. This "duty imposed by Congress on responsible corporate agents is *** one that requires the highest standard of foresight and vigilance." Id. at 673. While the Act "does not require that which is objectively impossible," it "imposes the highest standard of care and permits conviction of responsible corporate officials who, in light of this standard of care, have the power to prevent or correct violations of its provisions." *Id.* at 673, 676. Petitioners' knowing, unconditional guilty pleas to violations of 21 U.S.C. 331(a), standing alone, establish that they failed to discharge their statutory duty. See *United States* v. *Broce*, 488 U.S. 563, 570 (1989) ("By entering a plea of guilty, the accused is not simply stating that he did the discrete acts described in the indictment; he is admitting guilt of a substantive crime.").

Petitioners' sentences rest not merely on the content of their guilty pleas, but also on the facts the district court found at sentencing. In pleading guilty, petitioners expressly "underst[ood] and agree[d] to be sentenced based on facts to be found by the sentencing judge by a preponderance of the evidence," and they further agreed that "facts essential to the punishment need not be (1) charged in the Indictment or Information; (2) proven to a jury; or (3) proven beyond a reasonable doubt." Pet. App. 159a, 175a. On appeal, petitioners affirmatively disclaimed any argument that the "Sixth Amendment limited [the district court's] factfinding abilities" in weighing a possible custodial sentence. Pet. C.A. Br. 21 n.4; see Pet. App. 21a n.4 (Gruender, J., concurring in part and concurring in the judgment). The district court thus was empowered to find facts beyond those admitted by petitioners in pleading guilty, and to rely upon those additional facts in determining appropriate sentences for petitioners. See 18 U.S.C. 3553(a), 3661; Fed. R. Crim. P. 32(c)-(i); Nichols v. United States, 511 U.S. 738, 747 (1994).

Exercising that authority, the district court expressly premised its sentences not on petitioners' place on an "organizational flow chart," Pet. 13, but instead on their own blameworthy acts and omissions. The court found that petitioners had known for years of widespread Salmonella contamination throughout their company's facilities; they knew of the substantial risk that this widespread contamination posed to the safety of their eggs; and they knew of the necessary remedial measures (including measures petitioners had successfully used at other facilities). Pet. App. 60a-61a, 64a, 65a n.17, 77a, 80a. Yet petitioners failed to undertake such measures. With one exception, they did not test their eggs before July 2010, and they did not divert eggs from contaminated barns for pasteurization, contrary to the company's procedures and assurances to customers. Id. at 3a, 15a, 42a, 45a-46a, 61a, 80a, 141a-142a. The court thus found that petitioners were not "mere unaware corporate executive[s]" but instead had personally engaged in blameworthy conduct. Id. at 83a.

The court of appeals affirmed petitioners' sentences on the same basis. The lead opinion recited the facts that petitioners knew or should have known as well as their conduct, and it "conclude[d] that the record here shows that [petitioners] are liable for negligently failing to prevent the salmonella outbreak." Pet. App. 10a; see id. at 9a-10a. Judge Gruender, in his concurrence, agreed that petitioners were "responsible for their own failures to exercise reasonable care to prevent the introduction of adulterated food" and that "the district court found sufficient facts to support the conclusion that [petitioners] were negligent" in their own conduct. Id. at 21a. Indeed, Judge Gruender explained that, in his view, "a showing of negligence" was "require[d]" to uphold petitioners' sentences, and he joined the lead opinion "to the extent that it recognizes that [petitioners] were negligent." Id. at 17a-18a.

Regardless of whether a finding that petitioners themselves acted negligently was necessary, their sentences thus rest squarely on a finding that they did. This case accordingly does not raise the first question petitioners present: whether the Due Process Clause permits a sentence of imprisonment for "supervisory" or "vicarious" liability offenses based solely on the acts or omissions of others that are imputed to a corporate agent.⁴

b. The court of appeals' holding on the only due process issue it addressed is correct. The court properly concluded that due process did not prohibit petitioners' three-month custodial sentences based on their own acts and omissions, which the courts below found were negligent.

i. At the threshold, petitioners' substantive due process challenge to the nature or severity of their criminal sentences is misconceived because it is predicated on the wrong constitutional provision. This Court has repeatedly held that, "[w]here a particular Amendment provides an explicit textual source of constitutional protection against a particular sort of government behavior, that Amendment, not the more generalized notion

