

The Drug Quality and Security Act: Providing Quality, but Not Security, for Patients

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ABSTRACT: For millennia, pharmacists have used compounding to produce individualized medications that meet specific patients' needs. Because commercial drugs are not suitable for all patients, some patients rely on compounding as the only viable way to receive their medications. Since compounding pharmacies fill a unique need, the FDA has traditionally given them more freedom from regulation than drug manufacturers. Unfortunately, some drug manufacturers have masqueraded as compounding pharmacies in order to take advantage of this freedom. Such abuse has harmed patients, the most notable occasion being a 2012 meningitis outbreak caused by contaminated drugs. As a result, Congress enacted the Drug Quality and Security Act ("DQSA"). This Act was meant to increase regulation over manufacturers without overburdening compounding pharmacies. However, two provisions of the Act significantly hamper true compounding pharmacies: a ban on office use prescriptions and a severe restriction on pharmacies' ability to distribute and dispense drugs interstate. Both restrictions prevent patients from being able to access medications that they need. This Note suggests that Congress amend the DQSA to allow compounding pharmacies to distribute some office use prescriptions and remove the restriction on interstate dispensing.

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I. INTRODUCTION

When it comes to prescription drugs, one size does not fit all. For a variety of reasons, many patients cannot use the mass-produced medications dispensed in typical pharmacies.¹ These patients rely on pharmaceutical compounding—a process where a pharmacist creates an individualized medication to match a patient’s needs.² A compounding pharmacist from Texas tells a story of a young autistic patient in need of a compounded prescription:

His mom came in the store frantic, asking for help, because he would not take his medicine. It was a fight each and every day for her.

I asked her what his main challenge was with taking the medicine, and she said texture and taste. Things have to have a certain feel in

1. See *infra* Part II.A.

2. See *infra* Part II.A.

his mouth, and he likes lemon flavor – but just the right lemon flavor. So Jenny, my tech, and I went to work. It took several tries. I sat on the floor where I could be at eye level with him as we tried different versions. I cannot explain the feeling that came over me when we got it right. His whole demeanor immediately changed. His face brightened, his eyes sparkled and he just looked at me with this huge smile. It was great, and it still makes me cry five years later.³

Although compounded medications make up a very small percentage of the total number of pharmaceutical prescriptions dispensed annually, they are the only way that some patients can receive treatment.⁴

The Drug Quality and Security Act (“DQSA,” or “the Act”), which was passed in 2012, attempted to maintain the vital practice of compounding while increasing regulation over compounding pharmacies.⁵ The Act is laudable in its efforts to protect patient safety. However, the DQSA has had dire repercussions on patient access to drugs. This is because the Act restricts two perfectly valid compounding practices.

First, the DQSA prevents compounding pharmacies from producing office use prescriptions.⁶ Licensed physicians administer office use prescriptions to patients within the physician’s office.⁷ This practice is necessary in certain situations, such as when physicians need to administer drugs immediately or when drugs are too dangerous for patients to use them at home.⁸ The DQSA completely prohibits compounding pharmacies from dispensing⁹ office-use prescriptions, leaving a gaping hole in patient care that cannot be filled.¹⁰

3. *Compounding Success Stories*, PCCA, <http://www.pccarx.com/what-is-compounding/compounding-success-stories> (last visited Dec. 23, 2017).

4. See *infra* note 43 and accompanying text.

5. See *infra* Part III.

6. See *infra* Part IV.A.1.

7. See *infra* notes 122–24 and accompanying text.

8. See *infra* notes 126–27 and accompanying text.

9. This Note refers to office use prescriptions as being both “distributed” and “dispensed.” Pharmacists usually ascribe distinct meanings to these terms. See *infra* notes 165–66 and accompanying text. However, both terms have been used in regard to office use prescriptions, and it is ambiguous which is the correct one. See, e.g., *Randol Mill Pharmacy v. Miller*, 465 S.W.3d 612, 621 (Tex. 2015) (“Accordingly, in compounding the lipoic acid for Dr. Tan’s office use, the pharmacist defendants were engaged in ‘activities limited to the dispensing of prescription medicines.’” (quoting TEX. CIV. PRAC. & REM. CODE ANN. § 74.001(22) (West 2015))); Letter from C. Richard “Rick” Allen, RPH Dir., State of Ga. Drugs and Narcotics Agency, To Who it May Concern (Jan. 20, 2016), https://gbp.georgia.gov/sites/gbp.georgia.gov/files/related_files/press_release/Office%20Use%20Compounding%20Letter.pdf (describing office use prescriptions as being distributed).

10. See *infra* notes 131–36 and accompanying text.

Second, the DQSA severely limits the number of prescriptions that a compounding pharmacy can distribute¹¹ out of state.¹² Some states could face interstate distribution caps as low as five percent.¹³ Many patients rely on interstate distribution to receive their compounded medications.¹⁴ They may need to use an out-of-state compounding pharmacy because their state has a deficiency of compounding pharmacies.¹⁵ Additionally, many compounding pharmacies specialize, and there is no guarantee a specialty compounding pharmacy will be located within the borders of a patient's state.¹⁶ These patients may not be able to receive their prescriptions because of the distribution limitations.

The DQSA is a threat to patients who have relied on compounded office use prescriptions or prescriptions distributed from out-of-state compounding pharmacies. This Note proposes that Congress amend the DQSA to allow compounding pharmacies to produce a reasonable number of office-use prescriptions. This Note also argues that Congress should eliminate the restriction on out-of-state distribution of compounded prescriptions or at least raise the restriction to a reasonable percentage. Part II of this Note explains what compounding is and traces the history of compounding, and its regulation, from the ancient world to the passage of the DQSA. Part III lays out the prominent provisions of the DQSA. Part IV describes how those provisions prohibit compounding pharmacies from producing office-use prescriptions and limit interstate distribution of compounded medications. Part IV also discusses the effect these restrictions have on patients. Lastly, Part V suggests amending the DQSA in a way that continues to protect drug quality while also securing patients' access to compounded drugs.

II. BACKGROUND

A. WHAT IS COMPOUNDING?

Pharmaceutical compounding is the process of combining or altering drugs to tailor a prescription to a specific patient.¹⁷ Although the vast majority of prescription medications are commercially available, mass-produced

11. This Note frequently uses the term "distribute" to include "dispensing" in order to maintain consistency with the FDA's interpretations of these words. *See infra* note 169 and accompanying text. However, pharmacists usually ascribe distinct meanings to these terms. *See infra* notes 165–66 and accompanying text.

12. *See infra* Part IV.B.1.

13. *See infra* note 114 and accompanying text.

14. *See infra* notes 173–78 and accompanying text.

15. *See infra* text accompanying note 179.

16. *See infra* notes 180–85 and accompanying text.

17. *Compounding and the FDA: Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm> (last updated Nov. 11, 2017) (providing a definition of compounding).

medications are not feasible for all patient needs.¹⁸ For example, some patients may be unable to swallow capsules or tablets and, therefore, require alternative delivery methods.¹⁹ Compounding allows patients to receive drugs in a variety of forms, such as a liquids, lotions, troches,²⁰ suppositories, nasal sprays, or even lollipops.²¹ Additionally, some manufacturers only offer drugs in particular dosages; compounding pharmacists can prepare unique dosages so that patients do not receive too much or too little of a drug.²² Compounding can also produce medications that commercial providers do not manufacture at all.²³ Furthermore, compounding provides alternative options to patients who are allergic to dyes, preservatives, or inactive ingredients in commercial medications.²⁴ Additionally, some patients turn to compounding to combine several prescribed medications so that they can be administered simultaneously in a single delivery form.²⁵ Finally, some pharmacists use compounding to flavor medications when patients find them unpalatable.²⁶ In each of these scenarios, compounding focuses on patients with special characteristics because manufactured pharmaceuticals only meet the needs of average patients.

Pharmacists can compound medications in either a traditional pharmacy or a hospital setting.²⁷ Compounded medications are divided into two categories: sterile and nonsterile. Sterile compounds are generally medications that are injected or infused into the body or applied to the eyes.²⁸ Sterile compounds are subject to the stringent standards of the United States Pharmacopeia,²⁹ an authoritative book which provides instructions for the

18. See *id.* (explaining why certain patients need compounded prescriptions).

19. *Id.*

20. A troche is a small, circular, solid medication that dissolves when placed in the mouth. See *Troche*, DICTIONARY.COM, <http://www.dictionary.com/browse/troche> (last visited Dec. 23, 2017).

21. *Alternative Medication Forms*, PCCA, <http://www.pccarx.com/what-is-compounding/alternative-medication-forms> (last visited Dec. 23, 2017).

22. *What is Compounding?*, INT'L ACAD. OF COMPOUNDING PHARMACISTS, <http://www.iacprx.org/?page=1> (last visited Dec. 23, 2017). This can be particularly important in the case of children or infants who, because of their size, need very small dosages. See *id.*

23. *Id.* For example, some pharmaceutical companies discontinue medications that are not profitable to mass produce. *Id.*

24. *Id.*

25. *Id.* This can be beneficial for patients who struggle daily to remember which of their prescriptions they have taken. If a pharmacist compounds the prescriptions into one medication, the patient will only need to keep track of that single medication.

26. *Id.*

27. See generally Linda F. McElhiney, *Introduction to Hospital Compounding*, 10 INT'L J. PHARMACEUTICAL COMPOUNDING 245 (2006) (describing the origins of hospital compounding). Almost all hospitals engage in compounding. *What is Compounding?*, *supra* note 22.

28. Edward Lamb, *What Is Nonsterile Drug Compounding?*, VERYWELL (Apr. 13, 2017), <https://www.verywell.com/what-is-nonsterile-drug-compounding-2663873>.

29. Julie A. Golembiewski & Sheena Farragut Babin, *Safe Medication Compounding*, 28 J. PERIANESTHESIA NURSING 110, 111 (2013).

preparation of medications.³⁰ Sterile compounds are compounded in special “clean rooms,” which are separated from the outside environment in order to prevent contamination.³¹ Technicians and pharmacists who compound sterile medications must be specially trained in aseptic technique in order to maintain the purity of these medications.³² In contrast, nonsterile compounds are generally those that patients take orally or apply dermally.³³ Nonsterile compounds are subject to much more lenient standards than sterile compounds.³⁴

B. THE HISTORY OF COMPOUNDING

Compounding is not a new phenomenon, but rather the root of all modern pharmacy. Ancient civilizations compounded medications by mixing “animal, vegetable, and mineral” components.³⁵ These practices extended throughout Greece, Egypt, Rome, and Arabia.³⁶ Early remedies blended drugs with rituals intended to invoke the supernatural.³⁷ However, the work of Hippocrates made significant headway in untangling pharmacy and religion.³⁸ Still, mysticism continued to plague the practice of pharmacy through the Middle Ages.³⁹ Another blurred distinction in the ancient world was the difference in the roles of physicians and pharmacists.⁴⁰ The modern separation of disciplines did not arise until King Henry VIII issued a regulation that required physicians to be examined and ratified.⁴¹

The twentieth century changed the focus of pharmacy from compounding to mass manufacturing. In the 1920s, 80% of prescriptions

30. *Pharmacopeia*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/pharmacopoeia> (last visited Dec. 23, 2017).

