No. 21-183

In the Supreme Court of the United States

GAS PIPE, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether petitioners violated 18 U.S.C. 371 by conspiring "to defraud the United States" when they conspired to impede the Food and Drug Administration's functions of regulating drug labeling and approving new drugs.

2. Whether the court of appeals correctly determined that any error in the jury instructions regarding the elements of felony drug misbranding under 21 U.S.C. 331, 333(a)(2), and 352, as relevant to the jury's finding of an additional basis for Section 371 liability, was harmless beyond a reasonable doubt.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-21a) is reported at 997 F.3d 231. The orders of the district court (Pet. App. 22a-39a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 6, 2021. A petition for rehearing was denied on June 17, 2021 (Pet. App. 40a-41a). The petition for a writ of certiorari was filed on August 5, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Following a jury trial in the United States District Court for the Northern District of Texas, petitioners were convicted of violating 18 U.S.C. 371 by conspiring both to defraud the Food and Drug Administration

(FDA) and to commit misbranding with intent to defraud or mislead, in violation of 21 U.S.C. 331, 333(a)(2), and 352. Pet. App. 4a, 32a-33a. Petitioners Gerald Shults and Amy Herrig were sentenced to 36 months of imprisonment, to be followed by two years of supervised release. *Id.* at 4a. Petitioners Gas Pipe, Inc., and Amy Lynn, Inc., were each sentenced to a $25,000 fine. *Ibid.* The court of appeals affirmed. *Id.* at 1a-21a.

1. Petitioners Shults and Herrig (Shults's daughter) owned and operated a chain of smoke shops in Texas and New Mexico through their corporate entities, petitioners Gas Pipe, Inc., and Amy Lynn, Inc. Pet. App. 1a-2a & n.1. The stores sold "synthetic cannabinoid products branded as 'herbal incense,' 'potpourri,' or 'aroma therapy products,' commonly known as 'spice.'" *Id.* at 2a. "Spice, when smoked, produces a stimulant, depressant, or hallucinogenic effect on the central nervous system." *Ibid.* "[T]he federal government has scheduled various synthetic cannabinoids as illegal controlled substances." *Id.* at 2a-3a. "But regardless of whether a synthetic cannabinoid has been scheduled, it may not be sold for human consumption absent FDA approval and proper labeling." *Id.* at 3a.

Petitioners were aware that it was "illegal" to sell spice for human consumption without FDA oversight. C.A. ROA 8838-8840. And although—as they stipulated at trial—they knew that their products were intended for human consumption, they labeled their products as "not for human consumption." Pet. App. 3a; C.A. ROA 8721, 10,049. They also labeled them, falsely, as "[100%] synthetic cannabinoid free" and "50 state legal premium potpourri," and represented on labels that the substances were "[f]or aromatherapy" and did "not contain any cannabinoids or controlled substances." C.A. ROA

8743, 8756, 11,184-11,187. Between 2011 and 2014, petitioners sold more than two million units of spice that resulted in more than $40 million in revenue. Pet. App. 3a; C.A. ROA 9553-9554.

The Drug Enforcement Administration (DEA) began investigating petitioners' spice sales in 2013. Pet. App. 3a. DEA agents posing as customers made controlled purchases of more than 30 synthetic cannabinoid products from petitioners' Gas Pipe stores. *Ibid.* In some purchases, agents also bought items used to smoke spice, including smoking papers and a pipe. C.A. ROA 8735-8736, 8744-8746, 8751, 8755. During one purchase, an agent asked whether "body flushing" products would "work" with a particular product—"meaning, will that particular stuff flush out the synthetic cannabinoids" to avoid a positive drug test—and the Gas Pipe employee indicated that "so far everybody that used the urinalysis stuff was good." *Id.* at 8752-8753.

Laboratory testing confirmed that the spice obtained through these controlled purchases contained various synthetic cannabinoids. Pet. App. 3a. In more than half of the purchases, the spice contained a cannabinoid that had already been scheduled as a controlled substance. C.A. ROA 8767.

