No. 01-1188

In the Supreme Court of the United States

BALDEV RAJ BHUTANI, AND
ALRA LABORATORIES, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

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

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the district court committed reversible error in its instructions on proof of materiality under 21 U.S.C. 333(a)(2).

2. Whether petitioners' failure to maintain records as required by 21 U.S.C. 355(k) served as a valid basis for a conviction under 21 U.S.C. 333(a)(2).

3. Whether the district court's use of Sentencing Guidelines (Guidelines) § 2F1.1 violated the Ex Post Facto Clause.

4. Whether the evidence was sufficient to sustain petitioners' convictions for distributing contaminated Lactulose from leaking drums.

5. Whether the district court correctly determined that there was a fraud loss under Guidelines § 2F1.1.

6. Whether the court of appeals erred in determining that there was no inconsistency between the government's position on appeal and its position at trial.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-15) is reported at 266 F.3d 661. The opinion of the district court (Pet. App. 18-19) is unreported. An earlier opinion of the court of appeals (Pet. App. 22-35) is reported at 175 F.3d 572. An earlier opinion of the district court (Pet. App. 36-66) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on September 12, 2001. A petition for rehearing was denied on November 14, 2001 (Pet. App. 17). The petition for a writ of certiorari was filed on February 12, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Following a jury trial in the United States District Court for the Northern District of Illinois, petitioners Bhutani and Alra Laboratories, Inc. were convicted of adulterating the drug Lactulose by adding sodium hydroxide (Count 3), failing to record the addition of the sodium hydroxide (Count 4), and distributing the adulterated Lactulose (Count 6). In addition, petitioners were convicted of distributing the drug "K+10" after it was contaminated with metal shards (Count 10), and using contaminated Lactulose concentrate as a drug ingredient and then selling the contaminated drug (Counts 7 and 8). Finally, petitioners were convicted of a conspiracy to commit the above substantive offenses (Count 1).

The district court granted petitioners' motion for a new trial. The court of appeals reversed and remanded for sentencing. The district court sentenced petitioner Bhutani to 30 months' imprisonment and fined both petitioners. The court of appeals affirmed.

2. Petitioner Bhutani is the owner of petitioner Alra Laboratories, Inc. (Alra), a pharmaceutical company. Pet. App. 23. Alra produces generic drugs, including Lactulose, a drug that combats liver disease, and K+10, a potassium supplement. *Ibid.*

The government's evidence at trial established that Bhutani directed his employees to spike two lots of Lactulose with sodium hydroxide in order to conceal the age of those lots. Pet. App. 25. In response to Bhutani's directions, employees opened bottles of Lactulose, spiked them with sodium hydroxide, resealed the bottles, and repackaged them for distribution with an erroneous expiration date. *Ibid.*

The government's evidence also established that an Alra worker dropped a metal pipe into a mixer containing a large batch of K+10. The pipe was then ground up into tiny pieces. After unsuccessfully attempting to remove the metal pieces, petitioners tableted the drug and released it for sale. Gov't C.A. Br. 8-9.

The government's evidence further showed that Alra received 36 drums of concentrated Lactulose that were dented, punctured, and leaking. Under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape. Although Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption and would have to be destroyed, petitioners used the concentrate as a drug component and sold the contaminated drugs to the public. Gov't C.A. Br. 9.

3. After petitioners were convicted for their conduct, petitioners moved for a new trial, based on new evidence that Lactulose was effective with a pH as low as 2.5. Pet. App. 26. Petitioners asserted that the new evidence undermined the government's assertion that petitioners had a motive to spike the Lactulose, and that the spiking counts had a spillover effect on the other counts. The district court granted petitioners' motion. *Id.* at 36-66.

The court of appeals reversed. Pet. App. 22-35. The court first held that the government's failure to disclose the pH evidence did not violate *Brady* v. *Maryland*, 373 U.S. 83 (1963), because it did not come into the government's possession "until well after the trial had ended." Pet. App. 29. The court further held that the new evidence did not undermine the government's argument that petitioners had a motive to spike the Lactuolose. The court explained that the government never

claimed that petitioners spiked the Lactolose to mask the fact that the drug would soon become ineffective. *Id.* at 31. Instead, the government argued that petitioners spiked the Lactulose because the lots were old and petitioners wanted to conceal the age of the lots—an argument that was not undercut by evidence that the Lactulose was not close to becoming ineffective at the time it was spiked. *Ibid.* Finally, the court ruled that the new evidence had no bearing on petitioners' convictions on the counts that did not relate to the spiking of the Lactulose. *Id.* at 34.

