

Seeing Through the Murky Vial: Does the FDA Have the Authority to Stop Compounding Pharmacies from Pirate Manufacturing?

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I. INTRODUCTION

In late 2012 and early 2013, tainted steroid shots from the New England Compounding Center (“NECC”) caused fifty-five deaths and 745 cases of fungal meningitis in twenty states.¹ On October 1, 2012, the Food and Drug Administration (“FDA”) inspected NECC and found vials of steroids filled with enough floating contamination to be visible to the human eye.² These NECC steroid shots were distributed primarily to treat back pain, but the patients who received them were injected with foreign matter containing the deadly fungi *Exserohilum rostratum* or *Aspergillus fumigatus*.³ The earliest reported death from fungal meningitis caused by NECC was seventy-eight-year-old Kentucky Circuit Judge Eddie C. Lovelace.⁴ Judge Lovelace received three tainted steroid shots in July and August of 2012.⁵ In September, after experiencing confusion and dizziness, Judge Lovelace collapsed in his driveway on his way to pick up the morning paper.⁶ Fungal meningitis from the shots had spread to Judge Lovelace’s brain and caused a stroke.⁷ He passed away on September 17, 2012, just five days after the collapse.⁸ When such incidents of fungal meningitis became more widespread, the public and Congress demanded answers

1. *The Fungal Meningitis Outbreak: Could It Have Been Prevented?: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy & Com.*, 112th Cong. (2012) [hereinafter *House Hearing*] (statement of Dr. Margaret Hamburg, Comm’r, Food & Drug Administration); *Multistate Fungal Meningitis Outbreak Investigation*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hai/outbreaks/meningitis.html> (last updated Aug. 5, 2013).

2. Denise Grady et al., *In a Drug Linked to a Deadly Meningitis Outbreak, a Question of Oversight*, N.Y. TIMES (Oct. 12, 2012), <http://www.nytimes.com/2012/10/05/health/news-analysis-a-question-of-oversight-on-compounding-pharmacies.html>.

3. Jeffrey M. Drazen et al., *Compounding Errors*, NEW ENG. J. MED. (Dec. 20, 2012), <http://www.nejm.org/doi/full/10.1056/NEJMe1213569>.

4. Adam Tamburin, *Meningitis Outbreak’s First Victim Likely Was Kentucky Judge*, TENNESSEAN (Oct. 5, 2012), <http://www.tennessean.com/article/20121005/NEWS07/310060004/>.

5. Elizabeth Cohen, *Wife ‘Heartbroken’ at Death Blamed on Meningitis*, CNN (Oct. 16, 2012), <http://www.cnn.com/2012/10/15/health/meningitis-lovelace/index.html>.

6. *Id.*

7. *Id.*

8. *Id.*

from the FDA regarding its oversight of compounding pharmacies.⁹ How could such a devastating outbreak occur on the FDA's watch? Moreover, how could the agency explain its failure to take action after it sent a warning letter to NECC in 2006 regarding similar concerns?¹⁰

The FDA has described pharmacy compounding as "an age-old practice in which pharmacists combine . . . ingredients to create unique medications that meet specific needs of individual patients."¹¹ Indeed, the longstanding importance of compounding is illustrated by the very symbol of the pharmacy: the mortar and pestle.¹² Traditional compounding pharmacies are small-scale operations that meet specific patient needs that commercially manufactured drugs cannot meet, such as preparing a drug in liquid rather than tablet form for a child who cannot swallow pills.¹³ Other noncommercial formulations created by traditional compounding pharmacies involve removing allergens, dyes, or preservatives from products, changing doses, or adding flavoring to a product.¹⁴ The unique medications are traditionally created only upon receiving a prescription from a physician or other authorized prescriber.¹⁵ Historically, these traditional compounding pharmacies have been regulated by state pharmacy boards.¹⁶

Traditional compounding pharmacies differ from commercial drug manufacturers, which are characterized by extensive product development, high-volume drug production, distribution of drugs without prescriptions, and sophisticated marketing techniques. In the early 1990s, however, some large-scale compounding pharmacies

9. *Id.*; STAFF OF S. COMM. ON HEALTH, EDUC., LABOR, & PENSIONS, 112TH CONG., REP. ON THE NEW ENGLAND COMPOUNDING CTR. AND THE MENINGITIS OUTBREAK OF 2012: A FAILURE TO ADDRESS RISK TO THE PUB. HEALTH 11 (2012), *available at* http://www.help.senate.gov/imo/media/doc/11_15_12%20HELP%20Staff%20Report%20on%20Meningitis%20Outbreak.pdf ("The Committee will continue its investigation to determine how this tragic failure of oversight occurred, and how it can best be prevented in the future.")

10. FDA Warning Letter to New England Compounding Center (Dec. 4, 2006), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076196.htm>.

11. U.S. DEP'T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., IS IT REALLY FDA APPROVED? 2 (2009), *available at* <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM143301.pdf>.

12. Joseph L. Fink III, *Compounding Versus Manufacturing in Pharmacy Practice: A Regulatory Challenge*, 8 J. PHARM. PRAC. 103, 103 (1995).

13. INT'L ACAD. OF COMPOUNDING PHARMACISTS, THE INTERNATIONAL ACADEMY OF COMPOUNDING PHARMACISTS RESPONDS TO MENINGITIS OUTBREAK TIED TO COMPOUNDING PHARMACY 1 (2012), *available at* <http://www.iacprx.org/associations/13421/files/IACP%20Responds%20to%20Meningitis%20Outbreak%20Release%20October%202012.pdf>.

14. *Id.*

15. *Id.*

16. Jesse M. Boodoo, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 230 (2010).

arose.¹⁷ These so-called “pirate manufacturers” develop and distribute drugs in large quantities to many states under the guise of pharmacy compounding.¹⁸ After receiving a state license as a compounding pharmacy, the pirate manufacturers regularly deliver drugs without having a patient-specific prescription from a physician.¹⁹ Pirate manufacturers seek compounding licenses from state pharmacy boards to avoid registering with the FDA as a drug manufacturer.²⁰ In this way, these entities sidestep the expensive and rigorous FDA premarket approval process that drug manufacturers are required to follow.²¹ Fundamentally, pirate manufacturers engage in large-scale compounding akin to the practices of full-fledged manufacturers, while masquerading as traditional small-scale compounders overseen merely by state pharmacy boards.²²

The development and distribution of drugs by pirate manufacturers significantly amplifies the inherent risks in pharmacy compounding.²³ Whereas the FDA’s premarket approval process requires drug manufacturers to establish the safety, efficacy, strength, quality, and purity of products, compounding pharmacies are subject only to the limited requirements of state pharmacy boards, which do not include premarket testing.²⁴ Without the FDA’s premarket approval process, compounded medications pose serious risks.²⁵ Physicians often determine that the benefits of meeting the specific needs of an individual patient outweigh these risks, but all of these inherent dangers are exponentially amplified when pirate manufacturers produce and distribute large quantities of drugs.²⁶ Whereas an improperly mixed drug from a traditional compounding pharmacy would harm only the single patient receiving the drug, an improperly mixed drug from a pirate manufacturer could harm thousands of patients.²⁷ Indeed, the fungal meningitis outbreak in

17. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002).

18. Boodoo, *supra* note 16.

19. *Id.*

20. *Id.*

21. *Id.* at 225.

22. *Id.* at 229–30.

23. *Id.* at 230.

24. *Id.* at 225.

25. *Id.*; Kevin Outterson, *Regulating Compounding Pharmacies After NECC*, NEW ENG. J. MED. (Nov. 22, 2012), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1212667>.

26. Boodoo, *supra* note 16, at 230.

27. *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1409 (7th Cir. 1990) (“A drug improperly compounded on a large scale will harm more patients than the same compounding mistake made on a smaller scale.”).

2012–13 shows how contamination from only one compounding pharmacy can lead to deadly consequences on a large scale.²⁸

Whether the FDA could have prevented this meningitis outbreak necessarily depends upon the scope of its authority to regulate compounding pharmacies like NECC. The NECC was producing large volumes of compounded steroid shots without prescriptions and thus can hardly be described as a traditional compounding pharmacy. Instead, the operations of the NECC more closely resembled pirate manufacturing. FDA Commissioner Dr. Margaret Hamburg testified at a Senate hearing that due to the complex statutory and regulatory framework governing the FDA, the FDA's authority over pirate manufacturers like NECC was "limited, unclear, and contested,"²⁹ to which a Senator quipped, "Well that's a hell of an authority."³⁰ Dr. Hamburg's tepid response was also challenged by a former FDA Chief Counsel who claimed that the "FDA already has all the authority they need to go after the [NECCs] of the world. I'm honestly shocked by how FDA is now downplaying its authority in this regard."³¹ Key players in this arena are likewise divided; some call for a new statute, while others find that unnecessary.³²

Despite this confusion, there are enough indications in the FDA's current statutory and regulatory framework to help resolve the scope of the agency's authority to regulate pirate manufacturers like NECC. This framework began with the Food, Drug & Cosmetic Act ("FDCA") in 1938 and was further developed through guidance documents, the 1997 Food and Drug Administration Modernization Act ("FDAMA"), a Supreme Court decision invalidating a provision of the FDAMA, and a circuit split between the Fifth and Ninth Circuits

28. *Multistate Fungal Meningitis Outbreak Investigation*, *supra* note 1.

