

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED

February 6, 2009

No. 07-31119

Charles R. Fulbruge III
Clerk

UNITED STATES OF AMERICA

Plaintiff-Appellant

v.

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

Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Louisiana

Before REAVLEY, STEWART, and OWEN, Circuit Judges.

CARL E. STEWART, Circuit Judge:

Defendant-Appellee Maria Carmen Palazzo, M.D., Ph.D., MMM ("Dr. Palazzo"), a licensed medical doctor specializing in psychiatry, was a Medicare provider authorized to submit bills for reimbursement for certain medical services provided to eligible Medicare beneficiaries. Dr. Palazzo entered into contracts with SmithKline Beecham, Corporation ("SKB") to carry out clinical drug studies evaluating the efficacy and safety of Paxil in children and adolescents. She failed to comply with the study protocol and to review personally all information regarding the study subjects. Plaintiff-Appellant, the United States ("the Government"), brought charges against Dr. Palazzo for health care fraud and failure to maintain records of the clinical drug studies in

violation of 21 U.S.C. § 355(i). The grand jury returned a superseding indictment charging Dr. Palazzo with forty counts of health care fraud and fifteen counts for violations of § 355(i) and 21 C.F.R. §312.64(b). The district court dismissed the § 355(i) counts, forty-one through fifty-five of the superseding indictment. On appeal, the Government challenges the dismissal of those counts. For reasons discussed below, we REVERSE and REMAND.

I. FACTUAL AND PROCEDURAL BACKGROUND

Dr. Palazzo was a duly licensed Medical Doctor (M.D.) specializing in psychiatry, with offices located in New Orleans, Louisiana. Dr. Palazzo served as a Medicare provider authorized to submit bills for reimbursement for certain medical services provided to eligible Medicare beneficiaries.

On July 5, 2000, and July 27, 2001, Dr. Palazzo entered into professional services agreements with Touro Infirmary ("Touro") to provide consultation services for the Adult Psychiatric Programs at Touro. On June 1, 2002, and June 1, 2003, Dr. Palazzo and Touro entered into an agreement for Dr. Palazzo to serve as medical director for Touro's inpatient Adult Psychiatric and Adult Partial Hospitalization Programs. Each agreement was for a one-year term and provided compensation at a rate of \$150 per hour up to \$144,000 per year. The agreements expressly required Dr. Palazzo to provide a written monthly statement documenting the amount of time worked and detailing services rendered.

Touro sent its Medicare Part A claims to Mutual of Omaha, which received, settled, and paid the claims pursuant to a contract with the Centers for Medicare and Medicaid Services, an agency of the United States Department of Health and Human Services. Dr. Palazzo submitted Medicare Part B bills to Blue Cross/Blue Shield.

Apart from her consultation work at Touro, SKB hired Dr. Palazzo on October 31, 2000, as a clinical investigator to carry out clinical studies to

evaluate the efficacy and safety of Paxil in children and adolescents with obsessive-compulsive disorder. Dr. Palazzo received \$5,410 for each subject who completed the study and agreed to review personally all case report forms regarding each study subject. On February 9, 2001, SKB contracted with Dr. Palazzo to participate as a clinical investigator to assess the long term safety of Paxil in children and adolescents with major depressive disorder or obsessive-compulsive disorder. Dr. Palazzo received \$5,020 for each subject who completed the study, and she agreed to comply with the study protocol and personally review all information regarding the study subject. Dr. Palazzo did not comply with the criteria to provide satisfactory research records, and her contracts to participate in the drug studies were terminated.

On August 25, 2005, a grand jury indicted Dr. Palazzo with two counts of health care fraud and fifteen counts of failure to maintain records of the clinical drug studies in violation of 21 U.S.C. § 355(i). On January 14, 2007, a grand jury returned a superseding indictment charging Dr. Palazzo with forty counts of health care fraud and fifteen counts of violations of § 355(i) and 21 C.F.R. §312.62(b).¹

This appeal concerns the fifteen counts for violating § 355(i) and 21 C.F.R. § 312.62(b) for failure to properly prepare and maintain records with intent to defraud and mislead. Counts forty-one through fifty-two include allegations of inaccuracies in Dr. Palazzo's psychiatric evaluations of subjects participating in the Paxil studies. These counts allege that Dr. Palazzo's psychiatric evaluations stated that subjects suffered from disorders when the subjects had not been diagnosed with the disorders. Counts fifty-three through fifty-five allege that Dr. Palazzo reported examining a subject, when in fact she did not personally examine the subject.

