

CASENOTE

CLINICAL BOOK-COOKING: *UNITED STATES v. PALAZZO* AND THE DILEMMA OF ATTACHING CRIMINAL LIABILITY TO EXPERIMENTAL DRUG INVESTIGATORS FOR FAULTY RECORD-KEEPING

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I. INTRODUCTION

Over the past few centuries, the field of medicine has evolved exponentially, particularly in the area of drug and pharmaceutical development. With this growth has come an increased desire of both society and governments to create mechanisms that allow for protection of the public. Since the inception of the Food and Drug Administration (FDA) in 1930, the United States has expressed a desire to ensure the safety of the public through inspection and regulation of drugs.¹ Through the FDA, the United States government has remained active in protecting the public health through the creation of laws and rules that govern the testing, production, and marketing of pharmaceuticals.²

The FDA has played the most prominent role in protecting the public against faulty drugs. With the rise of modern medicine and the pharmaceutical industry, it has become necessary to ensure that drugs are safe for public consumption. The FDA regulations play a large part in overseeing the development and marketing of new drugs. However, great care must be taken to ensure that such regulations are not overly burdensome.

As with many legislative enactments, the FDA regulations pertaining to clinical drug investigations have created challenges for courts, which must strike a balance between granting deference to the interpreting agency and construing the intent of the legislature. When such interpretations arise in the context of imposing criminal liability for faulty record keeping, courts face additional challenges associated with questions of criminality. Despite the desire to protect the public, courts must tread carefully through the realm of criminal penalties when looking to the legislative intent behind statutory enactment and make certain that criminal liability is not

1. See U.S. Food & Drug Administration, Significant Dates in U.S. Food and Drug Law History, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last visited May 25, 2010).

2. *Id.*

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improperly imposed upon the relevant actors.

This Note addresses the issues pertaining to the requirements imposed upon clinical drug investigators, as compared to manufacturers or sponsors, and the determination of whether 21 U.S.C. § 355(i)³ authorizes the imposition of criminal liability upon clinical drug investigators for failure to maintain proper records under the FDA regulations. Part II of this Note contains a brief summary of the facts and holding in *United States v. Palazzo*,⁴ a federal Fifth Circuit Court of Appeals decision. Part III examines the statutory provisions, the relevant case law, and other principles related to the *Palazzo* decision. Part IV addresses the decision and reasoning of the Fifth Circuit. Part V analyzes the Fifth Circuit's decision in light of the full spectrum of issues and legal theories surrounding the determination of whether criminal liability should attach to clinical drug investigators.

II. FACTS AND HOLDING

On October 31, 2000, SmithKline Beecham, Corporation (SKB) hired Maria Carmen Palazzo, M.D., Ph.D., a licensed psychiatrist, to study the effectiveness of the drug Paxil, which was developed by SKB to treat Obsessive Compulsive Disorder (OCD) in children and adolescents.⁵ Several months later, Palazzo entered into an additional contract with SKB to serve as a clinical investigator of a study regarding the long-term effects associated with Paxil for those children with serious cases of OCD.⁶ As a clinical investigator, Palazzo was required to, among other things, "prepare and maintain adequate and accurate case histories."⁷

On August 25, 2005, a grand jury issued an indictment against Dr. Palazzo, charging her with two counts of health care fraud and fifteen counts of violating FDA record keeping requirements under 21 U.S.C. § 355(i).⁸ On June 14, 2007, a grand jury issued a superseding indictment, charging Dr. Palazzo with forty counts of health care fraud⁹ and fifteen

3. See discussion *infra* Part II.A.

4. *United States v. Palazzo*, 558 F.3d 400 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (U.S. 2009) (No. 08-1536).

5. *Id.* at 402.

6. *Id.*

7. 21 C.F.R. § 312.62(b) (2002); Superseding Indictment for Health Care Fraud at ¶ 61, *United States v. Palazzo*, No. 05-266, 2007 WL 6336143 (E.D. La. June 14, 2007).

8. See *generally* Indictment, *United States v. Palazzo*, No. 05-266, 2005 WL 6343623 (E.D. La. Aug. 25, 2005).

9. The June 14, 2007, indictment supersedes the previous August 25, 2005, indictment, which charged Palazzo with two counts of health care fraud and fifteen counts of violating 21 U.S.C. § 355(i). See *generally* Superseding Indictment for Health Care Fraud, *supra* note 7. The

counts of failure to maintain records as a clinical drug investigator, in violation of 21 U.S.C. § 355(i).¹⁰ The counts pertaining to health care fraud alleged that Palazzo acted to deceive Medicare, Medicaid,¹¹ and Touro Hospital¹² into paying more money to Palazzo than was actually owed through submission of fraudulent records.¹³ The charge for failure to maintain records under 21 U.S.C. § 355(i) asserted that Dr. Palazzo's drug investigation records were inaccurate and inadequate due to her exaggerated or incorrect psychiatric evaluations of the participants in the clinical drug study, as well as her fabrication of psychiatric disorders and failure to evaluate some candidates.¹⁴

The issue before both the lower court and the court of appeals was whether § 355(i) contemplates the imposition of criminal liability on a clinical investigator who fails to maintain accurate and adequate records required under the FDA regulations.¹⁵ Before the district court, Palazzo filed a motion to dismiss the counts relating to recordkeeping, and the court granted the request, finding that Congress did not authorize the imposition of criminal liability.¹⁶ Palazzo argued that, though § 355(i) allows the Secretary to impose record-keeping requirements on the sponsor of the investigation or drug manufacturer, the statute does not permit the imposition of criminal liability on clinical investigators.¹⁷

In considering Dr. Palazzo's motion to dismiss, the district court

forty counts of health care fraud were not at issue on appeal and are not addressed in this note. *See Palazzo*, 558 F.3d at 402.

10. *See generally* Superseding Indictment for Health Care Fraud, *supra* note 7.

11. Counts one through fourteen of the superseding indictment charged Palazzo with fraudulently billing Medicare for face-to-face services rendered to patients when she in fact did not perform the services. *Id.* at ¶¶ 35-37. Counts fifteen through twenty-seven charged Palazzo with submitting reports for reimbursement from Medicare and Medicaid for services she purportedly rendered when, in fact, a physician's assistant rendered the service. *Id.* at ¶¶ 38-40.

12. Counts twenty-eight through forty of the superseding indictment alleged that Palazzo falsely submitted reports for reimbursement to Touro for time spent in her administrative capacity when the hours billed were spent creating the fraudulent reports for face-to-face visits. Additionally, the counts assert that Palazzo knew she was causing Touro to submit false expense reports to Medicare, which resulted in partial reimbursement to Touro for the fraudulent invoices. Superseding Indictment for Health Care Fraud, *supra* note 7, at ¶¶ 41-51.

13. *Id.* at ¶¶ 19-34.

14. *Id.* at ¶¶ 65-66. The combined counts alleged that "Dr. Palazzo's psychiatric evaluations stated that subjects suffered from disorders when the subjects had not been diagnosed with the disorders" and that "Dr. Palazzo reported examining a subject, when in fact she did not personally examine the subject." *United States v. Palazzo*, 558 F.3d 400, 402 (5th Cir. 2009).

15. *United States v. Palazzo*, No. 05-266, 2007 WL 3124697, at *4-*7 (E.D. La. 2007), *rev'd*, 558 F.3d 400 (5th Cir. 2009); *United States v. Palazzo*, 558 F.3d 400, 402 (5th Cir. 2009).

16. *Palazzo*, 2007 WL 3124697, at *4, *7.

17. *Id.* at *4.

