No. 08-1536 JUN 10 2009

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

To regulate clinical testing in the pharmaceutical industry, Congress enacted 21 U.S.C. § 355(i), which requires a drug manufacturer and the clinical trial sponsor to keep records and file reports directly with the Secretary of Health and Human Services. This statute does not impose any record-keeping requirements on clinical investigators, and it specifically exempts clinical investigators from any direct reporting requirements. *See* 21 U.S.C. § 355(i)(4). To ensure compliance with its regulatory scheme, *Congress criminalized the failure to "establish or* maintain any record, or make any report, required under . . . 355(i)." *See id.* § 331(e). Notwithstanding the express language of the statute excluding clinical investigators, the United States Court of Appeals for the Fifth Circuit reinstated a criminal prosecution against Dr. Maria Carmen Palazzo, a clinical *investigator, who had been indicted for "fail[ure] to* prepare and maintain records required under 21 U.S.C. § 355(i) and 21 C.F.R. § 312.62(b)."

The question presented is whether the Fifth Circuit erroneously held, in conflict with the decisions of the Eighth and Ninth Circuit Courts of Appeals, that in 21 U.S.C. § 355(i), Congress delegated to the Secretary of Health and Human Services the authority to create criminally enforceable regulations governing physician clinical investigators.

PARTIES TO THE PROCEEDINGS

1. Maria Carmen Palazzo
2. The United States of America

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Maria Carmen Palazzo respectfully requests that the Court issue a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit issued in this case on February 6, 2009.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-18) is reported at 558 F.3d 400 (5th Cir. 2008). The opinion of the court of appeals denying Palazzo's petition for rehearing en banc (Pet. App. 46-47) is unreported. The district court's opinion dismissing the 15 criminal counts based on alleged violations of 21 U.S.C. §§ 355(i) and 331(e) (Pet. App. 19-45) is published at 2007 WL 3124697 (E.D.La. Oct. 24, 2007).

STATEMENT OF JURISDICTION

On October 10, 2007, in response to a motion by Palazzo to dismiss counts 41-55 of the superseding indictment that had been filed against her, the district court entered an order dismissing those counts. The Government timely appealed to the United States Court of Appeals for the Fifth Circuit. On February 6, 2009, that court reversed the district court. Palazzo timely filed a petition for rehearing en banc, which was denied on March 20, 2009. This Court has jurisdiction over this petition pursuant to 28 U.S.C.

§ 1254(1), and this petition is timely under Supreme Court Rules 13.1 and 13.3.

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

I. Constitutional Provisions

The Vesting Clause of the United States Constitution, U.S. Const. art. I, § 1, provides, in pertinent part:

> All legislative Powers herein granted shall be vested in a Congress of the United States. . . .

The Fifth Amendment to the United States Constitution, U.S. Const. amend. V, provides, in pertinent part:

> No person shall . . . be deprived of life, liberty, or property without due process of law. . . .

II. Statutory Provisions

21 U.S.C. § 355(i), Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary, provides:

> **(1)** The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and

experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon –

(A) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(B) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings;

(C) the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of

such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b) of this section; and

(D) the submission to the Secretary by the manufacturer or the sponsor of the investigation of a new drug of a statement of intent regarding whether the manufacturer or sponsor has plans for assessing pediatric safety and efficacy.

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including –

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

(3)

(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that –

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before November 21, 1997).

> **(C)** Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.
>
> **(4)** Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

21 U.S.C. § 331(e), provides as follows:

> The following acts and the causing thereof are prohibited:

> **(e)** The refusal to permit access to or copying of any record as required by section 350a, 350c, 350e, 354, 360bbb-3, 373, 374(a), 379aa, or 379aa-1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l) or (m), 360ccc-1(i), 360e(f), 360i, 360bbb-3, 379aa, or 379aa-1 of this title, or the refusal to permit access to or verification or copying of any such required record.