29. *Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak: Hearing Before the S. Comm. on Health, Educ., Labor, & Pensions*, 112th Cong. (2012) [hereinafter *Senate Hearing*], available at <http://www.help.senate.gov/hearings/hearing/?id=5f5def0d-5056-a032-5297-eab57634d209> (exchange occurring at 1:09:55 on the video).

30. *Id.* (statement of Dr. Margaret Hamburg, Comm'r, Food & Drug Admin.).

31. Matthew Perrone, *FDA Regulation of Pharmacies Has Knotty History*, ASSOCIATED PRESS (Oct. 12, 2012, 8:56 PM), <http://bigstory.ap.org/article/fda-regulation-pharmacies-has-knotty-history>.

32. Patrick Howley, *Moderate Republican, Dem Lawmakers Plan to Expand the FDA*, DAILY CALLER (Dec. 18, 2012, 12:54 AM), <http://dailycaller.com/2012/12/18/moderate-republican-dem-lawmakers-plan-to-expand-the-fda/> (Senators and Representatives called for a statute that "would give the FDA broad new regulatory powers over the entire compounding industry."); *id.* ("[P]harmacies are already regulated fairly strictly. This is not a problem that arose from a lack of regulation.").

over the scope of the Supreme Court's decision.³³ At the very least, defining the FDA's authority under the current statutory scheme will help determine whether or not a new federal statute is needed.³⁴

This Note analyzes whether the FDA can regulate and enforce actions against large-scale drug compounders acting as manufacturers. Part II will briefly explain the FDA's statutory and regulatory framework in this area. Part III analyzes the FDCA, recent court decisions, and FDA regulations and warning letters to determine whether the FDA has authority to regulate large-scale compounders. After demonstrating that the FDA maintains authority to regulate large-scale compounders under the current framework and that a new statutory authority is not required, Part IV explains why the FDA must vigorously implement its present authority through a consistent and effective enforcement regime.

II. BACKGROUND

This Part traverses the FDA's history of regulating compounding pharmacies from its inception to modern day. Section A chronicles the FDA's decision to regulate new drugs, while deferring regulation of compounding pharmacies to state pharmacy boards. Next, Section B explains the rise of large-scale compounding. Sections C–E describe recent attempts by the FDA, Congress, and the federal judiciary to deal with the problem of large-scale compounding. Establishing the legal framework in which the FDA currently operates is necessary to determine whether or not it maintains authority to regulate large-scale compounding pharmacies.

A. Early FDA Regulation of New Drugs and Deference to State Regulation of Compounding Pharmacies

Although Congress created the FDA in 1906 to regulate misbranded and adulterated drugs, the agency was not given the power of premarket review until 1938. That year, the country was reeling from the *Sulfanilamide* public health crisis, which was at least as devastating as the fungal meningitis outbreak of 2012.³⁵ The

33. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361–66 (2002); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 408–09 (5th Cir. 2008).

34. *Mukasey*, 536 F.3d at 399, 408–09.

35. JEFFREY N. GIBBS & PAMELA J. FURMAN, AM. HEALTH LAWYERS ASS'N, HEALTH LAW PRACTICE GUIDE § 16:2 (2012); JAMES T. O'REILLY & KELLIE ANN MOORE, FOOD AND DRUG ADMINISTRATION § 13:74 (3d ed. 2012); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1758 (1996); Outtersson, *supra* note 25.

Sulfanilamide disaster was caused by a Tennessee drug company that distributed an untested, highly toxic chemical similar to antifreeze, which resulted in over 100 deaths.³⁶ In response, Congress expanded the FDA's authority under the FDCA by authorizing federal regulation of "new drugs." The 1938 FDCA amendments required manufacturers to receive premarket approval from the FDA before marketing any new drugs.³⁷

While products manufactured by drug companies were clearly new drugs subject to the FDCA, it is less certain whether medications created by compounding pharmacies were covered.³⁸ At the time of the FDCA's enactment, half of all drugs in the United States were compounded; however, there was no mention of pharmacy compounding in the entire Act.³⁹ The first reference to compounding was a brief provision added by the Drug Amendments of 1962, which exempted pharmacies that "compound" from certain registration requirements.⁴⁰

The FDA also ignored compounding pharmacies in practice. For the first fifty years following the enactment of the FDCA, the FDA relied on state pharmacy boards to regulate compounding pharmacies.⁴¹ Thus, throughout this fifty-year period of deference, the question of whether the FDA actually maintained the authority to regulate compounding pharmacies remained open.⁴²

Nevertheless, the FDA eventually decided to target compounding pharmacies functioning as manufacturers. In 1978, the FDA took action against a chain of ten Florida acne treatment clinics that also produced medications.⁴³ The FDA claimed that the clinics engaged in manufacturing rather than compounding because they produced a large volume of drugs and compounded them on a wide-

36. GIBBS & FURMAN, *supra* note 35; Merrill, *supra* note 35.

37. Merrill, *supra* note 35.

38. 21 U.S.C. § 321(p)(1) (2012) (defining "new drug" as "[a]ny drug . . . the composition of which . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . ."). For more discussion of the definition of new drug, see Boodoo, *supra* note 16, at 231, and *infra* Part III.A.1.

39. Boodoo, *supra* note 16, at 231 ("[T]he original act featured no language specifically directed at the practice.").

40. Drug Amendments of 1962, Pub. L. No. 87-781, 7 Stat. 781; see *infra* Part III.B for more discussion of the registration exemption provision.

41. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 369 (2002) ("For approximately the first 50 years after the enactment of the FDCA, the FDA generally left regulation of compounding to the states.").

42. *Id.* at 362.

43. Fink, *supra* note 12, at 105.

scale basis, rather than for specific patients.⁴⁴ Soon thereafter, two district court judges sided with the FDA and held that the clinics were not exempt from FDA jurisdiction because they engaged in activities that went far beyond traditional pharmacy practices.⁴⁵ One judge outlined several factors that courts should use to determine whether a pharmacy was involved in compounding or manufacturing, including whether the firm solicited purchases, maintained significant out-of-state business, lacked a one-on-one relationship with patients, or offered only a single product.⁴⁶

B. The Rise of Large-Scale Compounding and the FDA's Response

In the late 1980s and early 1990s, the FDA witnessed a growing number of pharmacies engaged in large-scale drug distribution under the guise of traditional compounding, which led the FDA to reevaluate its quiescent role in the regulation of compounding pharmacies.⁴⁷ The FDA also observed compounding pharmacies increase their marketing activities and begin producing exact copies of FDA-approved drugs.⁴⁸ In 1992, the FDA responded to such practices by issuing a Compliance Policy Guide ("1992 CPG") to compounding pharmacies and FDA field staff that threatened to exercise the agency's authority over these large-scale compounding pharmacies.⁴⁹ Specifically, the 1992 CPG explained that the FDA would exercise its enforcement discretion "when the scope and nature of a pharmacy's activity raises the kinds of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the [FDCA]."⁵⁰

In addition to asserting the FDA's authority over compounding pharmacies, the 1992 CPG also enumerated a list of activities that the FDA would consider when determining whether to initiate action against a compounding pharmacy. The nine activities included:

1. soliciting business to compound specific drugs;
2. compounding copies of FDA-approved commercial drugs;

44. *Id.*

45. *Id.* at 110.

46. *Id.* at 111.

47. Boodoo, *supra* note 16, at 232-33 ("Commentators generally cite the rise of compounding-disguised-manufacturing as the single most important factor behind the FDA's renewed interest.")

48. *Id.* at 232.

49. U.S. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE 7132.16, MANUFACTURE, DISTRIBUTION AND PROMOTION OF ADULTERATED, MISBRANDED, OR UNAPPROVED NEW DRUGS FOR HUMAN USE BY STATE-LICENSED PHARMACIES, MAR. 16, 1992 [hereinafter 1992 CPG].