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focused on the nondelegation doctrine¹⁸ and its application to § 355(i), including case law originating out of the Eighth and Ninth Circuits that considered and interpreted the same issue.¹⁹ Noting that Congress can delegate legislative power “[s]o 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,”²⁰ the district court concluded that Congress failed to authorize criminal liability on clinical investigators for violations of § 355(i).²¹

The Government appealed the decision of the district court, and the Fifth Circuit reversed.²² After analyzing the decisions of the Eighth and Ninth Circuits and the district court, the Fifth Circuit found that the determination of whether clinical investigators are subject to criminal liability for faulty recordkeeping pertained to the scope of § 355(i), rather than whether the FDA has “authority to promulgate regulations.”²³ Ultimately, the court held that in “reviewing [21 C.F.R.] § 312.62(b) in conjunction with [21 U.S.C] §§ 355(i), 331(e), and 333(a)(1) . . . it [is] apparent that the scope of the statute allows clinical investigators to be subjected to criminal liability.”²⁴ Palazzo promptly submitted a petition for a writ of certiorari to the Supreme Court,²⁵ which was subsequently denied.²⁶

III. BACKGROUND

To adequately understand the myriad issues in answering the question

18. See *infra* Part III.B. for an explanation of the nondelegation doctrine.

19. *United States v. Palazzo*, No. 05-266, 2007 WL 3124697, at *5-*7 (E.D. La. 2007), *rev'd*, 558 F.3d 400 (5th Cir. 2009); *United States v. Palazzo*, 558 F.3d 400, 402 (5th Cir. 2009). Specifically, the district court considered *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994) and *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984). For a discussion of the *Garfinkel* and *Smith* decisions, see *infra* Part III.C.

20. *Palazzo*, 2007 WL 3124697, at *5 (quoting *Touby v. United States*, 500 U.S. 160, 165 (1991)) (alteration in original). The district court noted that the Supreme Court left open the question “as to whether more specific guidance is required when Congress authorizes another Branch to promulgate regulations that contemplate criminal sanctions . . . [that] pose a heightened risk to individual liberty.” *Id.* (internal quotations omitted) (alteration in original). For a discussion of the *Touby* decision, see *infra* Part III.B.2.

21. *Palazzo*, 2007 WL 3124697, at *7 (noting that the statute imposes duty only on drug manufacturers and clinical investigation sponsors and that the proper sanction for a clinical investigator would be the revocation of privilege to work with pending drugs).

22. *Palazzo*, 558 F.3d at 407-08.

23. *Id.* at 405.

24. *Id.* at 407.

25. Petition for Writ of Certiorari, *Palazzo v. United States*, 130 S. Ct. 196 (2009) (No. 08-1536), available at 2009 WL 1672658.

26. *Palazzo*, 130 S. Ct. 196.

whether clinical investigators can be held criminally liable for failing to maintain accurate records, it is necessary to investigate several aspects of the issue. First, it is important to recognize each relevant statute and the connections that exist among them. Second, it is necessary to understand the nondelegation doctrine and its application to the precise question. Finally, an investigation into the varying statutory interpretations will allow a greater understanding of the complexities faced by the Fifth Circuit.

A. RELEVANT STATUTORY PROVISIONS

Neither 21 U.S.C. § 355(i) nor 21 C.F.R. § 312.62(b) directly impose criminal liability for failure to maintain records as a clinical investigator. Section 355(i)(1) states:

The Secretary [of the Department of Health and Human Services] 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 drug²⁷

Additionally, § 355(i)(4) explicitly states 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.”²⁸

Because § 355(i) authorized the creation of regulations by the Secretary, the Fifth Circuit inferred that Title 21 of the Code of Federal Regulations, which includes the pertinent regulations implemented by the FDA, falls under the authority of § 355(i).²⁹ The relevant provision, 21 C.F.R. § 312.62(b), states “[a]n investigator is required 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 or employed as a control in the investigation.”³⁰

27. 21 U.S.C. § 355(i)(1) (2008) (emphasis added).

28. *Id.* § 355(i)(4) (emphasis added).

29. *See* United States v. Palazzo, 558 F.3d 400, 405, 407 (5th Cir. 2009).

30. 21 C.F.R. § 312.62(b) (2002).

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Therefore, these record-keeping requirements, as imposed by the FDA regulations, are authorized by 21 U.S.C. § 355(i).

The path used to impose criminal liability through these statutes is attenuated. 21 U.S.C. § 331(e) expressly prohibits violations of § 355(i).³¹ Furthermore, 21 U.S.C. § 333(a)(1) provides that “[a]ny person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.”³² Section 333(a)(1) served the basis for finding criminal liability by way of sections 331(e), 355(i), and 21 C.F.R. § 312.62(b).³³



B. THE NONDELEGATION DOCTRINE IN THE CONTEXT OF 21 U.S.C. § 355(i)

Before turning to case law which interpreted these statutory provisions, it is important to discuss the constitutional implications of the nondelegation doctrine, especially given that other federal appellate courts, deciding almost identical issues, have expressly relied upon the nondelegation doctrine.³⁴ The nondelegation doctrine is derived from Article I of the Constitution, which states that “all legislative Powers herein granted shall be vested in a Congress of the United States. . . .”³⁵ The Supreme Court has drawn the conclusion that “Congress may not constitutionally delegate its legislative power to another branch of government.”³⁶ However, “Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors.”³⁷ Such legislation is permissible “[s]o long as ‘Congress lays down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform’”³⁸ Therefore, Congress can delegate authority to other branches of

31. 21 U.S.C. § 331(e) (2006).

32. *Id.* § 333(a)(1).

33. *See* *United States v. Palazzo*, 558 F.3d 400, 407 (5th Cir. 2009).

34. ERWIN CHEMERINSKY, *CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES* 327-31 (2006) (explaining the nondelegation doctrine).

35. U.S. CONST. art. I, §1.

36. *Touby v. United States*, 500 U.S. 160, 165 (1991).

37. *Id.*

38. *Touby v. United States*, 500 U.S. 160, 165 (1991) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)).

government, as long as it provides principles and standards that serve as guidance to the agency.

1. CHEVRON, U.S.A., INC. v. NATURAL RESOURCES DEFENSE COUNCIL AND AGENCY CONSTRUCTION

In *Chevron v. Natural Resources Defense Council*,³⁹ the Supreme Court set forth the basic analysis for determining whether an agency properly construed a statute.⁴⁰ First, if Congress has clearly addressed the issue, either in the statute itself or in the legislative record, then the court and the agency must give deference to the unambiguous intent of Congress.⁴¹ However, if Congress has not directly addressed the issue or if the statute is silent or ambiguous on the question, the court then must ask whether the agency's interpretation of the statute is a permissible construction thereof.⁴² Thus, under *Chevron*, an agency's interpretation must be given deference if it is shown that such a construction is indeed plausible under the circumstances.⁴³

2. TOUBY v. UNITED STATES AND THE INTELLIGIBLE PRINCIPLE REQUIREMENT

In *Touby v. United States*⁴⁴ the Supreme Court further commented on the nondelegation doctrine and reiterated the "intelligible principle" requirement.⁴⁵ The Court noted that Congress does not violate the

39. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

40. *Id.* at 842-43. In *Chevron*, the Supreme Court was faced with the determination of whether the Environmental Protection Agency's (EPA) interpretation of the Clean Air Act amendments was a permissible construction of the statute. *Id.* at 843. The amendments impose requirements on states that did not achieve the national air quality standards implemented by the EPA, such as the establishment of a permit program for the regulation of "new or modified major stationary sources." *Id.* at 840. The EPA's interpretation of "stationary sources" allowed for states to adopt a plantwide definition of the term, thus allowing for existing plants to obtain permits for modifications or additions to a part of the plant as long as overall emissions do not increase. *Id.* The Court ultimately deferred to the EPA's interpretation because Congress did not specifically mandate nor exclude such an interpretation. *Id.* at 844-45.