⁴ Petitioners note that in *Park*, counsel for the government acknowledged that a sentence of imprisonment there might have presented "more serious due process problems." Pet. 6 (quoting Oral Arg. Tr. at 6, *Park*, *supra* (No. 74-215)). But the facts here bear little resemblance to *Park*. That case involved the CEO of a national grocery chain—with 874 retail stores and approximately 36,000 semployees—who played no role in day-to-day operations of the facility at issue. See 421 U.S. at 660, 663-664, 676-677. Petitioners, in contrast, were personally involved in management of the facilities, had "familiarity with the conditions in" them, knew or should have known of the risks of contamination and of remedial measures, and failed to undertake appropriate remedial measures. Pet. App. 9a.

of substantive due process, must be the guide for analyzing these claims." County of Sacramento v. Lewis, 523 U.S. 833, 842 (1998) (brackets and citations omitted); see, e.g., Portuondo v. Agard, 529 U.S. 61, 74 (2000); Conn v. Gabbert, 526 U.S. 286, 293 (1999); Graham v. Connor, 490 U.S. 386, 395 (1989). Because the Eighth Amendment's prohibition on "cruel and unusual punishments" explicitly addresses the subject of petitioners' challenge, U.S. Const. Amend. VIII, it is that Amendment, not principles of due process, that governs. See Chapman v. United States, 500 U.S. 453, 464-465 (1991) (rejecting due process challenge to length of sentence and explaining that a court may constitutionally "impose[] whatever punishment is authorized by statute for [the defendant's] offense," provided that "th[e] penalty is not cruel and unusual" and "not based on an arbitrary distinction that would violate the Due Process Clause") (citations omitted).

Although petitioners asserted an Eighth Amendment challenge in the court of appeals, they have abandoned it in this Court. Neither of their questions presented addresses that Amendment, and their petition for a writ of certiorari advances no argument that their sentences violate it. Even if that issue otherwise merited review, this case thus would provide no opportunity to address it. See *Glover* v. *United States*, 531 U.S. 198, 205 (2001) (this Court generally "does not decide issues outside the questions presented by the petition for certiorari"); *Taylor* v. *Freeland & Kronz*, 503 U.S. 638, 646 (1992).

In any event, the court of appeals correctly rejected petitioners' now-forfeited Eighth Amendment challenge. Pet. App. 13a-14a; *id.* at 17a n.1 (Gruender, J., concurring in part and concurring in the judgment). The Eighth

Amendment's "narrow proportionality principle forbids only extreme sentences that are 'grossly disproportionate' to the crime." Graham v. Florida, 560 U.S. 48, 59-60 (2010) (quoting Harmelin v. Michigan, 501 U.S. 957, 1001 (1991) (Kennedy, J., concurring in part and concurring in the judgment)). Petitioners' sentences fall far short of that bar. As Judge Murphy explained, petitioners' three-month sentences appropriately reflected Congress's emphasis on "protect[ing] consumers 'who are wholly helpless," as well as the scale of petitioners' conduct, which "may have affected up to 56,000 victims, some of whom were hospitalized or suffered long term injuries." Pet. App. 13a-14a (citation omitted). Petitioners' sentences, moreover, "fell at the low end of the prescribed statutory range" and were "within the stipulated guideline range of 0 to 6 months imprisonment." Id. at 14a, 16a. This is therefore "not 'the rare case in which a threshold comparison of the crime committed and the sentence imposed leads to an inference of gross disproportionality." Id. at 14a (citation omitted).

ii. Even if a due process challenge to petitioners' sentences were cognizable, the court of appeals correctly rejected it. Pet. App. 9a-13a. Although petitioners contend (Pet. 23-26) that imposing imprisonment for a "vicarious" offense violates due process, the court of appeals made clear that the FDCA does not impose "vicarious liability," and it upheld petitioners' sentences here based on their own negligence. See Pet. App. 9a-10a; see *id.* at 17a, 20a-22a (Gruender, J., concurring in part and concurring in the judgment). Petitioners cite no authority holding that due process prohibits a sentence of imprisonment for criminal acts based on a defendant's own negligence, particularly when they are responsible for an enterprise capable of harming large

numbers of consumers by distributing adulterated products.