31. See UNITED STATES PHARMACOPEIAL CONVENTION, UNITED STATES PHARMACOPEIA 637 (39th ed. 2016).

32. *Id.* at 645.

33. See Lamb, *supra* note 28.

34. Compare UNITED STATES PHARMACOPEIAL CONVENTION, *supra* note 31, at 626–70 (describing regulations for nonsterile compounding), with *id.* at 617–26 (describing regulations for sterile compounding).

35. JOHN F. MARRIOTT ET AL., PHARMACEUTICAL COMPOUNDING AND DISPENSING 3 (2006). Some of the drugs used in ancient compounding, such as licorice, opium, and myrrh, are still used as modern remedies. *Id.*

36. *Id.*

37. W. PAUL BRIGGS ET AL., PHARMACEUTICAL COMPOUNDING AND DISPENSING 7 (Rufus A. Lyman et al. eds., 1949). For example, in Homer’s *The Odyssey*, the enchantress Circe mixes a potion and a drug in an attempt to turn Odysseus into a swine. JOHN SCARBOROUGH, *The Pharmacology of Sacred Plants, Herbs, and Roots*, in PHARMACY AND DRUG LORE IN ANTIQUITY: GREECE, ROME, BYZANTIUM 138, 139 (2010) (citation omitted).

38. BRIGGS ET AL., *supra* note 37.

39. *Id.*

40. See *id.* (explaining that Greek physicians compounded their own medications).

41. See MARRIOTT ET AL., *supra* note 35, at 5.

were compounded.⁴² By the end of the century, scholars estimated that only one percent of prescriptions were compounded.⁴³ New developments in manufacturing catalyzed the shift from compounding to retail pharmacy.⁴⁴ Modern manufacturing allowed pharmaceutical companies to mass produce drugs, requiring far lower labor costs than compounding.⁴⁵ During this era, the pharmacist's role changed from mixing and preparing medications from scratch to dispensing pre-manufactured medications.⁴⁶ However, as mass production could not feasibly cover all patient needs, compounding pharmacists managed to retain a niche in the pharmaceutical market.⁴⁷ Today, compounding continues to be an important way for patients to receive specifically tailored medications that are not commercially available.⁴⁸

C. THE FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997

The coexistence of manufacturing and compounding has created conflict because overlap between the two has sometimes made their distinction unclear. For example, some pharmacies have engaged in the practice of mass producing drugs for reconstitution, a practice that on a small scale usually falls under the umbrella of compounding.⁴⁹ In the early 1990s, the tension over such practices began to build.⁵⁰ The FDA was worried that some pharmacies were using the pretense of compounding to bypass the

42. DAVID L. COWEN & WILLIAM H. HELFAND, *PHARMACY: AN ILLUSTRATED HISTORY* 186 (Ruth Eisenstein ed., 1990).

43. *Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients: Hearing Before the Committee on Health, Education, Labor, and Pensions on Examining State and Federal Oversight to Ensure the Safety and Quality of Drug Compounding—The Process of Mixing, Combining, or Altering Ingredients to Create a Customized Medication for an Individual Patient—by Pharmacies*, 108th Cong. (2003) (prepared statement of Steven K. Galson, M.D., MPH, Deputy Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration).

44. See Susanne A. Quallich, *Compounded Medications: Made to Order?*, 23 *UROLOGIC NURSING* 361, 361 (2003).

45. See *id.*

46. W. Thomas Smith et al., *There Is No Such Thing as a Compounding Manufacturer! (Or Is There?)*, *HEALTH LAW*, Jun. 2015 at 1, 1.

47. See James A. Sundberg, *Extemporaneous Compounding in the Hospital Pharmacy*, 1 *INT'L J. OF PHARMACEUTICAL COMPOUNDING* 314, 314-15 (1997).

48. *Id.*; see also Eyal Zur et al., *Pharmaceutical Compounding: A Valuable Unique Health Service or an Unreliable and Dangerous Field of Pharmacy?*, 35 *MED. & L.* 61, 71 (2016) (“There is a constant need for a flexible, small-scale, professional and experienced pharmaceutical system that can manufacture and dispense safe, effective and personalized medications according to physicians’ prescriptions and in relatively short turnaround times.”); *supra* Part II.A (describing the benefits of modern compounding).

49. Joseph L. Fink III, *Compounding Versus Manufacturing in Pharmacy Practice: A Regulatory Challenge*, 8 *J. PHARMACY PRAC.* 103, 104 (1995) (describing the practices of Baxter Healthcare Corporation, which came under sharp FDA scrutiny).

50. Rachael G. Pontikes, *FDA Authority Over Compounding Pharmacy*, *FOOD & DRUG L. INST. UPDATE MAG.* 42, 43 (2013).

regulations that dominated retail pharmacy.⁵¹ Under the Food, Drug, and Cosmetics Act of 1938, the FDA must approve new drugs before they can be sold to the public.⁵² As part of the approval process, manufacturers must administer stringent testing on proposed drugs.⁵³ Because of the complexity of this process, it usually takes ten years between when a manufacturer submits a new drug application and when the drug becomes available to the public.⁵⁴ Traditionally, the FDA has not considered compounding to be production of new drugs because compounded drugs are patient specific.⁵⁵ In the 1990s, the FDA was concerned that some large-scale manufacturers were hiding behind compounding-pharmacy façades, flooding the markets with new, mass-produced drugs while bypassing the rigorous testing process.⁵⁶ Although these manufacturers labeled themselves as compounding pharmacies, they did not function like traditional small-town compounding pharmacies.⁵⁷

In an attempt to curb these practices, the FDA created a Compliance Policy Guide, which outlined what activities indicated a pharmacy was mass-manufacturing medications rather than compounding them.⁵⁸ Some of these activities included: “[s]oliciting business . . . to compound specific drug products”; “[c]ompounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace”; “[o]ffering compounded drug products at wholesale to other state licensed persons or commercial entities for resale”; and “[d]istributing inordinate amounts of compounded products out of state.”⁵⁹ The Compliance Policy Guide also stated that the FDA would take action against any manufacturers hiding behind the façade of compounding.⁶⁰

The Compliance Policy Guide was a precursor to the Food and Drug Administration Modernization Act (“FDAMA”).⁶¹ The FDAMA attempted to separate compounding and manufacturing by providing specific criteria for

51. *Id.*

52. Smith et al., *supra* note 46, at 3.

53. *Id.* at 4. The testing consists of different phases, beginning with animal testing, but ultimately leading to human testing. *Id.*

54. *Id.*

55. *See id.*

56. *See id.*

57. Erika Lietzan & Mingham Ji, *Pharmacy Compounding After the Drug Quality and Security Act*, HEALTH L., Apr. 2014, at 1, 3.

58. *Id.* Compounding pharmacies responded to the Compliance Policy Guide by proposing bills that would protect compounding from FDA control, none of which passed. *See* Michelle Wilson, *Sterile Compounding Pharmacies: States that Do and Do Not Require Compliance with USP <797> Versus FDA 483s*, 50 THERAPEUTIC INNOVATION & REG. SCI. 279, 280 (2016).

59. Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 390 n.15 (5th Cir. 2008) (quoting U.S. FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., COMPLIANCE POLICY GUIDES MANUAL: SEC. 460.200, at 3–4 (2002)).

60. Pontikes, *supra* note 50.

61. *Id.* (stating that Congress codified portions of the Compliance Policy Guide when it enacted the FDAMA).

qualifying as a compounding facility. Under the FDAMA, compounded drugs were exempt from a number of FDA regulations if they met certain requirements, such as being made for individual patients, dispensed pursuant to a prescription, unsolicited, and compounded by a licensed pharmacist or physician.⁶² Compounding pharmacies could not “compound regularly or in inordinate amounts . . . any drug products that are essentially copies of a commercially available drug product.”⁶³ Neither could a compounding pharmacy distribute out of state more than five percent of the prescriptions it dispensed, unless the state in which the pharmacy was located entered into a “memorandum of understanding” with the Secretary of Health and Human Services (the “Secretary”).⁶⁴ Additionally, pharmacies could compound medications “only if the pharmacy, licensed pharmacist, or licensed physician [did] not advertise or promote the compounding of any particular drug, class of drug, or type of drug.”⁶⁵ It was this last provision of the FDAMA that drew the most attention and ultimately proved fatal to the Act.

Not long after the FDAMA was signed into law, a group of compounding pharmacies brought suit, arguing that the advertising restrictions violated their First Amendment freedom of speech.⁶⁶ The Ninth Circuit Court of Appeals addressed the FDAMA’s constitutionality in *Western States Medical Center v. Shalala*.⁶⁷ The Court found that the advertising restrictions violated the First Amendment and were therefore invalid.⁶⁸ Additionally, the Court held that the advertising restrictions were not severable from the rest of the statute, therefore, the court struck down the FDAMA in its entirety.⁶⁹ The Ninth Circuit’s decision was appealed to the Supreme Court of the United States in *Thompson v. Western States Medical Center*.⁷⁰ The Supreme Court affirmed the Ninth Circuit by finding that the FDAMA violated the pharmacies’ freedom of speech.⁷¹ However, the Supreme Court did not address the question of severability because that issue was not appealed.⁷² In response to these cases, the FDA created a new Compliance Policy Guide, which once again asserted the FDA’s opposition to manufacturing disguised

62. Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 353a(a), 111 Stat. 2296, 2328 (codified as amended 21 U.S.C. § 301 (2012)).

63. *Id.* § 353a(b)(1)(D). This is essentially the codification of the 1992 Compliance Policy Guide. *See supra* note 59 and accompanying text.

64. Food and Drug Administration Modernization Act of 1997 § 353a(b)(3)(B)(i-ii).

65. *Id.* § 353a(c).

66. *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1092 (9th Cir. 2001).

67. *See generally id.*

68. *Id.* at 1096.

69. *Id.* at 1098.

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

71. *Id.* at 377.

72. *Id.* at 366 (“Because neither party petitioned for certiorari on the severability issue, we have no occasion to review that portion of the Court of Appeals’ decision.”).

as compounding.⁷³ However, Congress did not enact any legislation to supplant the crippled FDAMA.