41. *Id.* at 842-43.

42. *Id.* at 843.

43. The *Chevron* Court noted that:

Once it determined . . . that Congress did not actually have an intent regarding the applicability of the bubble concept to the permit program, the question before [the court] was not whether in its view the concept is 'inappropriate' in the general context of a program designed to improve air quality, but whether the Administrator's view that it is appropriate in the context of this particular program is a reasonable one.

Id. at 845.

44. *Touby v. United States*, 500 U.S. 160 (1991).

45. *Id.* at 164-169 (1991). Congress passed the Controlled Substances Act (CSA), which created categories of controlled substances, the manufacture, possession, and distribution of which the Act either regulates or prohibits. *Id.* at 162. The petitioners were convicted of manufacturing

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nondelegation doctrine simply by legislating in a way that leaves certain aspects of decision-making open to other, nonlegislative actors.⁴⁶ Quoting an earlier decision, the Supreme Court stated, “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.’”⁴⁷

The petitioners, however, argued that, in a criminal context, Congress must do more than simply set forth an intelligible principle.⁴⁸ Specifically, the plaintiffs contended that “regulations [that contemplate criminal sanctions] . . . pose a heightened risk to individual liberty and that Congress must therefore provide more specific guidance.”⁴⁹ Recognizing that previous case law was unclear in answering this question, the Supreme Court declined to resolve the issue on this occasion because the statute “passe[d] muster even if greater congressional specificity is required in the criminal context.”⁵⁰

3. *UNITED STATES v. GARFINKEL* AND INTERPRETATION OF *TOUBY* IN THE CONTEXT OF 21 U.S.C. § 355(i)

In *United States v. Garfinkel*,⁵¹ the Eighth Circuit recognized that *Touby* left unresolved the question whether Congress should set forth more than an “intelligible principle” in the context of criminal liability.⁵² The *Garfinkel* court was faced with the determination of whether § 355(i) authorizes the FDA regulations and whether § 355(i) provides sufficient guidance to the FDA “for the issuance of clinical-investigator regulations that provide for criminal penalties.”⁵³ To address these questions, the *Garfinkel* court examined the statute in the context of both the Ninth

a schedule I drug known as “Euphoria.” *Id.* The question before the court was whether 21 U.S.C. § 811(h) (or § 201(h) of the CSA) was an unconstitutional delegation of legislative power to the Attorney General and whether the Attorney General’s later delegation to the Drug Enforcement Administration was allowed by the statute. *Id.*

46. *Touby v. United States*, 500 U.S. 160, 165 (1991).

47. *Id.* (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)) (alterations in original).

48. *Id.* at 165-66.

49. *Id.* at 166.

50. *Id.*

51. *United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994).

52. *Id.* at 457-58.

53. *Id.* The court noted that the “authorization” issue is one of statutory construction. *See* discussion *infra* Part III.C.2. The Eighth Circuit noted that the “sufficient guidance” issue requires analysis in the context of the nondelegation doctrine. *Garfinkel*, 29 F.3d at 453. However, the Fifth Circuit recognizes the “sufficient guidance” issue as the only issue on appeal. *See United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009). The court noted that the “authorization” issue is one of statutory construction. *See* discussion *infra* Part III.C.2.

Circuit's decision in *United States v. Smith*⁵⁴ and the nondelegation doctrine.⁵⁵

First, the court analyzed the *Smith* opinion, in which the Ninth Circuit held that the lack of guidelines given to the FDA in imposing criminal penalties violated the nondelegation doctrine.⁵⁶ Relying on *Smith*, Garfinkel argued that because the regulation imposed criminal penalties, Congress must do more than set forth an intelligible principle.⁵⁷ The Eighth Circuit acknowledged that the question of "whether . . . more specific guidance is in fact required [in the criminal context]" had not been specifically answered by the Supreme Court.⁵⁸ Thus, where *Touby* left the issue unresolved, *Smith* required a standard higher than an intelligible principle to hold clinical investigators liable under § 355(i).

Second, the court questioned whether the guidance set forth in § 355(i) provided an intelligible principle for the FDA.⁵⁹ Upon review of § 355(i), the court held that the statute passed the intelligible principle requirement because the rules set forth in § 355(i) surpassed the requirements of the statute at issue in *Touby*.⁶⁰ The court determined that § 355(i) includes restraints that are similar or in excess of those imposed under the *Touby* statute.⁶¹ Because § 355(i) is subject to judicial review and procedural requirements, the Eighth Circuit held that the standards of the constitutional nondelegation doctrine were surpassed.⁶²

The *Smith* and *Garfinkel* decisions represent the varying interpretations of the nondelegation doctrine in the context of criminal liability. The nondelegation doctrine specifies that Congress cannot

54. *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984). For a discussion of the *Smith* discussion, see *infra* Part III.C.1.

55. *United States v. Garfinkel*, 29 F.3d 451, 454, 457-58 (8th Cir. 1994).

56. *Id.* at 454 (discussing *Smith*, 740 F.2d 734). Please note that this finding is according to the Eighth Circuit's construction of the Ninth Circuit's decision.

57. *Id.* at 457 (alteration in original).

58. *Id.* (quoting *Touby v. United States*, 500 U.S. 160, 166 (1991)). In *Touby*, the Supreme Court recognized that the intelligible principle standard in the context of criminal conduct may be insufficient but declined to offer more specific guidance, finding that the particular statute at issue in *Touby* passed scrutiny even under a heightened standard. See generally *Touby*, 500 U.S. 160.

59. *Garfinkel*, 29 F.3d at 458. Section 351(i) imposes the following rules on the FDA's authority: (1) that the regulations must be for investigational drug studies, (2) the exemptions granted by the Secretary must pertain only to drugs used by experts, (3) such persons must be inspecting the efficacy of the drug, and (4) the regulations created for the safety of the general public must also be in relation to drug exemptions. *Id.*

60. *Id.* at 458-59.

61. *Id.*

62. *Id.*

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delegate its lawmaking authority to other branches of the government.⁶³ As long as Congress provides adequate safeguards, it may leave certain aspects of a law open to interpretation by the governing agency.⁶⁴ In *Chevron*, the Supreme Court set forth a two-prong test in determining whether the agency's interpretation of the law is proper: (1) the statute must be silent or ambiguous with respect to the interpretation in question and (2) the agency's construction of the statute must be permissible.⁶⁵ Under *Touby*, the Supreme Court further clarified that Congress does not violate the nondelegation doctrine as long as the statute in question sets forth an "intelligible principle" which the interpreting agency must follow.⁶⁶ However, the *Garfinkel* decision recognized the shortcomings of the Supreme Court's holding in *Touby* as applied in a criminal context.⁶⁷ This shortcoming—whether Congress is required to establish more than an intelligible principle in the context of criminal liability—is relevant to the analysis and holding of the Fifth Circuit in the *Palazzo* decision.⁶⁸

C. CONFLICTING JUDICIAL INTERPRETATIONS OF 21 U.S.C. § 355(i)

The question whether § 355(i) authorizes the imposition of criminal liability on the clinical investigators of new drugs has been addressed previously in other courts. Both the Ninth and the Eighth Circuits have addressed this issue, but their resolutions have fallen on two opposite ends of the spectrum.⁶⁹ The Ninth Circuit, in *United States v. Smith*, viewed the issue in the context of criminal statutory construction and the principle of lenity;⁷⁰ whereas, the Eighth Circuit, in *United States v. Garfinkel*, focused not on the criminality aspect, but on congressional intent and the FDA's interpretation of the statute.⁷¹

63. *Touby v. United States*, 500 U.S. 160, 164-65 (1991).

