CLOSING THE REGULATORY GAP IN PHYSICIAN COMPOUNDING: HOW NEW JERSEY CAN EFFECTIVELY REGULATE DRUG COMPOUNDING IN THE NON-PHARMACY SETTING

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I. INTRODUCTION

Drug compounding is an important part of the healthcare system and affords patients access to custom prescription medications that best fit their individualized needs.[1] There are a variety of reasons why certain standardized Food and Drug Administration ("FDA") approved drugs may need to be modified for specific patients, including a change in dosage, concentration, method of delivery, or to accommodate certain allergies.[2] To best fit these needs, drugs may be compounded by pharmacists in special compounding pharmacies, or even by physicians in their offices.[3] Interestingly, the regulations governing these compounding processes are very different.[4] The FDA articulated several broad guidelines to direct the compounding of medications in general, but state organizations enforce their own compounding regulations.[5] A state's board of pharmacy typically creates regulations to govern compounding in pharmacies; however, compounding done by physicians in their offices is much less regulated, if at all.[6] State

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[1] *See Compounding and the FDA: Questions and Answers,* U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers [hereinafter *Compounding and the FDA*] (last updated June 21, 2018); Pew Charitable Trusts et al., *State Oversight of Drug Compounding*, 4 (Feb. 2018), https://www.pewtrusts.org/media/assets/2018/02/drug_safety_assesment_web.pdf [hereinafter *State Oversight*].

[2] *Compounding and the FDA*, *supra* note 1; *See generally State Oversight*, *supra* note 1.

[3] *State Oversight*, *supra* note 1, at 1.

[4] *See generally State Oversight*, *supra* note 1.

[5] *See State Oversight*, *supra* note 1, at 4-5, 16; Joanne S. Eglovitch, *The FDA Aims To Strike Balance On Inspecting Physicians Who Compound*, PINK SHEET (Aug. 8, 2019).

[6] *National Reports Raise Questions About Oversight of Drug Compounding in Physicians' Offices*, 46 NEWSL. OF THE NAT. ASSOC. OF BDS. OF PHARMACY 3, 6-7 (Mar. 2017), https://nabp.pharmacy/wp-

pharmacy boards do not have jurisdiction over physicians and the board's regulations regarding medical compounding do not reach far enough to cover physicians.[7] Additionally, state medical boards govern a physician's practice, but rarely enact or enforce any regulations regarding drug compounding.[8] This legislative gap recently came to light when numerous public health crises arose relating to drug compounding.[9] These crises brought legislators and regulatory bodies together to establish more stringent regulations to create safer products for the consumer.[10] In order for New Jersey to safeguard its residents while still providing efficient access to the customized medications residents need, state legislators must make changes to the compounding regulatory process done inside physicians' offices.

Part II of this comment will examine the history of drug compounding, the benefits and risks associated with compounded medications, and the current status of regulations regarding compounding both in New Jersey and across the country. Part II will also detail the meningitis crisis of 2012 which highlighted the dangers of drug compounding and pushed regulators across the country to make a change to drug compounding regulations.[11] Part III of this comment will outline the different pathways New Jersey can take to change regulations regarding physician in-office compounding to promote a more perfect balance between efficiency of care and safety of patients. Part III begins with an analysis of the new regulations in Ohio, which were promulgated in 2017,[12] and then considers current FDA and United States Pharmacopeia ("USP") concerns. This comment will argue New Jersey would be best served by a new legislative and regulatory approach guided by the principles in the Ohio regulations. This new approach should stimulate the use of the more heavily regulated 503B outsourcing facilities by adopting stricter regulations on 503A facilities,

content/uploads/2016/07/Innovations_March__2017_Final.pdf [hereinafter *National Reports Raise Questions*].

7 *National Reports Raise Questions*, *supra* note 6, at 6.

8 *National Reports Raise Questions*, *supra* note 6, at 6, 7.

9 Stacey L. Worthy, *The Compounding Conundrum: How Insufficient Delineation of Regulatory Responsibility Has Created a Need for State and Federal Compounding Drug Law Reform*, 72 FOOD DRUG L. J. 506, 521 (2017).

10 *State Oversight*, *supra* note 1, at 4.

11 *State Oversight*, *supra* note 1, at 4.

12 OHIO REV. CODE. ANN. § 4729.541(c)-(d) (LexisNexis 2017); *Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding*, STATE OF OHIO BD. OF PHARM. (Feb. 11, 2017) https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal%20Distributor%20Requirements%20for%20Prescribers%20Possessing%20Compounded%20Drugs%20or%20Engaging%20in%20Drug%20Compounding.pdf.

and by incentivizing their usage through tax breaks.[13] In addition to these regulatory measures, to best serve New Jersey and its residents, this comment will also propose that New Jersey should create a hybrid committee comprised of members from both the New Jersey Board of Pharmacy and the New Jersey Board of Medical Examiners. This dynamic group, after intense collaborative research, can erect a comprehensive and effective set of regulations for physicians who choose to compound medications for patients in their own offices. Part IV of the comment will conclude with the different proposals outlined throughout the comment and once again highlight the need for and importance of this regulation.

II. BACKGROUND

A. *What is a Compounded Medication?*

Today, large pharmaceutical companies manufacture mass quantities of most medications available to consumers in the United States.[14] Physicians or other healthcare providers prescribe these drugs, and then pharmacists in traditional pharmacies dispense the drugs to patients.[15] In contrast to manufactured medications, compounded medications are modified drugs that physicians or pharmacists make in small doses specifically for an individual patient.[16] The USP, the only independent, nongovernmental pharmacopeia[17] in the world, defines compounding as "the preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription . . . based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice."[18] Stated more simply, a physician or a

[13] *See generally infra* note 52 (delineating the facilities that fall under 503A regulations.).