2. Petitioners and nine other co-defendants were charged with conspiracy to (a) "defraud the United States Food and Drug Administration * * * for the purpose of impeding, impairing, obstructing, and defeating [its] lawful governmental functions of regulating drug labeling and approving new drugs" and (b) "introduc[e] or deliver[] an adulterated or misbranded drug into interstate commerce with the intent to defraud or mislead" (felony misbranding), in violation of 21 U.S.C. 331, 333(a)(2), and 352—all in violation of 18 U.S.C. 371

(Count 1). C.A. ROA 430-442; Pet. App. 4a. Petitioners were also charged with conspiracy to commit mail and wire fraud (Count 2), "assorted controlled substance-related offenses," and conspiracy to commit money laundering. Pet. App. 4a & n.3. The government dismissed Count 2 before trial, and the jury acquitted petitioners on the remaining counts. *Id.* at 4a.

Before trial, the district court denied petitioners' motion to strike the conspiracy allegations in Count 1. See Pet. App. 22a-30a; C.A. ROA 3845. The court rejected petitioners' argument that the charged conspiracy to defraud the FDA was deficient, which relied on this Court's interpretation of a different statute in *Marinello* v. *United States*, 138 S. Ct. 1101 (2018), to advance the theory that Section 371 required the government to charge a "nexus" between petitioners' conduct and a specific FDA investigation or audit. Pet. App. 28a-29a; C.A. ROA 3849-3853. The court also denied petitioners' motion for judgment of acquittal at the close of the government's case and their renewed motion at the close of all the evidence. C.A. ROA 4685-4691, 9839, 10,016.

Petitioners then requested a *Marinello*-type jury instruction that would require the jury to find "a nexus between [their] agreement and a particular administrative proceeding" that was "pending" or "reasonably foreseeable" at the time of the agreement. C.A. ROA 4349. Petitioners also requested an instruction reflecting their view that the felony-misbranding provision contained a "materiality requirement." *Id.* at 10,029. The district court declined to give either instruction. *Id.* at 10,028, 10,031. The court did, however, instruct the jury that, to find guilt on the misbranding alternative on Count 1, it must find that a defendant "mis-

labeled the drug" and, "by such mislabeling, intended to defraud or mislead." *Id.* at 5787.

The jury found petitioners guilty on Count 1. Pet. App. 2a. In a special verdict form, the jury unanimously found that petitioners violated Section 371 both by conspiring to defraud the FDA and conspiring to commit felony misbranding. *Id.* at 18a; see C.A. ROA 5811-5812. The district court rejected petitioners' post-verdict motion for judgment of acquittal. Pet. App. 31a-38a. The district court sentenced petitioners Shults and Herrig to 36 months of imprisonment, to be followed by two years of supervised release. *Id.* at 4a. The court imposed a $25,000 fine on each of the corporate petitioners, Gas Pipe, Inc., and Amy Lynn, Inc. *Ibid.*

3. The court of appeals affirmed. Pet. App. 1a-21a. Although petitioners argued that "the word 'defraud,' as used in 18 U.S.C. § 371" in reference to conspiracies against the government is limited to instances where a defendant has "cheat[ed] the Government out of property or money," petitioners "acknowledge[d]" that their argument was foreclosed by "a long line of Supreme Court and circuit precedent hold[ing] otherwise." *Id.* at 5a.

The court of appeals also rejected petitioners' suggestion to "extend [the] rule announced in *Marinello*" to require the government to "show a 'nexus' between the defendant's conduct and a pending or reasonably foreseeable" administrative proceeding. Pet. App. 6a. The court relied on a prior circuit decision in which it had observed that *Marinello* interpreted a statutory element in the Internal Revenue Code—obstruction of "the due administration of" that Code—that "does not exist in and has no bearing on [Section] 371." *United States* v. *Herman*, 997 F.3d 251, 274 (5th Cir. 2021); see

Pet. App. 6a. The court accordingly declined to "extend the *Marinello* nexus requirement to [Section] 371's defraud clause." Pet. App. 6a.

The court of appeals additionally rejected petitioners' claim that their convictions should be reversed based on the district court's asserted error in omitting a materiality element from the jury instructions regarding misbranding under Section 333(a)(2). Pet. App. 7a-12a. The court of appeals observed that the "text and structure" of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, "cast doubt as to whether * * * [Section] 333(a)(2)'s felony misbranding offense" should be interpreted to include a materiality element, *id.* at 9a n.5, but the court did not resolve that issue, *id.* at 9a. "Assuming without deciding that materiality is an element of [Section] 333(a)(2)'s felony misbranding offense," the court explained that "any error was harmless" because a "review of the record" shows "beyond a reasonable doubt" that "the jury would have concluded that [petitioners'] misbranding tended to influence, or was capable of influencing, the FDA's decisionmaking." *Id.* at 9a-10a. The court then found it unnecessary to resolve petitioners' sufficiency-of-the-evidence challenge to the alternative felony-misbranding basis for conviction on Count 1. *Id.* at 18a.

