No. 08-1536

In the Supreme Court of the United States

MARIA CARMEN PALAZZO, PETITIONER

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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QUESTION PRESENTED

Whether 21 U.S.C. 355(i) authorizes the Secretary of Health and Human Services to promulgate record-keeping obligations for clinical investigators in trials of new drugs, the violation of which can be punished with criminal sanctions under 21 U.S.C. 331(e) and 333(a).

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-18) is reported at 558 F.3d 400. The opinion of the district court (Pet. App. 19-45) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on February 6, 2009. A petition for rehearing was denied on March 20, 2009 (Pet. App. 46-47). The petition for a writ of certiorari was filed on June 10, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

A grand jury in the Eastern District of Louisiana returned an indictment charging petitioner with 40 counts of health-care fraud, in violation of 18 U.S.C. 1347, and 15 counts of violating the record-keeping re-

quirements of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, in violation of 21 U.S.C. 331(e) and 333(a). The district court granted petitioner's motion to dismiss the record-keeping counts. The court of appeals reversed and remanded. Pet. App. 1-18.

1. Before any drug may be sold in the United States, the FDCA requires that the Food and Drug Administration (FDA) determine whether it is safe and effective for its intended use. 21 U.S.C. 355. Because the Act prohibits the distribution of an unapproved drug for human use, but also recognizes that pre-approval human studies are necessary to provide the clinical data on which FDA bases approval decisions, the Act allows for the testing of new drugs as part of FDA's drug-approval process. Specifically, 21 U.S.C. 355(i) directs the Secretary of Health and Human Services (Secretary) to issue regulations governing investigatory drug trials. Under Section 355(i), the Secretary must "promulgate regulations for exempting from" the blanket prohibition against the distribution of unapproved drugs, certain distributions of "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. 355(i)(1). The statute further provides that the regulations may impose "conditions relating to the protection of the public health" on such exemptions. *Ibid.* Based on that authority, the Secretary has adopted 21 C.F.R. 312.62, which, among other things, requires clinical investigators "to prepare and maintain adequate and accurate case histories" on each individual administered the drug or employed as a control in the investigation. 21 C.F.R. 312.62(b).

2. Petitioner was a psychiatrist who was hired by a drug manufacturer to carry out clinical studies in order to evaluate the efficacy and safety of Paxil, a prescription drug, for children and adolescents with obsessive-compulsive disorder. Superseding Indictment 1, 17-18. Petitioner was paid according to the number of children she enrolled in the study. Superseding Indictment 18. According to the indictment, petitioner violated the record-keeping requirements of 21 C.F.R. 312.62(b) by falsifying case histories and diagnoses of children who were not qualified to participate in the study because they did not in fact suffer from obsessive-compulsive disorder. *Id.* at 20-24. In so doing, she made the patients falsely appear to be eligible for the clinical trial. *Ibid.*

3. A grand jury in the Eastern District of Louisiana returned an indictment charging petitioner with 40 counts of health-care fraud, in violation of 18 U.S.C. 1347, and 15 counts of violating the record-keeping requirements of the FDCA, in violation of 21 U.S.C. 331(e) and 333(a). Pet. App. 4. Section 331(e) makes it a criminal offense to "fail[] to establish or maintain any record * * * required under section * * * 355(i)." 21 U.S.C. 331(e); see 21 U.S.C. 333(a).

Petitioner moved to dismiss the record-keeping counts, and the district court granted the motion. Pet. App. 19-45. According to the court, Section 355(i) "does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records." *Id.* at 35-36.

4. The court of appeals reversed and remanded. Pet. App. 1-18. Petitioner argued that Section 355(i) "only provides criminal sanctions for manufacturers and sponsors of clinical investigational studies," not for those

conducting the investigations. *Id.* at 12. The court of appeals rejected that argument, explaining that "Section 355(i) allows the Secretary to establish reporting requirements, and the Secretary promulgated regulations specific to investigators in 21 C.F.R. § 312.62(b)." *Id.* at 16. The court observed that those regulations "are properly considered to be 'required' reporting and record-keeping requirements under § 331(e)." *Ibid.* And, the court noted, Section 333(a) provides for criminal penalties for violations of requirements under Section 331(e). *Ibid.* In reaching that conclusion, the court emphasized that petitioner "conceded that § 355(i) provides the FDA with unambiguous authority to promulgate regulations requiring clinical investigators to adhere to specific record-keeping and reporting requirements." *Id.* at 17. Nothing in Section 331(e), the court continued, suggests "that it only serves to prohibit a failure to establish or maintain records and reports submitted directly to the Secretary." *Ibid.*[*]

ARGUMENT

Petitioner renews (Pet. 15-25) her claim that 21 U.S.C. 331(e) and 333(a) do not impose criminal liability on clinical investigators who violate FDA regulations adopted under 21 U.S.C. 355(i). The court of appeals correctly rejected that claim. Further review is not warranted.