4. On remand, petitioners once again moved for a new trial, claiming that the government's position on appeal contradicted its theory at trial. The district court denied the motion, holding that the court of appeals had already concluded that there was no inconsistency. Pet. App. 18-19. The district court also rejected petitioners' contention that the jury instructions were defective because they failed to require the jury to find materiality as an element of an FDCA violation. *Id.* at 19.

The court of appeals affirmed. Pet. App. 1-15. The court first rejected petitioners' contention that the government's position on appeal contradicted its trial theory. The court explained that "[a] second read of the trial transcripts reveals that the government's position at trial and on appeal has been consistent." *Id.* at 2. In particular, "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold

past its expiration date could not be detected." *Id.* at 2-3.

The court of appeals also rejected petitioners' contention that, because of a drafting error during a 1984 recodification, it was not a crime under 21 U.S.C. 331(e) for petitioners to alter their records with the intent to defraud or mislead. The court held that Congress clearly intended to make the alteration of records with the intent to mislead a felony. Pet. App. 6-10. The court emphasized that "in strictly construing a [criminal] statute, courts ought not deprive it of the obvious meaning intended by Congress, nor abandon common sense." *Id.* at 7.

The court of appeals also affirmed the district court's sentencing rulings. It held that the district court correctly applied the Sentencing Guideline applicable to offenses involving fraud or deceit. Pet. App. 10-11. The court further held that the district court correctly assessed the amount of the loss attributable to petitioners' deceit on the basis of petitioners' gain from selling the adulterated drugs. *Id.* at 11-14.

ARGUMENT

1. Petitioners contend (Pet. 17-20) that, under *Neder* v. *United States*, 527 U.S. 1 (1999), the jury was required to find materiality as an element of the offenses under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* That contention does not warrant review. The court of appeals did not address whether *Neder* requires a materiality finding for convictions under the FDCA. Nor was the resolution of that issue necessary in order to affirm petitioners' FDCA convictions. The jury was instructed to find materiality on the violation on which petitioners sought a materiality instruction, and the failure to give such an

instruction on the other FDCA counts did not constitute plain error.

Petitioners requested a materiality instruction relating to their failure to maintain accurate records. Pet. 19. Although the district court did not give the instruction that petitioners requested, it did instruct the jury that it was required to find materiality. In particular, the court instructed the jury that, in order to find petitioners guilty of failing to maintain accurate records, it was required to find that petitioners "*materially* altered the manufacturing procedures for [Lactulose] by causing sodium hydroxide to be added to this product more than two years after its original manufacture," and in concealing "this unauthorized procedure from the FDA, intentionally failed to document this unproved manufacturing procedure in the production batch records." Tr. 5842-5843 (emphasis added). Assuming that *Neder* requires a materiality instruction, the district court's instruction fulfilled that requirement.

Petitioners did not request a materiality instruction relating to any other FDCA violation. Thus, petitioners' contention that the district court erred in failing to give a materiality instruction on the other FDCA counts is subject to review only for plain error. See Fed. R. Crim. P. 52(b); *Johnson* v. *United States*, 520 U.S. 461 (1997). Under the plain error standard, petitioners must show not only that the court erred in failing to give a materiality instruction. They must also show that (1) the error is "plain" or "obvious," (2) the error "affect[ed] substantial rights" and (3) the error "seriously affect[ed] the fairness, integrity, or public reputation of judicial proceedings." *Johnson*, 520 U.S. at 467-468.

Even assuming that the district court erred in failing to give a materiality instruction on the other FDCA counts, that error was not plain or obvious under *Neder*. In *Neder*, the Court held that the mail fraud, bank fraud, and wire fraud statutes require proof of materiality. The Court reasoned that when Congress criminalizes "fraud," it intends to incorporate fraud's common law materiality requirement unless the statutory context dictates otherwise. 527 U.S. at 23. The FDCA, however, criminalizes violations of the Act that are committed with "the intent to defraud *or mislead*." 21 U.S.C. 333(a)(2) (emphasis added). *Neder* does not address whether such a statute incorporates a materiality requirement. *Neder* therefore does not make it "clear" or "obvious" that the FDCA requires proof of materiality.