ARGUMENT

Petitioners contend (Pet. 14-24) that the prohibition in 18 U.S.C. 371 against conspiring "to defraud the United States, or any agency thereof in any manner or for any purpose" is limited to conspiracies that either involve "cheat[ing] the government out of money or property" or have a nexus to a particularized governmental proceeding. The court of appeals correctly rejected that contention, which is inconsistent with over a

century of this Court's precedent. The courts of appeals are not divided on the issue, petitioners offer no sound reason for the Court to revisit it, and this Court has recently declined to review it. Moreover, this case would be a poor vehicle to examine that question given that petitioners' convictions under Section 371 do not rest on the statute's "defraud" clause alone.

Petitioners also assert that review is warranted to clarify "how harmless-error analysis works in cases of instructional error where the defendant contested the omitted (or misdescribed) element." Pet. 24. Petitioners rest that assertion on a misinterpretation of the court of appeals' decision, which considered all the record evidence. The decision does not conflict with decisions from any other circuit. And in any event, even had the court of appeals failed to review the entirety of the record, any instructional error would be harmless under the standard petitioners identify.

1. a. Section 371 makes it a crime to "conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose." 18 U.S.C. 371. The "defraud clause" of the statute has a long history, and as this Court explained when analyzing Section 371's predecessor, it includes "any conspiracy for the purpose of impairing, obstructing or defeating the lawful function of any department of [g]overnment." *Haas* v. *Henkel*, 216 U.S. 462, 479 (1910). And the Court reaffirmed in *Hammerschmidt* v. *United States*, 265 U.S. 182 (1924), that the provision covers fraudulent conduct undertaken with a "purpose and effect to defeat a lawful function of the [g]overnment and injure others," so long as it involves "fraud." *Id.* at 187. "To conspire to defraud the United States," the Court explained, "means

primarily to cheat the [g]overnment out of property or money, but it also means to interfere with or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest." *Id.* at 188.

Subsequent decisions of this Court have repeatedly recognized and reaffirmed the construction of the conspiracy statute's defraud clause adopted in *Haas* and *Hammerschmidt*. See, *e.g.*, *Glasser* v. *United States*, 315 U.S. 60, 66 (1942) ("The indictment charges that the United States was defrauded by depriving it of its lawful governmental functions by dishonest means; it is settled that this is a 'defrauding' within the meaning of [Section] 37 of the Criminal Code.") (citation omitted); *Dennis* v. *United States*, 384 U.S. 855, 861 (1966) ("It has long been established that this statutory language [in the defraud clause of Section 371] * * * reaches 'any conspiracy for the purpose of impairing, obstructing or defeating the lawful function of any department of Government'") (quoting *Haas*, 216 U.S. at 479); *McNally* v. *United States*, 483 U.S. 350, 359 n.8 (1987) (explaining that *Haas* and *Glasser* "held that [Section] 371 reaches conspiracies other than those directed at property interests").

b. Petitioners do not dispute that their convictions under the defraud clause are valid under *Haas*, *Hammerschmidt*, and other precedents of this Court. Nor do they contend that the outcome of this case would have been different in any other circuit. Instead, they suggest that this Court should grant certiorari and overturn over a century of well-established law, asserting (Pet. 15-20) that this Court's longstanding interpretation of Section 371 "cannot be reconciled with [the statute's] text, structure, or history." Pet. 15. Peti-

tioners' arguments lack merit, and this Court has previously declined to grant certiorari in response to similar requests. See *Flynn* v. *United States*, No. 20-1129 (June 28, 2021); *Coplan* v. *United States*, 571 U.S. 819 (2013) (No. 12-1299). It should follow the same course here.