[14] Burt's – Medicine, *Understanding the Difference Between Compounding and Pharmaceutical Manufacturing*, BURT'S RX (Jan. 6, 2018), https://burtsrx.com/difference-compounding-pharmaceutical-manufacturing/.

[15] *See id.*

[16] *Id*.

[17] A pharmacopeia is a collection of uniform pharmaceutical standards comprised of requirements regarding the quality of medicinal products, the substances used to manufacture them, and quality control methods; *See generally* J. Mark Wiggins & Joseph A. Albanese, *A Brief History of Pharmacopoeias: A Global Perspective*, BIOPHARM INT'L (Sept. 15, 2019).

[18] *Frequently Asked Questions About Pharmaceutical Compounding*, AM. PHARMACISTS ASS'N, https://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding [hereinafter *Frequently Asked Questions*] (last visited

pharmacist mixes and prepares compounded medications for a certain individual based on a prescription from a physician when no FDA-approved medication fits a patient's precise needs.[19] Often described as both an art and a science, this process allows patients to obtain individualized care tailored specifically to them.[20]

Specific needs that can be served by a compounded medication include changes in dosage or method of delivery as well as changes to accommodate certain allergies.[21] Changes in dosage and method of delivery are most common when physicians treat children, the elderly, and patients with other special healthcare needs.[22] For example, many children are unable to swallow oral tablet medications; this poses problems if a physician decides the child requires a medication that is only commercially manufactured in an oral tablet form.[23] However, drug compounding addresses this issue by allowing pharmacists or physicians to mix the same active ingredients of the oral tablet into a liquid or suppository in order for the child to ingest the medication.[24] This process may also be used for the elderly who may be unable or unwilling to take oral capsule medications.[25]

Additionally, compounded medications provide a unique solution for patients with various allergies.[26] Mass manufactured drugs are created to cause reactions in as few people as possible; however, there are some medications that include various allergens like lactose, gluten, or certain dyes.[27] Compounding allows for a pharmacist or physician to

Jan. 16, 2021). *See also Review of World Pharmacopoeias* 3 (WHO, Working Document QAS/12.512/Rev.1 (Mar. 2013), https://www.who.int/medicines/areas/quality_safety/quality_assurance/resources/InternationalMeetingWorldPharmacopoeias_QAS13-512Rev1_25032013.pdf (defining a pharmacopoeia as "a legally binding collection, prepared by a national or regional authority, of standards and quality specifications for medicines used in that country or region.").

19 *Frequently Asked Questions*, *supra* note 18.

20 *Frequently Asked Questions*, *supra* note 18.

21 *Compounding and the FDA*, *supra* note 1.

22 *See* Tricia Heitman, A. J. Day & August S. Bassani, *Pediatric Compounding Pharmacy: Taking on the Responsibility of Providing Quality Customized Prescriptions*, CHILDREN (BASEL) 1, 5 (May 4, 2019), https://www.ncbi.nlm.nih.gov /pmc/articles/ PMC6560512/.

23 *Id.* at 1.

24 *Id.*

25 *Compounding and the FDA*, *supra* note 1.

26 Burt's – Compounding *Six Medical Situations That Call for Compounded Medications*, BURT'S RX (July 21, 2017), https://burtsrx.com/6-medical-situations-compounded-medications/.

27 *Patients with Allergies Look to Compounding Pharmacies for Medication*, ARENA DISTRICT PHARM. (Nov. 25, 2017), https://www.arenadistrictpharmacycolumbus.com/

create an individualized version of that medication by either removing the additive and leaving only the active, essential ingredients; they can also add an antihistamine to the drug in order to combat an allergy.[28] Without compounding, these patients would not be able to get the medications they need, or, if the medication was particularly indispensable to their health, the patient would have to suffer the adverse consequences due to their allergy.[29]

Compounded medications are created when the exact strength of a drug "may not be commercially available" or when a patient needs "a drug that is currently in shortage" or when such drug has been discontinued for whatever reason.[30] In addition to the uses above, compounded medications are also used to treat hormone-related conditions, pain, and skin issues.[31] Most prescriptions for compounded medications come from dermatologists, pain specialists, endocrinologists, and gastroenterologists.[32] There have been significant increases in the dermatological compounds such as sprays, gels, foams, and ointments.[33] Usually pharmacists, or dermatologists themselves, compound these gels to contain one or more anesthetic, analgesic, sedative, antidepressant, anti-seizure or muscle relaxant drugs that are used to treat pain.[34]

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blog/26848/Patients-with-Allergies-Look-to-Compounding-Pharmacies-for-Medication/ [hereinafter *Patients with Allergies*].

[28] *Id.*

[29] *Id.*

[30] *Frequently Asked Questions*, *supra* note 18.

[31] Ronilee Shye, *What Are Compounded Medications?*, GOODRX (last visited Jan. 16, 2021), https://www.goodrx.com/blog/what-are-compounded-medications/.

[32] Aamir Hussain & Diana Bolotin, *The Drug Compounding Debate and its Importance to Dermatologists*, DERMATOLOGIST (last visited Jan. 16, 2021), https://www.the-dermatologist.com/article/drug-compounding-debate-and-its-importance-dermatologists; Ronilee Shye, *What Are Compounded Medications?*, GOODRX (last visited Dec. 12, 2020), https://www.goodrx.com/blog/what-are-compounded-medications/.