The court of appeals also correctly rejected petitioners' contention that their sentences violate due process because petitioners lacked actual knowledge that the eggs were contaminated. Pet. App. 10a. As the lead opinion explained, "[t]he elimination of a mens rea requirement does not violate the Due Process Clause," even where a statute provides for a possible jail sentence, so long as "the penalty is 'relatively small,' the conviction does not gravely damage the defendant's reputation, and congressional intent supports the imposition of the penalty"-all of which the court held were true here. Ibid. (quoting Staples v. United States, 511 U.S. 600, 617 (1994)). That conclusion correctly tracks this Court's reasoning in *Staples*, which applied those criteria in interpreting a statute that lacks an express mens rea requirement. See 511 U.S. at 616-618. And it accords with decisions of other courts of appeals construing analogous statutes not to require actual knowledge.⁵

⁵ See, e.g., United States v. Greenbaum, 138 F.2d 437 (3d Cir. 1943) (rejecting due process challenge to three-month sentence for company president who unknowingly shipped adulterated eggs); United States v. Unser, 165 F.3d 755, 762-764 (10th Cir.) (six-month sentence was "relatively small," and construing unauthorized use of motor vehicle in wilderness area as strict-liability offense) (citation omitted), cert. denied, 528 U.S. 809 (1999); United States v. Erne, 576 F.2d 212, 215 (9th Cir. 1978) (one-year sentence was "not vastly greater than penalties normally associated with other regulatory or public welfare offenses," and construing violation of procedural requirements of Internal Revenue Code as strict-liability offense); United States v. Ayo-Gonzalez, 536 F.2d 652, 658-660 (5th Cir. 1976) (one-year maximum sentence was "relatively small," and construing illegal fishing by foreign vessel as strict-liability offense) (citation omitted), cert. denied, 429 U.S. 1072 (1977).

c. Petitioners contend (Pet. 12-19) that review is warranted to resolve a conflict between the decision below and decisions of other circuits and state supreme courts addressing due process challenges to sentences of imprisonment for supervisory or vicarious-liability offenses. The alleged conflict, however, is illusory, and it rests on the same misapprehension of the decision below as petitioners' arguments on the merits.

Of the five cases petitioners identify (Pet. 12-16) as purportedly inconsistent with the decision below, three rendered no ruling on the federal Constitution's due process guarantees at all. In People ex rel. Price v. Sheffield Farms-Slawson-Decker Co., 121 N.E. 474 (N.Y. 1918), the Court of Appeals of New York expressly reserved judgment on whether an employer may be sentenced to imprisonment for acts or omissions of an employee. Id. at 477. The court upheld a fine against an employer for an employee's violation of a child-labor law, but it explicitly "le[ft] the question open" whether a prison term would be permissible. Ibid.; see id. at 475-477; id. at 477 (Pound, J., concurring). Two other cases petitioners cite addressed only the requirements of state constitutions, not the Fifth (or Fourteenth) Amendment's Due Process Clause. See State v. Guminga, 395 N.W.2d 344, 346-347 (Minn. 1986) (imposing any criminal penalties on employer whose employees violated state liquorsales law violated state constitution); Commonwealth v. Koczwara, 155 A.2d 825, 827-831 (Pa. 1959) (state constitution prohibited prison sentence for violations of such laws), cert. denied, 363 U.S. 848 (1960). Guminga, moreover, held that any "criminal penalties based on vicarious liability" would violate the state constitution, 395 N.W.2d at 346, a position that even petitioners do not advocate in their federal due process challenge here.

Petitioners' remaining two cases, *Lady J. Lingerie*, *Inc.* v. *City of Jacksonville*, 176 F.3d 1358 (11th Cir. 1999), cert. denied, 529 U.S. 1053 (2000), and *Davis* v. *City of Peachtree City*, 304 S.E.2d 701 (Ga. 1983), also do not conflict with the decision below. Neither case involved the FDCA. And neither held that a sentence of imprisonment imposed based on the defendant's own negligence as a responsible corporate agent would violate due process. Both concluded instead that due process prohibits imposing a prison sentence on a defendant for the acts of others if the defendant himself bears no responsibility for the wrongful acts.