As a threshold matter, revisiting that issue "would ill serve the goals of 'stability' and 'predictability' that the doctrine of statutory *stare decisis* aims to ensure." *CSX Transp., Inc.* v. *McBride*, 564 U.S. 685, 699 (2011) (quoting *Hilton* v. *South Carolina Pub. Rys. Comm'n*, 502 U.S. 197, 202 (1991)). As this Court has frequently recognized, "*stare decisis* in respect to statutory interpretation has 'special force,' for 'Congress remains free to alter what [the Court has] done.'" *John R. Sand & Gravel Co.* v. *United States*, 552 U.S. 130, 139 (2008) (quoting *Patterson* v. *McLean Credit Union*, 491 U.S. 164, 172-173 (1989)). Moreover, petitioners' attempt to relitigate this Court's early twentieth-century precedents is misplaced given that Congress long ago adopted the definition that those precedents provided.

When Congress codified the current conspiracy statute in 1948, see Act of June 25, 1948, ch. 645, 62 Stat. 701 (enacting 18 U.S.C. 371), this Court's interpretation of the phrase "defraud the United States in any manner or for any purpose" was already well-established. See *Haas*, 216 U.S. at 479-480; *Hammerschmidt*, 265 U.S. at 187-188; *Glasser*, 315 U.S. at 66. By incorporating that language into Section 371, Congress manifested its intent to incorporate the preexisting definition provided by this Court's decisions. "Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it reenacts a statute without change." *Lorillard* v. *Pons*, 434

U.S. 575, 580 (1978). Congress made no relevant change; if anything, it broadened the language of Section 371—which prohibits conspiring "to defraud the United States, *or any agency thereof* in any manner or for any purpose," 18 U.S.C. 371 (emphasis added)—since *Haas* was decided. See *Haas*, 216 U.S. at 479 (quoting Rev. Stat. § 5440 (1901), which did not then specifically refer to agencies). Congress's adoption of this Court's definition of the defraud clause refutes petitioners' contention that that definition is inconsistent with Section 371's "text" and "history." Pet. 15.

c. Petitioners' other objections to this Court's well-established precedent regarding the conspiracy statute's defraud clause likewise lack merit.

Petitioners first contend (Pet. 16) that *Haas*'s reading of the defraud clause "ignores" the "implications" of Section 371's clause barring conspiracies to commit offenses against the United States. See also Pet. 20-22. This Court has already explained, however, that the fact that a defendant's conduct also violates a specific statute "does not, in and of itself, make the conspiracy-to-defraud clause of [Section] 371 unavailable to the prosecution." *Dennis*, 384 U.S. at 864. That accords with this Court's general observation that even "substantial" "overlap" is "not uncommon in criminal statutes." *Loughrin* v. *United States*, 573 U.S. 351, 358 n.4 (2014); see *Pasquantino* v. *United States*, 544 U.S. 349, 358 n.4 (2005).

Petitioners relatedly suggest (Pet. 17-18) that a 1948 amendment to the statute's offenses clause, which specified lesser penalties for conspiracies to commit misdemeanors, Act of June 25, 1948, ch. 645, 62 Stat. 701 (enacting 18 U.S.C. 371), implicitly altered the longstanding construction of the government-fraud clause. But

the unchanged text of the government-fraud clause, against the well-developed interpretive backdrop of this Court's interpretation of that text, belies petitioners' suggestion of such an oblique amendment.

Furthermore, to the extent that petitioners would characterize (Pet. 18) use of the government-fraud clause in cases where defendants conspire to commit a misdemeanor as an "end run" around purported statutory limitations, their proposal to limit the defraud clause to "attempt[s] to cheat the government out of money or property," Pet. 14, would have the same feature. Congress punishes as misdemeanors multiple offenses that involve fraud targeting government property. See, *e.g.*, 18 U.S.C. 1030(a)(6) and (c)(2)(A) (fraud involving government computers); 18 U.S.C. 1923 (fraudulent receipt of payments to employees in "missing" status) (emphasis omitted); 20 U.S.C. 1097(a) (student loan fraud not exceeding $200); 26 U.S.C. 7207 (fraudulent tax returns); 38 U.S.C. 1987(a) (presenting fraudulent papers related to government life insurance); 42 U.S.C. 1307(a) (false statements relating to Social Security). Nor, in any event, is such a result problematic, given that this Court has long recognized Congress may punish a conspiracy to commit an offense more severely than the underlying offense. See *Clune* v. *United States*, 159 U.S. 590, 595 (1895) (upholding provisions imposing two years' imprisonment for a conspiracy to commit an offense that carried only a $100 fine). As the Court has observed, a "collective criminal agreement * * * presents a greater potential threat to the public than individual delicts." *Callanan* v. *United States*, 364 U.S. 587, 593 (1961). And any supposed problem is moreover absent from this case where the jury found by special verdict that petitioners conspired

to commit *felony* misbranding, punishable under 21 U.S.C. 333(a)(2). C.A. ROA 5812.