Although *Shalala* struck down the FDAMA in the Ninth Circuit, the FDAMA's validity in other circuits was still in question. In 2008, a group of compounding pharmacies challenged the FDA's ability to regulate compounded drugs as new drugs in *Medical Center Pharmacy v. Mukasey*.⁷⁴ The Fifth Circuit Court of Appeals found that this issue hinged on whether the FDAMA was still valid law.⁷⁵ Since the Supreme Court did not determine the severability of the advertising restriction in *Thompson*, the *Mukasey* court addressed the issue.⁷⁶ In contrast to the Ninth Circuit, the Fifth Circuit held that the advertising provision was severable, and the court upheld the rest of the FDAMA.⁷⁷ The resulting circuit split led to non-uniform enforcement of the FDAMA and left the Act's validity ambiguous in other circuits.⁷⁸ To make matters worse, the FDA did not even issue a stance on the circuit split.⁷⁹ The limits on compounding were a muddled mix of statutes, case law, and compliance policy guides, with no guarantees that pharmacies or patients were protected. This mess of regulation set the stage for tragedy.⁸⁰

D. THE 2012 MENINGITIS OUTBREAK

In September 2012, a substantial meningitis outbreak drew the attention of the Food and Drug Administration, the Centers for Disease Control, and a host of other health departments.⁸¹ The victims of the outbreak were patients who had used steroid injections dispensed by the New England Compounding Center ("NECC"), an entity that was registered as a compounding pharmacy but acted as a drug manufacturer.⁸² Seven-hundred and fifty-three patients were infected, and sixty-four died.⁸³ The outbreak affected patients from

73. Pontikes, *supra* note 50.

74. *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 392 (5th Cir. 2008).

75. *See id.* at 400.

76. *Id.* at 400–01.

77. *Id.* at 404–05.

78. Pontikes, *supra* note 50, at 44.

79. Lietzan & Ji, *supra* note 57, at 4.

80. *See* Kevin Outterson, *Regulating Compounding Pharmacies After NECC*, 367 NEW ENG. J. MED. 1969, 1971 (2012) ("It's possible that if the Supreme Court hadn't struck down Section [353a], the tragedy at [the New England Compounding Center] could have been averted.").

81. *Multistate Outbreak of Fungal Meningitis and Other Infections*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/HAI/outbreaks/meningitis.html> (last updated Feb. 18, 2016).

82. Kurt Eichenwald, *Killer Pharmacy: Inside a Medical Mass Murder Case*, NEWSWEEK (Apr. 16, 2015, 7:07 AM), <http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html>.

83. *Multistate Outbreak of Fungal Meningitis and Other Infections—Case Count*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html> (last updated Oct. 29, 2015). Victims of the outbreak experienced a variety of symptoms, ranging from headaches and nausea to strokes, epidural abscesses, and septic arthritis. *Pharmacy Compounding: Implications of the 2012 Meningitis Outbreak: Hearing of the Committee on*

twenty states.⁸⁴ During the investigation, the FDA uncovered fungal contamination in what were supposed to be sterile injections prepared by the NECC.⁸⁵ Fourteen NECC employees were arrested.⁸⁶ The NECC also faced a civil suit, which ended in a \$200 million settlement.⁸⁷

The infected patients and the NECC were not the only ones affected by the outbreak. Fear of unchecked pharmaceutical compounding gripped the public, and Congress reacted by passing the Drug Quality and Security Act (“DQSA”).⁸⁸ Congress hoped the DQSA would prevent further tragedy by

Health, Education, Labor, and Pensions on Examining Pharmacy Compounding, Focusing on Implications of the 2012 Meningitis Outbreak, 112th Cong. 14 (2015) [hereinafter *Implications Hearing*] (statement of Beth Bell, M.D., MPH). It is even possible that not all of the adverse health effects stemming from the outbreak have become apparent. *Id.*

84. See *Multistate Outbreak of Fungal Meningitis and Other Infections*, *supra* note 81. Seventeen thousand vials of the contaminated steroid had been shipped. *Lethal Medicine Linked to Meningitis Outbreak*, CBS NEWS (Mar. 10, 2013), <http://www.cbsnews.com/news/lethal-medicine-linked-to-meningitis-outbreak-10-03-2013>.

85. See *Implications Hearing*, *supra* note 83, at 19 (referencing the prepared statement of Margaret A. Hamburg, M.D.).

86. Greg Botelho, *14 Arrested in Connection with Deadly Meningitis Outbreak*, CNN, <http://www.cnn.com/2014/12/17/us/meningitis-outbreak-arrests/index.html> (last updated Dec. 17, 2014, 1:51 PM). See also generally *Preliminary Allegations*, United States v. Cadden, No. 1:14-cr-10363-RGS (D. Mass. Dec. 16, 2014), <https://www.justice.gov/file/188561/download> (alleging that fourteen NECC employees committed a variety of crimes, including racketeering, mail fraud, conspiracy, and introduction of adulterated drugs into interstate commerce). Two of the employees faced 25 charges of second degree murder. Botelho, *supra*. These two individuals, head pharmacist Barry J. Cadden and supervisory pharmacist Glenn A. Chin, were indicted for allegedly knowingly producing methylprednisolone acetate under unsafe conditions and authorizing distribution of the drug despite knowing that if the drugs were contaminated, they could kill patients. Press Release, U.S. Dep’t of Justice, *14 Indicted in Connection with New England Compounding Center and Nationwide Fungal Meningitis Outbreak* (Dec. 17, 2014), <https://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis>. Cadden was ultimately convicted of over fifty counts of racketeering and mail fraud, but he was acquitted of all murder charges. Jess Bidgood, *Compounding Pharmacy Owner Not Guilty of Murder After 60 Meningitis Deaths*, N.Y. TIMES (Mar. 22, 2017), <https://www.nytimes.com/2017/03/22/us/meningitis-new-england-compounding-center-barry-cadden.html>. Similarly, Chin was acquitted of murder but convicted for false labeling, conspiracy, racketeering, and mail fraud. Danny McDonald, *Pharmacist in NECC Meningitis Outbreak Case Acquitted of Murder*, BOSTON GLOBE (Oct. 25, 2017), <https://www.bostonglobe.com/metro/2017/10/25/chin/sSmR8IC4AZloK4HidEmGWI/story.html>.

87. *Judge Approves \$200 Million Settlement over Meningitis Outbreak*, CBS NEWS (May 20, 2015, 11:58 AM), <http://www.cbsnews.com/news/judge-approves-200-million-settlement-over-meningitis-outbreak>.

88. See Drug Quality and Security Act, Pub. L. No. 113–54, 127 Stat. 587 (2013) (codified in scattered sections of 21 U.S.C.A.). The NECC meningitis outbreak was not the only instance of patient injury due to improperly compounded medications. See *Examining Pharmaceutical Compounding, Focusing on a Proposed Legislative Solution: Hearing Before the Comm. on Health, Educ., Labor, and Pensions*, 113th Cong. 8–13 (2013) (prepared statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research at the Food and Drug Administration) (describing a variety of outbreaks caused by contaminated compounds). However, the NECC outbreak was unique in its scope, prompting new legislation in a way that these smaller incidents did not.

providing sufficient regulation over compounders that, like the NECC, were acting as manufacturers rather than pharmacies.⁸⁹

III. THE SCOPE OF THE DRUG QUALITY AND SECURITY ACT

The DQSA attempts to redraw the line between pharmacies and manufacturers, correcting the confusion that developed through the FDAMA and its messy history in the courts.⁹⁰ Congress intended the DQSA to impose stricter regulations on manufacturers, believing that they created a greater danger to public safety than pharmacies.⁹¹ Congress did not intend to smother compounding pharmacies. Congress recognized that compounding still serves a vital role in healthcare and meant to preserve the practice.⁹²

The DQSA retains much of the substance of the FDAMA, but it removed the notorious advertising restrictions.⁹³ The major addition was section 503b.⁹⁴ Whereas the FDAMA attempted to delineate the boundary between pharmacies and manufacturers by identifying a host of characteristics associated with manufacturing (such as inordinate production of commercially available drugs, solicitation of medications, significant out-of-state distribution, and production without receipt of prescription),⁹⁵ the DQSA incentivizes manufacturers to register as outsourcing facilities.

A. SECTION 503b—THE MANUFACTURER PROVISION

Under section 503b of the DQSA, manufacturers can elect to register as “outsourcing facilities” rather than compounding pharmacies.⁹⁶ Outsourcing

89. See *Implications Hearing*, *supra* note 83, at 4 (statement of Sen. Enzi) (“[The 2012 meningitis outbreak] represents a catastrophic failure by the regulatory agencies that are charged with protecting patients from unsafe drugs.”); Golembiewski & Babin, *supra* note 29 (“NECC appeared to be representing itself as a ‘compounding pharmacy,’ yet the quantities of product it produced were large and patient-specific prescriptions were not required.”).

90. See *supra* Part II.C (describing how the split between the Fifth and Ninth Circuits damaged the efficacy of the FDAMA).

91. See *Implications Hearing*, *supra* note 83, at 6–7 (statement of Sen. Roberts) (“We are here today because there have been bad actors who are using the good name of pharmacy compounding to mass produce products not approved by the FDA and provide them to patients.”).

92. See *id.* at 3 (prepared statement of Sen. Harkin) (“[D]rug compounding is essential and . . . most pharmacies that compound do so on a vastly smaller scale than NECC. We need to ensure that these pharmacists can continue to compound without a drastic increase in overhead.”); H.R. REP. NO. 115-XXX, at 67 (2017) (“In instances where a commercially manufactured drug is not appropriate for a patient for a specific reason, a compounded drug may be the difference between life and death.”).

93. Michael Gabay, *The Drug Quality and Security Act*, 49 HOSP. PHARMACY 615, 615 (2014); see also *supra* Part II.C (discussing the FDAMA and its advertising restriction).

94. Note that section 503b of the DQSA is section 353b of Title 21 of the United States Code. Likewise, section 503a of the DQSA is section 353a of Title 21 of the United States Code.

95. See *supra* notes 58–60 and accompanying text.

96. 21 U.S.C.A. § 353b(a) (West 2013).

facilities must be “under the direct supervision of a licensed pharmacist.”⁹⁷ They also must undergo regular inspections, the frequency of which depends on the number of “[r]isk factors” associated with the facility.⁹⁸ Additionally, outsourcing facilities must pay certain registration fees.⁹⁹ However, registering as an outsourcing facility provides benefits for the manufacturer. The DQSA exempts outsourcing facilities from a host of regulations,¹⁰⁰ including certain labeling requirements¹⁰¹ and restrictions on producing “new drugs.”¹⁰² These exemptions incentivize manufacturers to register as outsourcing facilities. However, the most lucrative incentive for manufacturers to register as outsourcing facilities is that outsourcing facilities can produce drugs that are not patient specific.¹⁰³ The fact that outsourcing facilities can produce non-patient-specific drugs is a major distinguishing point between outsourcing facilities and compounding pharmacies.¹⁰⁴

Although outsourcing facilities can manufacture some medications that compounding pharmacies cannot, the DQSA still imposes some limitations. Outsourcing facilities cannot ordinarily compound using bulk drugs,¹⁰⁵ although there are exceptions.¹⁰⁶ The ingredients an outsourcing facility uses must comply with the United States Pharmacopeia.¹⁰⁷ Outsourcing facilities

97. *Id.*

98. *Id.* § 353b(b)(4). The risk factors include “compliance history of the outsourcing facility”; “record, history, and nature of recalls linked to the outsourcing facility”; “[t]he inherent risk of the drugs compounded at the outsourcing facility”; and “[t]he inspection frequency and history of the outsourcing facility.” *Id.* § 353b(b)(4)(C).