Lady J. Lingerie involved a preenforcement challenge to a city ordinance that purported to make "owners of adult entertainment establishments criminally liable for acts committed by their servants, agents and employees" within the scope of employment. 176 F.3d at 1367. By "imput[ing]" employees' actions to the owners, the ordinance effectively created "respondeat superior" criminal liability. *Ibid.* Observing that the ordinance contemplated imprisonment as a punishment, the Eleventh Circuit held that "due process at least requires individualized proof of intent or act" in order for an owner to be imprisoned. *Id.* at 1368 (emphasis omitted).⁶

⁶ Contrary to petitioners' suggestion (Pet. 13), the Eleventh Circuit did not state that the Jacksonville ordinance was "materially indistinguishable from a *Park* offense." Instead, the court referred to *Park*'s "responsible relation" language in order to establish what the court viewed as the outer bound on the scope of substantive criminal liability that would be constitutionally permissible under the ordinance. *Lady J. Lingerie*, 176 F.3d at 1367. In stating that

Davis, like Guminga and Koczwara, involved a local liquor-sales ordinance. 304 S.E.2d at 702. The Supreme Court of Georgia held that the ordinance violated due process "because [it] provide[d] for the automatic criminal liability of a licensee for actions of his employees which are taken without his knowledge, consent, or authorization and which are not the result of negligence attributable to him." *Ibid.* The court invalidated a prison sentence imposed on a proprietor for his employee's sale of alcohol to a minor, of which the proprietor "had no knowledge" and "did not authorize." *Ibid.*; see *id.* at 702-704.

The decision below does not conflict with Lady J. Lingerie or Davis. Unlike the law in Lady J. Lingerie, the FDCA does not create "respondent superior" liability, 176 F.3d at 1367, but instead holds a corporate officer liable for the officer's personal failure to discharge his or her own duties. Pet. App. 9a; see Park, 421 U.S. at 672-673, 676. The court of appeals, moreover, made clear that petitioners' sentences were based not on "vicarious liability" for acts of others, but on their own "negligent[]" acts and omissions. Pet. App. 9a-10a (opinion of Murphy, J.); id. at 21a (Gruender, J., concurring in part and concurring in the judgment). Similarly, in contrast to Davis, petitioners' sentences were based on violations that were "the result of negligence attributable to [them]." 304 S.E.2d at 702. This Court's review is unnecessary because there is no lower-court conflict to resolve.

[&]quot;due process prohibits the state from imprisoning a person without proof of some form of personal blameworthiness more than a 'responsible relation," *ibid.*, the court appeared to equate *Park*'s test with *respondeat superior*. As discussed above, pp. 10-11, 15, *supra*, that is incorrect.

2. Despite pleading guilty to violations of 21 U.S.C. 331(a) below, petitioners now contend (Pet. 27) that Section 331(a) should not be "read to impose liability without proof of *mens rea* or personal participation." Recognizing that their interpretation of the statute is foreclosed by this Court's decisions in *Park*, *supra*, and *Dotterweich*, *supra*, they argue (Pet. 27) that both cases should be "overruled." See Pet. 27-33. That contention is not properly before the Court because petitioners waived any such argument by pleading guilty and forfeited it in the court of appeals. In any event, their challenge to this Court's well-settled interpretation of the FDCA does not merit review.

a. Petitioners' belated challenge to the statutory basis of their convictions is doubly barred by their unconditional guilty pleas and their conceded failure to raise any such argument in the court of appeals.

i. Petitioners each entered unconditional guilty pleas, which bar them from challenging the lawfulness of their convictions on appeal. An unconditional guilty plea generally waives all nonjurisdictional defenses to a prosecution. See Broce, 488 U.S. at 569-570; see also Fed. R. Crim. P. 11 advisory committee's note (1983) ("traditional, unqualified pleas" of guilty "constitute[] a waiver of all nonjurisdictional defects" in the charging instrument). "By entering a plea of guilty," a defendant does not "simply stat[e] that he did the discrete acts described in the" charging document, but further "admit[s] guilt of a substantive crime." Broce, 488 U.S. at 570; cf. Mabry v. Johnson, 467 U.S. 504, 508 (1984) ("It is well settled that a voluntary and intelligent plea of guilty made by an accused person, who has been advised by competent counsel, may not be collaterally attacked.").