Finally, petitioners contend that this Court's long-standing interpretation of the defraud clause is "so standardless that it invites arbitrary enforcement" and is thus unconstitutionally vague. Pet. 19 (quoting *Johnson* v. *United States*, 576 U.S. 591, 595 (2015)). But as this Court has clearly explained, the clause applies to conspiracies to "cheat the government out of property or money" and "to interfere with or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest." *Hammerschmidt*, 265 U.S. at 188. And while observing that the "broad language of the general conspiracy statute" requires indictments to "be scrutinized carefully," *Dennis*, 384 U.S. at 860, the Court itself has applied that test in multiple cases. See *Tanner* v. *United States*, 483 U.S. 107, 128 (1987); *Dennis*, 384 U.S. at 861; *Glasser*, 315 U.S. at 66.

The contours of the defraud clause have been defined for nearly a century—at least since this Court clarified in 1924 that the clause requires "deceit or trickery," rather than mere "open defiance" of a law, *Hammerschmidt*, 265 U.S. at 187, 189—and by 1942, the Court could say that "it [wa]s settled" that the general conspiracy statute applied to "depriving [the government] of its lawful governmental functions by dishonest means." *Glasser*, 315 U.S. at 66; see *Dennis*, 384 U.S. at 861 (observing that interpretation had "long been established"). And none of the lower-court decisions identified by the petitioners (Pet. 18-19) suggests, let alone holds, that this Court's broad interpretation of the clause is unconstitutionally vague. See *United States* v. *Coplan*, 703 F.3d 46, 61-62 (2d Cir. 2012), cert. denied,

571 U.S. 819 (2013); *United States* v. *Goldberg*, 105 F.3d 770, 775 (1st Cir. 1997); *United States* v. *Barker Steel Co., Inc.*, 985 F.2d 1123, 1129-1132 (1st Cir. 1993); see also *American Commc'ns Ass'n* v. *Douds*, 339 U.S. 382, 412 (1950) (focusing on whether a statute gave "fair notice to those to whom [it] is directed," rather than the statutory terms' "breadth," in evaluating vagueness challenge).

d. Petitioners suggest (Pet. 22-23) "[a]lternatively" that this Court should read into Section 371 a requirement for "a nexus between the defendant's conduct and a pending or reasonably foreseeable proceeding," as the Court did with a different statute in *Marinello* v. *United States*, 138 S. Ct. 1101 (2018). That suggestion lacks merit.

As an initial matter, the premise of that argument—that Section 371 is vague or has been interpreted too broadly—is incorrect, as explained above. Section 371 does not require the addition of an atextual limitation to "remedy '[a] lack of fair warning and related kinds of unfairness,'" Pet. 23 (quoting *Marinello*, 138 S. Ct. at 1108), obviating petitioners' request to disturb a century of precedent by extending *Marinello* to this context. But even assuming petitioners had presented a sound reason for this Court to reexamine its construction of Section 371, *Marinello* does not support engrafting the "nexus" requirement found in different statutory language in Title 26 onto conspiracies to defraud the United States under Title 18.

In *Marinello*, the Court examined the "Omnibus Clause" in 26 U.S.C. 7212(a), a tax provision, which proscribes "corruptly or by force or threats of force * * * obstruct[ing] or imped[ing], or endeavor[ing] to obstruct or impede, the due administration of" the Tax

Code. 26 U.S.C. 7212(a). This Court construed the phrase "due administration of [the Tax Code]," to "refer[] to specific interference with targeted governmental tax-related proceedings, such as a particular investigation or audit," not "routine administrative procedures" like tax-return processing. *Marinello*, 138 S. Ct. at 1104 (first set of brackets in original). And the Court located Section 7212(a)'s nexus requirement in that provision's language, context, and legislative history—none of which apply to Section 371. See, *e.g.*, *Marinello*, 138 S. Ct. at 1106 (reasoning that "the whole phrase—the due administration of the Tax Code—is best viewed * * * as referring to only some of those acts or to some separable parts of an institution or business").