99. *Id.* § 353b(a)(9).

100. *Id.* § 353b(a).

101. *See id.* (explicitly stating which sections of the Code do not apply to outsourcing facilities).

102. *See id.*

103. *See generally* 21 U.S.C. § 353(b) (2012) (containing no provisions requiring drugs produced by outsourcing facilities to be patient specific).

104. *See infra* note 113 and accompanying text (explaining that compounding pharmacies can only fill patient-specific prescriptions).

105. The Code of Federal Regulations defines bulk drugs as the same as an “active pharmaceutical ingredient” which is “any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body” but “does not include intermediates used in the synthesis of the substance.” 21 C.F.R. § 207.1 (2017).

106. 21 U.S.C.A. § 353b(a)(2) (West 2013). Two exceptions are when “the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need” and when “the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e.” *Id.* § 353b(a)(2)(A). In addition to meeting one of these two criteria, the bulk drug must also comply with an applicable monograph under a recognized compendium or pharmacopeia. *Id.* § 353b(a)(2)(B). Furthermore, the bulk drug must be “manufactured by an establishment that is registered under section 360.” *Id.* § 353b(a)(2)(C). Finally, the bulk drug substance must be “accompanied by a valid certificate of analysis.” *Id.* § 353b(a)(2)(D).

107. *Id.* § 353b(a)(3). Alternatively, the ingredients must comply with the National Formulary or another compendium of pharmacopeia that the Secretary approves. *Id.*

cannot compound drugs that are “essentially a copy of . . . approved drugs”¹⁰⁸ or that create “demonstrable difficulties for compounding.”¹⁰⁹ Finally, outsourcing facilities cannot sell any compounded drugs wholesale.¹¹⁰

B. SECTION 503A—THE COMPOUNDING PHARMACY PROVISION

Section 503a, which regulates traditional compounding pharmacies,¹¹¹ tracks closely with the FDAMA.¹¹² This provision limits pharmacies to compounding medications pursuant to patient-specific prescriptions.¹¹³ It also prevents pharmacies from distributing more than five percent of their prescriptions across state lines, unless the state in which the pharmacy is located and the Secretary enter into a memorandum of understanding.¹¹⁴

Like section 503b outsourcing facilities, section 503a pharmacies cannot regularly or inordinately compound drugs “that are essentially copies of a commercially available drug product.”¹¹⁵ They must only use ingredients that

108. *Id.* § 353b(a)(5). Although this provision exists to protect patients from unnecessary exposure to unapproved drugs, it is controversial. Because large pharmaceutical companies often use their monopolies on drugs to charge exorbitant amounts for medications, compounded versions of drugs may be the only viable option for some patients. For example, doctors prescribe hydroxyprogesterone caproate to pregnant mothers to prevent premature births. *Price of Progesterone Injection for Pregnant Women Skyrockets*, DENVER CHANNEL (Mar. 21, 2011, 9:01 AM), <http://www.the-denverchannel.com/lifestyle/health/price-of-progesterone-injection-for-pregnant-women-skyrockets>. When compounded, this medication cost mothers, on average, less than ten dollars a week. *Id.* However, in 2011 the FDA approved Makena, a mass-produced version of the same drug. *Id.* Makena cost patients up to one thousand two hundred dollars a week—a price that many patients could not afford. *Id.* After the FDA approved Makena, most compounded versions of hydroxyprogesterone caproate became copies of an approved drug. The FDA asserted its power to take action against compounding pharmacies that produced hydroxyprogesterone caproate, leaving some patients unable to receive their medication. See Press Release, U.S. Food & Drug Admin., Questions and Answers on Updated FDA Statement on Compounded Versions of Hydroxyprogesterone Caproate (The Active Ingredient in Makena) (last updated June 29, 2012), <https://wayback.archive-it.org/7993/20170113105722/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm310215.htm>; see also Letter from the FDA to Wedgewood Pharmacy (June 29, 2012), U.S. FOOD & DRUG ADMIN., <https://web.archive.org/web/20161024104619/http://www.fda.gov/downloads/NewsEvents/Newsroom/PressAnnouncements/UCM314387.pdf> (warning a compounding pharmacy that if it continued to mass produce hydroxyprogesterone caproate, the FDA would take action).

109. 21 U.S.C. § 353b(a)(6)(A).

110. *Id.* § 353b(a)(8).

111. James A. Boiani & Kim Tyrrell-Knott, *Major Changes in Drug Compounding and Drug Distribution Requirements (Part 1 of 2)*, EPSTEIN BECKER GREEN 1 (Oct. 2013), http://www.ebg-law.com/content/uploads/2014/06/58214_HCLS-Client-Alert-Drug-Compounding-and-Drug-Distribution-Requirements.pdf.

112. The major distinction is that section 503a does not contain FDAMA’s advertising restriction. See *supra* note 65 and accompanying text.

113. 21 U.S.C. § 353a(a)(2012).

114. 21 U.S.C.A. § 353a(b)(3)(B) (West 2013).

115. *Id.* § 353a(b)(1)(D). For a discussion of the controversy surrounding this provision, see *supra* note 105 (addressing controversy in the context of a nearly identical provision in section 353b).

comply with United States Pharmacopeia standards.¹¹⁶ They cannot compound drug products that have been removed from the market because they were ineffective or unsafe.¹¹⁷ However, unlike outsourcing facilities, compounding pharmacies can normally use bulk drugs to compound medications.¹¹⁸

IV. FLAWS IN THE DQSA

Congress enacted the DQSA in order to reign in manufacturers who were masquerading as compounding pharmacies. Section 503b incentivizes manufacturers to register as outsourcing facilities by allowing them to produce a wider range of medications than compounding pharmacies. However, section 503b imposes stricter regulations on outsourcing facilities than section 503a does on compounding pharmacies. Hopefully, regulating manufacturers closely will prevent tragedies like the 2012 meningitis outbreak from happening.¹¹⁹ However, although section 503b appears to fulfill congressional intent by increasing regulation of compounding manufacturers,¹²⁰ section 503a imposes heavy and unnecessary burdens on compounding pharmacies.

The DQSA prevents compounding pharmacies from engaging in some very important activities that are necessary to provide patient care. While the DQSA protects the quality of prescriptions, it also limits patient access to

116. *Id.* § 353a(b)(1)(B). An alternative is if the ingredients comply with the National Formulary. *Id.*

117. *Id.* § 353a(b)(1)(C).

118. *Id.* § 353a(b)(1)(A). Some exceptions to this rule exist. For example, compounding pharmacies cannot use bulk drug substances unless they “comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopeia chapter on pharmacy compounding” or “are components of drugs approved by the Secretary” or “appear on a list developed by the Secretary through regulations issued by the Secretary.” *Id.* § 353a(b)(1)(A)(i). Additionally, the bulk drugs must be “manufactured by an establishment that is registered under section 360” and “accompanied by valid certificates of analysis.” *Id.* § 353a(b)(1)(A)(ii)–(iii). Note that the default stance for compounding pharmacies is that bulk drugs are acceptable to use, while the default stance for outsourcing facilities is that bulk drugs are not acceptable. *Compare id.* § 353a(b)(1)(A), with 21 U.S.C.A. § 353b(a)(2) (West 2013).

119. *See supra* Part II.D (describing the 2012 meningitis outbreak).

120. The belief that section 503b adequately protects patients from compounding manufacturers is not unanimous. For example, critics have noted that registering as an outsourcing facility is a voluntary rather than mandatory process. Tyler Dinkelaker, Comment, *A False Sense of Safety: How the Drug Quality and Security Act Fails to Protect Patients from Harm*, 9 ST. LOUIS U. J. HEALTH L. & POL’Y 329, 356 (2016) (“[C]reating a *voluntary registration*, regardless of the safe harbor, has been realistically inefficient in identifying and encouraging those engaging in mass-compounding to register as an outsourcing facility.”). Additionally, section 503b’s definition of outsourcing facilities is limited to facilities “engaged in the compounding of sterile drugs.” 21 U.S.C. § 353b(d)(4)(A)(i). Some have stated that this narrow definition fails to provide adequate regulation over compounding manufacturers producing solely non-sterile medications. *See* Dinkelaker, *supra*, at 358–59.

perfectly safe prescriptions. Two ways that the Act does this is by preventing compounding pharmacies from dispensing prescriptions for office use and by severely limiting the number of prescriptions compounding pharmacies can distribute out of state.

A. OFFICE USE PRESCRIPTIONS

1. The Need and the Section 503a Ban

Office use prescriptions are a central component of compounding. Like normal prescriptions, office use prescriptions are authorized by licensed physicians.¹²¹ However, unlike normal prescriptions, office use prescriptions are not patient specific and patients do not take them home.¹²² Instead, doctors administer them to patients while the patients are in the doctor's office.¹²³ Some examples of office use prescriptions are "prefilled syringes for emergency or anesthesia use . . . and complex intravenous nutrition solutions."¹²⁴

Office use prescriptions serve very important needs in healthcare that traditional prescriptions cannot satisfy. For example, some conditions require immediate treatment, and patients cannot wait for a pharmacist to fill their prescription.¹²⁵ Office use prescriptions allow patients to immediately receive the medications they need. Additionally, some prescriptions can be very dangerous if misused, and office use prescriptions allow doctors to administer these medications without putting them into patients' hands.¹²⁶ Finally, some physicians administer office use medications during surgical procedures.¹²⁷

Prior to the DQSA, state law determined whether compounding pharmacies could distribute office use prescriptions.¹²⁸ The majority of states

121. See Smith et al., *supra* note 46, at 12.

122. See *id.* (stating that office use prescriptions are not patient specific because it would be impractical); *New Amendment May Help Save Compounded Drugs*, ALL. FOR NAT. HEALTH USA (June 16, 2015), <http://www.anh-usa.org/15975> [hereinafter *New Amendment*] ("Office use' is when a physician, in his or her office or other treatment area, administers a compounded medicinal preparation directly to a patient for the immediate treatment of a problem.").

123. *New Amendment May Help Save Compounded Drugs*, *supra* note 122.

124. Smith et al., *supra* note 46, at 12 (citation omitted).

125. *The Case for Compounded Medications for Office Use: Why Limitations on Office Use Threaten the Health and Safety of Men, Women, Children and Pets*, MYMEDSMATTER 4 (June 12, 2013), http://www.mymedsmatter.com/sites/default/files/The%20Case%20for%20Office%20Use%20061213_0.pdf [hereinafter *The Case for Compounded Medications*] (describing the use of compounded naltrexone and disulfiram to reverse overdoses).