STATEMENT OF THE CASE

Every year in the United States, thousands of physicians, acting as clinical investigators, conduct more than 80,000 clinical trials for drug manufacturers and other entities willing to sponsor such drug trials. To regulate this critical facet of the pharmaceutical industry, Congress created the scheme set forth in 21 U.S.C. § 355(i).

Put most simply, this statute requires manufacturers and sponsors to keep certain data and records, and to make reports directly to the Secretary of the Department of Health and Human Services (DHHS). The failure to do so may result in a manufacturer or a sponsor losing the exemption [from all other portions of the statute] necessary to conduct such trials, or it may result in a criminal prosecution under 21 U.S.C. § 331(e). In enacting section 355(i), Congress specifically provided, subsection 355(i)(4),

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."

And while section 355(i) does give the Secretary of the DHHS the authority to promulgate certain regulations, that authority is limited to promulgating regulations that *exempt* persons from the operation of "the foregoing subsections." Nowhere in the statute is the Secretary given either the authority to promulgate criminal regulations imposing affirmative duties, or the Congressional guidance that would be necessary for creating such criminal regulations, guidance that this Court found to be constitutionally necessary in its decision in *Touby v. United States*, 500 U.S. 160 (1991).

Nevertheless, in *Palazzo,* the Fifth Circuit found that a purely civil regulation, 21 C.F.R. § 312.62(b), which requires a clinical investigator to "prepare and maintain adequate and accurate case histories" – on pain of suspension from participation in clinical trials, but nothing more – could be made criminal first by incorporating it into section 355(i), and then by incorporating it into section 331(e).

The Fifth Circuit's opinion is in flat contradiction to that of the Ninth Circuit in *United States v. Smith*, 740 F.2d 734, 739 (9th Cir. 1984), which expressly held that "Congress did not provide sufficient guidance for the promulgation of regulations which would subject investigators to criminal liability for

noncompliance. Moreover, even if Congress had provided guidelines for such regulations, the regulatory language falls short of justifying the imposition of criminal sanctions for noncompliance."

The opinion of the Fifth Circuit in *Palazzo* also is in contradiction to that of the Eighth Circuit in *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994). Although the *Garfinkel* court did find that section 355(i) authorized the Secretary of the DHHS to promulgate criminally enforceable regulations, it could make that finding only by giving *Chevron* deference to the Secretary's interpretation of section 355(i). *Id.* at 456 (*citing Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.,* 467 U.S. 837, 843 (1984) (setting forth the legal test for determining whether to grant deference to a government agency's interpretation of its own statutory mandate)). Regretfully, the Eighth Circuit completely overlooked the fact that there is no *Chevron* deference in criminal cases.

In short, with its decision in *Palazzo*, the Fifth Circuit has created a new crime that will affect thousands of physicians, and that could upset the entire Congressional regulatory scheme for clinical trials. Worse, as will be shown below, the Fifth Circuit has done so in a way that flies in the face of straightforward statutory language and unambiguous case law from this Court.

I. The Proceedings In The District Court

On August 25, 2005, four days before Hurricane Katrina, a grand jury sitting in the Eastern District of Louisiana returned a 17-count indictment against Dr. Maria Carmen Palazzo, charging her with two counts of health care fraud (18 U.S.C. § 1347), and 15 counts of violating the record-keeping requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. §§ 331(e), 333(a)(2)). Following delays caused by Hurricane Katrina, and motions relating to the first indictment, a superseding indictment was returned in June 2007, charging Dr. Palazzo with 40 counts of health care fraud, and the same 15 counts of violating the record-keeping requirements of the FDCA.

In both the original and superseding indictments, the Government alleged that in October 2000, SmithKline Beecham, d/b/a GlaxoSmithKline (SKB), "a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as 'Paxil,' * * * hired MARIA CARMEN PALAZZO, a licensed psychiatrist practicing medicine in New Orleans, to participate as a Clinical Investigator in a study involving Paxil. . . ." The purpose of the study was "to evaluate the efficacy and safety of Paxil in children and adolescents with Obsessive-Compulsive Disorder (OCD)."