As petitioners admit (Pet. 10), they "conceded liability" for violating Section 331(a) by pleading guilty. Neither petitioner's plea agreement reserved the right to challenge Section 331(a)'s scope on appeal or to argue (as petitioners now contend in this Court) that, because violations of that provision can be punished by imprisonment, Section 331(a) must be read to require "mens *rea* or personal participation." Pet. 27. To the contrary, each petitioner agreed that he would "have no right to withdraw [his] guilty plea if the sentence imposed is other than [petitioner] hoped for or anticipated." Pet. App. 160a, 176a. Petitioners' unconditional guilty pleas thus preclude their argument that Section 331(a) should be construed not to encompass their conduct. Cf., e.g., United States v. Brown, 752 F.3d 1344, 1347 (11th Cir. 2014) (guilty plea waived claim that indictment failed to charge a federal offense because it failed to allege the required mens rea element of the crime); United States v. Rubin, 743 F.3d 31, 35-39 (2d Cir. 2014) (guilty plea waived claim that the indictment failed to charge a federal offense because it failed to allege actual knowledge and control of bets, which was assertedly a necessary element of the crime).⁷

⁷ Petitioners do not argue that any of the narrow exceptions to the general rule that unconditional guilty pleas waive nonjurisdictional defenses applies here. Cf. *Menna* v. *New York*, 423 U.S. 61, 62-63 (1975) (per curiam) (permitting defendant who pleaded guilty to challenge conviction as violation of Double Jeopardy Clause); *Blackledge* v. *Perry*, 417 U.S. 21, 29-31 (1974) (permitting defendant who pleaded guilty to assert constitutional claim of vindictive prosecution). Nor did they argue that the statute of conviction is unconstitutional. Cf. *Class* v. *United States*, No. 16-424 (Feb. 21, 2017) (granting certiorari to address whether a guilty plea waives such a claim). And they did not make *any* claim for such an exception in the court of appeals. This Court ordinarily does not opine on issues

ii. Even if petitioners had not waived any challenge to the statutory basis of their convictions by pleading guilty in the district court, they forfeited any such argument by failing to assert it on appeal. As petitioners admit (Pet. 27), they "did not challenge the validity of the Park doctrine below." Rather, in the court of appeals, petitioners challenged only the custodial term of their sentences, not the lawfulness of their underlying convictions. See Pet. C.A. Br. 69 (requesting that "the portion of the district court's judgment imposing sentences of imprisonment should be vacated" or alternatively that "the sentences should be vacated and the case remanded for resentencing"); see generally *id.* at 25-69; Pet. C.A. Reply Br. 4-34; see also Pet. App. 17a (Gruender, J., concurring in part and concurring in the judgment) ("[Petitioners] do not challenge either the constitutionality of [Section] 331(a) or the sufficiency of the factual basis for their pleas."). The court of appeals consequently did not address petitioners' contention.

Petitioners' argument thus was undisputedly "not raised or resolved in the lower court[s]." *Taylor*, 503 U.S. at 646 (citation omitted; brackets in original). This Court ordinarily does not address such issues absent "unusual circumstances." *Ibid.* (citation omitted); see, *e.g.*, *OBB Personenverkehr AG* v. *Sachs*, 136 S. Ct. 390, 397-398 (2015). Petitioners identify no unusual circumstances here that justify disregarding their forfeiture. And given their failure to challenge *Park* in the courts below, petitioners could not obtain relief without satisfying the requirements of the plain-error rule, Fed. R. Crim. P. 52(b), which they clearly could not do. Those

that were "neither raised nor resolved" in the court of appeals. *Glover*, 531 U.S. at 205. There is no reason to depart from that practice in this case.

multiple procedural obstacles make this an inapt vehicle for entertaining their current contentions.

b. Even if petitioners had properly preserved a challenge to their underlying convictions, their challenge to the scope of Section 331(a) and their request to overrule decades-old precedents would not merit review.

i. For more than 70 years, this Court has construed the FDCA to impose criminally enforceable legal duties not merely on the lower-level employees who physically produce, package, and ship a covered product, but also on corporate officials who control the production and distribution process. See Park, 421 U.S. at 670-676. As the Court explained in *Park*, reaffirming its earlier decision in *Dotterweich*, the Act places a duty on those with a "responsible share in the furtherance of the transaction which the statute outlaws." Id. at 669 (quoting *Dotterweich*, 320 U.S. at 284). It treats as "responsible corporate agents" those individuals who, "by reason of [their] position in the corporation," have the "responsibility and authority" to take necessary measures to prevent or remedy violations of the statute. Id. at 670, 673-674; see also Dotterweich, 320 U.S. at 281-283.