Petitioners also cannot establish the other two components of plain error. Count 3 charged petitioners with adulterating the drug Lactulose by adding sodium hydroxide, and Count 6 charged petitioners with distributing the adulterated Lactulose. The jury's finding of guilt with respect to record-keeping, on which a materiality instruction was requested and given, necessarily incorporated a finding that the addition of the sodium hydroxide was a material change. Moreover, petitioners did not contend at trial that adding sodium hydroxide would be insignificant or unimportant; they contended that the conduct did not happen. Tr. 5004, 5254, 5395. Petitioner's own expert witness, Dr. Robyt, made clear that adding sodium hydroxide to Lactulose would be highly material. He testified that sodium hydroxide injected into bottles of Lactulose would be potentially lethal. Tr. 4328, 4334. He further testified that if the sodium hydroxide got into the intestines it could make the patient very sick. Tr. 4338. In those

circumstances, the district court's failure to give a materiality instruction on Counts 3 and 6 neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Counts 7 and 8 charged that petitioners used contaminated Lactulose concentrate from dented and leaking drums as a drug ingredient and then sold the contaminated drug. The evidence that established that petitioners engaged in that conduct also established its materiality. Specifically, the evidence showed Alra received 36 drums of concentrated Lactulose that were leaking, that under Bhutani's directions, workers injected glue into the leaks and covered the leaks with duct tape, and that Bhutani admitted that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. A jury that credited that evidence could not have rationally concluded that petitioners' deception in relation to that conduct was immaterial. Accordingly, the failure to give a materiality instruction on those counts neither affected petitioners' substantial rights nor seriously affected the fairness, integrity, or public reputation of judicial proceedings. Count 10 charged that petitioners distributed K+10 that had been contaminated when a steel pipe was dropped into a blender and ground up into the product during the manufacturing process. Petitioners did not contend that the shipment of drug tablets that were contaminated by metal shards would be insignificant. Rather, they claimed that they destroyed the contaminated portion of the K+10 batch. Govt' C.A. Br. 8-9. The jury, however, rejected petitioners' version of the events, and found that petitioners sold tablets that were contaminated by metal shards. Because a deception relating to selling drugs contaminated with metal shards is obviously

material, the failure to give a materiality instruction on Count 10 neither affected petitioners' substantial rights, nor seriously affected the fairness, integrity, or public reputation of judicial proceedings.

Petitioners were also convicted of conspiring to commit the offenses discussed above. For the same reasons that the failure to give a materiality instruction did not constitute plain error on the substantive counts, it did not constitute plain error on the conspiracy count.

Petitioners contend (Pet. 18-19) that the decision below conflicts with the Ninth Circuit's holding in *United States* v. *Watkins*, 278 F.3d 961 (2002), that the FDCA requires proof of materiality. Because the court of appeals in this case did not address whether the FDCA requires proof of materiality, and because petitioners' FDCA convictions must be affirmed even if the FDCA requires proof of materiality, however, there is no conflict between the decision below and *Watkins*.

2. Petitioners also contend (Pet. 21-23) that review is warranted to decide whether Section 331(e) prohibited the failure to maintain accurate records when their charged conduct occurred. That question does not warrant review. In 1990, Congress clarified that Section 331(e) prohibits the failure to maintain records. See Vaccine and Immunization Amendments of 1990, Pub. L. No. 101-502, § 5(j), 104 Stat. 1289. Petitioners' contention that Section 331(e) did not cover such conduct when their charged conduct occurred therefore does not raise any issue of prospective importance. In addition, under the Sentencing Guidelines, petitioners' convictions for failing to maintain records did not add to the offense level that was produced by their convictions for adulterating the Lacutalose and distributing the adulterated product. A reversal of petitioners' conviction on the failure to maintain records count there-

fore would not have any practical impact on petitioners' sentences.

In any event, the court of appeals correctly held that petitioners' failure to maintain accurate records violated Section 331(e). In 1962, Congress amended the FDCA to require that drug manufacturers provide the FDA with information concerning drugs that the agency had previously approved for sale. That amendment added a new subsection to the FDCA, designated as 21 U.S.C. 355(j) (1994 & Supp. V 1999), which provided in pertinent part:

> (1) In the case of any drug for which an approval of [a new drug application] is in effect, the applicant shall * * * make such reports to the Secretary, of data relating to * * * information * * * with respect to such drug, as the Secretary may by general regulation * * * prescribe.

Drug Amendments of 1962, Pub. L. No. 87-781, § 103, 76 Stat. 782. The same 1962 legislation also amended 21 U.S.C. 331(e) to prohibit any failure to establish or maintain records required by 21 U.S.C. 355(j) (1994 & Supp. V 1999).

The FDCA then remained unchanged for 22 years. In 1984, Congress amended the FDCA to provide for new procedures relating to generic drugs. A new generic drug subsection was designated as Section 355(j), while the previous Section 355(j)—the record-keeping provision—was redesignated as Section 355(k). Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585.