1. As an initial matter, this Court's review is unwarranted at this time because the court of appeals reversed

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[*] While the appeal was pending, petitioner was tried by a jury on the remaining counts of the indictment, except for one count that was dismissed on the motion of the government. The jury found petitioner guilty on all counts, and she was sentenced to 87 months of imprisonment. Judgment 1-2.

the dismissal of a portion of the indictment and remanded to the district court for a trial, so the case is still in an interlocutory posture. This Court routinely denies petitions by parties challenging interlocutory determinations that may be reviewed at the conclusion of the proceedings. See, *e.g.*, *VMI* v. *United States*, 508 U.S. 946 (1993) (Scalia, J., respecting denial of certiorari); *Hamilton-Brown Shoe Co.* v. *Wolf Bros.*, 240 U.S. 251, 258 (1916). That practice ensures that all of a defendant's claims will be consolidated and presented in a single petition. Here, the interests of judicial economy would be best served by denying review now and allowing petitioner to reassert her claims at the conclusion of the proceedings, if she still wishes to do so at that time.

2. The court of appeals correctly held that the conduct alleged in the indictment constitutes a criminal violation of the FDCA. Section 333(a) prescribes criminal penalties for "[a]ny person who violates a provision of section 331," and Section 331(e) prohibits "the failure to establish or maintain any record" required under Section 355(i). Petitioner has conceded that Section 355(i) "provides the FDA with unambiguous authority to promulgate regulations requiring clinical investigators to adhere to specific record-keeping and reporting requirements." Pet. App. 17. But she argues (Pet. 22-24) that violations of those requirements may be criminally punished only when they are committed by drug manufacturers or sponsors of investigations, and not by clinical investigators. That is incorrect.

Petitioner's argument is inconsistent with the plain language of Section 355(i)(1), which provides that the Secretary, in promulgating regulations exempting investigational drugs from the new-drug-approval requirements, may impose "other conditions relating to the pro-

tection of the public health." The Secretary has reasonably determined that the protection of the public health requires that clinical investigators keep adequate records relating to drug trials. See 21 C.F.R. 312.62; see also H.R. Rep. No. 2464, 87th Cong., 2d Sess. 9-10 (1962) (noting that, under Section 355(i), "the regulations may require, among other things * * * the establishment and maintenance of adequate records"). A violation of those record-keeping requirements—including one committed by a clinical investigator—is a "failure to establish or maintain any record * * * required under section * * * 355(i)," and it is therefore a criminal offense. 21 U.S.C. 331(e).

Petitioner relies (Pet. 23) on language in Section 355(i)(4) providing that "[n]othing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." That provision is not relevant here, because 21 C.F.R. 312.62 does not require that investigators submit reports directly to the Secretary, but only that they prepare and maintain accurate records. Likewise, the indictment in this case does not allege that petitioner failed to submit reports to the Secretary. Instead, it alleges that she "failed to prepare and maintain records * * * on each individual administered the investigational drug or employed as a control in the investigation." Superseding Indictment 20.

3. The decision below is consistent with the result reached by the Eighth Circuit in *United States* v. *Garfinkel*, 29 F.3d 451 (1994), see Pet. App. 7-9 (describing *Garfinkel*), and any difference in rationale, see Pet. 18-19, would not warrant this Court's review. Petitioner asserts (Pet. 15-20) that this Court's review is necessary in order to resolve a conflict with the Ninth Circuit's

decision in *United States* v. *Smith*, 740 F.2d 734 (1984), but that claim is incorrect. In *Smith*, the court of appeals held that the FDCA does not "attach criminal liability to * * * clinical investigators" who fail to comply with regulations promulgated under Section 355(i). *Id.* at 737. The asserted conflict with *Smith* does not warrant review, however, because the issue does not appear to have arisen with any frequency in the 25 years since *Smith* was decided, and subsequent developments in the law suggest that the Ninth Circuit may reconsider its position if it is confronted with the issue again.

The court in *Smith* believed that the "general authorizing language" of Section 355(i) was "insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability," 740 F.2d at 738, but that reasoning has been undermined by this Court's more recent decision in *Touby* v. *United States*, 500 U.S. 160 (1991). In *Touby*, this Court upheld a criminal conviction for manufacturing a drug that the Attorney General, not Congress, had listed as a controlled substance. The governing statute authorized the Attorney General to list substances when doing so was "necessary to avoid an imminent hazard to the public safety." 21 U.S.C. 811(h)(1). The manufacturers of the drug argued that "Congress must * * * provide more specific guidance" when authorizing the issuance of regulations whose violation will be subject to criminal sanctions. *Touby*, 500 U.S. at 166. This Court rejected that argument, holding that the statutory language was adequate because it "meaningfully constrain[ed] the Attorney General's discretion to define criminal conduct." *Ibid.* Section 355(i)'s requirement that the Secretary's regulations pertain to "conditions relating to the protection of the public health" is similar to the "necessary to

avoid an imminent hazard to the public safety" standard upheld in *Touby*, so *Touby* essentially renders invalid the reasoning in *Smith*.

As an alternative basis for its decision, *Smith* emphasized that "the regulatory language [fell] short of imposing an explicit affirmative duty on the investigators to maintain accurate records." 740 F.2d at 738. The regulatory context has since changed. At the time, the Secretary's regulations required only that the sponsor of the investigation "obtain from each investigator * * * a signed statement" committing the investigator to keep accurate records. *Id.* at 738 n.4 (quoting 21 C.F.R. 312.1(a)(12) and (13) (1985)). After *Smith*, the FDA amended its regulations and added a series of new provisions devoted entirely to the responsibilities of clinical investigators and containing explicit record-keeping requirements. 21 C.F.R. 312.60-312.70 (1987). Those requirements alleviate the *Smith* court's concerns about the adequacy of notice. 740 F.2d at 738. Accordingly, *Smith*'s reasoning is inapplicable to the current regulatory regime.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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