[33] *Compounding Pharmacies Market to Hit $14 Billion by 2026*, PR NEWSWIRE (last visited Dec. 12, 2020), https://www.prnewswire.com/news-releases/compounding-pharmacies-market-to-hit-14-billion-by-2026-global-market-insights-inc-301073406.html; *See also Research Pushes Back on Benefits of Compounded Topical Pain Creams*, JOHNS HOPKINS MED. (Feb. 5, 2019), https://www.hopkinsmedicine.org/news/newsroom/news-releases/research-pushes-back-on-benefits-of-compounded-topical-pain-creams.

[34] *Research Pushes Back on Benefits of Compounded Topical Pain Creams*, JOHNS HOPKINS MED. (Feb. 5, 2019), https://www.hopkinsmedicine.org/news/newsroom/news-releases/research-pushes-back-on-benefits-of-compounded-topical-pain-creams; However, there is a growing body of research that suggests these topical creams have no scientific benefit, and are not nearly as effective as the oral equivalents of these medications. This comment will not discuss the effectiveness of these drugs and will instead focus on their

It is important to note that the FDA itself does not regulate the approval process of compounded drugs.[35] The FDA seeks control over compounded medications by enacting federal regulations that must be enforced by state regulatory agencies.[36] Although FDA regulations surround and attempt to regulate compounded drugs, these drugs are not subject to the same quality assurance standards as are mass-manufactured medications.[37]

B. *Who Can Compound Medications?*

Those engaged in human drug compounding can be divided into two distinct categories: traditional and non-traditional compounders.[38] Traditional compounders consist of pharmacists and physicians.[39] The most common compounding is done by licensed pharmacists in compounding pharmacies.[40] Currently, about 7,500 compounding pharmacies in the United States specialize in advanced compounding services.[41] Of these compounding pharmacies, approximately 3,000 of them produce sterile products that must be made under stricter standards than non-sterile products.[42] Injections or infusions traditionally use sterile compounds.[43] Typically suspensions, ointments, creams, or capsules use non-sterile products.[44] In addition to pharmacists, physicians may also compound drugs in their offices.[45] The scope of physician in-office compounding is quite unknown and the National Association of Boards of Pharmacy has opined that the number

prevalence in the field. This comment will also address how this practice factors into physician in-office compounding and will highlight the need for new regulations.

[35] *Compounding and the FDA*, *supra* note 1; This point will be explained in greater detail below.

[36] *See Compounding and the FDA*, *supra* note 1.

[37] *Compounding and the FDA*, *supra* note 1.

[38] *See State Regulation of Compounding Pharmacies*, NAT'L CONF. OF STATE LEGS. (Oct. 1, 2014), http://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx; *see also* Drug Quality and Security Act, H.R. 3204, 113th Cong. (2013-2014).

[39] *Frequently Asked Questions*, *supra* note 18.

[40] *Frequently Asked Questions*, *supra* note 18.

[41] Daniel J. DeNoon, *What Are Compounding Pharmacies? Meningitis Outbreak From Compounded Drug Raises Questions Over Pharmacies*, WEBMD (Oct. 10, 2012), https://www.webmd.com/brain/news/20121010/what-are-compounding-pharmacies#1.

[42] *Id.*

[43] *Sterile vs Non-Sterile Compounding Pharmacies*, RENUE PHARMACY (last visited Oct. 3, 2020) https://renuerx.com/sterile-vs-non-sterile-compounding-pharmacies/.

[44] *Id.*

[45] *National Reports Raise Questions*, *supra* note 6.

of physician-compounders varies widely by specialty.[46] Physicians who are general practitioners may perform no in-office compounding, while other more specialized physicians (like allergists and dermatologists) may treat hundreds of patients with compounded medication.[47] Specialists like allergists, dermatologists, immunologists, oncologists, ophthalmologists and rheumatologists are most likely to engage in in-office compounding, and therefore, are most likely to be affected by any new compounding regulations.[48]

In 2013, through the Drug Quality and Security Act ("DQSA"), Congress created a new regulatory category of drugs compounders called "outsourcing facilities."[49] DQSA established a new section of the Federal Food, Drug, and Cosmetic Act ("FDCA"), Section 503B, that set forth regulations for these facilities to compound drugs in compliance with the FDA.[50] The FDA categorizes these facilities as being non-traditional compounders because their drugs need only be compounded under the *supervision* of a licensed pharmacist.[51] Additionally, outsourcing facilities are able to produce large batches of popular, compounded drugs with or without a prescription to be sold to healthcare facilities because those drugs are non-patient specific.[52] Drugs compounded by facilities in compliance with 503B qualify for exemptions from some FDA approval requirements, including drug approval processes, labeling requirements, and supply chain tracking requirements.[53] However, this registration does not excuse outsourcing facilities from current good manufacturing process ("CGMP") requirements.[54] Outsourcing facilities registered with the FDA are also subject to inspection by the FDA according to a risk-based schedule and must also report to the FDA adverse events that occur at the facility.[55]

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[46] *National Reports Raise Questions*, *supra* note 6.

[47] *National Reports Raise Questions*, *supra* note 6.

[48] *National Reports Raise Questions*, *supra* note 6.

[49] *Center for Drug Evaluation and Research: Outsourcing Facility Information*, U.S. FOOD AND DRUG ADMIN. 2 (Sept. 2017), http://www.fda.gov/media/107569/download.