50. *Id.*

3. using source ingredients not made in FDA-approved facilities;
4. using source ingredients that do not meet official compendia requirements;
5. using commercial-scale manufacturing or testing equipment for compounding;
6. compounding inordinate amounts of drugs in anticipation of receiving prescriptions relative to the amounts of drugs compounded after receiving valid prescriptions;
7. offering compounded products at wholesale or for other commercial entities to resale;
8. distributing inordinate amounts of compounded drugs out of state; and
9. failing to operate in compliance with state law regulating pharmacy practice.⁵¹

The 1992 CPG concluded by listing the range of enforcement actions available against compounding pharmacies, including warning letters, injunctions, and criminal charges, which the FDA can take upon discovery of any of the nine listed activities.⁵²

The 1992 CPG stated that traditional compounding activities, where compounders “manipulate[] reasonable quantities of drugs upon receipts of a valid prescription for an individually identified patient from a licensed practitioner,” were not the subject of the guidance document.⁵³ Nonetheless, pharmacy lobbyist groups perceived the guidance document as a fundamental threat to professional autonomy, representing a potentially seismic increase in federal regulation of compounding pharmacies.⁵⁴

In reaction to the 1992 CPG, the American Pharmaceutical Association and the International Academy of Compounding Pharmacists lobbied Congress and the FDA to eliminate federal oversight of compounding pharmacies.⁵⁵ This campaign led to the introduction of the Pharmacy Compounding Preservation Act of 1994.⁵⁶ The bill received initial support but was ultimately defeated due to resistance from the FDA and the Democrats in Congress⁵⁷

51. *Id.*; Boodoo, *supra* note 16, at 233.

52. 1992 CPG, *supra* note 49.

53. *Id.*

54. Boodoo, *supra* note 16, at 234; Fink, *supra* note 12, at 110.

55. Boodoo, *supra* note 16, at 234.

56. H.R. 598, 104th Cong. (1995).

57. Boodoo, *supra* note 16, at 234.

The FDA also encountered litigation relating to the validity of the 1992 CPG itself.⁵⁸ A group of pharmacies sued the FDA claiming that the 1992 CPG was invalid because it was a “substantive rule” issued in violation of the notice-and-comment requirements of the Administrative Procedure Act.⁵⁹ However, in 1995, the Fifth Circuit held that the 1992 CPG was a “policy statement” or an “interpretive rule,” neither of which needs to be promulgated through notice-and-comment rulemaking.⁶⁰ In upholding the validity of the 1992 CPG, the Fifth Circuit emphasized that the FDA issued warning letters prior to the 1992 CPG and that the document “merely provides guidance on an old problem—unregulated drug manufacturing.”⁶¹ Nonetheless, in response to public resistance to the 1992 CPG, the FDA was hesitant to enforce the guidance document.⁶²

C. Congress, the Ninth Circuit, and the Supreme Court Attempt to Clarify FDA Authority

The lobbying and litigation efforts against the 1992 CPG prompted Congress to attempt to clarify the FDA’s role in the regulation of compounding pharmacies. After a lengthy legislative debate, Congress passed the Food and Drug Administration Modernization Act in 1997, which amended the FDCA.⁶³ The FDAMA added § 503A to the FDCA, entitled “Pharmacy Compounding.”⁶⁴ This section sought to clarify the FDA’s regulation of compounding pharmacies whose activities went beyond the scope of traditional pharmacy practices.⁶⁵

FDCA § 503A created a narrow exemption from the Act’s regulations of new drugs for compounded drugs that satisfied seven requirements.⁶⁶ These requirements were largely derived from the list of nine activities identified in the 1992 CPG that the FDA considered

58. *Prof’ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593–95 (5th Cir. 1995).

59. *Id.* at 594.

60. *Id.* at 602.

61. *Id.*

62. Boodoo, *supra* note 16, at 234; Fink, *supra* note 12, at 110.

63. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 127, 111 Stat. 2296, 2328 (1997) (codified at 21 U.S.C. § 353a (2012)).

64. *Id.*

65. OFFICE OF CONGRESSMAN EDWARD J. MARKEY, COMPOUNDING PHARMACIES COMPOUNDING RISK 5 (2012), available at http://interactive.snm.org/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0.pdf.

66. 21 U.S.C. § 353a.

when determining whether to exercise its enforcement discretion.⁶⁷ The seven requirements for exemption included the following:

1. Drugs must be compounded for an individual patient based on a prescriber's prescription or in limited quantities before receipt of a prescription for an individual patient where there is an established physician-pharmacist relationship.⁶⁸
2. Drugs must be compounded using approved ingredients or bulk substances.⁶⁹
3. Drugs must not be compounded that copy a drug product that has been removed from the market for safety or effectiveness problems.⁷⁰
4. Copies of commercially available drug products must not be compounded regularly or in inordinate amounts.⁷¹
5. Drugs must not be listed on an FDA list of drug products that present demonstrable difficulties for compounding.⁷²
6. The pharmacy must not distribute more than five percent of the total prescription orders dispensed out of state.⁷³
7. A drug may only be compounded if the pharmacy does not advertise or promote the drug.⁷⁴

FDCA § 503A created a safe harbor for traditional compounding pharmacies that was more clearly defined than the 1992 CPG. Specifically, § 503A imposed a ceiling on out-of-state drug distribution; any amount distributed over the five percent out-of-state maximum caused the compounding pharmacy to lose its exemption.⁷⁵ Also, § 503A allowed some anticipatory compounding for individual patients if the pharmacy has an established relationship with the prescribing physician, whereas the 1992 CPG stated that pharmacies could only compound drugs upon receipt of a patient-specific prescription.⁷⁶ The implication is that the FDA has authority to regulate compounding pharmacies that fall outside of this safe harbor.

Almost immediately after its passage, litigants challenged the validity of § 503A by focusing on the prohibitions on advertising and

67. Boodoo, *supra* note 16, at 235.

68. 21 U.S.C. § 353a(a).

69. *Id.* § 353a(b)(1)(A)–(B).

70. *Id.* § 353a(b)(1)(C).

71. *Id.* § 353a(b)(1)(D).

72. *Id.* § 353a(b)(3)(A).

73. *Id.* § 353a(b)(3)(B).

74. *Id.* § 353a(a), (c); Boodoo, *supra* note 16, at 235.

75. 21 U.S.C. § 353a(b)(3)(B).

76. *Id.* at § 353a(a); 1992 CPG, *supra* note 49.

promoting drugs.⁷⁷ A group of compounding pharmacies sued the FDA in 1998 claiming that the advertising restrictions violated their First Amendment rights.⁷⁸ In *Western States Medical Center v. Shalala*, the Ninth Circuit sided with the pharmacies and held that the advertising restrictions were an impermissible limitation on commercial free speech.⁷⁹ The Ninth Circuit not only struck down the provision restricting advertising, but it also struck down the rest of § 503A because it determined that the requirements were interdependent.⁸⁰

In 2002, the Supreme Court in *Thompson v. Western States Medical Center* affirmed the Ninth Circuit's holding that the provisions restricting advertising violated the First Amendment, but the Court did not explicitly rule on the severability issue.⁸¹ The Court determined that the FDA could achieve its goal of "drawing a line between compounding and large-scale manufacturing" through non-speech-related means, including restricting the quantity of compounded drugs that could be produced or restricting the use of manufacturing equipment.⁸² The dissent argued that the prohibition on advertising was constitutional and that Congress could not achieve its safety objectives through less restrictive means.⁸³ Furthermore, the dissent believed that the majority undervalued Congress's interest in protecting public health, explaining that allowing advertising would increase the risks associated with compounded drugs, which could cause "infection, serious side effects, or even death."⁸⁴

D. A Murky Mixture: The FDA's Response to the Supreme Court and the Fifth Circuit's Disagreement with the Ninth Circuit

After *Thompson*, the FDA and compounding pharmacies confronted a confusing and uncertain regulatory realm. Before the Supreme Court's decision, the FDA had promulgated regulations under § 503A, set up a Pharmacy Compounding Advisory Committee, and sent warning letters to pharmacies based on violations of § 503A. However, the Court's decision in *Thompson* forced the FDA to state

77. 21 U.S.C. § 353a(a), (c).

78. *W. States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1291 (D. Nev. 1999).

79. 238 F.3d 1090, 1097–98 (9th Cir. 2001).

80. *Id.*

81. 535 U.S. 357, 366, 377 (2002).

82. *Id.* at 372.

83. *Id.* at 385 (Breyer, J., dissenting).