That phrase has no analogue in Section 371's prohibition on defrauding federal agencies. The Court in *Marinello* emphasized that "statutory context confirms that [due administration of the Tax Code] refers to specific, targeted acts of administration," because it serves as a "catchall" for the obstructive conduct set forth elsewhere in Section 7212 "refer[ring] to corrupt or forceful actions taken against individual identifiable persons or property." 138 S. Ct. at 1106-1107 (citation omitted). Section 371 does not share those features, nor does it mirror the "similarly worded criminal statute" prohibiting obstruction of justice, 18 U.S.C. 1503(a), whose limitation to specific judicial proceedings this Court found instructive in *Marinello*. 138 S. Ct. at 1105-1106 (discussing *United States* v. *Aguilar*, 515 U.S. 593 (1995)). And this Court's review of Section 7212's legislative history, which focused on protecting IRS agents, is equally inapposite here. See *Marinello*, 138 S. Ct. at 1107. Indeed, Section 371's statutory history manifests Congress's intent to codify this Court's longstanding

interpretation of its language as a broad prohibition against deceptive obstruction of government functions. See p. 9-10, *supra*.

Accordingly, every court of appeals to consider the issue has recognized that *Marinello* does not apply to conspiracies to defraud the United States under Section 371. See *United States* v. *Herman*, 997 F.3d 251, 273-274 (5th Cir. 2021) (explaining that *Marinello* "lives in a separate vein of law" and did not "did not address, cite, or analogize to 18 U.S.C. § 371 or *Hammerschmidt* and its progeny"); *United States* v. *Flynn*, 969 F.3d 873, 879 (8th Cir. 2020), cert. denied, No. 20-1129 (June 28, 2021) (observing that, unlike the statute in *Marinello*, "the broad language in [Section] 371 makes no reference to the 'due administration [of the Internal Revenue Code]'") (second set of brackets in original); *United States* v. *Atilla*, 966 F.3d 118, 131 (2d Cir. 2020) ("*Marinello* is * * * wholly unrelated to [Section] 371's defraud clause"); see also *United States* v. *Parlato*, No. 15-CR-149, 2019 WL 988450, at *2 (W.D.N.Y. Mar. 1, 2019) (observing that "the language and scope of the statutes are different," and "declin[ing] to apply *Marinello* to a statute it did not consider"). That judicial consensus does not warrant this Court's review.

e. Even if the longstanding and uniform interpretation of Section 371's defraud clause warranted reconsideration, this case would be an unsuitable vehicle for it. Because the jury found petitioners guilty under Section 371 for conspiring both under the defraud clause and the offense clause, petitioners would have to overturn the jury's finding regarding the offense clause in order to obtain any potential relief on remand. And as explained below, the challenge petitioners raise in connection with the offense clause in their petition lacks merit.

2. In connection with the jury's finding that petitioners alternatively violated Section 371's offense clause by conspiring to engage in felony misbranding, petitioners contend (Pet. 24) that this Court's review is warranted to clarify "how harmless-error analysis works in cases of instructional error where the defendant contested the omitted (or misdescribed) element." According to petitioners, "[m]ost courts consider all of the evidence at trial" when determining whether the error was harmless, whereas "the Fifth Circuit regularly considers only the strength of the government's evidence." Pet. 26. But petitioners misstate the Fifth Circuit's approach, which is consistent with *Neder* v. *United States*, 527 U.S. 1 (1999), and does not conflict with decisions of other circuits.

a. *Neder* held that the failure to submit an element of an offense to a jury "is an error that is subject to harmless-error analysis." 527 U.S. at 15. The Court explained that such an omission is harmless where it is "clear beyond a reasonable doubt that a rational jury would have found the defendant guilty absent the error." *Id.* at 18. In *Neder*, this Court found the omission of a materiality element harmless because the "evidence supporting materiality was so overwhelming" that the defendant did not even argue that his false statements were immaterial. *Id.* at 16. But it recognized that an error would not be harmless beyond a reasonable doubt "where the defendant contested the omitted element and raised evidence sufficient to support a contrary finding." *Id.* at 19.