[50] *Id.*

[51] *Id.*

[52] *Compounding Pharmacies: Understanding 503A vs. 503B Designations and Why It Matters*, WELLS PHARMACY NETWORK (last visited Oct. 3, 2020), http://www.wellsrx.com/503a-vs-503b-compounding-pharmacies/ [hereinafter *Understanding 503A vs. 503B*].

[53] *Id.*; Joanna Shepherd, *Regulatory Gaps in Drug Compounding: Implications for Patient Safety, Innovation, and Fraud*, 68 DEPAUL L. REV. 385, 396 (2019).

[54] *Understanding 503A vs. 503B*, *supra* note 52.

[55] *Center for Drug Evaluation and Research: Outsourcing Facility Information*, U.S. FOOD AND DRUG ADMIN. 4 (Sept. 2017), http://www.fda.gov/media/107569/download.

C. *What are the Benefits and Risks Associated with Compounded Medications?*

Compounding drugs has been a cornerstone of the pharmaceutical and medical professions since their ancient beginnings.[56] In the 1930s, approximately 60% of all medications were compounded by pharmacists.[57] As times changed and major pharmaceutical companies in the United States began mass producing most medications, the art of compounding steeply declined.[58] In the mid-twentieth century, pharmacists moved from being the makers of medicine to mere dispensers of mass-produced products.[59] But as the twentieth century progressed, medical professionals have revived the compounding movement, realizing the benefits that custom medications afford their patients.[60] In 2019 alone, the drug compounding industry had an estimated U.S. market size of $8.9 billion.[61]

Custom compounded medications provide patients with a variety of benefits they cannot obtain by mass-produced pharmaceuticals. One of the most important, and most interesting, benefits is that compounded medications can allow patients access to medications that large pharmaceutical manufacturers have discontinued.[62] Patients who still need this discontinued medication can receive it through compounding, where a pharmacist or physician can recreate the medication using pharmaceutical ingredients and the latest research.[63] This process allows patients who need vital medicines to receive them continuously, regardless of the pharmaceutical industry's red tape. Additionally, compounded medications allow patients with allergies to obtain the benefits of the medication without the unwanted side effects.[64] For example, if a patient is allergic to dyes, gluten, or lactose, a physician or pharmacist could make the medication without the offensive ingredient. This practice allows patients the ability to take

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[56] *History and Evolution of Compounding*, MEDISCA (last visited Dec. 12, 2020), https://www.medisca.com/compounding/history-and-evolution.

[57] *Frequently Asked Questions about Pharmaceutical Compounding*, Doug's Compounding Pharmacy (last visited Dec. 12, 2020), https://www.dougsrx.com/faq/.

[58] *History and Evolution of Compounding*, MEDISCA (2019), https://www.medisca.com/compounding/history-and-evolution.

[59] *Id.*

[60] *Id.*

[61] Greg Levine, Joshua Oyster & Rebecca Williams, *Outsourcing Facilities Face Rising Drug Compounding Risks*, LAW 360 (Sept. 18, 2019), https://www.law360.com/articles/1199983/outsourcing-facilities-face-rising-drug-compounding-risks.

[62] *Frequently Asked Questions*, *supra* note 18.

[63] *Frequently Asked Questions*, *supra* note 18.

[64] *Frequently Asked Questions*, *supra* note 18.

necessary medications without the sometimes painful and bothersome side effects.[65] Customized compounded medications also allow for changes in dosage and method of delivery in order to benefit specific patients like children and the elderly, as previously described above.[66]

While there certainly are benefits to compounded medications, there are a variety of risks associated with them.[67] The FDA approves and controls drugs manufactured by pharmaceutical companies and dispensed by pharmacists.[68] The Center for Drug Evaluation and Research ("CDER"), a branch of the FDA, evaluates all new drugs before they become available for use by consumers.[69] The CDER drug approval process requires a team of highly-trained physicians, chemists, and pharmacologists to evaluate the clinical testing performed on a particular drug.[70] Simply put, this in-depth analysis assesses how a medication seeks to treat a particular illness and ensures that the intended benefits of the medication outweigh the potential risks.[71] A stamp of approval from CDER, and subsequently the FDA, allows physicians and their patients peace of mind in knowing that the prescribed medication is effective and safe for use.[72]

As stated before, the FDA itself does not regulate the approval process of compounded medications.[73] Therefore, the FDA cannot verify the safety, effectiveness, and quality of compounded medications as it does with manufactured drugs.[74] Although the FDA has regulations in place and frequently issues guidance documents regarding compounded medications, the lesser oversight subjects consumers to a heightened risk of unsafe formulations. For example, "[i]n 2001 and in 2006, FDA investigators found that [thirty percent] of compounded drug samples they tested contained either too little or too much of the active ingredient."[75] Additionally, unlike the flurry of regulations and

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65 *Patients with Allergies*, *supra* note 27.

66 Heitman, *supra* note 22.

67 Jennifer Gudeman et. al, *Potential Risks of Pharmacy Compounding*, 13 DRUGS IN R&D 1, 1-8 (Mar. 23, 2013), https://link.springer.com/article/10.1007%2Fs40268-013-0005-9.

68 *Development and Approval Process*, U.S. FOOD & DRUG ADMIN. (2019), https://www.fda.gov/drugs/development-approval-process-drugs.

69 *Id.*

70 *Id.*

71 *Id.*

72 *Id.*

73 *Compounding and the FDA*, *supra* note 1.

74 *Compounding and the FDA*, *supra* note 1.