84. *Id.* at 382–83.

that “all of section 503A is now invalid.”⁸⁵ In order to provide stability and reassert authority over large-scale compounding, the FDA issued a Compliance Policy Guide in 2002 (“2002 CPG”).⁸⁶ This guide was a reissuance of the 1992 CPG with minor changes.⁸⁷ The 2002 CPG removed the two factors from the 1992 CPG that pertained to advertising restrictions and out-of-state distribution of compounded drugs.⁸⁸ In the mid-2000s, the FDA initiated enforcement activities based on the 2002 CPG and the FDCA.⁸⁹ From the issuance of the 2002 CPG through the end of 2007, the FDA issued twenty-eight warning letters to compounding pharmacies and conducted numerous investigations.⁹⁰

In July 2008, the temporary stability that existed from nationwide application of the 2002 CPG was interrupted by a Fifth Circuit decision, *Medical Center Pharmacy v. Mukasey*, that resurrected significant provisions of § 503A of the FDCA.⁹¹ First, the Fifth Circuit held that compounded drugs are covered under the definition of new drug under the FDCA and are subject to FDA jurisdiction.⁹² The Fifth Circuit then analyzed the severability question and, relying heavily on the existence of a severability clause

85. Boodoo, *supra* note 16; FDA Warning Letter to Med-Mart Pulmonary Services (Sept. 30, 2002), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2002/ucm145144.htm>; see also 21 C.F.R. § 14.100(c)(18) (1998).

86. U.S. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE § 460.200 (2002) [hereinafter 2002 CPG], available at <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074398.htm>; FDA Warning Letter to Carneys Drug (May 27, 2003), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2003/ucm147501.htm> (“Because of the Supreme Court decision, FDA determined that it needed to issue guidance to the field and compounding industry on what factors the agency will consider in exercising its enforcement discretion regarding pharmacy compounding.”).

87. 2002 CPG, *supra* note 86; Boodoo, *supra* note 16, at 238.

88. 2002 CPG, *supra* note 86; Boodoo, *supra* note 16, at 238.

89. See *FDA’s Electronic Reading Room – Warning Letters*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?webSearch=true&qryS tr=pharmacy+compounding&Search=Search> (last visited Sept. 1, 2013).

90. *Id.* As of February 23, 2013, the FDA’s easily accessible web page entitled “Pharmacy Compounding: FDA Actions” included the warning letters sent to compounding pharmacies from 2002–2013. As of August 8, 2013, this web page has been changed to only include warning letters sent to compounding pharmacies from 2008–2013. The updated web page omits the warning letter sent to NECC in 2006. *Pharmacy Compounding: FDA Actions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm> (last visited Sept. 1, 2013). The 2002–2007 warning letters are now more difficult to find, but are available through searching FDA’s Electronic Reading Room. *FDA’s Electronic Reading Room – Warning Letters*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?webSearch=true&qryS tr=pharmacy+compounding&Search=Search> (last visited Sept. 1, 2013).

91. 536 F.3d 383, 408–09 (5th Cir. 2008). *Mukasey* resurrected all of § 503A except for the advertising restrictions provision that was struck down by the Supreme Court. See *id.*

92. *Id.* at 395.

in the 1938 FDCA, ruled that the unconstitutional advertising restrictions were severable from the rest of § 503A.⁹³

Thus, *Mukasey* created a circuit split between the Fifth and Ninth Circuits over the severability issue.⁹⁴ The Fifth Circuit determined that the non-advertising related provisions were valid and created a narrow safe harbor for compounding pharmacies that otherwise satisfied the requirements of § 503A.⁹⁵ In response to the circuit split, the FDA applied § 503A in the Fifth Circuit (i.e., Texas, Louisiana, and Mississippi), but in the rest of the country, it applied the 2002 CPG.⁹⁶

E. Placing NECC Within the Statutory and Regulatory Landscape

The 2012 meningitis outbreak that was traced to NECC occurred in this regulatory landscape, with the Fifth Circuit governed by § 503A and the rest of the country governed by the 2002 CPG. The FDA's interaction with NECC first occurred in 2004 when state and federal investigators inspected NECC facilities.⁹⁷ After an additional inspection in 2005, the FDA sent a warning letter to NECC in December 2006, citing multiple violations of the FDCA.⁹⁸ The letter accused NECC of violating a number of the 2002 CPG enforcement factors by making copies of commercially available drug products and compounding without a valid prescription (the firm allegedly told physician offices that using a staff member's name, instead of a patient's name, was acceptable).⁹⁹ The FDA's 2006 warning letter also raised concerns about "potential microbial contamination" resulting from the "manipulation of sterile products."¹⁰⁰ After waiting almost two years to follow up, the FDA sent NECC another warning letter saying:

Your firm must promptly correct the violations noted in the December 4, 2006, Warning Letter, and establish procedures to assure that such violations do not occur. Its failure to do so may result in enforcement action including seizure of the firm's products and/or an injunction against the firm and its principals. In a future inspection, we will confirm the commitments that you made in your response. We also will verify that your firm's compounding practices are consistent with the policy articulated in the CPG, and that

93. *Id.* at 405.

94. *Id.*; *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1097–98 (9th Cir. 2001).

95. *Mukasey*, 536 F.3d at 395.

96. FDA Warning Letter to Steven's Pharmacy (Nov. 12, 2008), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048074.htm>.

97. FDA Warning Letter to New England Compounding Center, *supra* note 10.

98. *Id.*

99. *Id.*

100. *Id.*

your firm's operation is not otherwise at odds with the conditions under which the agency exercises enforcement discretion towards pharmacy compounding.¹⁰¹

This was the last communication before the meningitis outbreak in 2012. Tragically, when the FDA inspected NECC after the fungal meningitis outbreak, inspectors discovered “microbial growth” in allegedly “sterile injectable drugs.”¹⁰²

So the question remains whether the FDA actually had the authority to enforce the threats in its warning letters to NECC. The following Part explores the answer.

III. ANALYSIS

The FDA cannot prevent public health crises like the 2012 meningitis outbreak unless it has authority to regulate compounding pharmacies like NECC that function as manufacturers. This Part will analyze the FDCA and recent cases to determine if, as FDA Commissioner Hamburg opined, the agency is hampered from confronting pirate manufacturing because its authority is “limited, unclear, and contested.”¹⁰³ First, Section A will analyze whether the FDCA's definition of new drugs includes compounded drugs.¹⁰⁴ Then, Section B will determine whether the FDCA's inspection and registration exemption provisions authorize the FDA to distinguish between traditional compounding pharmacies and large-scale compounders.¹⁰⁵

A. Are Compounded Drugs New Drugs Under the Food, Drug & Cosmetic Act of 1938?

Analyzing the text of the FDCA is integral to determining the FDA's authority over compounding pharmacies.¹⁰⁶ The FDCA governs the application process and the adulteration and misbranding

101. Memorandum from the Staff of the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce to the Members of the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce 23 (Nov. 14, 2012) [hereinafter Oversight and Investigations Memorandum], available at <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/Hearings/OI/20121114/HMTG-112-HHRG-IF02-20121114-SD001.pdf>.

102. FDA Inspection Letter of New England Compounding Center (Oct. 26, 2012), available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/UCM325980.pdf>.

103. *Senate Hearing*, supra note 29 (statement of Dr. Margaret Hamburg, Comm'r, Food & Drug Administration).

104. 21 U.S.C. § 321(p) (2012).

105. *Id.* §§ 374(a), 360(g).

106. *Id.* §§ 301–450.

requirements for new drugs.¹⁰⁷ Thus, whether the FDA has jurisdiction over compounded drugs depends on whether they are new drugs under the FDCA. According to one view, the text of the FDCA, and the FDA's interpretation of it, demonstrates that compounded drugs qualify as new drugs.¹⁰⁸ But, according to another view, classifying compounded drugs as new drugs would lead to the absurd result of banning all compounded drugs.¹⁰⁹

1. FDCA Text and the FDA's Own Interpretation Show Compounded Drugs Are New Drugs

The text of the FDCA supports the view that compounded drugs are new drugs that fall under the purview of the FDA. A new drug is defined in § 201(p) of the FDCA as:

*Any drug the composition of which . . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except [older drugs that have been "grandfathered" in].*¹¹⁰

The Fifth Circuit in *Mukasey* clarified the definition as "'any drug . . . the composition of which' has not already been approved by the FDA."¹¹¹

Straightforward application of this definition to pharmacy compounding suggests that compounded drugs are new drugs. When compounders mix ingredients to create a concoction, the final product can be categorized as "any drug . . . the composition of which" has not been approved by the FDA.¹¹² The descriptor "any" in "any drug" is expansive, and, as the Fifth Circuit succinctly stated, "Compounded drugs are, after all, drugs."¹¹³ Because the definition of new drug emphasizes the composition and use of a drug, the origin of the drug—

107. *Id.* §§ 321(p), 355(b), 352.

108. *See* *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 395 (5th Cir. 2008) ("The FDA argues that the language of the FDCA's 'new drug' definition is both plain and expansive.").

109. *See id.* at 397 ("[The Pharmacies] suggest that including compounded drugs under the FDCA's 'new drug' definition would effectively outlaw the common practice of compounding . . .").