126. *Id.* (stating that compounded benzocaine/lidocaine/tetracaine cream can be fatal if misapplied).

127. *Id.* at 4–5 (explaining that physicians use compounded anesthetics in dental and nasal procedures).

128. Ronald M. McGuff, *Drug Quality and Security Act: How It's Changing the Practice of Pharmacy and Medicine*, TOWNSEND LETTER (Oct. 2014), <https://web.archive.org/web/20160316043730/http://www.townsendletter.com/Oct2014/drug1014.html>.

allowed compounding pharmacies to produce office use prescriptions.¹²⁹ After Congress passed the DQSA, it was hotly contested whether pharmacy-produced office use prescriptions were abolished by section 503a, since section 503a does not explicitly address office use prescriptions.¹³⁰ However, the FDA has interpreted the DQSA to prohibit compounding pharmacies from filling any office use prescriptions.¹³¹ Section 503a limits compounding pharmacies to dispensing prescriptions “for an identified individual patient.”¹³² Since office use prescriptions are not written for specific patients, the FDA has taken the stance that office use prescriptions are inherently off limits to compounding pharmacies.¹³³

Several times, Congress has stated that it never intended for the DQSA to completely prevent compounding pharmacies from producing office use prescriptions.¹³⁴ Congress has called on the FDA to reform its stance on office use prescriptions to reflect this intent.¹³⁵ However, the FDA has not altered its interpretation of the DQSA, and, as a result, the DQSA continues to prevent compounding pharmacies from producing office use prescriptions.¹³⁶

2. How the Section 503a Ban Hurts Patients

Outsourcing facilities cannot produce all of the office use medications that patients need.¹³⁷ Section 503b of the DQSA technically allows outsourcing facilities to produce office use medications, because outsourcing

129. H.R. REP. NO. 114-XXX, at 66 (2017).

130. See *New Amendment May Help Save Compounded Drugs*, *supra* note 122.

131. See *id.*; see also U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., PRESCRIPTION REQUIREMENT UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT 10–11 (2016), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf> (approving compounding of office use prescriptions for outsourcing facilities, but not for pharmacies); Letter from Thomas A. Kraus, Associate Commissioner for Legislation, to H. Morgan Griffith, House of Representatives (Sept. 15, 2014), http://c.ymcdn.com/sites/www.iacprx.org/resource/resmgr/FDA/FDA_response_on_Office_Use_S.pdf (explaining that the FDA will use its authority to enforce the DQSA by preventing pharmacies from producing office use prescriptions).

132. 21 U.S.C. § 353a(a) (2012).

133. However, it is important to note that section 503a’s failure to explicitly prohibit office use compounds has led to conflict. “[S]ome [state boards of pharmacy] still permit the practice on a limited basis thus creating a rift between state and federal law.” Dinkelaker, *supra* note 120, at 359. As a result, some compounding pharmacies “roll the dice” and continue to provide non-sterile office use compounds to practitioners. *Id.*

134. H.R. REP. NO. 115-XXX, at 67 (2017); H.R. REP. NO. 114-xxx, at 66 (2016); H.R. REP. NO. 114-205, at 67.

135. H.R. Rep. No. 115-XXX, at 67; H.R. Rep. No. 114-xxx, at 66-67; H.R. Rep. No. 114-205, at 67 (2015).

136. See *Urge Your Representatives to Cosponsor HR 2871, VOTERVOICE*, <https://www.votervoice.net/mobile/IACP/Campaigns/53342/Respond?vvsn=BomBXAyqACeBNAiatCR7BAA> (last visited Dec. 23, 2017); see also H.R. 2871, 115th Cong. § 2 (2017) (positing that the DQSA should be amended to explicitly allow compounding pharmacies to dispense office use prescriptions).

137. McGuff, *supra* note 128.

facilities can manufacture prescriptions that are not patient specific.¹³⁸ However, section 503b also limits what drugs outsourcing facilities can use to compound medications.¹³⁹ Outsourcing facilities can only use bulk drugs when the Secretary has determined they fulfill “a clinical need” or when the finalized compound is “on the drug shortage list.”¹⁴⁰ This limitation reduces the range of medications that outsourcing facilities can compound.¹⁴¹ Additionally, even if an outsourcing facility has the authority to produce a certain office use prescription, the facility will likely only produce medications that are cost effective to mass manufacture.¹⁴² This means that physicians probably will not be able to receive office use medications that serve only a narrow sliver of patients.

Prohibiting compounding pharmacies from producing office use prescriptions weakens the relationship between pharmacists and physicians. A physician must approve orders for office use prescriptions before receiving them. Although compounding pharmacists have never had a direct relationship with office use patients, “[u]nder no circumstances [was] the pharmacist dispensing medication without [a] relationship with the prescriber who [was] directly involved in treating patients.”¹⁴³ This relationship allowed physicians to carefully choose which compounding pharmacies they wanted to fill their prescriptions. Physicians could work closely with pharmacies that they trusted to ensure that their patients received quality medications. Office use prescriptions encouraged a strong pharmacist–physician connection in the pharmacist, physician, and patient triad.¹⁴⁴ Unfortunately, when the DQSA prohibited compounding

138. See *id.* Compare 21 U.S.C. § 353a(a) (2012) (limiting pharmacies to compounding prescriptions for identified patients), with 21 U.S.C.A. § 353b(a) (West 2013) (failing to require patient-specificity for drugs produced by outsourcing facilities).

139. McGuff, *supra* note 128.

140. 21 U.S.C.A. § 353b(a)(2)(A)(i)–(ii). See also *supra* note 105 and accompanying text (describing additional restrictions on outsourcing facilities’ ability to compound using bulk drugs). However, compounding pharmacies can generally compound with bulk drugs. See *supra* note 118 and accompanying text.

141. See McGuff, *supra* note 128. Although section 503b provides that outsourcing facilities can compound with bulk drugs if the Secretary establishes that “there is a clinical need,” this offers no guarantee. See 21 U.S.C.A. § 353b(a)(2)(A)(i); see also McGuff, *supra* note 128 (“[W]e do not know how the FDA will apply ‘clinical need,’ a requirement for a drug to be included on the approved bulk drug substance list.”). Because compounded drugs often serve small niches of patients, it is unlikely that the Secretary will establish a clinical need for all of the medications previously dispensed for office use.

142. Stephen Barlas, *Compounding Pharmacists Unhappy with New FDA Guidance Documents: Rules Severely Limit Distribution*, 41 PHARMACY & THERAPEUTICS 466, 466 (2016) (“[O]ne bulk manufacturer explained that because of the high cost of meeting the FDA’s 503[b] safety and manufacturing requirements, it doesn’t pay for him to manufacture many of the dental, pediatric, and ophthalmological drugs that would otherwise be supplied by 503[a] pharmacies for office use.”).

143. *The Case for Compounded Medications*, *supra* note 125, at 2.

144. See Rodney W. Hicks, *Understanding Medication Compounding Issues*, 99 AORN J. 466, 468–69 (2014) (outlining the compounding triad).

pharmacies from producing office use prescriptions, it dissolved these close-knit relationships. The DQSA forces practitioners to work with large and impersonal outsourcing facilities rather than small pharmacies. Although restricting office use prescriptions to outsourcing facilities sounds attractive, in reality, it severs an important relationship.¹⁴⁵

B. INTERSTATE DISTRIBUTION

1. The Section 503a Distribution Cap

The DQSA sets a default limit for the number of prescriptions that a compounding pharmacy can distribute out of state. Section 503a establishes that compounding pharmacies cannot normally distribute out of state more than five percent of the gross number of prescriptions that they distribute and dispense.¹⁴⁶ This limit may increase if the state and the Secretary “enter[] into a memorandum of understanding.”¹⁴⁷ The memorandum must determine consequences for inordinate interstate distribution of compounds.¹⁴⁸ It also must set up procedures requiring the state to investigate complaints regarding any compounds distributed outside of the state.¹⁴⁹ On its face, this memorandum-of-understanding exception appears to remove any specific restriction on the number of compounded drugs a pharmacy can distribute out of state. However, in practice, this provision significantly restricts compounding pharmacies from distributing prescriptions out of state.

Since the DQSA requires an agreement between a state and the Secretary in order to raise the five percent limit on out-of-state distribution, the FDA has direct control over how much that limit will be raised. The FDA first exercised this power on February 13, 2015, when it issued a draft memorandum of understanding.¹⁵⁰ In any state that accepts the draft memorandum, compounding pharmacies will only be allowed to distribute out of state less than 30% of the total number of prescriptions they distribute each month.¹⁵¹ Anything greater than this will be considered an inordinate

145. See Alan J. Zillich et al., *Influential Characteristics of Physician/Pharmacist Collaborative Relationships*, 38 ANNALS PHARMACOTHERAPY 764, 764 (2004) (“[P]harmacists often can impact patient outcomes through a cooperative relationship with a patient’s physician.”); see also Barbara A. Muller & Deanna L. McDanel, *Enhancing Quality and Safety Through Physician–Pharmacist Collaboration*, 63 AM. J. HEALTH-SYS. PHARMACY 996 (2006) (describing the emerging importance of a close physician–pharmacist relationship).

146. 21 U.S.C. § 353a(b)(3)(B)(ii) (2012).

147. *Id.* § 353a(b)(3)(B)(i).

148. *Id.*

149. *Id.*

150. See Mike Druckman et al., *FDA Publishes Draft Guidances and Memorandum of Understanding on Drug Compounding and Repackaging*, HOGAN LOVELLS (Feb. 23, 2015), <http://www.hlregulation.com/2015/02/23/fda-publishes-draft-guidances-and-memorandum-of-understanding-on-drug-compounding-and-repackaging>.

151. U.S. FOOD & DRUG ADMIN., DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE STATE OF

amount.¹⁵² The memorandum of understanding requires the state to take action whenever a compounding pharmacy breaches this limit.¹⁵³ “State action may include a warning letter, enforcement action, suspension or revocation of a license, or other action consistent with State law.”¹⁵⁴

Although the 30% limit imposed by the memorandum of understanding is a significant improvement over the DQSA’s five percent limit, there is no guarantee that the 30% cap will remain static. Compounding pharmacies are completely at the mercy of the FDA because the FDA decides the terms of the memorandum. Even if a state enters into a memorandum of understanding, the FDA can lower the out-of-state distribution limit at any time.¹⁵⁵ According to one pharmacist, “The [memorandum of understanding] has the potential to nearly eliminate all interstate shipment of a compounded prescription.”¹⁵⁶

Additionally, states are not required to enter into a memorandum of understanding. In fact, states have an incentive not to enter into the memorandum of understanding because the memorandum makes states assume responsibility for regulating compounding pharmacies.¹⁵⁷ The draft memorandum of understanding requires a state to follow stringent procedures, such as: thoroughly investigating any complaints about compounded drugs that have been distributed out-of-state,¹⁵⁸ notifying the FDA within 72 hours after receiving any such complaint regarding a public health risk,¹⁵⁹ taking appropriate action against any such valid complaint,¹⁶⁰ reviewing compounding pharmacy records to determine when pharmacies have breached the out-of-state distribution restrictions,¹⁶¹ notifying the FDA within seven days of any breach of this restriction,¹⁶² and taking appropriate

[insert STATE] AND THE U.S. FOOD AND DRUG ADMINISTRATION 4, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM434233.pdf> (last visited Dec. 23, 2017) [hereinafter DRAFT MEMORANDUM]. This restriction does not apply to “prescriptions dispensed to a patient (or patient’s agent), if the patient (or patient’s agent) to whom the drug is dispensed carries the drug across State lines after it has been dispensed to the patient (or patient’s agent) at the facility in which the drug was compounded.” *Id.*

152. *Id.*

153. *Id.* at 3–4.