The court of appeals here faithfully applied the *Neder* standard to petitioners' claim that the felony misbranding provision, Section 333(a)(2), contains a materiality element that the district court omitted from the

jury instructions. The court recounted *Neder*'s standard, observing that it could find the omission of a materiality element harmless if, "after a thorough examination of the record, [it was] able to conclude beyond a reasonable doubt that the jury verdict would have been the same absent the error." Pet. App. 10a (brackets and internal quotations omitted) (quoting *United States* v. *Cessa*, 785 F.3d 165, 186 (5th Cir.), cert. denied, 577 U.S. 993 (2015), and citing *Neder*, 527 U.S. at 19). And the court explained that its "review of the record shows, beyond a reasonable doubt, that the jury would have concluded that [petitioners'] misbranding" was material because it "tended to influence, or was capable of influencing, the FDA's decisionmaking." *Ibid.*

Nothing in the decision below supports petitioners' assertion (Pet. 28) that the court of appeals considered only "the government's evidence, standing alone," and "never considered whether a jury viewing the record *as a whole* might have acquitted." On the contrary, the court recognized that *Neder* requires a "thorough examination of the record" and stated that its harmless-error finding was based on its "review of the record" and the "evidence presented at trial." Pet. App. 10a (internal quotation marks omitted). Although it highlighted the testimony of two government witnesses, *id.* at 10a-11a, it never suggested that it was considering *only* the government's evidence or disregarding the defense case. And nothing in *Neder* suggests that a court of appeals must recite every piece of evidence it considers as part of a harmless-error analysis.

Moreover, contrary to petitioners' suggestion, Pet. 24, 26, 31, they never "contested" the issue of materiality at trial or elicited any evidence that their representations were immaterial. See C.A. ROA 9854-9949,

9964-10009, 10,015-10,016 (defense case). Instead, petitioners "contested" materiality only "on appeal" by pointing to purported "holes in the government's case." Pet. 31 (citing Pet. C.A. Br. 79). Although they allege that the court of appeals "did not consider * * * substantial evidence that spice's labeling did not affect consumer decision making," Pet. 30, any such evidence would in no way undercut the testimony of multiple witnesses that the mislabeling was material to FDA regulation, see Pet. App. 10a-11a. Because petitioners offered no evidence to rebut materiality—and now invoke only evidence that the government itself elicited during its case-in-chief—they cannot show that the court of appeals somehow disregarded relevant evidence in making its harmlessness determination.

Petitioners also cite (Pet. 28) *United States* v. *Skilling*, 638 F.3d 480 (5th Cir. 2011), cert. denied, 566 U.S. 956 (2012), in support of their claim that the Fifth Circuit "regularly considers only the strength of the government's evidence and never asks whether" the "record as a whole" could have resulted in a rational jury acquitting absent the error. Pet. 26. *Skilling* does not support that claim. The Fifth Circuit there expressly recounted *Neder*'s statement that an error is not harmless "[i]f the defendant 'raised evidence sufficient to support a contrary finding.'" *Skilling*, 638 F.3d at 482 (quoting *Neder*, 527 U.S. at 19). It then carefully considered both the government's evidence *and* the defendant's contrary evidence before concluding that the evidence on a valid theory of guilt was "overwhelming." *Id.* at 483-488. And when the defendant in *Skilling* sought this Court's review, alleging an improper application of *Neder*, this Court denied certiorari. *Skilling* v. *United States*, 566 U.S. 956 (2012); see Br. in Opp.,

Skilling v. *United States*, No. 11-674, 2012 WL 988699, at *7-*12 (Mar. 12, 2012).

Nor does the decision below conflict, as petitioners claim (Pet. 26-27), with *United States* v. *Prigmore*, 243 F.3d 1 (1st Cir. 2001), or *United States* v. *Miller*, 767 F.3d 585 (6th Cir. 2014). In *Prigmore*, the court determined that, although the evidence was "more than sufficient to permit a retrial on a properly formulated theory," it was not "so one-sided as to render harmless the underlying instructional error." 243 F.3d at 22. In *Miller*, "considerable evidence" supported the defendants' theory, and the district court had remarked that it might be "impossible" to prove the mental state that the court of appeals held was required. 767 F.3d at 599-600 (internal quotation marks omitted). Nothing in those fact-specific decisions conflicts with the fact-specific decision in this case, which, as explained above, considered "the record" as a whole before finding the asserted error harmless. Pet. App. 10a.

b. In any event, this case would be a poor vehicle for reviewing the court of appeals' application of the harmless-error standard.