110. *Id.* (emphasis added). The provision excepting "grandfathered" older drugs states: such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use

Id.

111. *Mukasey*, 536 F.3d at 394.

112. *Id.*

113. *Id.* at 395.

whether from a pharmacy or manufacturer—does not appear to be relevant.¹¹⁴ Thus, if a compounder combines an approved drug with other ingredients to create a different substance, this substance is a new drug.¹¹⁵

Furthermore, since the definition of new drug creates specific exceptions, and since there is no specific exception for compounded drugs, Congress most likely intended to limit the exceptions to those enumerated.¹¹⁶ The definition of new drug exempts older drugs that were subject to the Food and Drugs Act of 1906 and that maintained the same labeling representations they had under that regime.¹¹⁷ A second exemption from the definition of new drug appears in FDCA § 505(i), which exempts drugs intended only for investigational use.¹¹⁸ According to a longstanding canon of statutory construction, when Congress enumerates specific exceptions to an expansive provision, then the proper inference is that Congress considered the issue of exceptions and decided to limit the exceptions in the statute to those enumerated.¹¹⁹ Thus, since Congress chose to exempt old drugs and investigational drugs, no general exemption for compounded drugs can be read into the statute.¹²⁰

The FDA's practice also indicates that the agency has long understood compounded drugs to be new drugs. In 1974, the FDA promulgated 21 C.F.R. § 310.3(h)(1)–(2), clarifying when a new drug is created.¹²¹ The FDA explained that the newness of a drug may arise by reason of “the newness for a drug use of a combination of two or more substances, none of which is a new drug,” and “the newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.”¹²² Both of these provisions apply to compounding. Under these regulations, when a pharmacist creates a new dosage form or an emulsion, a new drug results.¹²³ Thus, under the FDA's view, all compounded drugs appear to be new drugs.

114. *Id.*

115. *Id.*

116. *Id.*

117. 21 U.S.C. § 321(p)(1) (2012).

118. *Id.* § 355(i).

119. 536 F.3d at 395 (citing *United States v. Johnson*, 529 U.S. 53, 58 (2000)).

120. *Id.*

121. 21 C.F.R. § 310.3(h)(1)–(2) (1974).

122. *Id.*

123. *Id.*; Fink, *supra* note 12, at 106.

FDA warning letters to compounding pharmacies also state that compounded drugs are new drugs under the FDCA.¹²⁴ The numerous warning letters sent to compounding pharmacies in the 2000s all cite the FDCA definition of new drug as the basis of FDA's authority.¹²⁵ For example, a typical FDA warning letter to a compounding pharmacy states: "FDCA establishes Agency jurisdiction over 'new drugs' . . . [C]ompounded drugs are 'new drugs' within the meaning of [21 U.S.C. § 321], because they are not 'generally recognized, among experts . . . as safe and effective' for their labeled uses."¹²⁶ The warning letters then fortify this statement by citing cases and stating, "There is substantial judicial authority supporting FDA's position."¹²⁷ Next, the warning letters read: "[B]ecause they are 'new drugs' under the FDCA, compounded drugs may not be introduced into interstate commerce without FDA approval."¹²⁸ Finally, the authority section concludes by stating that the FDA will use its enforcement discretion based on the 2002 CPG factors and that it does not historically enforce actions against traditional compounding pharmacies.¹²⁹

Straightforward application of the FDCA's expansive definition of new drug to the act of compounding, combined with the FDA's well-supported position in its regulations and warning letters, suggests that compounded drugs are "new drugs." Thus, the FDA maintains global jurisdiction over all compounded drugs—not only the NECCs of the world, but also traditional mom-and-pop compounding pharmacies.¹³⁰

124. See, e.g., FDA Warning Letter to New England Compounding Center, *supra* note 10.

125. See, e.g., FDA Warning Letter to Newman Inc. (June 24, 2008), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048230.htm>.

126. *Id.*

127. *Id.* The Warning Letter cites *Professionals and Patients for Customized Care v. Shalala*, for additional judicial authority. 56 F.3d 592, 593 n.3 (5th Cir. 1995) ("Although the [FDCA] does not expressly exempt 'pharmacies' or 'compounded drugs' from the new drug . . . provisions, the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding."); *In re Establishment Inspection of: Wedgewood Vill. Pharmacy, Inc.*, 270 F. Supp. 2d 525, 543–44 (D.N.J. 2003), *aff'd*, *Wedgewood Vill. Pharmacy, Inc. v. United States*, 421 F.3d 263, 269 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions from the new drug . . . provisions. Neither pharmacies nor compounded drugs are expressly exempted." (citation omitted)).

128. FDA Warning Letter to Newman Inc., *supra* note 125.

129. *Id.*

130. See Bruce Patsner, *Pharmacy Compounding of Bioidentical Hormone Replacement Therapy (BHRT): A Proposed New Approach to Justify FDA Regulation of These Prescription Drugs*, 63 FOOD & DRUG L.J. 459, 464 (2008) ("FDA would have to selectively decide when to exercise its claimed global jurisdiction over a compounded prescription drug or class of drugs.").

The FDA's claim of global jurisdiction over compounding pharmacies is bolstered by the provision in the FDCA explicitly allowing the FDA to choose not to prosecute "minor violations" of the Act.¹³¹ 21 U.S.C. § 336 states that "[n]othing in this chapter shall be construed as requiring the Secretary to report for prosecution . . . minor violations of this chapter."¹³² This provision explains why, despite the fact that compounded drugs are illegal new drugs under the FDCA, the FDA can choose not to initiate enforcement actions against traditional compounding pharmacies without violating its responsibility under the Act.¹³³

Further support for the perspective that compounded drugs are new drugs comes from analyzing how the 1997 FDAMA amendments changed the original 1938 FDCA. Because § 503A of the FDAMA, without the prohibitions on advertising, is still good law in the Fifth Circuit, it can be instructive in construing the definition of new drug in the 1938 FDCA.¹³⁴ The FDAMA created an exemption from the new drug requirements, adulteration provisions, and misbranding provisions for compounded drugs that are produced through traditional compounding practices.¹³⁵ The FDAMA begins with the premise that compounded drugs fall under the definition of new drugs, but the statute then carves out a space for certain compounded drugs that meet the prerequisites for the exemption.¹³⁶ This means the 1938 FDCA could not have implicitly exempted compounding pharmacies from its purview because subsequently passing the FDAMA to create an explicit exemption for certain pharmacies would have been superfluous.¹³⁷ In short, the FDAMA could not have carved out a space for compounded drugs unless the drugs were previously new drugs under the statute.

In the three states where it applies, the FDAMA framework limits the FDA's jurisdiction over compounded drugs by creating a narrow exemption for pharmacies that satisfy certain requirements.¹³⁸ However, it does reaffirm the FDA's ability to bring enforcement actions against compounding pharmacies that function like manufacturers. The prerequisites for receiving the exemption require adherence to traditional compounding practices, including

131. 21 U.S.C. § 336 (2012).

132. *Id.*

133. *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 399 (5th Cir. 2008).

134. *Id.* at 401.

135. 21 U.S.C. § 353a.

136. *Id.*; *Mukasey*, 536 F.3d at 405.

137. 21 U.S.C. § 353a; *Mukasey*, 536 F.3d at 405.

138. 21 U.S.C. § 353a; *Mukasey*, 536 F.3d at 405.

compounding drugs for individual patients and not compounding copies of commercially available drugs—requirements that NECC never would have satisfied.¹³⁹

2. Pharmacies Argue that the History of FDA Enforcement and the FDA's "Absurd" Interpretation Suggest Compounded Drugs Cannot Be New Drugs

On the opposite extreme from the FDA's claim of global jurisdiction lies the view that all drugs created by compounding pharmacies are *per se* exempt from the definition of new drug because such companies are licensed as pharmacies rather than manufacturers.¹⁴⁰ This view finds support in *Medical Center Pharmacy v. Gonzales*, a district court decision which was later reversed by the Fifth Circuit in *Mukasey*.¹⁴¹ The *Gonzales* court sided with pharmacies by holding that "any drugs" created by the compounding process were "implicitly exempt from the new drug approval process and the definitions found in 21 U.S.C. §§ 321(p)(1) and (v)(i)."¹⁴² The district court offered no significant textual analysis of the definition of new drug; instead, it flatly asserted that it "examin[ed] relevant case and statutory law, as well as legislative intent"¹⁴³ to find that compounded drugs were not "new drugs."¹⁴⁴

Although the *Gonzales* court's holding was overturned on appeal, some commentators believe the district court's reasoning—that compounding pharmacies are not producing "new drugs" and are *per se* exempt from the requirements and prohibitions of the FDCA—could gain traction and eventually threaten the FDA's jurisdiction over compounding pharmacies.¹⁴⁵ This argument is supported by the history of the FDA's regulation of compounding pharmacies, where fifty years passed with the agency almost completely ceding

139. 21 U.S.C. § 353a; *Mukasey*, 536 F.3d at 405; *Senate Hearing*, *supra* note 29.