64. *Id.* at 165.

65. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984).

66. *Touby*, 500 U.S. at 165-69.

67. *United States v. Garfinkel*, 29 F.3d 451, 457-58 (8th Cir. 1994) (discussing *Touby*, 500 U.S. 160).

68. *See United States v. Palazzo*, 558 F.3d 400, 404 (5th Cir. 2009). For a full discussion of the court's analysis and holding in *Palazzo*, see *infra* Part IV.B.

69. *Compare United States v. Garfinkel*, 29 F.3d 451 (8th Cir. 1994) (holding that § 355(i) meets the requirements of the nondelegation doctrine), *with United States v. Smith*, 740 F.2d 734 (9th Cir. 1984) (holding that § 355(i) does not impose criminal liability on clinical investigators for failure to maintain proper records without more specific language to that effect).

70. *Smith*, 740 F.2d at 738-39.

71. *Garfinkel*, 29 F.3d at 456-59.

1. *UNITED STATES v. SMITH* AND THE PRINCIPLE OF LENITY

In *United States v. Smith*, the Ninth Circuit, framing the issue in relation to the rule of lenity, determined that § 355(i), in conjunction with the other relevant statutes, does not authorize the imposition of criminal liability upon clinical investigators.⁷² In *Smith*, Roland Smith, M.D., and his associates served as clinical investigators for experimental drugs.⁷³ They were indicted for five counts of failure to maintain records as required under 21 U.S.C. § 331(e) and 21 U.S.C. § 355(i).⁷⁴ The question before the court was “whether 21 U.S.C. §§ 355(i) and 331(e) in conjunction with 21 C.F.R. § 312.1⁷⁵ make it a crime for a clinical investigator to maintain inadequate or inaccurate records.”⁷⁶ The district court dismissed the counts, finding that the statutes only impose a duty on the manufacturers and sponsors and not clinical researchers.⁷⁷ The Ninth Circuit affirmed the decision.⁷⁸

The Ninth Circuit read § 355(i) to expressly require manufacturers and sponsors to maintain records and submit them to the Secretary but found that the statute failed to extend such requirements, with the attachment of criminal liability, to clinical investigators.⁷⁹ Relying on the plain language of the statute, the court stated that the “general authorizing language [of the statute] . . . is insufficient legislative guidance for the issuance of regulations which, if violated, would furnish the basis for criminal liability.”⁸⁰ Thus, the statute contained inadequate instruction and language for criminal liability to attach for a violation of any one section.⁸¹

Recognizing the ambiguity in the statute in reference to clinical investigators, the court refused to allow the imposition of criminal liability

72. *United States v. Smith*, 740 F.2d 734, 739 (9th Cir. 1984).

73. *Id.* at 735.

74. *Id.* The indictment also included nine counts of causing the Sterling-Winthrop pharmaceutical company to submit false statements to the FDA, in violation of 18 U.S.C. § 1001. *Id.* These counts are irrelevant in the present context.

75. 21 C.F.R. § 312.1 (2002). Section 312.1 provides the general provisions for applying for a new drug investigation in accordance with FDA regulations. *See id.* In *Palazzo*, the indictment charged the defendant with violating 21 C.F.R. § 312.62(b). Superseding Indictment for Health Fraud, *supra* note 7, at ¶ 66; *see also* 21 C.F.R. § 312.62(b).

76. *Smith*, 740 F.2d at 735. The *Smith* court also faced the question of when a statute of limitations begins to toll for a violation of 18 U.S.C. § 1001; however, this issue was not relevant for the court’s analysis in *Palazzo*. *Id.* at 737.

77. *Id.* at 736.

78. *Id.* at 739.

79. *Id.* at 737-39.

80. *Id.* at 738.

81. *Id.* (noting that the general authority granted to the Secretary is insufficient to allow the imposition of criminal liability to any violation thereof).

for purported violations that were not clearly linked to those persons in question.⁸² The court relied on the rule of lenity, which provides that “[w]hen Congress leaves to the Judiciary the task of imputing to Congress an undeclared will, the ambiguity should be resolved in favor of lenity.”⁸³ This principle is based on the Supreme Court’s view that “when [a] choice has to be made between two readings of what conduct Congress has made a crime, it is appropriate, before we choose the harsher alternative, to require that Congress should have spoken in language that is clear and definite.”⁸⁴ The reasoning behind the principle is twofold. First, lenient statutory construction ensures that the public is given a “fair warning . . . ‘of what the law intends to do if a certain line is passed.’”⁸⁵ 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.’”⁸⁶

Additionally, the Ninth Circuit recognized that although the rule of lenity requires strict construction of general statutes, an unyielding adherence to the text of the statute that undermines the intent of the legislature is not permissible.⁸⁷ With regard to those statutes enacted for the benefit of public health, it is important to ensure the safety of society in implementing the law.⁸⁸ Noting that the role of the judiciary is to construe those laws which Congress has created,⁸⁹ the *Smith* Court, relying on the rule of lenity, held that 21 U.S.C. § 355(i) does not impose criminal liability on clinical investigators.⁹⁰

82. *United States v. Smith*, 740 F.2d 734, 737-38 (9th Cir. 1984).

83. *Id.*; *Ladner v. United States*, 358 U.S. 169, 178 (1958) (quoting *Bell v. United States*, 349 U.S. 81, 83 (1955)).

84. *United States v. Universal C.I.T. Credit Corp.*, 344 U.S. 218, 221-22 (1954); *see also* 73 AM. JUR. 2d *Statutes* § 197 (2009) (explaining the interpretation of ambiguous penal statutes in accordance with the rule of lenity).

85. *Smith*, 740 F.2d at 738 (quoting *United States v. Bass*, 404 U.S. 336, 348 (1971)).

86. *Id.* (quoting *United States v. Bass*, 404 U.S. 336, 348 (1971)).

87. *Id.*

88. *Id.* at 738.

89. *Id.* (quoting 62 Cases, More or Less, Each Containing Six Jars of Jam v. *United States*, 340 U.S. 593, 596 (1951) (“[O]ur problem is to construe what Congress has written. . . . Congress expresses its purpose by words. It is for us to ascertain—neither to add nor to subtract, neither to delete nor to distort.”)).

90. *Id.* at 738-39. In addition to following the principle of lenity, the *Smith* court noted 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.” *Id.* (emphasis in original).

2. *UNITED STATES v. GARFINKEL* AND PERMISSIBLE STATUTORY CONSTRUCTION

The Eighth Circuit took a different approach in *United States v. Garfinkel*, holding that § 355(i) authorizes the imposition of criminal liability on clinical investigators because there exists nothing in the congressional record that conflicts with the FDA's interpretation as such.⁹¹ Barry Garfinkel, a child psychiatrist, served as a clinical investigator of the drug Anafranil.⁹² A grand jury returned a twenty-five count indictment against him, including two counts of failing to maintain accurate records as required under FDA regulations.⁹³ Garfinkel argued that § 355(i) imposes a recordkeeping duty on sponsors and manufacturers but not on clinical investigators.⁹⁴ Relying upon *Smith*, Garfinkel further argued that the FDA does not have the authority to promulgate regulations which attach criminal liability, absent "sufficient congressional guidelines and standards for the exercise of that authority."⁹⁵ The government responded by asserting that the FDA regulations at issue in *Smith* had been superseded by a newer variation of the regulations.⁹⁶ The district court adopted *Smith* and dismissed the counts, finding that Congress's amendments to § 355(i) did not legislatively overrule *Smith* and that the government had ignored the Ninth Circuit's finding that Congress failed to properly delegate authority to the Secretary.⁹⁷

One issue addressed in *Garfinkel* was whether § 355(i) authorized the FDA regulations,⁹⁸ which required the court to engage in statutory construction.⁹⁹ The court noted that § 355(i) contains a provision which states that the regulations imposed by the Secretary can "relat[e] to the protection of the public health. . . ."¹⁰⁰ The court found that imposing recordkeeping requirements on the sponsor or manufacturer is in the interest of protecting public health but that, in reference to clinical investigators, the statute is ambiguous.¹⁰¹

91. *United States v. Garfinkel*, 29 F.3d 451, 456-57 (8th Cir. 1994).

