AUG 24 2009

No. 08-1536

In The
Supreme Court of the United States

MARIA CARMEN PALAZZO, M.D., Ph.D., MMM,

Petitioner,

v.

THE UNITED STATES OF AMERICA,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

REPLY BRIEF FOR PETITIONER MARIA CARMEN PALAZZO

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG,
EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo

COCKLE LAW BRIEF PRINTING CO. (800) 225-6964
OR CALL COLLECT (402) 342-2831

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In 1962, when Congress enacted the statute at issue, 21 U.S.C. § 355, it placed very clear limits on the regulatory authority of the FDA. Moreover, Congress decided that *it*, not the FDA, would retain the power to determine precisely which conduct under the statute would be criminal – by limiting the delegation of power to the FDA to the creation of *exemptions* from the blanket prohibition against the distribution of unapproved drugs. In 1962 it was clear – at least to Congress – that the FDA had no power whatsoever to create criminally-enforceable regulations regarding physician clinical investigators.

This Congressional limitation has been under siege by the FDA for 25 of the last 47 years. During that time, the FDA has flatly ignored one circuit court of appeals, it has persuaded another to apply the *Chevron* deference doctrine in a criminal case, and most recently, in this proceeding, it convinced a court of appeals that there is no difference between a civil regulation and one enforceable by criminal sanctions.

Respondent suggests that the usurpation of Congressional power by the FDA should not be disturbed by this Court, because: (1) this case is "still in an interlocutory posture," and thus "the interests of judicial economy would be best served by denying review now and allowing petitioner to reassert her claims at the conclusions of the proceedings, if she still wishes to do so at that time[;]" and (2) the court of appeals "correctly held that the conduct alleged in

the indictment constitutes a criminal violation of the FDCA." Resp't Opp'n 5.

With regard to the first contention, Respondent is simply in error – as to both the procedural posture of the case and the interests of judicial economy. With regard to the second, Respondent, like the Fifth Circuit, finds it necessary to omit the words "exempting" and "exemption" from its reading of the statute in order to fashion a coherent delegation argument. Worse, the remainder of Respondent's argument rests on the dubious proposition that the phrase "conditions relating to the protection of the public health" provides constitutionally adequate guidance for the creation of criminally-enforceable regulations. Resp't Opp'n 7.

In short, Respondent fails to rebut the compelling reasons for granting review in this proceeding: (1) the divided opinions of the courts of appeals on this issue; (2) the Fifth and Eight Circuits' misapplication of *Touby v. United States*, 500 U.S. 160 (1990); and (3) the national significance of permitting the FDA to exercise direct criminal regulatory power over physicians conducting clinical trials. The Petition for the Writ of Certiorari should be granted.

1. This Case Is Not In An Interlocutory Posture.

When the district court dismissed the 15 counts alleging violations of the FDCA, the Government elected to do two things: (1) it filed a notice of appeal

on the dismissed counts; and (2) it proceeded to trial on the remaining counts of the superseding indictment. In effect, the Government created two separate prosecutions. On the latter, Petitioner stood trial, was convicted, and sentenced. Her appeal from that conviction is now before the Fifth Circuit as proceeding No. 09-30039. Accordingly, Respondent can only be suggesting that this matter is "interlocutory" because Petitioner has not yet stood trial on these specific charges.

Recognizing that in many instances it is fundamentally unfair to compel a petitioner to stand trial on criminal charges of highly questionable legality, this Court has not hesitated to grant certiorari in procedurally analogous, if not identical situations. *See, e.g., United States v. Helstoski*, 442 U.S. 477 (1979); *Serfass v. United States*, 420 U.S. 377 (1975). There is every reason to do so in this case.

Respondent would have Petitioner stand trial (again); and if convicted,[1] take an appeal to the Fifth Circuit – an appeal whose outcome is a foregone conclusion. Then, following that second adverse decision from the Fifth Circuit, Respondent would require Petitioner to file a second petition for a writ of

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[1] Ironically, if Petitioner were to be acquitted at her trial, Respondent would still "win." Respondent's view that the statute permits it to enact criminally-enforceable regulations governing physicians would remain the law of the Fifth Circuit, and that court's ruling would be unchallengeable by the only party with standing to do so – Petitioner.

certiorari – all to present the very issues that are now squarely before the Court. If this is judicial economy, as Respondent suggests, more of it will bring the federal courts to a halt.

2. The Opinion Of The Court Of Appeals Is Manifestly Erroneous And Conflicts With The Decisions Of This Court.

Petitioner does not dispute, and in fact conceded at oral argument in the Fifth Circuit that the FDA has the authority to create regulations – including the authority to create the specific regulation at issue: 21 C.F.R. § 312.62. However, both Respondent and the Fifth Circuit persist in ignoring the vast difference between a civil regulation that compels physician record keeping on pain of the loss of an exemption from the FDA's blanket prohibition against the distribution of unapproved drugs, and a criminal regulation that can put a violator in federal prison for five years.