75 Catherine Staes et. al., *Description of Outbreaks of Healthcare Associated Infections Related to Compounding Pharmacies 2000-2012*, AM. J. HEALTH SYS. PHARM (Aug. 1, 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3886339/.

testing performed on manufactured medications, there are fewer safety regulations regarding compounded medications. For example, there are currently no state regulations that require pharmacists or physicians to have specialized drug compounding training.[76] It is concerning that individuals tasked with mixing individualized medications are not required to have any additional training regarding the drugs or the compounding preparation. Lastly, because the FDA does not approve or regulate compounded drugs, they do not require compounders to report adverse events.[77] This is particularly concerning because the FDA, and consequently consumers, may never know of potentially serious issues that exist in compounding pharmacies or physicians' offices.

The most important illustration of these risks came in October 2012 when the United States experienced a serious fungal meningitis outbreak that occurred as the result of contaminated compounded drugs.[78] Contaminated injectable methylprednisolone, a type of steroid injection manufactured by New England Compounding Center ("NECC") in Framingham, Massachusetts, caused this outbreak.[79] This contaminated compounded drug affected patients in over nineteen states across the country.[80] Estimates suggest that this single compounding pharmacy put over thirteen thousand people at risk.[81] The Center for Disease Control and Prevention ("CDC") reports that over 750 patients developed serious illnesses including meningitis, stroke, joint infections, and other central nervous system infections. Sixty-four of those patients died as a result of their injuries.[82] Additionally, those who survived the incident still suffer consequences, enduring years of medical treatments and devastating pain.[83]

Although this outbreak is the most well-known incident, compounded drugs caused eleven other infectious incidents between 2000 and 2012.[84] These prior cases involved 207 patient injuries

[76] *Frequently Asked Questions*, *supra* note 18.

[77] *Compounding and the FDA*, *supra* note 1.

[78] Staes, *supra* note 75, at 2.

[79] Staes, *supra* note 75, at 2.

[80] Staes, *supra* note 75, at 2.

[81] DeNoon, *supra* note 41.

[82] *How the NECC Case Changed Compounding Pharmacy*, MJH LIFE SCIENCES (June 14, 2017), [hereinafter *NECC*], https://www.drugtopics.com/latest/how-necc-case-changed-compounding-pharmacy; Sydney Lupkin, *5 Things We Didn't Know About the Fungal Outbreak Last Year*, ABC NEWS (last visited Jan. 16, 2020), https://abcnews.go.com/Health/things-fungal-outbreak-year/story?id=20661674.

[83] *Id.*

[84] Staes, *supra* note 75 at 1.

resulting in seventeen deaths[85] and an overall fatality rate of 8.2%.[86] Including the 2012 outbreak, thirteen different drugs produced at twelve different compounding pharmacies in ten different states caused these incidents.[87] Additionally, authorities only discovered ten of the outbreaks after a "cluster of case-patients from a common hospital or clinic presented with similar clinical characteristics to a common setting."[88] This means that compounding pharmacies, free from requirements to report adverse events like outbreaks, could have been distributing dangerous contaminated drugs for an extended period of time.[89] Lastly, an investigation into one of these compounding facilities, performed only after several patients fell ill, found a second contaminated drug with the potential to harm the public.[90]

D. *Who Regulates Drug Compounding?*

The regulations surrounding drug compounding are complex in nature, come from a variety of sources, and lack clarity.[91] Although all compounded drugs pose the same risks, different regulations apply to compounding performed in different settings.[92] According to the FDA, "quality requirements for compounded drugs differ depending on the setting where compounding occurs."[93] Additionally, because the regulations vary so much, they are particularly hard to enforce, creating more potential for harm to consumers.[94] Although the FDA does not follow a strict approval process for compounded drugs in the same way that they do manufactured drugs, it still has set standards.[95] State regulatory agencies, whose practices can vary widely from state to state, then enforce these federal regulations.[96] This section will summarize the regulations.

85 Staes, *supra* note 75, at 1.

86 Staes, *supra* note 75, at 1.

87 Staes, *supra* note 75, at 8-9.

88 Staes, *supra* note 75, at 9.

89 *See generally* Staes*, supra note 75*.

90 Staes, *supra* note 75, at 10.

91 *Compounding Confusion: Uncertainty Swirls in Compound Pharmacy Regulation*, QUARLES & BRADY, LLP (Aug. 7, 2017), https://www.quarles.com/news/compounding-confusion-uncertainty-swirls-in-compound-pharmacy-regulation/.

92 *Id.*

93 *Compounding and the FDA*, *supra* note 1, at 3.

94 *Compounding and the FDA*, *supra* note 1, at 3.

95 *Compounding and the FDA*, *supra* note 1, at 2-3.

96 *See State Regulation of Compounding Pharmacies*, *supra* note 38.

1. Federal Regulations

In November of 2013, Congress passed bipartisan legislation called the Drug Quality and Security Act (DQSA), which sought to create more oversight and accountability in the making of compounded medications.[97] This legislation was a direct response to the 2012 meningitis outbreak that resulted from unsafe compounded medications.[98] DQSA clearly identified the two types of compounders—"traditional" and "non-traditional" compounders.[99] Traditional compounders are pharmacies or physicians who prepare medications in light of a specific patient's needs via an individual prescription.[100] Section 503A of the FDCA governs these compounders.[101] Non-traditional compounders, enumerated for the first time in the DQSA, are known as outsourcing facilities.[102] Essentially, these facilities are companies who produce inventory of commonly compounded drugs, created without a patient-specific prescription, and sell them to physicians for office use.[103] Section 503B of the FDCA governs these outsourcing facilities.[104] The FDA solely regulates these facilities and these facilities are not subject to the same state-level regulations as traditional compounders, as will be explained below.[105]

The Food and Drug Administration Modernization Act of 1997 added Section 503A to the FDCA.[106] Section 503A sets forth the conditions that must be satisfied for drug products compounded by a licensed pharmacist or physician in order to be exempt from the following three sections of the FDCA.[107] Compounding pharmacies do not have to comply with: (1) Section 501(a)(2)(B) concerning current good manufacturing practice; (2) Section 502(f)(1) concerning the labeling of drugs with adequate directions for use; and (3) Section 505 concerning the approval of drugs under new drug applications.[108]

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97 Drug Quality and Security Act, H.R. 3204, 113th Cong. (2013-2014).