Congress neglected in its 1984 legislation to amend 21 U.S.C. 331(e) to reflect that what had previously been Section 355(j) was now Section 355(k). Section 331(e) therefore continued to prohibit "the failure to

establish or maintain any record * * * required under [21 U.S.C. 355(j)]," even though the new Section 355(j), relating to generic drug approvals, did not include record-keeping and reporting requirements. In 1990, Congress enacted a clarifying amendment to Section 331(e) that struck the reference to Section 355(j) and substituted a reference to Section 355(k). § 5(j), 104 Stat. 1289.

Because petitioners' charged conduct occurred after the 1984 amendments, but before the 1990 clarifying amendment, the relevant question is whether Section 331(e) prohibited the failure to maintain records during that period. In resolving that question, the court of appeals either had to interpret the lingering reference to Section 355(j) as a reference to the redesignated Section 355(k), or it had to give the prohibition in Section 331(e) against failing to establish or maintain required records no meaning at all. The court of appeals correctly chose the interpretation that gave continuing meaning to that prohibition, rather than the one that would have rendered it a nullity. Read in the manner suggested by petitioners, Congress's 1984 amendments to the FDCA repealed the 22-year-old sanction against failure by a drug manufacturer to prepare records that it was still required to maintain, and they did so while still leaving in place language in Section 331 that prohibited the failure to maintain required records. The court of appeals correctly rejected that result as inconsistent with Congress's clear intent and common sense.

This Court and numerous courts of appeals have interpreted criminal laws to prohibit conduct that Congress clearly intended to prohibit notwithstanding the presence of inadvertent drafting errors that rendered the conduct outside the literal reach of the laws. See

United States v. *Lacher*, 134 U.S. 624, 625-632 (1890); *United States* v. *Graham*, 169 F.3d 787, 790-791 (3d Cir.), cert. denied, 528 U.S. 845 (1999); *United States* v. *Warren*, 149 F.3d 825, 827-828 (8th Cir. 1998); *United States* v. *Rossetti Bros., Inc.*, 671 F.2d 718, 720 (2d Cir. 1982); *United States* v. *Scrimgeour*, 636 F.2d 1019, 1021-1024 (5th Cir. Unit B), cert. denied, 454 U.S. 878 (1981); *United States* v. *Moore*, 613 F.2d 1029, 1039-1045 (D.C. Cir. 1979), cert. denied, 446 U.S. 954 (1980); *United States* v. *Babcock*, 530 F.2d 1051, 1053-1054 (D.C. Cir. 1976). The court of appeals' decision in this case is consistent with those decisions.

Petitioners contend (Pet. 21-22) that the decision below conflicts with the decisions in *United States* v. *Faygo Beverages, Inc.*, 733 F.2d 1168 (6th Cir. 1984), and *United States* v. *RSR Corp.*, 664 F.2d 1249, 1253 (5th Cir. Unit A), cert. denied, 459 U.S. 1016 (1982). Neither of those decisions, however, involved an interpretation of Section 331(e). Instead, they involved a construction of two provisions of the Interstate Commerce Act that have since been amended. While there is some tension between the general approach to statutory interpretation adopted by those older decisions and the approach adopted by the court below, that tension is not a sufficient basis for granting review in this case. Should any tension in general approach lead to conflicting interpretations of the same statute, review by this Court might then be warranted. Because there is no conflict in the circuits concerning the correct interpretation of Section 331(e), because the issue arising under Section 331(e) has no prospective importance, and because a reversal of petitioners' conviction on that count would not affect their sentences, review in this case is unwarranted.

3. Petitioners contend (Pet. 22-23) that the district court erred in applying Guidelines § 2F1.1, the fraud Guideline, rather than Guidelines § 2N2.1(b), the drug regulation Guideline. Guidelines § 2N2.1(b), however, expressly states that "[i]f the offense involved fraud, apply § 2F1.1." Since petitioners' conduct involved fraud, the district court correctly applied Guidelines Section 2F1.1.

Nor did the application of Section 2F1.1 violate the Ex Post Facto Clause. As petitioners note, the Sentencing Commission did not adopt the cross-reference in Section 2N2.1(b) until 1992, after their charged conduct occurred. But the Guidelines in effect at the time of petitioners' criminal conduct also required the application of Guidelines § 2F1.1 to fraudulent conduct. At that time, the commentary to Section 2N2.1 specified that "[i]f the offense involved theft, fraud, bribery, revealing trade secrets, or destruction of property, apply the guideline applicable to the underlying conduct, rather than this guideline." Guidelines § 2N2.1, comment. (n.2) (1988) (emphasis added). That Commentary reflected a binding interpretation of the Guidelines. *Stinson* v. *United States*, 508 U.S. 36, 43 (1993). Thus, even before the Commission adopted the 1992 cross-reference, the courts of appeals uniformly applied Section 2F1.1 to FDCA cases involving the intent to defraud or mislead. *United States* v. *Cambra*, 933 F.2d 752 (9th Cir. 1991); *United States* v. *Anderson*, 45 F.3d 217, 220 (7th Cir. 1995); *United States* v. *Arlen*, 947 F.2d 139, 146 (5th Cir. 1991), cert. denied, 503 U.S. 939 (1992). Because the Guidelines required application of Section 2F1.1 to FDCA cases involving fraud both at the time of petitioners' criminal conduct and at the time of petitioners' sentencing, the district court's use of that