140. See Patsner, *supra* note 130, at 467 ("[T]here is a statutory basis . . . that a pharmacy engaged in the practice of compounding cannot, by definition, be a manufacturer, and is not subject to the manufacturing requirements of the FDCA.").

141. *Mukasey*, 536 F.3d at 392; *Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854, 868 (W.D. Tex. 2006).

142. *Mukasey*, 536 F.3d at 409 n.20; *Gonzales*, 451 F. Supp. 2d at 865 (concluding that summary judgment was "granted on [the Pharmacies'] claim that compounded drugs do not fall under the new drug definitions").

143. *Gonzales*, 451 F. Supp. 2d at 858.

144. *Id.* at 856 ("[A] declaration that drugs compounded by licensed pharmacists are not 'new drugs' . . . *per se* under 21 U.S.C. §§ 321(p)(1) and (v)(1).").

145. Boodoo, *supra* note 16, at 244 ("[I]f the FDA is correct in maintaining that the FDAMA is unseverable and invalid, then the 'new drug' question is far more difficult.").

responsibility to the states.¹⁴⁶ Surely, the argument goes, the FDCA never authorized the FDA to regulate compounding pharmacies since the FDA failed to initiate any such statutory duty for half a century. If the FDA has global jurisdiction in this area, why did it allow compounding pharmacies to produce drugs unfettered by federal regulation?

While the *Gonzales* court provided virtually no textual or logical arguments to support its *per se* exemption for compounded drugs, a more compelling rejection of the FDA's claim of global jurisdiction is that this broad interpretation leads to the absurd result that all compounding is effectively illegal.¹⁴⁷ Since the definition of new drug does not include an exemption carving out space for traditional compounding pharmacies, technically, even the patient-specific medications these small operations create would be outlawed.¹⁴⁸ The practice of extemporaneously compounding for immediate patient needs seems antithetical to the rigorous and lengthy requirements of the new drug application process. Furthermore, it would be impossible for a local hospital or outpatient pharmacy to spend the estimated \$800 million in research-and-development costs¹⁴⁹ for a new drug to achieve FDA approval. Without approval, all compounded drugs would be rendered illegal new drugs. Given the FDA's repeated recognition of the essential role that traditional compounding pharmacies serve in meeting patient needs,¹⁵⁰ it seems absurd for the FDCA to effectively outlaw compounded drugs as unapproved new drugs, despite its technical language to the contrary.

Proponents of this view have cited the elephant-in-mousehole doctrine to argue that the FDA's claim of global jurisdiction over new drugs is untenable.¹⁵¹ According to the elephant-in-mousehole

146. *Id.* at 245.

147. *Mukasey*, 536 F.3d at 388.

148. Boodoo, *supra* note 16, at 232.

149. Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 180 (2003) (estimating the total cost to bring a drug to market through the FDA premarket approval process at \$802 million).

150. See 2002 CPG, *supra* note 86 ("FDA recognizes that pharmacists traditionally have extemporaneously compounded and manipulated reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. This traditional activity is not the subject of this guidance."); FDA Warning Letter to Med-Mart Pulmonary Services, *supra* note 85 ("[T]he agency now utilizes its longstanding policy to recognize and exercise its enforcement discretion for extemporaneous compounding, where reasonable quantities of drugs are manipulated upon receipt of valid prescriptions from licensed practitioners for individually identified patients.").

151. *Mukasey*, 536 F.3d at 397 ("The Pharmacies argue, in essence, that this is an elephant-in-mousehole case.").

doctrine, Congress does not fundamentally change a regulatory scheme in vague terms.¹⁵² Applied here, Congress would have explicitly mentioned compounded drugs if it wished to broadly regulate compounding pharmacies. Congress cannot have intended to effectively outlaw compounded drugs through the broad and indefinite definition of new drug.¹⁵³ Pharmacies have argued that regulating compounded drugs through the FDCA's definition of new drug "hides an elephant in a mousehole," just like regulating nicotine through the FDCA's "drug" definition, which the Supreme Court deemed an impermissible interpretation in *FDA v. Brown & Williamson*.¹⁵⁴ In that case, the Court held that even though nicotine met the FDCA's technical definition of drug, "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."¹⁵⁵ Similarly, pharmacies claim that Congress could not have intended to outlaw compounding, a common and widespread practice in 1938, through a broad definition of new drug.¹⁵⁶

In *United States v. Franck's Lab*, a federal district court relied on the elephant-in-mousehole doctrine to reject the FDA's assertion of global jurisdiction, but the court held that pharmacies that function like manufacturers create new drugs under the FDA's purview.¹⁵⁷ The court accepted the FDA's authority to "regulate pharmacy compounding as a disguise for manufacturing"; however, it believed the FDA was attempting to "expand its statutory authority by enjoining an individual pharmacy engaged in traditional compounding."¹⁵⁸ The court analogized *Brown & Williamson* and similar cases to hold that "the elephant-in-mousehole[] doctrine is equally applicable here: it is not at all clear that Congress meant to hide the elephant of the FDA's regulation of traditional compounding in the mousehole of the FDCA's new drug approval process."¹⁵⁹ The court rejected the FDA's claim of global jurisdiction over compounding

152. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

153. *Mukasey*, 536 F.3d at 397.

154. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132–33 (2000); *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1241–42 (M.D. Fla. 2011).

155. *Brown & Williamson*, 529 U.S. at 132–33.

156. *Boodoo*, *supra* note 16, at 231 ("[T]he original act featured no language specifically directed at the practice.").

157. *Franck's Lab*, 816 F. Supp. 2d at 1241–42.

158. *Id.* at 1250.

159. *Brown & Williamson*, 529 U.S. at 132–33; *Franck's Lab*, 816 F. Supp. 2d at 1243.

pharmacies as “overreach[ing].”¹⁶⁰ Temporarily, the case created a space for traditional compounding pharmacies not acting like manufacturers; however, to the disappointment of organized pharmacy, *Franck’s Lab* was vacated on appeal and dismissed as moot.¹⁶¹

3. *Mukasey* Rejects Absurdity Argument and Confirms Compounded Drugs Are New Drugs

In *Mukasey*, the Fifth Circuit rejected the absurd-consequences argument along with the elephant-in-mousehole doctrine, pointing out that it is not absurd for the FDA to claim global jurisdiction because the FDA exercises discretion in enforcement.¹⁶² The *Mukasey* court explained that the Supreme Court’s jurisprudence guided courts not to infer an absurd result from a “maximalist interpretation” of FDA authority when the authority is tempered by enforcement discretion.¹⁶³ Furthermore, the court in *Mukasey* determined that the factors from the 2002 CPG, where the FDA draws the line between traditional compounding pharmacies and large-scale compounders, effectively standardized the FDA’s enforcement discretion.¹⁶⁴ In short, the court accepted the FDA’s authority to regulate all compounded drugs, so long as the FDA does not regulate traditional compounders.¹⁶⁵ Pharmacies have described this regulatory regime as requiring them to “live in sin,” where their businesses’ viability depends on “the FDA’s good graces.”¹⁶⁶

The *Mukasey* court also rejected the argument that the legislative history behind the 1938 FDCA shows that Congress did not intend the statute to cover pharmacies.¹⁶⁷ The pharmacies cited legislative statements to show that Congress only intended to cover manufacturers.¹⁶⁸ For instance, one U.S. Representative stated, “Pharmacists are licensed to compound and dispense drugs But there is no such control to prevent incompetent drug manufacturers

160. *Franck’s Lab*, 816 F. Supp. 2d at 1250.

161. *Id.*, vacated appeal dismissed, United States v. Frank’s Lab, Inc., No. 11-15350-BB (11th Cir. Oct. 18, 2012); see also Joint Motion to Vacate and Dismiss as Moot at 3, *Franck’s Lab*, 816 F. Supp. 2d 1209 (No. 11-15350-BB), available at <http://www.hpm.com/pdf/blog/Francks%20Motion%20to%20Dismiss%20Appeal.pdf>.

162. *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 399 (5th Cir. 2008).

163. *Id.*

164. *Id.*

165. *Id.*

166. *Id.* at 400.

167. *Id.* at 397.