The intent of Congress could not have been plainer: not once, but twice, 21 U.S.C. § 355 specifically tied the promulgation of regulations by the Secretary to *exemptions*. Respondent ignores this unambiguous language.

Worse, although both Respondent and the Fifth Circuit concede that on its face 21 U.S.C. § 355 does not apply to clinical investigators, they treat this deliberate omission by Congress as a mere inconvenience. Instead of being guided by the [Congressional]

statute, both chose to ground the authority for the criminal prosecutions in a subsequent [administrative] regulation.

This lack of Congressional authority is precisely why the Ninth Circuit, in *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984) flatly rejected the FDA's attempt to criminalize inaccurate record keeping by a clinical investigator. As in this case, the FDA claimed the right to criminally prosecute under the statute's general regulatory authority, "which allows the Secretary to establish 'other conditions relating to the protection of public health.'" *Id.* at 737.

Significantly, the Ninth Circuit rejected this argument on two grounds: first, "[s]uch general authorizing language is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability[;]" and second, " . . . even if Congress had provided standards for extending the recordkeeping requirement to investigators by regulation, the regulatory language falls short of imposing an explicit affirmative duty on the investigators to maintain accurate records." *Id.*

As noted by Respondent, after *Smith*, the FDA amended its regulations. Resp't Opp'n 8. What Respondent fails to mention is that when it did so, the FDA deliberately ignored the first half of the holding in *Smith*:

> FDA recognizes that some may view the decision by the Ninth Circuit in the [sic] *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984),

> which involved criminal charges against a clinical investigator, as raising questions about the agency's authority to promulgate enforceable regulations on the obligations of clinical investigators. **After considering the court's opinion, FDA concludes that it has ample authority to issue such regulations.**

New Drug, Antibiotic, and Biologic Drug Product Regulations, 52 Fed. Reg. 8798, 8827 (Mar. 19, 1987) (to be codified as 21 C.F.R. pts. 312, 314, 511, and 514) (emphasis added).

Thus, while the FDA may have "cured" the second problem noted by the Ninth Circuit – the absence of a regulation that imposed specific record-keeping requirements upon clinical investigators – by promulgating 21 C.F.R. § 312.62, the FDA never addressed the Ninth's Circuit's constitutional objection. Plainly, it felt no need to do so. Petitioner is hopeful, however, that this Court views such blatant disregard for the opinion of a court of appeals somewhat differently.

Notably, Respondent makes no effort to defend the Eighth Circuit's opinion in *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994), but simply notes that "[t]he decision below [in the Fifth Circuit] is consistent with the result reached by the Eighth Circuit . . . and any difference in rationale . . . would not warrant this Court's review." Resp't Opp'n 6. To the contrary, there is much more at stake than a difference in rationale. What is before the Court are

two deeply flawed opinions that rely on plainly erroneous readings of the law.

As noted in Petitioner's original brief, the Eighth Circuit mistakenly relied upon the *Chevron* deference rule to reach its result in *Garfinkel*. The FDA made the very same deference arguments to the Fifth Circuit in this case. In fact, it was represented by the same attorney who represented it in *Garfinkel*. While the Fifth Circuit did not rely on the *Chevron* doctrine in this case, it made it clear that it would do so, if the "parties disputed whether § 355(i) *authorized* the FDA regulations at issue in this case. . . ." *United States v. Palazzo,* 558 F.3d 400, 405 (5th Cir. 2009). Oddly enough, that is precisely what Petitioner believed she was doing by arguing that the FDA did not have the authority to issue criminally-enforceable regulations governing clinical investigators. Nevertheless, it is apparent that review by this Court is necessary to prevent the courts of appeals from applying the *Chevron* deference rule in criminal cases.

Given these significant concerns, it is not true that the precise "issue [presented by this case] does not appear to have arisen with any frequency in the 25 years since *Smith* was decided. . . ." Resp't Opp'n 7. In one sense, it has arisen every day since the FDA decided in 1987 that it actually possessed the authority that *Smith* denied it. And from *Palazzo* forward, the issue will become a daily factor in the life of all clinical investigators, who now face federal

criminal prosecution for failing to keep "accurate records" – whatever that means.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

New Orleans, Louisiana, this 24th day of August, 2009.

Respectfully submitted,

HERBERT V. LARSON, JR.
Counsel of Record
WILLIAM P. GIBBENS
SCHONEKAS, WINSBERG,
EVANS & MCGOEY, L.L.C.
650 Poydras Street, Suite 2105
New Orleans, Louisiana 70130
(504) 680-6050

Attorneys for Petitioner
Maria Carmen Palazzo