154. *Id.* at 4. This is in addition to the power to take action that the FDA retains. *Id.* (“FDA may also take action regarding any pharmacy, pharmacist, or physician that distributes inordinate amounts of compounded human drug products interstate.”).

155. *See id.* at 6 (stating that the Draft Memorandum allows either party to terminate it with a thirty-day notice).

156. David Miller, *Standing Together Fixing the Drug Quality and Security Act!*, COMPOUNDING MATTERS Q., Winter 2015 at 16, 17.

157. *See New Amendment May Help Save Compounded Drugs*, *supra* note 122.

158. DRAFT MEMORANDUM, *supra* note 151, at 2.

159. *Id.* at 3.

160. *Id.*

161. *Id.*

162. *Id.*

action against any such breach.¹⁶³ The memorandum of understanding places significant procedural burdens on a state—procedural burdens that carry economic burdens.¹⁶⁴ While some states will likely enter into a memorandum of understanding, others probably will not do so in order to minimize these burdens, leaving compounding pharmacies with the five percent out-of-state distribution limitation.

Since the passage of the DQSA, Congress has clarified that it only intended for section 503a to limit compounding pharmacies' interstate *distribution* of compounded drugs, as opposed to pharmacies' interstate *dispensing* of compounded drugs. The difference between distribution and dispensing is a fine one, but it is an important distinction for pharmacies regulated under section 503a. Usually, the term “dispense” describes providing a patient, or a patient’s agent, directly with a prescription.¹⁶⁵ In contrast, “distributing” is usually defined as “the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product.”¹⁶⁶ The five percent default limitation addressed in section 503a only explicitly limits the *distribution* of compounded drugs.¹⁶⁷ Furthermore, section 503a specifies that the memorandum of understanding is intended to address the *distribution* of compounded drugs.¹⁶⁸ However, the FDA has interpreted the term “distribution,” as it is used in the DQSA, to include dispensing.¹⁶⁹ Therefore, the FDA has used the DQSA distribution cap to regulate dispensing practices.¹⁷⁰ Congress has responded by clarifying that it meant for the FDA to only apply limitations to interstate distribution and not to dispensing.¹⁷¹ However, the FDA continues to include dispensing within the definition of “distribution;” therefore, as the DQSA is currently applied, it limits both the dispensing and distribution of drugs compounded by pharmacies. As a result, section 503a’s distribution cap significantly and needlessly impedes the valid practices of compounding pharmacies.¹⁷²

163. *Id.* at 3–4.

164. *Take Action to Ensure Your Right to Access Compounded Medications*, CITIZENS FOR HEALTH (July 7, 2015), <https://www.citizens.org/ensure-right-access-compounded-medications> [hereinafter *Take Action*].

165. See DRAFT MEMORANDUM, *supra* note 151, app., at 8.

166. 21 U.S.C.A. § 360eee(5) (West 2017).

167. 21 U.S.C. § 353a(b)(3)(B)(ii) (2012).

168. *Id.* § 353a(b)(3)(B)(i).

169. DRAFT MEMORANDUM, *supra* note 151, app., at 8 (“Distribution includes delivery or shipment to a physician’s office, hospital, or other health care setting for administration *and dispensing to an agent of a patient or to a patient* for the patient’s own use.” (emphasis added)).

170. See *id.*

171. H.R. REP. NO. 115-XXX, at 67–68 (2017); H.R. REP. NO. 114-xxx, at 74 (2016); H.R. REP. NO. 114-205, at 71–72 (2015).

172. Some may argue that the solution to compounding’s current plight is for the FDA to alter its interpretation of the DQSA to match congressional intent. However, this Note argues that the DQSA should be amended to explicitly increase compounding pharmacies’ ability to distribute and dispense compounds interstate. This Note takes that stance for several reasons.

2. How the Distribution Cap Hurts Patients

Both the DQSA's five percent and the memorandum of understanding's 30% distribution limits pose significant problems. In *Thompson v. Western States Medical Center*,¹⁷³ Justice Breyer stated that restricting out-of-state distribution of compounded medications could prevent patients from getting the medications that they need.¹⁷⁴ Many compounding pharmacies allow patients to choose whether they would like to pick up their prescriptions or have them shipped directly.¹⁷⁵ The DQSA's limit on out-of-state distribution does not appear to prevent patients from crossing state lines themselves to physically pick up their prescriptions.¹⁷⁶ But for some patients, the only feasible way they can receive their medications is having their pharmacy ship or deliver their prescriptions.¹⁷⁷ Limiting out-of-state distribution of compounds cuts these patients off from their medications.¹⁷⁸

Theoretically, patients could just receive their medications from compounding pharmacies within their own state borders. However, there are two problems with this theory. First, there are a limited number of compounding pharmacies in each state, and some states have a deficiency of compounding pharmacies.¹⁷⁹ Second, certain compounding pharmacies specialize in specific kinds of prescriptions. For example, some compounding

First, many of the problems with the DQSA have arisen because the DQSA did not use clear language to explain policies. For example, the DQSA did not mention office use prescriptions or clearly define "distribution" and "dispensing." Therefore, the best way to protect compounding pharmacies is to amend the DQSA to explicitly raise the cap on interstate distribution and dispensing. Second, Congress has asked the FDA to change its interpretation multiple times, and the FDA has yet to alter its interpretation. *See supra* note 171. Finally, even if the FDA did change its interpretation, without the safety net of explicit language, the FDA could later return to its former interpretation.

173. *See supra* text accompanying notes 70–72 (discussing the holding of *Thompson*).

174. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 385–86 (2002) (Breyer, J., dissenting).

175. *See Refill a Prescription*, PAVILION COMPOUNDING PHARMACY, <http://www.pavilioncompounding.com/refill> (last visited Dec. 23, 2017) (providing a delivery option for compounded prescriptions); *Refill Your RX*, DISTRICT DRUGS, http://www.districtdrugs.com/refill_requests.htm (last visited Dec. 23, 2017) (providing a mailing option for compounded prescriptions); *RX Refill*, HERBST PHARMACY, <http://www.herbstpharmacy.com/refill.html> (last visited Dec. 23, 2017) (offering to deliver or mail prescriptions).

176. *Cf.* DRAFT MEMORANDUM, *supra* note 151, at 4 (“[The] FDA does not intend to include, in the consideration of inordinate amounts, prescriptions dispensed to a patient (or patient’s agent), if the patient (or patient’s agent) to whom the drug is dispensed carries the drug across State lines after it has been dispensed to the patient (or patient’s agent) at the facility in which the drug was compounded.”).

177. For example, elderly patients who have restricted mobility may not be able to pick up their prescriptions in person.

178. *See Memorandum of Understanding*, PROTECT MY COMPOUNDS, <http://www.protectmycompounds.com/memorandum-of-understanding> (last visited Dec. 23, 2017).

179. *See supra* text accompanying notes 42–46 (discussing the declining prevalence of compounding during the twentieth century).

pharmacies specialize in nuclear pharmacy.¹⁸⁰ This niche of compounding requires special training¹⁸¹ and facilities.¹⁸² Because the market for specialized compounding is so small,¹⁸³ the DQSA's interstate-distribution restriction threatens patients' abilities to obtain specialized medications.¹⁸⁴ And even if a specialized compounding pharmacy operates within a patient's state, that patient will be prevented from being able to shop around and use out-of-state pharmacies with the best reputations for specialized compounding.¹⁸⁵

Interstate distribution limitations are especially detrimental in hospital pharmacy settings.¹⁸⁶ Hospital systems often transport drugs between facilities.¹⁸⁷ Frequently, these systems span state borders.¹⁸⁸ Under the DQSA, transporting compounds between facilities in different states qualifies as out-of-state distribution and is subject to limitation.¹⁸⁹ A limit on interstate distribution could wreak havoc on hospital systems that cross state lines, preventing them from providing vital drugs to patients.¹⁹⁰

180. See *What Is Nuclear Pharmacy*, PURDUE U., <https://nuclear.pharmacy.purdue.edu/what.php> (last visited Dec. 23, 2017) (“Nuclear pharmacy is a specialty area of pharmacy practice dedicated to the compounding and dispensing of radioactive materials for use in nuclear medicine procedures.”).

181. See, e.g., James A. Ponto & Joseph C. Hung, *Nuclear Pharmacy, Part II: Nuclear Pharmacy Practice Today*, 28 J. NUCLEAR MED. TECH. 76, 76–77 (2000) (discussing nuclear pharmacy training through undergraduate courses, internships, and postgraduate nuclear pharmacy programs).

182. See *What Is Nuclear Pharmacy*, *supra* note 180 (“[M]ost [nuclear] compounding is done behind leaded glass shielding and using leaded glass syringe shields and lead containers . . .”).

183. In 2000, it was estimated that there were only 25 to 30 pharmacists who graduated from “college-based nuclear pharmacy training programs” practicing in the United States. Ponto & Hung, *supra* note 181, at 76.

184. *Take Action*, *supra* note 164; see also *Memorandum of Understanding*, *supra* note 178 (“Compounding pharmacies specialize in the creation of certain personalized medication. Often times they are located in another state. With the arbitrary limitation of 30%, pharmacies will have to choose which patients get their medication and which ones don’t.”).

185. *Take Action*, *supra* note 164 (“Every patient and practitioner should have the right to choose the compounding pharmacy of their choice.”).

186. Although some larger hospital pharmacies have registered as outsourcing facilities, many are classified as 503a pharmacies. U.S. DEP’T OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., HOSPITAL AND HEALTH SYSTEM COMPOUNDING UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT: GUIDANCE FOR INDUSTRY 1 (2016), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496287.pdf>.

187. See Stephen Barlas, *Interstate Compounding Plan Jars Hospitals: The Definitions of “Distribution” and “Inordinate” Stir Concern*, 40 PHARMACY & THERAPEUTICS 621, 621 (2015).

188. See *id.*

189. See *id.*

190. *Id.*; see also Barlas, *supra* note 142, at 466 (explaining that Baptist Memorial Health Care Corporation, a hospital system which operates in rural Tennessee, Arkansas, and Mississippi, will likely have to stop using oncology infusions to treat patients because of the DQSA distribution restrictions).