168. *Id.*

from marketing any kind of lethal poison.”¹⁶⁹ Another statement from testimony at a Senate subcommittee hearing explained, “Regulations governing . . . the practice of pharmacy by pharmacists are very strict, but the privileges of unlicensed persons operating outside of pharmacies are so extensive that the public enjoys little protection in the matter of sales of packaged medicines.”¹⁷⁰ However, the court in *Mukasey* said the statements only showed Congressional intent to regulate drug manufacturing, not intent to exempt pharmacies *per se*.¹⁷¹ The court explained that these statements are consistent with the FDA drawing the line between small-scale and large-scale compounders and deciding to regulate the latter.¹⁷² Furthermore, the court explained that “statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils”—here, pharmacies that function as drug manufacturers.¹⁷³

In sum, none of the main arguments raised by pharmacies have merit. First, pharmacies cite *Gonzales* to argue that compounded drugs are *per se* exempt from the definition of new drug because the FDCA pertains to registered manufacturers and not licensed pharmacies.¹⁷⁴ However, *Gonzales* relied on conclusory arguments and has since been overturned.¹⁷⁵ Second, pharmacies may cite *Franck’s Lab* to invoke the elephants-in-mousehole doctrine and argue that a space exists for traditional compounding pharmacies that the FDA cannot reach.¹⁷⁶ However, *Franck’s Lab* made clear that the space it created did not protect large-scale compounders, and regardless, the case was vacated on appeal.¹⁷⁷ Thus, pharmacies are most likely stuck with *Mukasey*, whereby pharmacies “live in sin” and the FDA’s global jurisdiction is only tempered by its enforcement discretion.¹⁷⁸ Of course, firms in the Fifth Circuit that meet the traditional-compounder prerequisites for the FDAMA exemption avoid the watchful eye of FDA global jurisdiction.¹⁷⁹ Either way, under global

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.*

174. *Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854, 856 (W.D. Tex. 2006).

175. *Id.* at 858; *see also Mukasey*, 536 F.3d at 408–09.

176. 816 F. Supp. 2d 1209, 1243 (M.D. Fla. 2011).

177. *Id.*, *vacated appeal dismissed*, *United States v. Frank’s Lab, Inc.*, No. 11-15350-BB (11th Cir. Oct. 18, 2012); *see also* Joint Motion to Vacate and Dismiss as Moot at 3, *Franck’s Lab*, 816 F. Supp. 2d 1209 (No. 11-15350-BB), *available at* <http://www.hpm.com/pdf/blog/Francks%20Motion%20to%20Dismiss%20Appeal.pdf>.

178. *Mukasey*, 536 F.3d at 399.

179. *Id.* at 408–09.

jurisdiction with enforcement discretion or with a narrow traditional-compounder exemption, it is clear that large-scale compounded drugs fall under the definition of new drug and can be regulated by the FDA.

B. Exemptions from Inspection and Registration Requirements Show the FDCA Draws a Line Between Traditional Compounding Pharmacies and Large-Scale Compounders

Additional FDCA provisions show that the statute authorizes the FDA to regulate pirate manufacturers in particular. While the definition of new drug suggests that the FDA has global jurisdiction over compounded drugs, the only two provisions in the FDCA that directly reference “compounding”—the inspection and registration provisions¹⁸⁰—show Congress’s intention to create a space for traditional compounding pharmacies and to still allow the FDA to regulate large-scale compounders. These inspection and registration provisions were enacted in 1962 and remain good law in all jurisdictions.¹⁸¹ The inspection provisions authorize the FDA:

[T]o enter, at reasonable times, any factory, warehouse, or establishment in which . . . drugs . . . are manufactured, processed, packed, or held, for introduction into interstate commerce [and] to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.¹⁸²

The statute then explains that the FDA can inspect “all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether . . . drugs . . . are adulterated or misbranded within the meaning of this chapter.”¹⁸³ However, this records provision is followed by an exemption provision, § 374(a)(2)(A), excluding “pharmacies which maintain establishments in conformance with any applicable local laws” and “which do not . . . manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.”¹⁸⁴

In *Wedgewood Village Pharmacy v. United States*, the Third Circuit analyzed this language and emphatically held that the FDCA authorizes FDA inspections of pharmacies.¹⁸⁵ The pharmacy in that

180. 21 U.S.C. §§ 374(a), 360(g) (2012).

181. Drug Amendments of 1962, Pub. L. No. 87-781, 7 Stat. 781 (1962).

182. 21 U.S.C. § 374(a).

183. *Id.*

184. *Id.* § 374(a)(2)(A).

185. 421 F.3d 263, 270 (3d Cir. 2005).

case claimed that pharmacies were completely exempt from all FDA inspections because it viewed the exemption in § 374(a)(2)(A) as all-encompassing.¹⁸⁶ But the Third Circuit explained that if pharmacies meet the prerequisites for the exemption, then they are only exempted from enhanced records inspections and are still subject to the FDA's general inspection authority over "any factory, warehouse, or establishment in which . . . drugs . . . are manufactured, processed, packed, or held, for introduction into interstate commerce."¹⁸⁷ The court emphasized that pharmacies did not receive a categorical exemption by saying, "It is therefore clear that the text of § 374(a) authorizes the FDA to inspect pharmacies."¹⁸⁸

Furthermore, the Third Circuit held that the pharmacy did not meet the prerequisites of the narrow exemption because it was functioning like a manufacturer rather than a traditional compounding pharmacy.¹⁸⁹ To receive the exemption under § 374(a)(2)(A) the pharmacy must not "compound . . . drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail."¹⁹⁰ The court agreed with the FDA that since the pharmacy was selling large volumes of drugs without specific prescriptions for individual patients, it failed to meet the condition that it only compound in the regular course of dispensing or selling drugs at retail.¹⁹¹ The court rejected the pharmacy's view that the volume of compounding was immaterial; otherwise, "much of the FDCA would become a nullity" because a pharmacy "could essentially act as a commercial drug manufacturer and totally circumvent the approval requirements of the FDCA."¹⁹² Thus, although traditional compounding pharmacies are exempted from enhanced records inspections, a pharmacy that functions as a manufacturer receives no exemption and is subject to inspection at the discretion of the FDA.

The second provision in the FDCA that clearly references compounding pharmacies is an exemption for certain pharmacies from the FDA's registration requirement.¹⁹³ The registration requirement in § 510 of the FDCA requires that "every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug . . . shall immediately register with the

186. *Id.* at 269.

187. *Id.* at 270.

188. *Id.*

189. *Id.* at 274.

190. 21 U.S.C. § 374(a)(2)(A) (2012).

191. *Wedgewood Vill. Pharmacy*, 421 F.3d at 274.

192. *Id.*

193. 21 U.S.C. § 360(g).

Secretary.”¹⁹⁴ However, some entities are exempted from the registration requirement including “pharmacies . . . which do not . . . compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail.”¹⁹⁵ The prerequisites for the registration exemption mirror those of the enhanced records-inspection exemption.¹⁹⁶ Due to this parallelism, the reasoning of *Wedgewood* should apply here as well. Accordingly, pharmacies that function as manufacturers, through selling large volumes of medication without prescriptions or through selling drugs to another pharmacy at wholesale, will not satisfy the prerequisite to only sell drugs at retail in the regular course of business.¹⁹⁷

The conclusion from analyzing the FDCA’s definition of new drug is that there is no general exemption for compounding pharmacies from the FDCA. Also, the analysis shows the narrow inspection and registration exemptions do not apply when a pharmacy is functioning as a manufacturer. The CEO of the International Academy of Compounding Pharmacists reached a similar conclusion in a statement prepared for the same Senate Hearing where FDA Commissioner Hamburg was interrogated: “In short, a pharmacy engaged in manufacturing is subject to the same laws, inspections, restrictions, and penalties as a commercial drug manufacturer.”¹⁹⁸

IV. A TRANSPARENT SOLUTION: THE FDA MUST EXERCISE ITS AUTHORITY OVER COMPOUNDING PHARMACIES ACTING AS MANUFACTURERS THROUGH AGGRESSIVE AND CONSISTENT ENFORCEMENT

In reaction to the 2012 meningitis outbreak, Congress, the FDA, public health officials, and many citizens called for a new statute to clarify the authority of the FDA over compounding pharmacies.¹⁹⁹ Demands for legislation are a common reaction to crises.²⁰⁰ Commissioner Hamburg testified that the FDA itself seeks a “legislative framework” to pursue compounding pharmacies acting as

194. *Id.* § 360(c).

195. *Id.* § 360(g).

196. Fink, *supra* note 12, at 107.

197. *See Wedgewood Vill. Pharmacy*, 421 F.3d at 274; Fink, *supra* note 12, at 107.

198. INT’L ACAD. OF COMPOUNDING PHARMACISTS, *supra* note 13, at 15.

199. *Senate Hearing*, *supra* note 29.