Guideline did not violate the Ex Post Facto Clause. *Johnson* v. *United States*, 529 U.S. 694, 699 (2000).

4. Petitioners contend (Pet. 23-24) that there was insufficient evidence to support the jury's finding that the Lactulose they sold from the leaking drums was contaminated. Specifically, petitioners argue that the jury was required to defer to their expert witness who testified that microrganisms would not have entered the leaking drums. That contention is without merit. On cross-examination, the government established that the witness' opinion was both incomplete and based on limited information. For example, the defense witness admitted that he did not test for mold, dirt, glue residue, or other possible contaminants. Gov't C.A Br. 9. The jury also heard ample evidence that the Lactulose from the leading drums was contaminated. In particular, petitioner Bhutani told an insurance adjuster that the Lactulose concentrate was not fit for human consumption. Gov't C.A. Br. 9. In those circumstances, the court of appeals correctly declined petitioners' "invitation to reweigh the evidence." Pet. App. 15.

5. Petitioners contend (Pet. 25-26) that the district court erred in determining that there was a loss attributable to their fraud under Guidelines § 2F1.1. That contention is without merit and does not warrant review. The district court correctly ruled that, because petitioners' customers did not receive the drugs for which they had bargained, the amount they paid for the drugs should be considered the amount of their loss. The court then adopted a very conservative estimate of that loss—$200,000. Gov't C.A. Br. 44.

The district court's approach is fully consistent with decisions of other courts of appeals construing the fraud Guideline. See *United States* v. *Marcus*, 82 F.3d 606 (4th Cir. 1996); *United States* v. *Gonzalez-Alvarez*, 277

F.3d 73, 78 (1st Cir. 2002). The courts recognize that economic gain, as measured by gross sales, is an appropriate measure of loss when, as here, there is actual, probable, or intended loss to consumers. In the context of adulterated prescription drug sales, economic gain to the manufacturer is the proper measure of loss when drugs do not meet FDA specifications and are thus of unknown value. *Marcus*, 82 F.3d at 608 (a change in formula "rendered the [drug] something other than what it purported to be because the altered formula had not been approved by the FDA and was of unknown safety and efficacy"); *id.* at 610 ("as such, consumers did not receive that for which they bargained—an FDA-approved drug of *known* safety and efficiency").

Petitioners err in asserting (Pet. 25) that the Seventh Circuit's ruling on that point conflicts with the Fourth Circuit's ruling in *United States* v. *Chatterji*, 46 F.3d 1336 (4th Cir. 1995). In *Chatterji*, the Fourth Circuit held that customer loss should not be used where the efficiency and safety of the drug is not implicated by the defendant's conduct. In *Marcus*, the Fourth Circuit subsequently clarified that *Chatterji* does not apply where, as here, the adulteration of the drug implicates the safety and efficiency of the product. The court of appeals here expressly followed the rationale of *Marcus*. Pet. App. 12-14. Thus, there is no conflict on that issue between the Seventh and Fourth Circuits. In any event, any conflict in interpretation of the Guidelines is appropriately resolved by the Sentencing Commission. *Braxton* v. *United States*, 500 U.S. 344, 347-348 (1991).

6. Finally, petitioners contend (Pet. 26-30) that they should have obtained a new trial because the government presented a different theory on appeal than the one it presented to the jury. In petitioners' view, the

government's theory at trial was that the Lactulose was medically ineffective or would soon become medically ineffective, and that petitioners' spiked the Lactulose to mask that fact, while the government's theory on appeal was that petitioners' spiked the Lactulose in order to mask its age. After "[a] second read of the trial transcript," however, the court of appeals determined that "the government's position at trial and on appeal has been consistent." Pet. App. 2. In particular, the court found that "[t]he government did not show at trial that the [old] Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation." *Id.* at 2-3. The court further determined that the government's theory at both stages was that, "in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected." *Id.* at 3. None of the excerpts from the trial cited by petitioners (Pet. 27-30) undermines the court of appeals' determination. In any event, that fact-bound issue does not warrant review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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