3. The Distribution Cap Does Not Increase Patient Safety

Historically, inordinate out-of-state distribution has been a way to help distinguish manufacturers from pharmacies.¹⁹¹ However, section 503b of the DQSA makes it unnecessary to use interstate distribution as a distinguishing factor. Under the DQSA, the major distinguishing point between manufacturers and pharmacies is whether they produce non-patient-specific prescriptions.¹⁹² Previous attempts to identify manufacturers did not capitalize on this identifier.¹⁹³ The new focus on patient specificity makes the restrictions on out-of-state distribution a hindrance to compounding pharmacies rather than an effective method to distinguish them from manufacturers. Some might argue that limiting compounding pharmacies' out-of-state distribution increases the incentive for manufacturers to register as outsourcing facilities. However, manufacturers already need to register as outsourcing facilities in order to produce medications that are not patient specific. Any extra incentive created by limiting the interstate distribution of compounding pharmacies is marginal and simply comes at too high a price.

Facially, limiting the number of compounded medications distributed between states appears to distinguish between small-town pharmacies and national manufacturers. In reality, the limitation is overbroad. It has no impact on some activity associated with manufacturers and hinders the perfectly legitimate distribution patterns of some pharmacies. The DQSA allows pharmacies to distribute unlimited prescriptions throughout the state, even if the pharmacy is distributing to patients hundreds of miles from the pharmacy.¹⁹⁴ At the same time, the DQSA significantly limits a compounding pharmacy's ability to distribute prescriptions to patients in neighboring states, even if the patients are only a few miles away from the pharmacy.¹⁹⁵ The FDA

191. See *supra* Part I.I.C (describing how both the FDA's Compliance Policy Guide and the FDAMA used inordinate interstate distribution to identify compounding manufacturers).

192. See *supra* note 113 and accompanying text.

193. The Compliance Policy guide made no mention of patient specificity and the FDAMA simply prohibited all compounding of non-patient-specific prescriptions. See *supra* note 58 and accompanying text.

194. *FDA Pretends to Lighten Burden on Compounding Pharmacies Even as It Tightens Its Stranglehold on Them*, ALLIANCE FOR NAT. HEALTH USA (Feb. 24, 2015), <http://www.anh-usa.org/fda-pretends-to-lighten-burden-on-compounding-pharmacies-even-as-it-tightens-its-stranglehold-on-them> [hereinafter *FDA Pretends*].

195. *Id.*; U.S. GOV'T ACCOUNTABILITY OFF., GAO-17-64, DRUG COMPOUNDING: FDA HAS TAKEN STEPS TO IMPLEMENT COMPOUNDING LAW, BUT SOME STATES AND STAKEHOLDERS REPORTED CHALLENGES 47 (2016), <http://www.gao.gov/assets/690/681096.pdf>. Consider District Drugs & Compounding Center, an Illinois pharmacy located less than a mile away from the Iowa border. See *Contact*, DIST. DRUGS, <http://www.districtdrugs.com/contactus.htm> (last visited Dec. 23, 2017). Additionally, the DQSA discriminates against states based on their size. For example, compounding pharmacies in Texas can ship unlimited prescriptions anywhere within the 261,797 square miles that the state covers. See *U.S. States by Size*, WORLDATLAS, <http://www.worldatlas.com/aatlas/infopage/usabysiz.htm> (last visited Dec. 23, 2017). However,

recognized this discrepancy and considered allowing unlimited distribution of prescriptions when the prescriptions were distributed within fifty miles of the pharmacy.¹⁹⁶ However, the FDA ultimately rejected this exception, reasoning that raising the out-of-state distribution restriction to thirty percent and exempting prescriptions carried over state lines by patients themselves provided enough freedom for compounding pharmacies.¹⁹⁷

A final argument against the current out-of-state distribution restriction is that the percentages chosen are arbitrary.¹⁹⁸ In light of the draft memorandum of understanding, it appears that the FDA has determined that distributing compounded prescriptions out of state is perfectly acceptable until that distribution reaches thirty percent of a pharmacy's total distribution, at which point the practice suddenly becomes unsafe.¹⁹⁹ The FDA provided no rationale for why thirty percent is the magic number.²⁰⁰ There is no evidence that facilities distributing more than thirty percent of their prescriptions out of state are actually manufacturers rather than pharmacies. Without such evidence, the out-of-state distribution limitation needlessly decreases patient access to prescriptions.

V. SUGGESTED AMENDMENTS TO THE DQSA

A. OFFICE USE PRESCRIPTIONS

Since office use prescriptions serve a vital purpose for both practitioners and patients,²⁰¹ Congress should amend section 503a of the DQSA to explicitly allow compounding pharmacies to distribute some office use prescriptions.²⁰² However, compounding pharmacies should not be able to distribute unlimited office use prescriptions. The primary way the DQSA separates compounding pharmacies from outsourcing facilities is by restricting pharmacies to dispensing patient-specific prescriptions while allowing outsourcing facilities to distribute non-patient-specific prescriptions.²⁰³ Completely eliminating the restriction on office use

compounding pharmacies in Rhode Island are limited in the number of prescriptions they can distribute beyond the 1,045 square miles of that state. *See id.*

196. *See Draft Standard Memorandum of Understanding (MOU)*, U.S. FOOD & DRUG ADMIN., 11, <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM446238.pdf> (last visited Dec. 23, 2017). This rule would only have applied when pharmacies distributed to contiguous states. *Id.*

197. *Id.*

198. *See FDA Pretends*, *supra* note 194; *Memorandum of Understanding*, *supra* note 178; *Take Action*, *supra* note 164.

199. *See FDA Pretends*, *supra* note 194.

200. *See Take Action*, *supra* note 164.

201. *See supra* Part IV.A.1 (discussing the purposes of office use prescriptions).

202. In early 2017, Congress clarified that its intent was for the DQSA to allow some pharmacy production of office use prescriptions, but the FDA has interpreted the language of the DQSA otherwise. *See supra* notes 131–36 and accompanying text.

203. *Compare* 21 U.S.C. § 353a(a) (2012), *with* 21 U.S.C.A. § 353b(a) (West 2013).

prescriptions would likely create a large loophole in compounding regulation.²⁰⁴ This would disincentivize manufacturers from registering as outsourcing facilities²⁰⁵ and effectively make the DQSA impotent. Therefore, Congress would need to strike a balance between providing enough of an incentive for manufacturers to register as outsourcing facilities while still allowing compounding pharmacies to provide vital office use prescriptions. The proper percentage balance is beyond the scope of this Note.²⁰⁶ For the remainder of this discussion, this proposed limitation on how many office use prescriptions a compounding pharmacy can distribute will be referred to as the “Office Percent.”

In addition to establishing the Office Percent, Congress would need to safeguard against potential ways that compounding pharmacies could abuse it. One potential abuse would be to dispense prescriptions in large quantities but only count such dispensings as one prescription. For example, if a pharmacy normally dispenses dental anesthetic gel in 50 gram quantities, the pharmacy could start dispensing it to physicians in 100 gram quantities in order to maximize output while remaining under the Office Percent.²⁰⁷ The best way to prevent this abuse would be to require pharmacies to count each instance a physician administers an office use medication to a patient as an individual prescription. To do this, physicians would need to keep records of which patients received compounded medications in their offices. The physicians would need to provide these records to the pharmacy that dispensed the office use medication so that the pharmacy could ensure that it remains under the Office Percent.²⁰⁸

204. Essentially, while pharmacies still could not mass produce normal non-patient-specific prescriptions, they could mass produce non-patient-specific office use prescriptions without limit.

205. If a compounding manufacturer could mass produce non-patient-specific prescriptions without paying the fees for registering as an outsourcing facility and placing itself under the close scrutiny of the FDA, it would not likely register as an outsourcing facility. However, it is important to acknowledge that there would still be some possible incentives to register as an outsourcing facility. For example, hospitals might only do business with facilities registered as outsourcing facilities. Lietzan & Ji, *supra* note 57, at 5. This could result either from hospitals autonomously choosing to use FDA regulated outsourcing facilities or from hospitals succumbing to FDA pressure to use outsourcing facilities. *See id.*

206. Determining an appropriate percentage would require extensive research in light of the fact that other restrictions of the DQSA have been criticized as arbitrary. *See supra* text accompanying notes 198–200 (arguing that the out-of-state distribution limit for compounding pharmacies is arbitrary).

207. At first glance, the threat of such abuse may seem unlimited. However, compounded drugs must comply with strict expiration-date deadlines. For example, topical medications that contain water generally cannot be used later than thirty days after compounding. UNITED STATES PHARMACOPELAL CONVENTION, *supra* note 31, at 622. Oral medications that contain water generally cannot be used later than fourteen days after they are compounded. *Id.* These expiration dates would prevent pharmacies from dispensing huge quantities of drugs under one dispensing.

208. Of course, one of the drawbacks to this structure is that pharmacies may not know how many patients a physician will treat with a medication until after the physician has completely used the medication. Therefore, it could be argued that pharmacies would not be able to

This might appear to be a heavy burden on the physician. However, in addition to preventing compounding pharmacies from abusing the system, this procedure will increase patient safety. First, it will require close contact between physicians and pharmacists.²⁰⁹ A closer relationship between prescribers and pharmacists is always preferable to an arms-length dealing.²¹⁰ Collaboration increases physician knowledge of drugs and decreases the likelihood of prescribing errors.²¹¹ Second, stringent records that indicate which patients received which treatments will be extremely beneficial in situations where drugs are recalled.²¹² The FDA will be able to quickly trace the distribution chain of unsafe batches of drugs to the specific patients who received them. In fact, if physicians supply patient lists to pharmacists, the FDA will be able to bypass physicians when tracing the drugs to patients, speeding up the recall process.

accurately gauge whether they are complying with the Office Percent until after the fact. Returning to the anesthetic gel example, a pharmacist would not likely know exactly how many patients a batch of that medication will treat. Physicians might apply one gram of gel to one patient and two grams to another depending on the procedure or patient. Even so, physicians could most likely use their professional judgment to assist pharmacists by estimating how many patients a batch will treat. Additionally, if a physician's office would regularly order the same or a similar office use prescription, the pharmacy would have records of how many patients a batch treated in the past. Finally, if Congress set the Office Percent to an appropriate level, most compounding pharmacies would not be skirting the limitation so closely that an estimate would risk pushing them over the limit.

209. See *supra* note 144 and accompanying text (discussing the compounding pharmacist-patient-physician triad in the office use prescription context).

210. See Deborah V. Kelly et al., *Pharmacist and Physician Views on Collaborative Practice: Findings from the Community Pharmaceutical Care Project*, 146 CANADIAN PHARMACISTS J. 218, 218–19 (2013) (explaining that physician-pharmacist collaboration in the hospital setting has been found to decrease mortality rates). “The increasing complexity of medication therapies underscores the need for strong working relationships between pharmacists and physicians to optimize patient care.” *Id.* at 218.