First, even if petitioners were correct that the court of appeals failed to consider "the record *as a whole*," Pet. 28, the error would still be harmless because that record makes clear beyond a reasonable doubt that the jury would have found petitioners' mislabeling conduct satisfied any materiality requirement. A misrepresentation is material if it has "a natural tendency to influence, or is capable of influencing," a decisionmaker. *Neder*, 527 U.S. at 16 (brackets and citation omitted). The evidence overwhelmingly showed that petitioners' mislabeling of their spice had a natural tendency to influence the FDA and government investigators.

One of petitioners' spice suppliers testified that he labeled his product "Not for Human Consumption" because that was "the only way that we could sell it to the public. If it was stated for human consumption, it would be subject to FDA regulations." Pet. App. 10a-11a (emphasis omitted). A former Gas Pipe store manager testified that petitioners sold spice as "herbal incense" or "potpourri" even though "[i]t really wasn't" and that such terminology was "important" to petitioners Shults and Herrig "[b]ecause of the legality of what spice was." *Id.* at 11a (brackets in original). The store manager testified that Shults and Herrig "didn't want to sell [spice] as a consumable because it would have to go through the FDA." *Ibid.* (emphasis omitted; brackets in original).

The government's FDA witness confirmed as much, testifying that "the FDA is supposed to know everything that's on the market," C.A. ROA 9799; that synthetic cannabinoids are "drugs" when "intended for human consumption," *id.* at 9794; and that over-the-counter drugs must be labeled with the ingredients, directions for use, and warnings, *id.* at 9795. Petitioners were highly aware of FDA regulations, subscribing to the Federal Register and "keeping a close eye on" what substances were banned. C.A. ROA 8992-8993, 11,276. Thus, the entire scheme of mislabeling the spice as "not for human consumption" was to falsely indicate to regulators and investigators that the products were not subject to FDA regulation.

Petitioners point out that the FDA witness "never suggested that the government was actually misled in any respect." Pet. 30-31. But that disregards the materiality standard, which asks whether a false statement is "*capable* of influencing" a decisionmaker. *Neder*, 527 U.S. at 16 (emphasis added). The government need not

show "reliance" on the misrepresentation to prove materiality. *Id.* at 24-25. Regardless of whether the FDA was actually deceived by the mislabeling, the false statements that the spice products were "not for human consumption" and were 100% "synthetic cannabinoid free," C.A. ROA 8890, were capable of influencing government investigators on the lookout for unapproved or mislabeled drugs being sold for human consumption.

In addition, and contrary to petitioners' assertion (Pet. 30), the mislabeling could have influenced petitioners' customers. Even if customers were not capable of being misled by the "Not for Human Consumption" language, the labels contained other false statements with a natural tendency to influence consumers. Many of the products were labeled as "100 percent synthetic cannabinoid free" and "50 state legal premium potpourri," C.A. ROA 8743, 8890, or represented that they did "not contain any cannabinoids or controlled substances," *id.* at 8756, even though they contained synthetic cannabinoids that were controlled substances at the time of sale, see *id.* at 8743, 8756-8759, 8914. Those false claims were capable of influencing customers by making them believe they were buying products with different ingredients or products that were legal. Because the record as a whole proved beyond a reasonable doubt that the petitioners' labeling misrepresentations were material, requiring the court of appeals to conduct a renewed harmless-error analysis would not lead to a different result.

Second, this case is a poor vehicle for review because the court of appeals did not actually resolve—and petitioners do not ask this Court to resolve—whether Section 333(a)(2)'s misbranding provision contains a materiality element. See Pet. App. 9a-10a. The court ob-

served that the "text and structure" of the Federal Food, Drug, and Cosmetic Act "cast doubt" on whether *Neder*'s materiality analysis "extends to [Section] 333(a)(2)'s felony misbranding offense," *id.* at 9a n.5, but did not address that issue in this case where it found any error to be harmless, see *id.* at 9a-10a. The issue is outside the questions presented here, and because the court of appeals could potentially affirm on that alternative basis on remand, review of the court of appeals' harmless-error determination might not affect the ultimate outcome in this case. And the dispositive nature of the issue is even more doubtful in light of the alternative finding of guilt under Section 371's government-fraud clause. No further review is warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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