92. *Id.* at 453.

93. *Id.*

94. *Id.*

95. *Id.*; see also *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984).

96. *Garfinkel*, 29 F.3d at 453.

97. *Id.* (citing *United States v. Garfinkel*, 822 F. Supp. 1457, 1460-61 (D. Minn. 1993)).

98. A second issue pertains to whether § 355(i) includes the requisite safeguards in order to impose criminal liability on clinical investigators. *Id.* at 458; see also discussion *supra* Part.III.B. concerning the nondelegation doctrine.

99. *Garfinkel*, 29 F.3d at 453, 455-57.

100. *Id.* at 455 (quoting 21 U.S.C. § 355(i) (2006)).

101. *Id.* at 456.

In light of § 355(i)'s ambiguity, the court turned next to the determination of whether the FDA's construction was a permissible interpretation of the statute.¹⁰² Though not binding on the courts, an agency's interpretation of a statute is generally granted deference by the courts.¹⁰³ To determine whether the FDA's construction of the statute was plausible, the court was required to investigate Congress' intent in passing the statute.¹⁰⁴ After reviewing the congressional record, the court agreed with Garfinkel that "Congress's focus was on the manufacturers and sponsors of investigational drugs," but found "nothing in the legislative history to indicate that Congress intended to limit [the] FDA's authority to the sponsors and manufacturers."¹⁰⁵ Thus, the court held that the FDA's interpretation was a permissive construction of § 355(i) because it did not directly conflict with Congress's expressed intent, and consequently, that § 355(i) authorized the establishment of recordkeeping requirements on clinical investigators.¹⁰⁶

D. THE DECISION OF THE DISTRICT COURT

Over ten years after the *Garfinkel* decision (and over twenty since *Smith*), the eastern district of Louisiana was faced with the same question of whether clinical investigators can be criminally penalized for failing to properly keep records.¹⁰⁷ The district court in *Palazzo* employed a variation of the nondelegation doctrine, which rests on *Touby*'s intelligible principle analysis.¹⁰⁸ Recognizing that *Touby* did not concern criminal penalties for a violation of a statute, the district court insisted that *Touby* is instructive in such situations.¹⁰⁹ Though the FDA regulations were amended post-*Smith* to include clear language requiring the investigator to keep records, the question remained as to the imposition of criminal liability with respect to the investigators for violating § 355(i), as opposed to the regulations themselves.¹¹⁰ Furthermore, the district court analyzed both the *Smith* and *Garfinkel* decisions and chose to follow the Ninth Circuit's finding in *Smith*, that criminal liability could not attach to clinical investigators for

102. *United States v. Garfinkel*, 29 F.3d 451, 456-57 (8th Cir. 1994).

103. *See* 73 C.J.S. *Public Admin. Law & Proc.* § 212 (2009) (explaining the procedure and policy behind deference given to an agency's construction or interpretation of a statute or regulation).

104. *Garfinkel*, 29 F.3d at 456.

105. *Id.*

106. *Id.* at 456-57.

107. *United States v. Palazzo*, No. 05-0266, 2007 WL 3124697, at *4-7 (E.D. La. Oct. 24, 2007), *rev'd*, 558 F.3d 400 (5th Cir. 2009).

108. *Id.* at *5-*6.

109. *Id.* at *5.

110. *See id.* at *6-*7 (discussing *Garfinkel*, 29 F.3d 451).

violations of § 355(i).¹¹¹ Finally, the district court directly confronted the decision in *Garfinkel* and held that nowhere in the language of § 355(i) did Congress include an intelligible principle with respect to clinical investigators.¹¹² In agreeing with *Smith* and rejecting *Garfinkel*, the district court effectively discounted the nondelegation argument and favored the rule of lenity.

IV. THE FIFTH CIRCUIT'S DECISION

In *United States v. Palazzo*, the Fifth Circuit was faced with resolving an issue that had already surfaced as a split among other appellate jurisdictions and one that the Supreme Court has yet to clarify.¹¹³ The Fifth Circuit first reviewed the relevant case law, including the decisions of the Eighth and Ninth Circuits, and then decided the issue based strictly on determining the scope of the statute.

A. THE FIFTH CIRCUIT'S REVIEW OF PREVIOUS TREATMENT

The Fifth Circuit began its discussion by acknowledging that the issue of whether § 355(i) authorizes the imposition of criminal penalties on clinical investigators has been resolved in varying ways in other federal appellate courts.¹¹⁴ The Fifth Circuit recognized that the Ninth Circuit in *Smith* analyzed the ambiguity with respect to clinical investigators in the context of the principle of lenity and that the Ninth Circuit refused to impose criminal liability in the face of such ambiguity.¹¹⁵ Likewise, the Fifth Circuit acknowledged that, in *Garfinkel*, the Eighth Circuit focused on the ambiguity in the context of whether the FDA's interpretation was permissible and imposed criminal liability.¹¹⁶ The Fifth Circuit viewed the opinion of the district court as one of statutory interpretation because the court engaged in an analysis of whether an intelligible principle was enacted by Congress.¹¹⁷

B. THE FIFTH CIRCUIT'S APPROACH

After reviewing and interpreting the relevant case law and precedent, the Fifth Circuit set forth a legal framework for analyzing the remainder of

111. *United States v. Palazzo*, No. 05-0266, 2007 WL 3124697, at *6-7 (E.D. La. Oct. 24, 2007), *rev'd*, 558 F.3d 400 (5th Cir. 2009).

112. *Id.* at *7.

113. *Palazzo's* petition for a writ of certiorari was denied by the Supreme Court. *Palazzo v. United States*, 130 S. Ct. 196 (2009).

114. *Palazzo*, 558 F.3d at 402-04, *cert. denied*, 130 S. Ct. 196 (2009).

115. *Id.* at 403.

116. *Id.* at 403-04.

117. *Id.* at 404-05.

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the case.¹¹⁸ The court deviated from previous cases and determined that the issue pertained to the scope of the statute, instead of framing the issue in terms of *Chevron* deference or the nondelegation doctrine.¹¹⁹ The Fifth Circuit pointed out that the nondelegation doctrine would be an issue “[i]f 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. . . .”¹²⁰ Moreover, the court stated that “if the parties disputed whether § 355(i) *authorized* the FDA regulations . . . , [then the] . . . court would need to engage in a *Chevron* analysis.”¹²¹ The court then asserted that the only issue on appeal was whether the relevant statutes “allow the imposition of criminal penalties on clinical investigators who violate the record-keeping requirements found in [the FDA regulations].”¹²²

The court looked solely to the plain language of the statute in determining whether it authorized criminal penalties.¹²³ In doing so, the court recognized three distinct issues written into § 355(i) in relation to clinical drug testing.¹²⁴ First, the Secretary is required to create FDA regulations for exempting drugs from research.¹²⁵ Second, the Secretary is allowed to create FDA regulations in relation to the exemptions for the purpose of protecting public health.¹²⁶ Third, § 355(i) requires sponsors and manufacturers to submit reports to the Secretary when conducting clinical investigations.¹²⁷

After recognizing the explicit requirements and permissions granted under § 355(i), the court acknowledged that the statute does not authorize

118. *United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009) *cert. denied*, 130 S. Ct. 196 (2009).