211. See Sandeep Nijjer et al., *Effective Collaboration Between Doctors and Pharmacists*, 15 HOSP. PHARMACIST 179, 179 (2008) (describing the benefits of doctor-pharmacist collaboration in a hospital context). If physicians began providing compounding pharmacies with lists of patients who received office use prescriptions, pharmacists would be able to enter this information into their systems under each patient's file. This would increase the likelihood that pharmacists would identify any adverse drug interactions the patient might have. See *id.*

212. Title II of the DQSA, The Drug Supply Chain Security Act (“DSCSA”), requires drug dispensers to keep records concerning the prior history of a compounded drug's distribution. Drug Supply Chain Security Act, Pub. L. No. 113-54, 21 U.S.C. § 582(d)(1)(A)(iii), 127 Stat. 587 (2013). As a result, if there is a drug recall, the FDA will be able to track a drug's distribution path. See *id.* However, the DSCSA does not require physicians to keep such records. *Id.* § 582(d)(5). Therefore, by requiring physicians to keep records of which patients they administered office use compounds to, the FDA will be able to quickly track office use drugs to individual patients. See *id.* The DSCSA's effects on compounding pharmacies is beyond the scope of this Note, but for an argument that the DSCSA threatens compounding pharmacies, see generally Diana Yap, *APhA to FDA: As Track and Trace Is Implemented, Consider Disparities Between Supply Chain Participants*, 20 PHARMACY TODAY 56 (July 2014).

Finally, if Congress amends the DQSA to allow compounding pharmacies to distribute some non-patient-specific prescriptions, it should specify that these prescriptions are limited to administration by the specific physician who requested the prescription. Without such a limitation, physicians could act as wholesalers²¹³ by distributing compounded medications to other physicians.²¹⁴ This practice would once again essentially turn compounding pharmacies into manufacturers. Of course, only allowing the ordering physician to administer the medication would prevent that physician's coworkers from using the medication to treat their own patients.²¹⁵ However, requiring physicians to personally write prescriptions for office use medications ensures that the physician is actually knowledgeable about the medication in addition to strengthening the physician-pharmacist bond.

B. INTERSTATE DISTRIBUTION

1. Removing the Limit on Interstate Distribution of Patient-Specific Drugs

Congress should also amend the DQSA to remove the limitation on interstate distribution of patient-specific drugs. Limiting interstate distribution prevents patients from receiving the medications that they need.²¹⁶ Additionally, the current limitations on interstate distribution are not necessary to incentivize manufacturers to register as outsourcing facilities²¹⁷ and are arbitrary.²¹⁸

Of course, removing this restriction would eliminate the need for memoranda of understanding between states and the Secretary.²¹⁹ Without the memoranda of understanding, states would not likely assume responsibility for monitoring interstate distribution of compounded medications. If Congress wanted to incentivize states to assume this responsibility, it would need to find other ways of doing so. Any such suggestions are beyond the scope of this Note. In any event, it is debatable

213. The DQSA prohibits outsourcing facilities from distributing non-patient-specific prescriptions to wholesalers. 21 U.S.C.A. § 353b(a)(8) (West 2013).

214. This creates additional problems when coupled with the DQSA's section 503a limitation on out-of-state distribution. See 21 U.S.C. § 353a(b)(3)(B)(i)-(ii) (2012). Essentially, pharmacies could skirt around the distribution restrictions by dispensing to in-state physicians who could then distribute the prescriptions to out-of-state physicians.

215. For example, if two physicians practice in one office, and one writes an office use prescription for prefilled syringes which reverse allergic reactions, the other will not be able to administer any of those syringes to her own patients. Instead, the second physician will need to write her own prescription for office use syringes to use on her patients.

216. See *supra* Part IV.B.2.

217. See *supra* notes 191-93 and accompanying text (arguing that the DQSA's reliance on patient specificity is sufficient to incentivize manufacturers to register as outsourcing facilities).

218. See *supra* notes 198-200 and accompanying text.

219. See *supra* text accompanying note 114.

whether the DQSA, as it is written, adequately incentivizes states to enter into memoranda of understanding.²²⁰

2. Limiting Interstate Distribution of Non-Patient-Specific Drugs

Although Congress should not limit the number of patient-specific prescriptions a pharmacy can distribute out of state, Congress should limit the number of non-patient-specific prescriptions a pharmacy can distribute out of state. Of course, as the DQSA stands, pharmacies can only compound patient-specific medications, making this point moot. However, if Congress amended the DQSA to allow compounding pharmacies to distribute some office use prescriptions, this issue would be highly relevant.²²¹

Patient specificity is the main way that the DQSA differentiates between compounding pharmacies and manufacturers. Therefore, any exception to the rule that compounding pharmacies can only dispense patient-specific medications must be closely circumscribed.²²² Allowing compounding pharmacies to distribute the entire Office Percent out of state might disincentivize manufacturers from registering as outsourcing facilities. It would surely increase the threat of manufacturers masquerading as pharmacies. Once again, Congress would need to consider the balance between allowing pharmacies to distribute medications that patients need and preventing pharmacies from acting as manufacturers. Research would need to be conducted to determine what percentage of office use prescriptions compounding pharmacies should be allowed to distribute out of state.²²³

3. Alternatively Raising the Limit on Interstate Distribution of Patient-Specific Drugs

This Note suggests that Congress remove the limitation on interstate distribution of patient-specific compounds. However, if Congress were to provide evidence that this limitation is necessary to incentivize manufacturers to register as outsourcing facilities, completely removing the limitation would be inappropriate. In that case, Congress should impose a non-arbitrary

220. See *supra* text accompanying notes 146–53.

221. See *supra* Part V.A (arguing that Congress should amend the DQSA to allow compounding pharmacies to dispense some office use prescriptions).

222. See *supra* notes 201–06 and accompanying text (proposing limiting how many office use prescriptions a pharmacy can distribute).

223. It could be argued that since the proposed amendment to the office use ban only allows compounding pharmacies to dispense a limited number of office use prescriptions, there is no need to further limit the dispensing of office use prescriptions. However, in the past, both interstate distribution of medications and non-patient-specific production have been indicators that a pharmacy is acting as a manufacturer. When interstate distribution coincides with non-patient-specific compounding, there is a substantial increase in the likelihood that a compounding pharmacy is actually acting as a manufacturer. Therefore, while this Note suggests removing some of the restraints on non-patient-specific prescriptions and most of the restraints on interstate distribution, Congress must not create a gap in regulation in which abuse could flourish.

limitation on interstate distribution and dispensing of patient-specific prescriptions. Even so, Congress would certainly need to raise the default limitation above five percent. If Congress raised—rather than eliminated—the limitation on interstate distribution of patient-specific compounds, states could continue to enter into memoranda of understanding with the Secretary. States could still bargain with the FDA, offering to closely monitor interstate shipment of compounded drugs in exchange for alleviation of interstate distribution and dispensing limitations.²²⁴ However, if Congress provided a reasonable default limitation, compounding pharmacies would not be placed at the complete mercy of the FDA, as they currently are.²²⁵

Determining the exact limit Congress should place on interstate distribution and dispensing of patient-specific compounds would require extensive research. However, one way that Congress could evaluate this would be by looking at the statistics of the slew of pharmacies that have been shut down since the 2012 meningitis outbreak.²²⁶ Congress could use these pharmacies' records to determine on average what percentage of prescriptions they shipped across state lines. To create an incentive to register as an outsourcing facility, the percent limit would need to be below this average. Congress could also study compounding pharmacies that have successfully passed inspections to determine the average percentage of prescriptions that these pharmacies ship out of state. The percent limit would need to be above this average in order to prevent the DQSA from interfering with legitimate pharmacy practices. Although more research would need to be done to decide where the limitation should fall between these numbers, the resulting range would provide a starting point.²²⁷

However, if Congress did retain a limitation on interstate distribution of patient-specific compounds, that limitation should not apply to hospital systems because it would hamper legitimate hospital practices.²²⁸ Still, Congress should circumscribe this “hospital exception” in order to prevent

224. See generally DRAFT MEMORANDUM, *supra* note 151 (allowing states to increase interstate distribution of compounded drugs if the state provides greater regulation of such practices).

225. See *supra* notes 155–56 and accompanying text.

226. See, e.g., Jessica Bartlett, *Two Compounding Pharmacies Closed After Inspections*, BOS. GLOBE (Aug. 20, 2013), <https://www.bostonglobe.com/2013/08/20/compounding-pharmacies-quincy-norwood-closed-after-surprise-state-inspection/obZxQCjsb7vrBu8Qk8AWoI/story.html>; Abby Goodnough, *Massachusetts Orders Another Pharmacy To Close*, N.Y. TIMES (Oct. 28, 2012), <http://www.nytimes.com/2012/10/29/health/massachusetts-shuts-down-another-compounder.html>; Alicia Wallace, *Brown's Compounding Closed After FBI, DEA Execute Search Warrant*, DENVER POST, <http://www.denverpost.com/2015/06/12/browns-compounding-closed-after-fbi-dea-execute-search-warrant> (last updated Apr. 23, 2016, 1:08 AM).

227. Alternatively, if the difference between these averages is negligible, Congress would have statistical evidence that out-of-state distribution is not a valid indicator of manufacturing. In that case, interstate distribution of patient-specific compounds should not be limited.

228. See *supra* notes 186–90 and accompanying text (describing how the limitations on interstate transportation of compounded medications prevents hospital facilities that span state borders from transferring medications between facilities).

massive, multi-state hospital systems from abusing their freedom. Congress should only allow the exception when the medications are being distributed or dispensed to other facilities within the same hospital system and within 50 miles of the compounding facility.²²⁹ However, if Congress amended the DQSA to strike down all interstate distribution limitations on patient-specific compounds, this problem within hospital systems could be avoided entirely.

VI. CONCLUSION

Congress enacted the Drug Quality and Security Act in order to protect patients from substandard medications. The Act was meant to differentiate compounding pharmacies and manufacturers, restraining manufacturers while allowing pharmacies to continue their essential activities. Unfortunately, in practice, the Act significantly burdens compounding pharmacies, preventing them from providing safe medications to patients. Two of the ways that the DQSA does this is by prohibiting compounding pharmacies from distributing office use prescriptions and severely limiting the number of prescriptions that compounding pharmacies can distribute out of state. Congress should amend the DQSA to allow compounding pharmacies to distribute a reasonable number of office use prescriptions. Congress should also completely eliminate, or at least significantly reduce, the limitations on interstate shipment of patient-specific drugs. Doing so would reduce the negative effects of the DQSA and allow patients to receive necessary medications. However, it would still allow the DQSA to distinguish between manufacturers and pharmacies, thereby protecting patients from unsafe prescriptions.

229. *Cf. supra* notes 196–97 and accompanying text (discussing a similar 50-mile exception to all interstate compounding distribution, which was ultimately rejected by the FDA).