It was alleged that Dr. Palazzo, "with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. § 355(i), and 21

C.F.R. § 312.62(b), to-wit, adequate and accurate case histories on each individual administered the investigational drug or employed as a control in the . . . *investigation.*" *The common inaccuracy alleged for* each case history was that the subject was not qualified to participate in the study because the subject was not suffering from OCD.

Between the original indictment and the superseding indictment, Dr. Palazzo moved to dismiss the 15 counts charging violations of the record-keeping requirements of the FDCA, sections 331(e) and 333(a)(2), on the grounds that the statute in question did not authorize the imposition of criminal liability upon a *clinical investigator* for failing to maintain accurate records.

More specifically, Dr. Palazzo argued:

1. In these counts, she was charged with violating 21 U.S.C. §§ 331(e) and 333(a)(2);

2. 21 U.S.C. § 331 states that "[t]he following acts and the causing thereof are prohibited: (e) . . . the failure to establish or maintain any record, or make any report, required under section . . . 355(i)."

3. Section 355(i) imposes record-keeping and reporting requirements on the *manufacturer*, or the *sponsor* of the investigation of such drug, but *not* on the clinical investigators.

4. Consequently, since Dr. Palazzo did not fall within the plain language of the statute, she was not subject to criminal liability.

Following oral argument on the motion, the district court dismissed these 15 counts. In its opinion, the district court looked first to the plain language of the statutes in question, then to the constitutional issues, and then finally to the relevant case law, and concluded as follows:

> The court agrees with the reasoning of the Ninth Circuit in *Smith* that § 355(i) does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records. Congress did not grant broad authority, but specifically singled out manufacturers and sponsors, not clinical investigators. Unlike the decision in *Garfinkel*, the court concludes that nothing in the language of § 355(i) provides sufficient guidelines regarding clinical investigators to serve as an intelligible principle to which the HHS or the FDA is directed to conform. The statute falls short of the multiple restrictions or mandatory requirements of *Touby* with regard to any party other than the manufacturer or the sponsor of the investigation. Although the amended, post-*Smith* regulations impose responsibility on clinical investigators to maintain adequate and accurate records, the focus of the constitutional inquiry is not directed to the amended regulations, but to the language of § 355(i) and whether the

> statute is specific as to the restraints on imposing criminal conduct. Accordingly, the court concludes that Congress did not specifically authorize regulations giving rise to criminal liability under § 355(i), and the motion to dismiss counts 41-55 of the superseding indictment is granted.

Pet. App. 35-36. Thereafter, the Government appealed to the Fifth Circuit.

II. The Opinion Of The Court Of Appeals

On appeal, the Government made two arguments: (1) that section 355(i) authorizes criminally enforceable regulations requiring clinical investigators to maintain adequate and accurate records; and (2) that the statute contains sufficient guidelines and is fully consistent with the non-delegation doctrine.

Conversely, Palazzo contended that section 355(i) did *not* authorize the creation of criminally enforceable regulations for clinical investigators, because under its plain language, the statute only permits the Secretary to create *exemptions* from the overarching regulatory scheme approved by Congress. The FDA is permitted to condition the granting of those exemptions upon compliance with regulations promulgated by the Secretary, but those conditions only may be imposed upon those entities with a direct reporting relationship to the FDA – the manufacturers of the new drug or sponsors of the investigation of the new drug. Palazzo argued that these are the only entities that

are required to establish and maintain records for the Secretary, and the only entities required to report to the Secretary.

In response to the arguments of the parties, the Fifth Circuit noted that "[t]he Ninth Circuit, Eighth Circuit, and district court each used different legal frameworks to analyze the question of whether § 355(i) allows the FDA to criminalize conduct of clinical investigators who fail to adhere to the FDA's regulations regarding record-keeping and reporting requirements." Pet. App. 6. After reviewing the decisions of all three, the Fifth Circuit proceeded to use a fourth framework, one shaped by the court's conclusion that "the issue on appeal requires this court to engage *only* in statutory interpretation." Pet. App. 11.