119. *Id.*

120. *Id.* (emphasis in original).

121. *Id.* This determination of the Fifth Court was challenged by Palazzo in her reply brief submitted to the Supreme Court:

[T]he 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. . . .’ . . . 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.

Reply Brief of Petitioner at 7, *United States v. Palazzo*, 130 S. Ct. 196 (2009) (No. 08-1536), available at 2009 WL 2625868 (citation omitted).

122. *Palazzo*, 558 F.3d at 405.

123. *Id.* at 406.

124. *Id.*

125. *Id.* at 406.

126. *Id.*

127. *Id.*

criminal liability on its face.¹²⁸ Rather, criminal liability is inferred by connecting several statutes together.¹²⁹ Inherent in § 355(i) is the grant of authorization to the Secretary to create regulations which exempt drugs under clinical investigation when it relates to the public health.¹³⁰ The Fifth Circuit concluded that § 355(i) grants authority to the Secretary in creating regulations over the conduct of clinical investigators, which includes 21 C.F.R. § 312.62(b), the provision under which Palazzo was indicted.¹³¹ Once the court determined that the FDA regulations in question were authorized by § 355(i), it observed that violations of § 355(i) are prohibited by 21 U.S.C. § 331(e), violations of which are criminally sanctioned by 21 U.S.C. § 333(a).¹³² The Fifth Circuit concluded that in light of the three statutes, “the scope of the statute allows clinical investigators to be subjected to criminal liability.”¹³³

In determining that § 355(i) allows the imposition of criminal liability on clinical investigators, the court reasoned that it need not address the statutory construction of the interrelated statutes because Palazzo failed to point to any ambiguity in § 331(e) “that would cause her to be unclear about whether she could be prosecuted for violating the FDA’s record-keeping requirements”¹³⁴ The Fifth Circuit concluded that Palazzo was properly indicted for violating 21 C.F.R. § 312.62(b) because the Secretary is authorized to create such regulations for the protection of public health under § 355(i).¹³⁵ The court reasoned that criminal liability should attach to clinical investigators because criminal liability is imposed under § 333(a)(1) for violating § 331(e), which prohibits violations of § 355(i).¹³⁶ Thus, the Fifth Circuit linked the relevant statutory provisions with the FDA regulations at hand and concluded that criminal liability was authorized.

128. *United States v. Palazzo*, 558 F.3d 400, 406 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (2009).

129. *Id.* (discussing 21 U.S.C. §§ 331(e), 333(a) (2006)).

130. *See* 21 U.S.C. § 355(i) (2006).

131. *Palazzo*, 558 F.3d at 407.

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.* Part of the Fifth Circuit’s reasoning was its assertion that Palazzo conceded that the FDA is authorized to impose record-keeping requirements on clinical investigators. *Id.* However, Palazzo’s Petition for a Writ of Certiorari states that “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.” Petition for a Writ of Certiorari at 20, *United States v. Palazzo*, 130 S. Ct. 196 (2009) (No. 08-1536), *available at* 2009 WL 1672658.

136. *Palazzo*, 558 F.3d at 407.

V. ANALYSIS

In determining the criminality of failing to maintain records as a clinical investigator, the Fifth Circuit seemed to develop its own variation of analysis. After reflecting on the relevant cases in the Eighth and Ninth Circuits, as well as commenting on the district court's decision, the Fifth Circuit declined to adopt any of the aforementioned courts' reasoning and delved into an investigation of the statute's scope. This approach, however, failed to recognize the constitutional issues under the nondelegation doctrine and the lenient reading generally given to ambiguous laws in reference to criminal punishments.

A. THE VARYING METHODS OF DETERMINING WHETHER 21 U.S.C. § 355(i) IMPOSES CRIMINAL LIABILITY UPON CLINICAL INVESTIGATORS

In *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*,¹³⁷ the Supreme Court set forth the basic test when faced with determining whether a governmental agency, which has been granted administrative authority by Congress, has properly interpreted the statute over which it has authority to implement.¹³⁸ First, if Congress has clearly expressed its intent behind the statute, then the court, as well as the agency, must construct the statute so as to "give effect to the unambiguously expressed intent of Congress."¹³⁹ For Dr. Palazzo, however, § 355(i) remains ambiguous as to whether Congress intended to impose criminal liability upon clinical investigators of new drugs. When such is the case, the appropriate question under *Chevron* is whether the agency's construction of the statute is permissible,¹⁴⁰ or in the context of the rule of lenity, whether the statute should be construed in favor of the defendant.¹⁴¹

In reference to § 355(i), it is clear that Congress intended to impose criminal sanctions on the manufacturers and sponsors of drug investigations because they are expressly mentioned in the statute itself and in the legislative history.¹⁴² The statute, nevertheless, remains ambiguous as to

137. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

138. *See id.* at 842-43.

139. *Id.*

140. *Id.* at 843.

141. *United States v. Boss*, 404 U.S. 336, 347-49 (1971) ("[W]here there is ambiguity in a criminal statute, doubts are resolved in favor of the defendant.").

142. 21 U.S.C. § 355(i) (2006). The Senate Report expressly states

the bill would . . . permit the Secretary to require *manufacturers* to keep records and make reports of investigational use of and clinical experience with new drugs and antibiotics. . . . Failure to keep such records and to make such reports would be made a prohibited act, subject to specified penalties, which could be enjoined.

the clinical investigators.¹⁴³ In the context of the nondelegation doctrine, § 355(i)'s ambiguity with respect to clinical investigators raises the issue of whether the FDA is authorized to promulgate recordkeeping requirements over clinical investigators and, if so, whether Congress provided guidelines sufficient to allow the imposition of criminal sanctions for a violation.¹⁴⁴ However, it is also equally plausible that once § 355(i) is deemed ambiguous, the rule of lenity applies because the application of § 355(i) in this case pertains to the imposition of criminal liability.¹⁴⁵ To determine the proper analysis of the statute, it is necessary to first consider the range of analyses that courts have used to resolve this issue and the propriety of each.

On one end of the spectrum rests the *Garfinkel* decision, in which the Eighth Circuit deferred to the FDA's construction of the statute.¹⁴⁶ The court held that the FDA's interpretation of § 355(i) did not conflict with Congress's expressed intent and that § 355(i) contained an intelligible principle as required by the nondelegation doctrine.¹⁴⁷ The Fifth Circuit found the Eighth Circuit's approach in *Garfinkel* irrelevant to the determination of whether § 355(i) authorizes the criminal liability imposed on Dr. Palazzo and ignored inherent questions relevant to the nondelegation doctrine, which the Eighth Circuit correctly recognized.¹⁴⁸

Even though the *Palazzo* court did not rely on the Eighth Circuit's decision in *Garfinkel*, it took the same risk as the Eighth Circuit in not considering the principle of lenity. In failing to identify the principle of lenity when interpreting criminal statutes, both courts risked improperly placing clinical investigators, who are not expressly named in the statute, in jeopardy of criminal liability when Congress may not have ever intended to extend such liability to this particular class of persons. While it is plausible that the FDA's interpretation of § 355(i) is permissible because there is no direct conflict with the stated legislative intent, it is equally likely that the

S. REP. NO. 87-1744 (1962), reprinted in 1962 U.S.C.C.A.N. 2884, 2886 (emphasis added).

143. See 21 U.S.C. § 355(i). Section 355(i) does not mention clinical investigators in reference to record keeping and expressly states 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.” *Id.* § 355(i)(4) (emphasis added).

144. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984); see also *United States v. Garfinkel*, 29 F.3d 451, 458 (8th Cir. 1994) (stating that § 355(i) must be analyzed “to determine whether it imposes sufficient standards upon the FDA to satisfy the constitutional requirements of the nondelegation doctrine . . .”).