¹ 21 U.S.C. § 331 sets out certain prohibited acts, and § 331(e) prohibits "the failure to establish or maintain any record, or make any report, required under section . . . 355(i)."

The district court granted Dr. Palazzo's motion to dismiss counts forty-one through fifty-five based on the nondelegation doctrine. The district court determined that § 355(i) does not permit the U.S. Food and Drug Administration ("FDA") to promulgate regulations making clinical investigators criminally liable for failure to properly keep records and report accurate information. In making this determination, the district court analyzed two cases that previously dealt with the application of § 355(i) to clinical investigators, *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984) and *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994). The district court adopted the reasoning of *Smith*, and dismissed the counts based on the nondelegation doctrine. *United States v. Palazzo*, No. 05-0266, 2007 U.S. Dist. LEXIS 78986 (E.D. La. Oct. 24, 2007).

II. STANDARD OF REVIEW

A constitutional challenge to a federal statute is a question of law that this court reviews *de novo*. *United States v. Pierson*, 139 F.3d 501, 503 (5th Cir. 1998) (citation omitted). Issues of statutory interpretation are also reviewed *de novo*. *United States v. Santos-Riviera*, 183 F.3d 367, 369 (5th Cir. 1999); see also *United States v. Boren*, 278 F.3d 911, 913 (9th Cir. 2002) (stating that the Ninth Circuit reviews a district court's dismissal of an indictment based on its interpretation of a federal statute *de novo*).

III. DISCUSSION

A. Previous Treatment of § 355(i)

The 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.

1. Ninth Circuit's *Smith* Opinion

The Ninth Circuit based its analysis on prior circuit caselaw which states that "[e]xecutive 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.’” Smith, 740 F.2d at 738 (citation omitted). The court found that the statute placed the burden for record-keeping and reporting requirements on only manufacturers and sponsors. The court stated that the general authorization language contained in the statute to be “insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability.” Id. at 738. Ultimately, the court found § 355(i) to be ambiguous as applied to clinical investigators, invoked the rule of lenity,² and affirmed the district court’s dismissal of the indictment against the defendant-clinical investigator.

2. Eighth Circuit’s Garfinkel Opinion

The Eighth Circuit first determined that whether § 355(i) provides sufficient guidance for the issuance of clinical investigator regulations that resulted in criminal penalties presented a (1) statutory issue related to whether § 355(i) authorized the FDA regulations at issue and a (2) constitutional issue related to the nondelegation doctrine. Garfinkel, 29 F.3d at 453-54. The Garfinkel court began its analysis of § 355(i) by interpreting the Ninth Circuit’s decision in Smith, and determined that, while not explicitly mentioned, the Smith decision was premised on the Ninth Circuit’s determination that § 355(i) violated the nondelegation doctrine. Id. at 454. The Eighth Circuit also noted that the Smith court’s initial basis for dismissing the indictment was “that §355(i) lacked sufficient standards for [the] FDA to promulgate regulations imposing criminal penalties upon clinical investigators.” Id.

² “The rule of lenity provides that ‘when a choice must be made between two readings of what conduct Congress has made a crime, it is appropriate, before choosing the harsher alternative, to require that Congress should have spoken in language that is clear and definite.’” United States v. Orellana, 405 F.3d 360,370 (5th Cir. 2005) (citation omitted).

The Eighth Circuit then analyzed § 355(i) and held the language of the statute to be ambiguous as it related to the FDA's authority over clinical investigators. *Id.* at 456. The court engaged in a Chevron doctrine analysis to determine whether the "FDA's interpretation of § 355(i) 'reflect[ed] a plausible construction of the plain language of the statute and does not otherwise conflict with Congress'[s] expressed intent.'" *Id.* (citation omitted). See also *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).³ The Garfinkel court reviewed § 355(i)'s legislative history and held that § 355(i) authorized the promulgation of clinical investigator record-keeping regulations. *Garfinkel*, 29 F.3d at 457.

The Eighth Circuit then analyzed § 355(i) under the constitutional issues presented by the nondelegation doctrine. *Id.* The court examined the language of § 355(i); the purpose of the Food, Drug, and Cosmetic Act, along with its factual background; and the statutory context of the Act's standards. *Id.* at 458. Ultimately, the court disagreed with what it characterized as the Ninth Circuit's determination that the statute violated the nondelegation doctrine, and held that "the standards enunciated by the Act, along with judicial review and the procedural requirements dictated by the [Administrative Procedure Act], impose[d] sufficient restraints upon FDA to satisfy the constitutional concerns underlying the nondelegation doctrine." *Id.* 459.