Petitioners face an exceedingly difficult task in urging the Court to depart from that long-settled interpretation of the FDCA. "Stare decisis" is "a foundation stone of the rule of law." Kimble v. Marvel Entm't, LLC, 135 S. Ct. 2401, 2409 (2015) (citation omitted). Parties challenging any precedent of this Court thus carry a heavy burden of demonstrating "a 'special justification,'" beyond "the belief 'that the precedent was wrongly decided,'" to depart from the prior decision. Ibid. (quoting Halliburton Co. v. Erica P. John Fund, Inc., 134 S. Ct. 2398, 2407 (2014)). Stare decisis "carries enhanced force when a decision," such as *Park* and *Dot*terweich, "interprets a statute." *Ibid.* The "burden" a party asking the Court "to overrule a point of statutory construction" must carry is therefore even "greater." *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 172 (1989).

Petitioners' task is made still more difficult because the statutory interpretation adopted in *Dotterweich* and reaffirmed in *Park* has survived for "more than half a century," despite legislative consideration of proposals to abrogate those decisions. *Kimble*, 135 S. Ct. at 2409-2410; cf. Watson v. United States, 552 U.S. 74, 82-83 (2007) (observing, in criminal context, that "long congressional acquiescence * * * 'enhance[s] even the usual precedential force' we accord to our interpretations of statutes"). On multiple occasions, Congress has considered whether to amend the FDCA to narrow the scope of liability for responsible corporate agents and other defendants, but each time opted against any change. See S. Rep. No. 684, 94th Cong., 2d Sess. 30 (1976) (discussing failed bill that would have amended 21 U.S.C. 333(a) to impose liability only on individuals who "knowingly, or willfully, or negligently violated" the Act); see also Park, 421 U.S. at 672 n.15 (noting that a 1948 Senate amendment, which would have imposed liability "only for violations committed 'willfully or as a result of gross negligence," was stricken in conference committee) (quoting 94 Cong. Rec. 6760 (1948)). Congress's decisions to "rebuff[] [those] bills," even as it has "rework[ed]" the FDCA in other respects over the years. "further supports leaving [this Court's] decision[s] in place." Kimble, 135 S. Ct. at 2410.

ii. Petitioners do not come close to carrying their burden of demonstrating a special justification for revisiting these statutory precedents. They argue (Pet. 28-30) that *Dotterweich* and *Park* misread the statute. But such a claim of error alone does not merit reconsidering those decisions. See *Kimble*, 135 S. Ct at 2409 ("[A]n argument that we got something wrong—even a good argument to that effect—cannot by itself justify scrapping settled precedent.").

Petitioners more specifically contend (Pet. 27-29) that this Court's settled interpretation of the FDCA bears too "little connection to the statutory text" and relied too heavily on the FDCA's "perceived 'purposes.'" That critique, too, is of no moment. *Stare decisis* applies to this Court's statutory holdings "regardless whether [this Court's prior] decision focused only on the statutory text or also relied * * * on the policies and purposes animating the law." *Kimble*, 135 S. Ct. at 2409 ("All our interpretive decisions, in whatever way reasoned, effectively become part of the statutory scheme, subject (just like the rest) to congressional change.").

In any event, petitioners' criticism is incorrect. Section 331(a) prohibits not only the "introduction or delivery for introduction into interstate commerce" of an adulterated food, but also conduct that "caus[es]" such an introduction to occur. 21 U.S.C. 331(a). Confirming the statute's breadth, Section 333(a) imposes criminal liability on "[a]ny person who violates a provision of [S]ection 331." 21 U.S.C. 333(a)(1). This language is naturally read to impose liability on those who "share[] responsibility in the business process resulting in unlawful distribution" of the regulated article. *Dotterweich*, 320 U.S. at 284. As *Park* explained, "responsible corporate agents are held criminally accountable for 'causing' violations of the Act." 421 U.S. at 673. In this case, it is perfectly consistent with ordinary usage to say that petitioners' own failure to discharge their operational responsibilities over food safety "caus[ed]" the distribution of unsafe foods in interstate commerce.