145. See *United States v. Smith*, 740 F.2d 734, 738 (9th Cir. 1984).

146. *Garfinkel*, 29 F.3d 451. For a discussion of the *Garfinkel* decision, see *supra* Part III.C.2.

147. *Garfinkel*, 29 F.3d at 456-59.

148. *United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (2009). For a discussion of the *Palazzo* decision, see *supra* Part IV.B.

FDA incorrectly interpreted it as imposing criminal liability in the absence of a clear legislative intent to do so. Since Congress has not clearly interpreted the statute as authorizing criminal liability and the Supreme Court has yet to determine whether the intelligible principle is sufficient for criminal statutory interpretation, the Eighth Circuit expanded criminal liability in a situation where such an imposition was not proper, due to a failure to recognize the principle of lenity. Though the Fifth Circuit did not engage in the same analysis as the court in *Garfinkel*, the *Palazzo* decision reflects the same shortcomings of *Garfinkel* in declining to discuss the nondelegation doctrine in the context of the principle of lenity.

The *Smith* decision rests at the opposite end of the continuum, in which the Ninth Circuit utilized the principle of lenity in construing § 355(i).¹⁴⁹ In *Smith*, the Ninth Circuit recognized § 355(i)'s exclusion of clinical investigators and found that liability cannot extend to the investigators without an express intent from Congress or, at the very least, additional legislative guidance.¹⁵⁰ The *Smith* court cited the rule of lenity, stating that it provides "fair warning of what the law intends to do if a certain line is passed," and that in the absence of a clear articulation as to whom these laws apply, the doctrine of lenity should come into force.¹⁵¹ The Ninth Circuit preferred lenity, relying on a need for clear articulation of criminal provisions and also a concern for proper separation of powers.¹⁵²

In light of the *Smith* decision, the Fifth Circuit properly framed the issue in terms of whether § 355(i) authorizes the imposition of criminal penalties but failed to address the relevant issues related to criminal sanctions, in particular, the rule of lenity.¹⁵³ The *Smith* decision recognized the importance of statutes that are enacted for the promotion and protection of public health but stated that the concern articulated by the creation of such statutes "does not vest [the] court[s] with a license to rewrite the statute, . . . [but instead, courts must] 'construe what Congress has written . . .'"¹⁵⁴ Thus, the Ninth Circuit correctly acknowledged the criminal issues involved with interpreting § 355(i), and the Fifth Circuit should have found the *Smith* decision to be persuasive.

149. *United States v. Smith*, 740 F.2d 734 (9th Cir. 1984). The Fifth Circuit acknowledged the holding of *Smith* and the district court's reliance thereon but failed to address why the two opinions were incorrect. See *Palazzo*, 558 F.3d at 403-05.

150. *Smith*, 740 F.2d at 737-38.

151. *Id.* at 738 (internal citation omitted).

152. *Id.*

153. See *United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (2009).

154. *Smith*, 740 F.2d 734 at 738 (quoting 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 596 (1951)).

B. THE FIFTH CIRCUIT'S DEVIATION FROM THE DECISIONS IN *SMITH* AND *GARFINKEL*

Even though the Fifth Circuit considered *Garfinkel* and *Smith*, it failed to accurately identify the importance of both analyses to the issue at hand. The court investigated the scope of § 355(i) and neglected to recognize the constitutional implications under the nondelegation doctrine and the harshness of an indefinite criminal penalty.¹⁵⁵ Specifically, the court failed to recognize the issue of determining whether Congress provided adequate direction to the FDA in imposing criminal liability on a group of persons not directly named in the statute.

The Fifth Circuit failed to address the nondelegation doctrine in *Palazzo* and found that the issue presented was neither whether § 355(i) authorized the FDA regulation in question, nor whether “§ 335(i) provided sufficient guidance for the FDA to promulgate regulations requiring clinical investigators to adhere to certain record-keeping requirements.”¹⁵⁶ Instead, the court focused solely on determining the scope of the statute.¹⁵⁷ On its face, § 355(i) does not impose any requirements on the clinical investigators.¹⁵⁸ Only after the court drew connections among multiple statutory provisions did the hazy lines of criminality begin to appear. If engaging in a particular course of action creates criminal liability, such a harsh penalty requires communication by express statutory language. The Fifth Circuit, however, connected a string of statutes to formulate criminal liability.

The Fifth Circuit disregarded certain canons of statutory construction, including the principle of lenity.¹⁵⁹ As mentioned previously, the principle of lenity provides guidance for statutory interpretation of ambiguous statutes where criminal liability may attach.¹⁶⁰ Instead of addressing the issue of where the principle of lenity fit into the complex question faced by the court, the Fifth Circuit ignored the issue in its entirety, choosing only to

155. *United States v. Palazzo*, 558 F.3d 400, 405 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (2009).

156. *Id.* The Fifth Circuit did not provide much reasoning as to why it framed the issue in such a manner. *See id.* The court merely stated that the parties did not question whether § 355(i) provided enough guidance, under the nondelegation doctrine, and the parties did not dispute whether § 355(i) authorized the FDA regulations in question under a *Chevron* analysis. *Id.*

157. *Id.*

158. *Id.* at 406.

159. For a discussion on the interplay between the rule of lenity and *Chevron* deference, see Elliot Greenfield, *The Lenity Exception to Chevron Deference*, 58 BAYLOR L. REV. 1 (2006); *see also* Kristin E. Hickman, *Of Lenity, Chevron, and KPMG*, 26 VA. TAX REV. 905, 933-40 (2007).

160. *See, e.g., United States v. Smith*, 740 F.2d 734, 738 (9th Cir. 1984). For a discussion of the principle of lenity, *see supra* Part III.C.1.

state that the *Smith* court found no liability based on the rule of lenity.¹⁶¹ In doing so, the Fifth Circuit overlooked the considerations connected with the principle, such as ensuring actors of fair warning as to prohibited conduct and the public policy against imposing criminal liability where the legislative intent to do so is unclear.¹⁶²

C. ADDITIONAL CONSIDERATIONS

Beyond the Fifth Circuit's deviance from relevant federal appellate jurisprudence, the court neglected to clearly articulate its reasoning for holding *Palazzo* liable under § 355(i). First, the court formulated its approach based on a method of reasoning that would quickly impose liability on a criminal defendant it deemed worthy of punishment instead of reasoning soundly based on prior case law and legal analysis. Second, the court failed to utilize additional aids of statutory construction when interpreting ambiguous statutes. Finally, the court declined to realize that the nature of clinical drug investigations should naturally insulate clinical investigators from liability and hold the manufacturers and sponsors liable for improperly kept records.

It is possible that the Fifth Circuit recognized *Palazzo* as a culpable defendant and, in the face of unclear law, sought a route for punishment. The court cast aside the nondelegation argument and *Chevron* analysis on the basis that the issue before the court did not pertain to either the sufficiency of § 355(i)'s guidance for the FDA to promulgate regulations or whether § 355(i) authorized the FDA regulations.¹⁶³ The court erred, however, because the issue of whether the statute authorizes criminal liability for clinical investigators involves the nondelegation doctrine in that Congress did not provide specific legislative guidance on this issue and this statutory ambiguity requires a balancing of both the *Chevron* doctrine and

161. *United States v. Palazzo*, 558 F.3d 400, 403 (5th Cir. 2009), *cert. denied*, 130 S. Ct. 196 (2009).

162. *United States v. Smith*, 740 F.2d 734, 738 (9th Cir. 1984). In *Smith*, the Ninth Circuit articulated two main reasons behind the principle of lenity: "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.'" *Id.* (quoting *United States v. Bass*, 404 U.S. 336, 348 (1971)) (internal citation omitted).