3. District Court's Analysis

The district court examined § 355(i) and concluded that it does not authorize criminal penalties for violations by clinical investigators in maintaining adequate and accurate records. In making this determination, the

³ Courts apply an analysis of the Chevron doctrine when a party challenges an administrative agency's authority to construe a statute, specifically the agency's authority to interpret the statute and promulgate regulations in accordance with that interpretation. See generally *Chevron*, 467 U.S. at 837.

district court first examined the nondelegation doctrine and the Supreme Court's decision in *Touby v. United States*, 500 U.S. 160, 165 (1991).

In *Touby*, the Supreme Court stated that "Congress may not constitutionally delegate its legislative power to another branch of Government," but Congress does not violate the Constitution as long as it provides "an intelligible principle to which the person or body authorized to [act] is directed to conform." *Id.* (emphasis added). The district court noted, however, that *Touby* did not resolve the issue as to whether more specific guidance is required "when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions . . . [and that] pose a heightened risk to individual liberty." *Id.* The district court concluded that in *Touby*, the Attorney General was permitted to promulgate regulations resulting in criminal sanctions because the relevant statute included six specific factors that the Attorney General must consider in making its determination regarding criminal sanctions.

The district court then examined *Smith* and *Garfinkel* and agreed with the reasoning in *Smith*. The district court concluded that the language of § 355(i) does not provide sufficient guidelines to the FDA regarding clinical investigators to satisfy *Touby*'s intelligible principle requirement. The district court correctly noted that the newer, more explicit FDA regulations imposing responsibility on clinical investigators to maintain adequate and accurate records are not dispositive on the issue of whether the actual statutory language survives the constitutional inquiry.⁴ The district court, therefore, focused solely on the

⁴ While not directly referenced by the district court, it is important to note that the Eighth Circuit relied in part on changed regulations that are not dispositive of the nondelegation doctrine issues in this case. In *Whitman v. American Trucking Associations, Inc.*, the Supreme Court explained that in a delegation challenge "the constitutional question is whether the statute has delegated legislative power to the agency." 531 U.S. 457, 472 (2001). An agency cannot cure "an unconstitutionally standardless delegation of power by declining to exercise some of that power." Therefore, the change in the FDA's regulations to

language of § 355(i) and concluded that Congress did not specifically authorize regulations giving rise to criminal liability under § 355(i), and dismissed counts forty-one through fifty-five of the superseding indictment.

B. Proper Legal Framework

Dr. Palazzo concedes that the FDA has authority to impose record-keeping requirements on clinical investigators through regulations and properly did so through 21 C.F.R. § 312.62. If the parties questioned whether § 355(i) provided sufficient guidance for the FDA to promulgate regulations requiring clinical investigators to adhere to certain record-keeping requirements, the nondelegation doctrine would be an issue in this case. See, e.g., *Garfinkel*, 29 F.3d at 453-54. Similarly, if the parties disputed whether § 355(i) authorized the FDA regulations at issue in this case, this Court would need to engage in a *Chevron* analysis to assess § 355(i)'s statutory construction. See, e.g., *Id.*

The sole issue on appeal in the instant case, however, is whether 21 U.S.C. §§ 351(e) and 355(i) allow the imposition of criminal penalties on clinical investigators who violate the record-keeping requirements found in 21 C.F.R. § 312.62. This issue involves the scope of § 355(i), not the FDA's authority to promulgate regulations, and we must merely "ascertain[] the scope of [§ 355(i)], which in turn requires us to construe the statute." See *United States v. Kay*, 359 F.3d 738, 740 (5th Cir. 2004). Thus, the issue on appeal requires this court to engage only in statutory interpretation.

"The starting point for interpreting a statute is the language of the statute itself." *Id.* at 742. (quotation omitted). We follow the "plain and unambiguous meaning of the statutory language." *Id.* (quotation omitted). "If the statute is

more specific language dealing with clinical investigators, after the *Smith* decision and before the *Garfinkel* decision, is not dispositive of the issue of whether § 355(i) provides a constitutional delegation of authority to the FDA to promulgate regulations criminalizing conduct of clinical investigators for failing to maintain proper record-keeping and reporting requirements.

ambiguous, we may look to the legislative history or agency interpretations for guidance.” *United States v. Orellana*, 405 F.3d 360,365 (5th Cir. 2005) (citation omitted).