98 *See Compounding Laws and Policies*, U.S. FOOD AND DRUG ADMIN. (last visited Dec.12, 2020), https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.

99 Drug Quality and Security Act, H.R. 3204, 113th Cong. (2013-2014).

100 *Id.*; *See Frequently Asked Questions*, *supra* note 18.

101 *See Frequently Asked Questions*, *supra* note 18.

102 H.R. 3204.

103 *Id.*

104 *Id.*

105 *Id.*

106 *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, U.S. FOOD AND DRUG ADMIN. (June 2016), https://www.fda.gov/media/94393/download.

107 *Id.*

108 *Id.*

In contrast, Section 503B governs outsourcing facilities that compound medications that are sold to healthcare facilities for in-office use.[109] The FDA is the sole regulator of these outsourcing facilities; thus, all outsourcing facilities are required to register with the FDA.[110] Section 503B also requires that these outsourcing facilities comply with USP Sections 795 and 797, as well as with the CGMP.[111] This extra compliance with the CGMP makes the standards stricter under Section 503B than for compounding pharmacies under Section 503A.[112] Additionally, these regulations force outsourcing facilities to follow DQSA labeling requirements while compounding pharmacies under Section 503A are not required to follow these same regulations. Hence, drugs compounded at outsourcing facilities under more regulations will likely have higher indicia of safety than those compounded at traditional facilities regulated under Section 503A.

Since the deadly meningitis outbreak in 2012, the FDA has provided numerous guidance documents, including priorities plans highlighting their drug compounding initiatives.[113] In 2018, the FDA shared a Compounding Priorities Plan that emphasized the administration's key priorities for the coming years.[114] In its 2018 regulations, the FDA stated that one of its goals was having more compounding pharmacies register as 503B facilities because they are subject to higher quality standards and better oversight than any other compounding facility.[115]

2. State Regulations

At the same time that federal regulations were being debated to ensure that a public health crisis similar to the meningitis outbreak would not occur again, many states began to re-examine their drug compounding regulations. Although the specific duties and functions may vary slightly from state to state, each state has a collection of professional regulatory boards that serve the public by governing the licensing and practicing of individuals within a particular occupation.[116]

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109 *See Understanding 503A vs. 503B*, *supra* note 52.

110 *See Understanding 503A vs. 503B*, *supra* note 52.

111 *Understanding 503A vs. 503B*, *supra* note 52.

112 *See Understanding 503A vs. 503B*, *supra* note 52.

113 *See e.g., Compounding and the FDA*, *supra* note 1.

114 *2018 Compounding Priorities Plan*, U.S. FOOD AND DRUG ADMIN. (June 21, 2018), https://www.fda.gov/drugs/human-drug-compounding/2018-compounding-policy-priorities-plan.

115 *Id.*

116 *See id.*; *See What is the Role of the Regulatory Board in Credentialing Programs?*, PROFESSIONAL TESTING, INC. (2006),

A regulatory board is usually comprised of various members of the profession as well as members of the general public who have a significant interest in the functioning of the board.[117] These boards create and enforce detailed licensing requirements which help safeguard the public by ensuring that the individuals in a specific profession have the necessary education and training.[118] Additionally, these boards ensure that the licensed professionals act in compliance with the specific rules and regulations put in place by that board.[119] Most boards have a detailed disciplinary process should they find, usually via a complaint process, that a member is not acting in accordance with their regulations.[120] The board has the power to suspend, revoke, or deny licensure to an individual who it deems noncompliant with its regulations.[121]

State pharmacy boards are responsible for licensing pharmacists practicing within their state.[122] More specifically, they are responsible for enforcing regulations regarding compounding done by pharmacists in pharmacies.[123] While the FDA oversees pharmaceutical manufacturing, each state has their own specific regulations regarding compounding and their own enforcement procedures. New Jersey's specific requirements are codified in the regulations and contain standards for pharmacy compounding including storage, recordkeeping, and safety protocols.[124]

In contrast, state medical boards are responsible for the licensing and regulating of physicians within a particular state.[125] Their main goal is to assure the public that the physicians licensed in their state are, not only qualified, but also provide patients with the highest standard of

https://www.proftesting.com/test_topics/pdfs/regulatory_boards.pdf [hereinafter *Role of the Regulatory Board*].

117 *See e.g.,* Board Members, The New Jersey Board of Pharmacy (last visited Jan. 16, 2019), https://www.njconsumeraffairs.gov/phar/Pages/members.aspx.

118 *See Role of the Regulatory Board, supra* note 116.

119 *See Role of the Regulatory Board, supra* note 116.

120 *See Role of the Regulatory Board, supra* note 116; *see also* Ike Devji, *What You Need To Know About Medical Board Complaints*, PHYSICIAN'S PRACTICE (Aug. 28, 2019), https://www.physicianspractice.com/view/what-you-need-know-about-medical-board-complaints.