Having concluded implicitly that all of its predecessors were in error, the Fifth Circuit first found that Dr. Palazzo was required to keep records, by virtue of 21 C.F.R. § 312.62(b), then found that section 355(i) allows the Secretary to establish reporting requirements, and that the provisions of 21 C.F.R. § 312.62(b) properly are considered to be "'required' record-keeping and reporting requirements." Because the record-keeping and reporting was "required," criminal liability would attach by virtue of 21 U.S.C. § 331(e). In the words of the Fifth Circuit:

> Thus, reviewing § 312.62(b) in conjunction with §§ 355(i), 331(e), and 333(a)(1) makes it apparent that the scope of the statute allows

> clinical investigators to be subjected to criminal liability.

Pet. App. 17. The Court of Appeals then reversed the district court, and remanded the matter for further proceedings.

REASONS FOR GRANTING THE PETITION

I. The Courts Of Appeals Are Divided As To Whether Clinical Investigators Can Be Prosecuted Under 21 U.S.C. § 331(e) For Violations Of 21 U.S.C. § 355(i).

The question raised in this petition first arose 25 years ago in *United States v. Smith,* 740 F.2d 734 (9th Cir. 1984). In *Smith*, defendants were charged "with failure to maintain accurate drug testing records in violation of 21 U.S.C. §§ 331(e), 333(b) and 355(i). Specifically, the indictment alleged that the defendants had failed to maintain accurate records by placing falsified and fraudulent data, including false consent forms, in patient files." *Id.* at 735-36.

As in Palazzo's case, the defendant, a physician clinical investigator, moved to dismiss these counts in the indictment. And as in this case, the Government appealed the district court's ruling dismissing the counts. Unlike the Fifth Circuit, however, the Ninth Circuit affirmed the district court, reasoning as follows:

Although the statute expressly authorizes regulations which impose affirmative duties on manufacturers and the sponsors of clinical investigations, we are reluctant to read the statute as authorizing criminal penalties for the violation of any regulation promulgated pursuant to the statute's *general* authorizing language. In creating the obligation to maintain drug testing records, Congress expressly imposed the burden on manufacturers and sponsors. § 355(i)(3). The government asks that we extend the statutory obligation to include clinical investigators pursuant to the statute's general regulatory authority which allows the Secretary to establish "other conditions relating to the protection of public health" before exempting manufacturers from the statute's basic drug approval application requirements. § 355(i). Such general authorizing language, however, is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability. Executive agencies have the authority to establish regulations which are enforced by criminal penalties only when Congress has provided "sufficient guidelines and standards for the exercise of the authority."

Moreover, 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.

The regulations do not make it clear that the investigator violates the statute by failing to submit accurate test data to the sponsor. Absent such a clear articulation of duty, we are not prepared to fasten criminal liability to the investigator who fails to fulfill his or her obligation to the sponsor.

Generally, when a criminal statute is ambiguous, courts are reluctant to find criminal liability for those activities which are only questionably within its ambit. This principle of lenity is rooted in two major concerns. First, it ensures that there is fair warning "of what the law intends to do if a certain line is passed." Second, because of the serious nature of criminal sanctions "and because criminal punishment usually represents the moral condemnation of the community, legislatures and not courts should define criminal activity." Adhering to the principle embodying these concerns, we are unwilling to find criminal liability here.

* * *

The statute and regulations at issue here do not impose a clear duty on investigators to maintain accurate records. They only impose affirmative duties on drug manufacturers and the sponsors of clinical investigations. If the FDA discovers that an investigator has falsified information in forms submitted to the sponsor, the FDA, pursuant to the regulations, may conduct an administrative hearing and revoke the investigator's entitlement to work with

> investigational drugs. 21 C.F.R. § 312.1(c). Under these circumstances, we cannot fairly read the pertinent statute and regulations to attach criminal liability to these defendants.

Smith, 740 F.2d at 737-39 (internal citations and footnote omitted).

Ten years later, the issue returned in *United States v. Garfinkel,* 29 F.3d 451 (8th Cir. 1994), in which the Government was again appealing the dismissal of criminal charges brought against a physician clinical investigator under 21 U.S.C. §§ 331(e) and 355(i).