163. *Palazzo*, 558 F.3d at 405. The Court cast aside the nondelegation doctrine on the basis that the question presented by the parties was not "whether § 355(i) provided sufficient guidance for the FDA to promulgate regulations requiring clinical investigators to adhere to certain record-keeping requirements . . ." *Id.* Furthermore, the court rejected a *Chevron* approach to because the dispute was not "whether § 355(i) authorized the FDA regulations at issue in this case . . ." *Id.*

the rule of lenity.¹⁶⁴ Throughout its analysis, the court declined to rely upon or support its contention with case law and found liability based only on the scope of the statute.¹⁶⁵

Beyond the aforementioned methods of interpreting ambiguous statutes, such as the rule of lenity and permissible construction, the Fifth Circuit declined to utilize an additional tool of statutory interpretation when deciding the *Palazzo* case. As a general rule, when the statute expressly mentions one thing, it impliedly excludes the other, or *expressio unius est exclusio alterius*.¹⁶⁶ This principle suggests that where the legislature excludes certain items from an enumerated list in the statute, such exclusions are intentional.¹⁶⁷ To an extent, the *Smith* court utilized this principle when it found that “Congress expressly imposed the burden [of maintaining drug testing records] on manufacturers and sponsors.”¹⁶⁸ In refusing to extend liability to clinical investigators absent a clearer legislative intent, the Ninth Circuit effectively used the principle of implied exclusion.¹⁶⁹ Furthermore, § 355(i)(4) expressly places recordkeeping requirements on the manufacturers and sponsors of the drug study and specifically states that there is no similar requirement for clinical investigators to submit reports directly to the Secretary.¹⁷⁰ The *expressio unius* principle, combined with § 355(i)(4)’s explicit statement in reference to clinical investigators, shows that criminal liability does not attach to clinical investigators for failure to maintain records. Because Congress did not clearly articulate a desire to impose criminal liability on clinical investigators and expressly exempted clinical investigators from reporting to the Secretary of the FDA, the Fifth Circuit should have held that § 355(i) only applied to manufacturers and sponsors.

164. However, it is entirely possible that the Fifth Circuit reached an incorrect result in the *Palazzo* decision because § 355(i) is not ambiguous at all. *Palazzo* specifically makes this argument before the Fifth Circuit and the Supreme Court. See Brief of Defendant-Appellee, *United States v. Palazzo*, 558 F.3d 400 (5th Cir. 2009) (No. 07-31119), available at 2008 WL 6082642; Petition for Writ of Certiorari, *Palazzo v. United States*, 130 S. Ct. 196 (2009) (No. 08-1536), available at 2009 WL 1672658; Reply Brief for Petitioner, *Palazzo*, 130 S. Ct. 196 (No. 08-1536), available at 2009 WL 2625868.

165. See *United States v. Palazzo*, 558 F.3d 400, 403-07 (5th Cir. 2009), cert. denied, 130 S. Ct. 196 (2009). The analysis section, which spans two pages, cites each of the relevant statutory provisions, but fails to rely upon any supporting case law from any jurisdiction. See *id.* at 405-07.

166. See 73 AM. JUR. 2D *Statutes* § 129 (2009).

167. *Id.*

168. *United States v. Smith*, 740 F.2d 734, 737 (9th Cir. 1984) (citing 21 U.S.C. § 355(i)(3) (2006)).

169. See *id.* at 737-39.

170. See 21 U.S.C § 355(i)(4) (“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.”).

Despite the Fifth Circuit's reasoning, its holding is certainly reasonable. Drug regulation schemes are adopted in order to protect the public from drugs which may be harmful or poorly regulated. When a clinical investigator fails to maintain proper records and those records are later submitted to the FDA for determination of whether a drug is marketable, considerations of public safety are implicated. However, the express provision which declines to require clinical investigators to submit reports to the Secretary places the ultimate burden upon the sponsor or manufacturer to ensure that such submissions are indeed accurate.¹⁷¹ If a clinical investigator fails to maintain such reports, whether by fraud or accident, which are later submitted to the FDA by the manufacturer, the ultimate responsibility should rest with the manufacturer to ensure that its submissions are correct.¹⁷² Additionally, such manufacturers or sponsors have the means to ensure that the clinical investigators submit correct reports.¹⁷³ By analogy, the manufacturers and sponsors are vicariously liable for the intentional or inadvertent wrongdoings of their clinical investigators because they have the responsibility of ensuring that those who conduct such studies are doing so with proper certification and form. Furthermore, the manufacturers and sponsors have the ability to screen, hire, and remove the clinical investigators. Thus, because § 355(i) imposes requirements on the sponsors and manufacturers, rather than the clinical investigators, and both the sponsors and manufacturers are better equipped to ensure that records are submitted properly to the FDA, clinical investigators are not subject to criminal liability for failing to properly maintain records.

Without a doubt, it is important for the government to oversee and ensure that the public is only allowed to purchase those drugs that have been properly tested. However, the overriding desire to protect the public does not give the courts license to construe statutes as imposing criminal

171. See 21 U.S.C § 355(i)(4) (2006).

172. This contention is supported by Palazzo's argument submitted in her brief before the Fifth Circuit:

[W]hile it is true that the Secretary has the authority to impose record keeping requirements on clinical investigators, and has done so, in the form of the regulations found at 21 C.F.R. § 312.62, (the regulations referred to in the indictment), it is very significant that the only penalty that can attach to a violation of those regulations, even for the deliberate and repeated submission of false data, is disqualification from other investigational studies.

Brief of Defendant-Appellee, *supra* note 164, at 14.

173. For example, because § 355(i) specifically states that the clinical investigators are not required to submit reports, but rather that the sponsor or manufacturer must do so, it ultimately falls upon the latter parties to ensure that they are not misrepresenting their reports to the Secretary. Furthermore, the sponsors and manufacturers should not allow clinical investigators to conduct such important studies without oversight. They should take responsibility for ensuring proper record keeping and testing of the drugs which they seek to administer.

liability where such liability is not clear on the face of the law. As the Ninth Circuit stated in the *Smith* decision:

We recognize that the general rule requiring strict construction of criminal statutes is somewhat tempered in the context of public health and other remedial legislation. . . . [This,] however, does not vest this court with a license to rewrite the statute, for “our problem is to construe what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain—neither to add nor to subtract, neither to delete nor to distort.”¹⁷⁴

The Fifth Circuit’s decision in *Palazzo* adds another dimension to the question of whether clinical investigators can be criminally liable for faulty record keeping. The approach of the *Palazzo* court, in connecting the statutes to form a chain of liability, could lead to a virtually endless ability of federal agencies to impose criminal sanctions where Congress has been silent on the matter.¹⁷⁵ In light of the unclear precedent on the interplay between the nondelegation doctrine and the rule of lenity, courts faced with a similar determination in the future should tread lightly to ensure a fair balance of the laws and policies which permeate this debate.

VI. CONCLUSION

Though the Secretary of Health and Human Services has the authority to promulgate the FDA regulations, the question of whether such regulations can be criminally enforced against a certain group of persons is an entirely different issue. When faced with this decision, the Fifth Circuit declined to follow the previous determinations of either the Eighth or Ninth Circuits, and instead connected the statutes to create criminal liability. In the absence of a clear legislative desire to impose criminal liability on clinical investigators, the statute should be construed in the way most favorable to the defendant, under the principle of lenity. Until such time that Congress clearly expresses the intention of the statute in reference to clinical investigators, § 355(i) should be read to apply only to manufacturers and sponsors of drug investigations.

Megan S. Peterson

174. *United States v. Smith*, 740 F.2d 734, 738 (9th Cir. 1984) (quoting *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951)).

175. This is especially true due to the expansive administrative state present in our federal government.