121 *See Role of the Regulatory Board*, *supra* note 116; *see also* Ike Devji, *What You Need To Know About Medical Board Complaints*, PHYSICIAN'S PRACTICE (Aug. 28, 2019), https://www.physicianspractice.com/view/what-you-need-know-about-medical-board-complaints

122 *See State Regulation of Compounding Pharmacies*, *supra* note 38.

123 *See State Regulation of Compounding Pharmacies*, *supra* note 38.

124 *See State Regulation of Compounding Pharmacies*, *supra* note 38.

125 *See Role of the Regulatory Board*, *supra* note 116.

care.[126] Because the compounding of drugs can be performed by both pharmacists and physicians alike, quality and safety control falls directly upon these two regulating bodies and can often get lost in the shuffle. While it is clear that boards of pharmacy have control over pharmacists who compound drugs, they do not always have jurisdiction over physicians who do so.[127]

Additionally, state medical boards are usually complaint-driven agencies.[128] This means that the board does not typically inspect or examine a doctor's office until a patient has filed a complaint against them.[129] Therefore, unsafe and hazardous compounding conditions are only found after a patient suffers harm. This could create a dangerous situation if a physician is compounding a large quantity of unsafe drugs. The situation will only come to light and be remedied once an injured or aggrieved party files a complaint with the board, which could ultimately be too late.

In New Jersey, the Board of Pharmacy governs compounding done by pharmacists in the state and sets out specific regulations that must be followed in these compounding pharmacies.[130] The state medical board is silent, however, on regulating physician compounding.[131] Therefore, only professional standards set by the profession itself regulate physicians who compound in New Jersey.[132]

III. ANALYSIS

A. *Ohio as a Test State for Implementing Stricter Regulations*

In order to decide what will best serve New Jersey, this comment will first analyze the changes that were made to compounding regulations in other states like Ohio. Then, this comment will propose a pathway that New Jersey regulators can adopt in moving forward with stricter regulations on physician in-office compounding. The strongest,

126 *See Role of the Regulatory Board*, *supra* note 116.

127 Rebecca Burke, *Physician Compounding Comes Under Scrutiny*, AHLA WEEKLY (Jun. 1, 2018), https://www.powerslaw.com/wp-content/ uploads/ 2018/06/ Weekly_Burke.pdf.

128 John W. Rusher, *How To Prevent, Respond To A Complaint To State Medical Board*, APP NEWS (last visited Jan. 16, 2020), https://www.aappublications.org/news/2018/03/02/law030218.

129 *Id.*

130 N.J. ADMIN. CODE § 13:39-11 (2020); These specific regulations will not be discussed in detail as they do not apply to physicians compounding in their offices. These regulations are standard and in compliance with the FDA and USP standards for compounding after 2013.

131 N.J. STAT. ANN. § 45:9 et seq.

132 *Id.*

and most important argument will be that New Jersey should implement stricter regulations on physicians that force them to take advantage of 503B outsourcing facilities. In doing so, residents will maintain access to compounded drugs, and rest assured they are created in the safest environments with the strictest regulations.

Ohio was one of the first states to pioneer changes to state-level regulations involving drug compounding after federal-level changes to the industry in 2013.[133] Currently, Ohio has the strictest drug compounding laws in the country; it serves as the prototype for other states as they contemplate changes to their own drug compounding regulations.[134] In order to better oversee the process of drug compounding in the most effective way, the Ohio Board of Pharmacy oversees all compounding done by traditional compounders, including physicians.[135]

As of April 1, 2017, the Ohio Board of Pharmacy requires that all prescribers who possess compounded drugs obtain a license as a terminal distributor of dangerous drugs ("TDDD").[136] Additionally, those who engage in the compounding of dangerous drugs (i.e. prescription drugs), must obtain this TDDD license as well.[137] After April 1, 2017, any facility possessing compounded drugs or engaging in the compounding of drugs without complying with the TDDD licensing requirements violates Ohio law.[138] The TDDD licensing requirements includes the completion of "a 17-page form, an annual $160.00 fee, and an agreement to have the premises inspected at any time without notice."[139]

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133 *See* Brett Coldiron, *The Compounding Struggle Continues*, MD EDGE (Oct. 23, 2018), https://www.mdedge.com/dermatology/article/177795/business-medicine/compounding-struggle-continues-write-now-help-your.

134 *See id.*

135 *See National Reports Raise Questions*, *supra* note 7 at 8.

136 OHIO REV. CODE. ANN. § 4729.541(c)-(d) (LexisNexis 2017); *Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding*, STATE OF OHIO BD. OF PHARM. (Feb. 11, 2017), https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal%20Distributor%20Requirements%20for%20Prescribers%20Possessing%20Compounded%20Drugs%20or%20Engaging%20in%20Drug%20Compounding.pdf.

137 *Id.*

138 *Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding*, STATE OF OHIO BD. OF PHARM. (Feb. 11, 2017) https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal%20Distributor%20Requirements%20for%20Prescribers%20Possessing%20Compounded%20Drugs%20or%20Engaging%20in%20Drug%20Compounding.pdf.

139 Elizabeth Muennich & Brett Coldiron, *Barriers to Compounding in Physician Offices: The Future Is Now*, J. AM ACAD. DERMATOLOGY (Mar. 2019), https://www.jaad.org/action/showPdf?pii=S0190-9622%2818%2932581-7.