In *Garfinkel,* the Eighth Circuit found that the question of criminal liability comprised two separate issues: (1) whether section 355(i) *authorized* the FDA regulations at issue; and (2) whether section 355(i) provided *sufficient guidance* for the issuance of clinical investigator regulations that provide for criminal penalties. *Id.* at 454-55. As the Court noted, "[t]he first argument raises a question of statutory construction, while the second argument raises a question of constitutional dimension, namely, the effect of the nondelegation doctrine." *Id.* at 455.

The Eighth Circuit found that section 355(i) authorized the FDA regulations at issue. Significantly, and unfortunately, in so finding, the Eighth Circuit failed to draw a distinction between the authority to issue civil regulations, and the authority to issue criminally enforceable regulations. Had it done so, it never would have conducted a *Chevron*

deference analysis expressly and explicitly relying on deference to the FDA's interpretation of the statute in question. *Id.* at 456. *Chevron* deference is not given to criminal statutes because of the very basic principle, grounded in due process, that there is no deference to the Government's interpretation of a statute in criminal cases – the rule of lenity applies, not the *Chevron* rule of substantial deference to an agency's interpretation of a statute. *See Gonzales v. Oregon*, 546 U.S. 243, 264 (2006). *See also* William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from* Chevron *to* Hamdan, 96 Geo. L.J. 1083, 1115-16 (2008) (describing the policy in criminal cases as "anti-deference," and noting that one "interconnected thread" for the anti-deference policy is the rule of lenity).

Thus, the Eighth Circuit's labored conclusion "that the standards enunciated by the Act, along with judicial review and the procedural requirements dictated by the APA, impose sufficient restraints upon FDA to satisfy the constitutional concerns underlying the nondelegation doctrine" is not only in contradiction to the Ninth and Fifth Circuits, it is just plain wrong. *Garfinkel*, 29 F.3d at 459.

In stark contrast to the approach of the Eighth Circuit, with its lengthy delegation doctrine analysis, is the one used by the Fifth Circuit, which concluded that it did not need to address the doctrine at all, because Palazzo "conceded" that the regulation at issue was a valid one. The Fifth Circuit has not only

misstated the nature of Palazzo's "concession," its entire approach turns the delegation doctrine upside down.

Palazzo contended from the outset that the Secretary had no authority to create *criminally* enforceable regulations. Her only "concession" – one made at oral argument – was that 21 C.F.R. § 312.62, which requires clinical investigators to "prepare and maintain adequate and accurate cases histories," was a valid *civil* regulation. But what is most disconcerting, and most worthy of this Court's attention, is the Fifth Circuit's creation of a criminal regulatory scheme, the validity of which depends upon concessions from those affected by it. This would be risible, were the consequences not so severe.

II. The Fifth And Eighth Circuits Have Ignored The Basic Structure Of The Congressional Regulatory Scheme For Clinical Trials Of Drugs, And Have Misapplied This Court's Opinion In *Touby*.

A. In Enacting 21 U.S.C. § 355(i) Congress Did Not Delegate To The Secretary The Authority To Impose Criminal Sanctions On Anyone – Drug Manufacturers, Sponsors, Or Clinical Investigators

Even a casual reading of 21 U.S.C. § 355(i) compels the conclusion that the only power Congress delegated to the Secretary in that statute is the power to create exemptions from existing laws

enacted by Congress – not the affirmative power to create crimes:

> **(1)** *The Secretary shall promulgate regulations for exempting* from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, *provide for conditioning such exemption upon* –

21 U.S.C. § 355(i)(1) (emphasis added). At the risk of sounding simplistic, it is self-evident that regulations creating exemptions from "the operation of the foregoing subsections" are necessarily very different – both conceptually and legally – from regulations imposing criminal liability. The former allow one to escape the application of a law, the latter compel compliance with it.