200. Outterson, *supra* note 25 (“Food and Drug Administration . . . rules are often forged in crisis.”).

manufacturers.²⁰¹ In actuality, within the current framework, the FDA already maintains authority over pirate manufacturers. On first inspection, the existing regulatory and statutory framework—multiple amendments to the FDCA, the Supreme Court invalidating statutory provisions based on First Amendment violations, a circuit split over severability, and multiple guidance documents from the FDA—could feel like trying to see through one of NECC’s murky vials. However, this Note has demonstrated that the FDA maintains authority over large-scale compounding pharmacies and, therefore, no new legislation is required.

The 1938 FDCA and its subsequent amendments in 1962 and 1997 authorize the FDA to take enforcement actions against drug manufacturers that are operating under the guise of pharmacy compounders.²⁰² Under either the FDAMA (in the Fifth Circuit) or the 2002 CPG (everywhere else), the FDA can “draw a line between small-scale compounding and large-scale drug manufacturing.”²⁰³ The text of the FDCA shows that compounded drugs are new drugs, while creating a space for traditional compounding pharmacies through exemptions from registration and inspection requirements.²⁰⁴ The FDAMA creates a safe harbor from the application, adulteration, and misbranding provisions for new drugs if and only if a pharmacy operates as a traditional compounding pharmacy.²⁰⁵ This reinforces the view that “Congress intended that the FDCA, both in its original form and as amended, allow the FDA broad enforcement powers to fulfill its mandate that it protect the public from unsafe medication.”²⁰⁶

There is evidence that the FDA abdicated its responsibility in regulating NECC and preventing the 2012 meningitis outbreak. The FDA’s call for a new statute should be viewed through this lens.²⁰⁷ Before the meningitis outbreak, the FDA repeatedly asserted in warning letters and lawsuits that it had clear authority over

201. *Senate Hearing*, *supra* note 29 (statement of Dr. Margaret Hamburg, Comm’r, Food & Drug Administration).

202. 21 U.S.C. §§ 301–450 (2012).

203. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 358 (2002).

204. 21 U.S.C. §§ 321(p), 374(a), 360(g).

205. *Id.* § 353a.

206. *In re Establishment Inspection of: Wedgewood Vill. Pharmacy, Inc.*, 270 F. Supp. 2d 525, 549 (D.N.J. 2003).

207. FDA Warning Letter to New England Compounding Center, *supra* note 10.

compounding pharmacies.²⁰⁸ After the outbreak, the FDA retreated from this assertive stance and claimed its authority was ambiguous.²⁰⁹

This change in position should not be shocking given that the FDA sent a warning letter to NECC in 2006, which raised similar concerns as those that ultimately led to the outbreak.²¹⁰ In the warning letter, the FDA warned NECC that “[f]ailure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure or injunction against you and your firm.”²¹¹ After the owner of NECC wrote a letter to the FDA protesting these allegations, the FDA waited almost two years before responding.²¹² In 2008, the FDA wrote NECC saying that future inspections would occur and could result in drug seizures or an injunction if NECC did not immediately correct the violations.²¹³

Despite these clear warnings, this was the last communication between NECC and the FDA before the meningitis outbreak.²¹⁴ The FDA failed to follow through with enforcement procedures that may have prevented the outbreak.²¹⁵ After this fiasco, it is possible that the FDA changed its position regarding its authority in order to provide an explanation for its failure to take action against NECC.²¹⁶ In essence, by focusing on its allegedly unclear authority and calling for a new statute, the FDA may be diverting attention away from its failure to follow through with its stated enforcement procedures.²¹⁷

The FDA’s failure to take action against NECC is representative of the weak regulatory environment that compounding pharmacies currently face—a creature of the FDA’s own making.²¹⁸

208. See, e.g., FDA Warning Letter to Newman Inc., *supra* note 125; see also *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 395 (5th Cir. 2008) (“The FDA argues that the language of the FDCA’s ‘new drug’ definition is both plain and expansive.”).

209. *Senate Hearing*, *supra* note 29 (statement of Dr. Margaret Hamburg, Comm’r, Food & Drug Administration).

210. FDA Warning Letter to New England Compounding Center, *supra* note 10.

211. *Id.*

212. Oversight and Investigations Memorandum, *supra* note 101.

213. *Id.*

214. *Id.*

215. *Id.*

216. Letter from Pub. Citizen’s Health Research Grp. to Sec’y Kathleen Sebelius, Dep’t of Health and Human Servs. 1 (Dec. 18, 2012), *available at* <http://www.citizen.org/documents/2087.pdf> (“Commissioner Hamburg’s testimony was evasive, included numerous inaccurate statements, and reflected an ongoing concerted effort by the FDA to dodge responsibility for the agency’s policy, oversight, and enforcement failures that clearly contributed to the outbreak . . .”).

217. *Id.*

218. Letter from Public Citizen’s Health Research Group to Comm’r Margaret A. Hamburg, U.S. Food & Drug Admin. 10 (Nov. 29, 2012), *available at* <http://www.citizen.org/documents/2085.pdf>.

After recognizing potential public health concerns from compounding pharmacies functioning as manufacturers, the FDA has repeatedly responded slowly and inconsistently in following up after inspections and warning letters.²¹⁹ In some instances, the FDA issued warning letters as late as 592 and 623 days after inspecting a pharmacy.²²⁰ One pharmacy explained the self-fulfilling prophecy created by the FDA's weak enforcement: "We assume that if the potential risk to the public health were in fact dire, the FDA would not have waited 18 months to issue the [warning] letter."²²¹

The FDA can change this situation by establishing a more rigorous enforcement regime and following up with the large-scale compounders that it flags through investigations and warning letters. The FDA should publish its follow-up actions, including re-inspections and prosecution proceedings, on its website to warn other large-scale compounders of the FDA's intention to take action. Historically, the the FDA website did not identify inspections or enforcement actions taken against firms after the issuance of a warning letter, which now contributes to a weak regulatory environment.²²² By responding quickly and consistently to the pharmacies already identified as problematic, the FDA can immediately assume a strong enforcement role in this arena.

To maintain a rigorous enforcement environment, the FDA should work closely with state pharmacy boards to uncover pharmacies operating as manufacturers. Specifically, state pharmacy boards and the FDA should be jointly vigilant about identifying compounding pharmacies that produce substantial quantities of drugs, operate manufacturing equipment, distribute drugs to many states, or distribute without receiving prescriptions. The FDA can use the 2002 CPG and the FDAMA enforcement factors to effectively and consistently draw the line between valuable traditional compounding and harmful pirate manufacturing.

As the tragic meningitis outbreak of 2012 proves, weak FDA enforcement poses a dire risk to the public health. The FDA does not need a new statute to prevent future public health crises. Instead, the

219. *Id.* at 9; Oversight and Investigations Memorandum, *supra* note 101, at 23.

220. Letter from Public Citizen's Health Research Group to Comm'r Margaret A. Hamburg, *supra* note 218, at 9.

221. *Id.*; Letter from Custom Scripts Pharmacy to Emma R. Singleton, Dir., Fla. Dist., U.S. Food & Drug Admin. (Jan. 4, 2007), available at <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm171345.htm> (providing a complete response to a prior warning letter).

222. Letter from Public Citizen's Health Research Group to Comm'r Margaret A. Hamburg, *supra* note 218, at 10.

FDA must use the authority it already possesses to engage in aggressive and consistent enforcement activity of compounding pharmacies that function as manufacturers. The FDA needs to respond rapidly to potential pirate manufacturers through effective inspections. If problems are discovered, the FDA should promptly issue warning letters. If firms do not correct the problems identified in agency warning letters, the FDA needs to file injunctions or seize the drugs. The FDA can change the weak regulatory environment involving pirate manufacturers by engaging in a rigorous enforcement campaign. An aggressive enforcement regime would allow the FDA to stop future NECCs and to “fulfill its mandate [to] protect the public from unsafe medication.”²²³

V. CONCLUSION

As this Note illustrates, under current legislation, the FDA already maintains the authority to regulate compounding pharmacies that function as manufacturers. Throughout the country, the FDA can legitimately draw a line between traditional compounding pharmacies that provide a necessary service and pirate manufacturers that risk public health through widely distributing unapproved drugs. Although the statutory and regulatory history of the FDA’s authority over large-scale compounding is complex, sound legal analysis shows that the FDA can regulate these types of pharmacies. In order to avoid future public health crises like the 2012 meningitis outbreak, it is imperative that the FDA invoke its authority and implement a rigorous enforcement regime over large-scale compounding pharmacies. Only through developing a strong enforcement environment will the FDA prevent the future NECCs of the world from causing another tragedy.

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²²³ *In re* Establishment Inspection of: Wedgewood Vill. Pharmacy, Inc., 270 F. Supp. 2d 525, 549 (D.N.J. 2003).

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