C. Analysis

Dr. Palazzo argues that § 355(i) only provides criminal sanctions for manufacturers and sponsors of clinical investigational studies. Therefore, she concludes that she cannot be held criminally liable for violating §§ 331(e) and 355(i) because she is not a manufacturer or sponsor of an investigational study. Dr. Palazzo maintains that the only permissible or lawful penalty for failure to adhere to these record-keeping requirements is disqualification from other investigational studies, a stated penalty within the FDA regulations. See 21 C.F.R. § 312.70. In addition, Dr. Palazzo argues that § 355(i) only gives the Secretary the authority to grant exemptions from criminal liability, not the authority to impose criminal liability on clinical investigators who violate the FDA’s properly promulgated regulations.

The Government asserts that the FDA regulations fill in the details of the criminal statute. The Government notes that Congress may broadly assign authority to the Executive Branch. In this instance, the Government argues that the plain language of § 355(i) and its legislative history demonstrate that Congress authorized the FDA to promulgate criminally enforceable record-keeping regulations that apply to clinical investigators.

1. The Scope of Section 355(i)

Section 355(i) states:

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary.

(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--

.....

(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); and

.....

(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. 355(i) (emphasis added).

Based on the text of the statute, it is clear that § 355(i) addresses three separate issues regarding clinical drug testing. First, § 355(i) explicitly requires the Secretary of the FDA to promulgate regulations providing exemptions of drugs for research from earlier subsections contained in 21 U.S.C. § 355, which regulate “New Drugs.” Second, § 355(i) allows the Secretary, in his/her discretion, to issue regulations regarding those exemptions in an effort to “protect[] the public health.” Section 355(i) provides a non-exhaustive list of conditions upon which the Secretary may provide exemptions. Third, § 355(i) provides requirements for sponsors and manufacturers to make direct reports

to the Secretary and explicitly states that clinical investigators are not required to submit reports directly to the Secretary.

On its face, § 355(i) does not provide criminal liability for sponsors and manufacturers of investigational drug studies or clinical investigators. Violations of § 355(i) are prohibited in 21 U.S.C. § 331(e), and criminal penalties for violating § 331(e) are found in 21 U.S.C. § 333(a). In addition, § 355(i) does not contain an explicit requirement governing the conduct of clinical investigators. The record-keeping and reporting requirements applicable to clinical investigators are contained in the regulations promulgated by the FDA in accordance with the authority given the FDA by Congress. Thus, we must turn to §§ 331(e) and 333 and the FDA's regulations concerning clinical investigators to determine whether clinical investigators are subject to criminal liability for failing to adhere to certain record-keeping and reporting requirements.

2. FDA Regulations and 21 U.S.C. §§ 331(e) and 333

The FDA regulations at issue in this case fall squarely within the second statutory category: the Secretary's ability to promulgate regulations to protect the public health. Accordingly, the Secretary promulgated extensive regulations governing the conduct of clinical investigators.

We first look to the specific section of the regulations which Dr. Palazzo is charged with violating, 21 C.F.R. § 312.62(b). 21 C.F.R. § 312.62 is entitled "[i]nvestigator record[-]keeping and record retention." Section 312.62(b) provides requirements for clinical investigators, like Dr. Palazzo, "to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug." We must now consider how this properly promulgated regulation fits within the statutory context of the FDA, specifically §§ 355(i), 331(e) and 333.

21 U.S.C. § 331 sets out certain prohibited acts under the Food, Drug, and Cosmetics Act, and § 331(e) prohibits a failure to establish or maintain any record, or make any report, required under § 355(i), but § 331(e) does not limit its prohibition only to reports required to be made directly to the Secretary. 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). These are properly considered to be “required” reporting and record-keeping requirements under § 331(e), as § 355(i) allows the Secretary discretionary authority to issue regulations in an effort to protect the public health. The penalties for violating § 331(e) are found in 21 U.S.C. § 333, and specifically state that those violating § 331(e) “shall be imprisoned for not more than one year or fined not more than \$1,000, or both.” 21 U.S.C. § 333(a)(1).

As stated previously, Dr. Palazzo 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. Dr. Palazzo, therefore, was required under § 355(i), via 21 C.F.R. 312.62(b), to adhere to the FDA’s record-keeping and reporting requirements. Section 331(e) delineates what acts are prohibited, and specifically prohibits a failure to establish or maintain any record or make any report as required under § 355(i). Nowhere in § 331(e) does the statute indicate that it only serves to prohibit a failure to establish or maintain records and reports submitted directly to the Secretary of the FDA. Furthermore, the Government correctly notes that Dr. Palazzo points to no ambiguous language in § 331(e) that would cause her to be unclear about whether she could be prosecuted for violating the FDA’s record-keeping requirements established by §312.62(b). 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.

IV. CONCLUSION

For the foregoing reasons, the district court's dismissal of counts forty-one through fifty-five is REVERSED and REMANDED to the district court for further proceedings consistent with this opinion.