Nevertheless, both the Fifth and Eighth Circuits have found that, notwithstanding the plain language of the statute, the Secretary of DHHS has the Congressional authority to create criminally enforceable regulations, and that such regulations can be extended to clinical investigators.

B. Any "Intelligible Principle" That Can Be Found In 21 U.S.C. § 355(i) Would Preclude The Prosecution Of Clinical Investigators

Unquestionably, Congress may delegate the task of "filling in the details" of a criminal statute, and that such a delegation may be quite broad. In the words of this Court in *Touby v. United States*:

> We have long recognized that the nondelegation doctrine does not prevent Congress from seeking assistance, within proper limits, from its coordinate Branches. Thus, Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. So long as Congress "lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power."

500 U.S. 160, 165 (1991) (internal citations omitted).

The Court has summarized the "intelligible principle" test in these terms: a delegation of legislative power will be "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta v. United States,* 488 U.S. 361, 372-73 (1989).

But even if it can be assumed that Congress intended to delegate to the Secretary the power to

create criminally enforceable regulations, the statute on its face would limit the application of those regulations to drug manufacturers and the sponsors of clinical trials.

First, section 355(i) requires no record or report from any clinical investigator. As the Fifth Circuit acknowledged, "[o]n its face, § 355(i) does not provide criminal liability for sponsors and manufacturers of investigational drug studies or clinical investigators. [ ] In addition, § 355(i) does not contain an explicit requirement governing the conduct of clinical investigators." Pet. App. 15. In fact, they are explicitly *excluded* from its reporting requirements: "Nothing in this subsection shall be construed to *require* any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs." 21 U.S.C. § 355(i)(4).

Second, the statute requires no record keeping by clinical investigators. The only section of the statute to address record keeping, section 355(i)(1)(C), requires "the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such drug."

Any fair reading of this statute, and any reasonable interpretation of this regulatory scheme can lead to only one conclusion: Congress gave the Secretary of the DHHS the power to regulate the conduct of drug manufacturers and sponsors of investigations by giving the Secretary the power to

grant *exemptions* from what would otherwise be criminal conduct; and it gave the Secretary the power to condition those exemptions by making the manufacturers and sponsors meet certain record-keeping and reporting requirements. And for good measure, *Congress*, not the Secretary, criminalized the failure to satisfy those requirements.

Congress expressly rejected the creation of a direct reporting relationship between clinical investigators and the Secretary, and with it, the imposition of criminal consequences on clinical investigators. The legislative history of the statute completely supports that contention:

> Moreover, we note that the Senate Report accompanying the adoption of § 355 indicates that Congress was primarily concerned with the lack of adequate information from drug *manufacturers* regarding the use of experimental drugs. The proposed legislation was designed to "permit the Secretary to issue regulations requiring that *manufacturers* keep records and make reports of such investigations and clinical experience" S. Rep. No. 1744, *reprinted in* 1962 U.S. Code Cong. & Ad. News 2884, 2891 (emphasis added). The legislative history does not indicate that Congress was attempting to impose affirmative responsibilities on investigators working at the manufacturer's direction.

Smith, 740 F.2d at 739.

III. This Case Presents An Issue Of National Importance Because Of Its Potential Impact On Thousands Of Physicians.

It goes without saying that the process of determining the safety and efficacy of drugs must be regulated. Unquestionably, DHHS is the appropriate agency to handle such regulation. But with regard to clinical trials, Congress has limited such regulation by the DHHS to the imposition of reporting and record-keeping requirements upon drug manufacturers and sponsors only. It is the courts, acting at the behest of the DHHS, that have expanded those requirements.

The Congressional limitation is not illogical – Congress well may have believed that attempting to regulate physicians conducting such clinical trials was tantamount to the regulation of the practice of medicine, a matter that has traditionally been left to the States. But if the DHHS now is going to enter that field and regulate physicians conducting clinical trials by means of criminal sanctions, the authority to do so should be unmistakable – not the inconsistent and confused product of 25 years of litigation in three different circuits.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

New Orleans, Louisiana, this 10th day of June, 2009.

Respectfully submitted,

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