Nor have the "statutory and doctrinal underpinnings" of Park and Dotterweich "eroded over time." Kimble, 135 S. Ct. at 2410. To the contrary, this Court's subsequent decisions have adhered to their holding that the FDCA imposes liability on "corporate officer[s] or employee[s] 'standing in responsible relation' * * * [to] a corporation's violations of the [Act]." Meyer v. Holley, 537 U.S. 280, 287 (2003) (citation omitted). It has long been "settled law in the area of food and drug regulation" that criminal liability may permissibly be imposed "upon a person otherwise innocent but standing in responsible relation to a public danger." United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 91 (1964) (quoting Dotterweich, 320 U.S. at 281); see Austin v. United States, 509 U.S. 602, 618 n.11 (1993) (reaffirming that "[the Court] ha[s] permitted punishment in the absence of conscious wrongdoing" on the part of "corporate officer[s] strictly liable under the [FDCA]"); *Liparota* v. United States, 471 U.S. 419, 433 (1985) (similar); United States v. Freed, 401 U.S. 601, 609 (1971) (similar).

Indeed, this Court and others have relied on *Dotterweich*'s analysis in construing other federal statutes. See, *e.g.*, *United States* v. *Wise*, 370 U.S. 405, 408-409 (1962) (relying on *Dotterweich* in construing Sherman Act, 15 U.S.C. 1 *et seq.*, to impose liability on "all officers who have a responsible share in the proscribed transaction"); *United States* v. *Johnson & Towers*, *Inc.*, 741 F.2d 662, 665-667 (3d Cir. 1984) (same regarding Resource Conservation and Recovery Act of 1976, 42 U.S.C. 6901 et seq.), cert. denied, 469 U.S. 1208 (1985); United States v. Rachal, 473 F.2d 1338, 1341-1342 (5th Cir.) (same regarding Securities Act of 1933, 15 U.S.C. 77a et seq.), cert. denied, 412 U.S. 927 (1973). Petitioners' attack on Park and Dotterweich thus not only risks "unsettl[ing] stable law" under the FDCA, but doing so throughout federal law. Kimble, 135 S. Ct. at 2411.

iii. Petitioners finally urge the Court (Pet. 31) to revisit its interpretation of the FDCA in *Park* and *Dotterweich* because it creates "practical" difficulties by "expos[ing] a large number of people to criminal liability even where no personal culpability exists." Petitioners' contention (*ibid.*) that responsible corporate agents held liable for failing to discharge their own statutory duty are not "personal[ly] culpab[le]" simply misunderstands the statutory scheme, which this Court has explained imposes an affirmative duty on such persons to help prevent their companies from distributing adulterated food. See *Park*, 421 U.S. at 672-673.

In any event, petitioners identify only two other recent cases in which responsible corporate agents have received a jail sentence for an FDCA offense. Pet. 21-22 (citing *United States* v. *Hermelin*, No. 11-cr-85 (E.D. Mo. Mar. 24, 2011) (imposing 17-day sentence), and *United States* v. *Higgins*, No. 09-cr-403-4, 2011 WL 6088576 (E.D. Pa. Dec. 7, 2011) (imposing nine-month sentence)).⁸ Neither case lends credence to petitioners' concerns of

⁸ Three other defendants in *Higgins* also received jail sentences for their roles in the same course of illegal conduct. See *United States* v. *Bohner*, No. 09-cr-403-5 (E.D. Pa. Dec. 13, 2011) (eightmonth sentence); *United States* v. *Huggins*, No. 09-cr-403-3 (E.D. Pa. Nov. 22, 2011) (nine-month sentence); *United States* v. *Walsh*, No. 09-cr-403-6 (E.D. Pa. Nov. 22, 2011) (five-month sentence).

prosecuting corporate officers unaware of their companies' wrongdoing. In both Hermelin and Higgins, the sentencing courts emphasized the seriousness of the defendants' own personal conduct as a justification for imposing a custodial sentence. See Sent. Tr. at 41, 49, Hermelin, supra (No. 11-cr-85) (describing defendant's behavior as reflecting "greed, abuse of power, [and] recklessness," and emphasizing "seriousness" of the offense, which involved sale of misbranded drugs containing excessive morphine); Higgins, 2011 WL 6088576, at *10 (finding that defendant was not a mere "unaware corporate executive," but had knowingly participated in carrying out "patently illegal[] clinical trials" that led to several deaths). Petitioners' fear that Park and Dotterweich will lead to widespread incarceration of innocent executives with no personal involvement in FDCA violations is unsubstantiated. Petitioners have demonstrated no reason to grant review to revisit those precedents.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

JEFFREY B. WALL Acting Solicitor General CHAD A. READLER Acting Assistant Attorney General DOUGLAS N. LETTER SCOTT R. MCINTOSH JEFFREY E. SANDBERG Attorneys

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