The new regulations define compounding broadly to encompass almost any mixing of two or more prescription drugs; the regulations also do not differentiate between sterile and non-sterile medications.[140] Additionally, the regulations provide that compounded drugs used within six hours of preparation must be prepared in a designated, clean "medication area" by authorized personnel with proper hand hygiene.[141] Compounded drugs that are used more than six hours after being prepared require a designated "clean room" with environmental control devices and additional equipment which is limited to authorized personnel whom have had additional training.[142]

B. *Proposals for New Jersey*

1. Using Ohio as a Guidepost for Flexible Regulations and Incentivizing Outsourcing Facilities

Physicians in Ohio have had negative reactions and strongly oppose the new regulations that were put in place in 2017.[143] It is important for New Jersey to recognize the Ohio medical communities' feedback, and work to find a balance that works favorably for physicians and consumers. Such attention should be paid because it will be crucial to use Ohio's regulations as a guidepost for designing New Jersey regulations going forward.

The main complaint from physicians regarding Ohio's regulations is that they believe requiring all compounders to acquire a TDDD is too strict.[144] Additionally, physicians claim that the standards attached to the TDDD license are unduly restrictive and unnecessary. These standards also impose serious financial burdens on the physicians.[145] New Jersey could certainly come up with a different licensing

140 *See* OHIO REV. CODE ANN. § 4729.01(c) (LexisNexis 2017).

141 *See Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding*, STATE OF OHIO BD. OF PHARM. (Feb. 11, 2017) https://www.pharmacy.ohio.gov/Documents/Licensing/TDDD/General/Terminal%20Distributor%20Requirements%20for%20Prescribers%20Possessing%20Compounded%20Drugs%20or%20Engaging%20in%20Drug%20Compounding.pdf.

142 *Id.*; *Cost of a Cleanroom per Square Foot*, MERCART CLEANROOMS, https://www.mecart-cleanrooms.com/cost-cleanroom-per-square-foot/. Necessitating a "clean room" space would require physician compounders to create an entirely new space where physicians could compound medications in line with the standards promulgated in Ohio, which could be incredibly expensive. Clean rooms, for example, may need to include certain ventilation systems, air pressure systems, fume hoods, and separate areas for personnel to dress in gowns and other protective equipment. The cost of implementing one of these rooms can range from $100 - $1000 per square foot.

143 *See* Coldiron, *supra* note 133.

144 *See* Coldiron, supra note 133.

145 *See* Coldiron, *supra* note 133133.

requirement for compounding physicians that is less strict than a TDDD license. It is in the best interests of the State to create an entirely new licensing process for physicians altogether since there are little to no regulation in this area of the law. Working with a hybrid committee, as explained below, could allow regulators and physicians to come up with an option that is less burdensome while still acting to protect patients from potentially dangerous drugs. An intense study of the Ohio rules, as well as a collaborative effort involving all interested parties, would certainly make for the most efficient outcome. However, the result of this process must increase safety for consumers of physician compounded drugs in New Jersey.

One of the most innovative programs regarding compounding regulations has been the creation of outsourcing facilities that are regulated under Section 503B.[146] As previously stated, these facilities are able to produce mass quantities of commonly compounded drugs without patient-specific prescriptions.[147] These compounded medications are then sold to physicians and other healthcare facilities for in-office use.[148] The outsourcing facilities are regulated under stricter rules than Section 503A facilities because they must comply with CGMP in addition to other USP regulations.[149] These facilities are required to register with the FDA, in addition to the state's Boards of Pharmacy, so they are subject to risk-based inspections by the FDA.[150] All of these additional regulations indicate that drugs produced at these facilities are likely to be safer for the consumer—the explicit goal the FDA expressed in both its 2018 and 2019 compounding guidance documents.[151]

New Jersey should incentivize the creation of outsourcing facilities in our state because of the benefits mentioned above, including lower risk to patients who use compounded medications. If New Jersey were to adopt strict standards for compounding that are similar to Ohio's, physicians who use compounded medications to treat their patients regularly, but not enough to necessitate compliance with tedious TDDD requirements, would likely outsource their compounding needs. By forcing physician compounders to either comply with stricter regulations or utilize 503B outsourcing facilities, compounded drugs will inevitably be subject to more regulations and, thus will be safer for

146 Shepherd, *supra* note 53, at 395-96.

147 *Understanding 503A vs. 503B*, *supra* note 52.

148 *Understanding 503A vs. 503B*, *supra* note 52.

149 *Understanding 503A vs. 503B*, *supra* note 52.

150 *2018 Compounding Priorities Plan*, *supra* note 114, at 1.

151 *2018 Compounding Priorities Plan*, *supra* note 114, at 1-3.

consumers. Incentives like tax breaks or tax exemptions would stimulate the creation of outsourcing facilities in New Jersey.[152] Additionally, bringing these facilities into the state would create more jobs and help to stimulate New Jersey's economy.[153]

2. Giving the State Board of Pharmacy Jurisdiction Over Physicians

New Jersey can help close the gap in legislation regarding compounding pharmacies and physician in-office compounding by granting the New Jersey Board of Pharmacy jurisdiction over physicians who compound in their offices. Although this would create more work for the New Jersey Board of Pharmacy, it would also create regulations for the direct oversight of physicians who compound in their offices. Ohio did this in 2017 and it has been met with some opposition, but that controversy stems from the strictness of the regulations, not the fact that the Ohio Board of Pharmacy has jurisdiction over physician in-office compounding.

3. Creating a Hybrid Committee

Another important step that would help close the regulatory gap between compounding pharmacies and physician in-office compounding includes New Jersey establishing a hybrid committee consisting of members of the New Jersey Board of Pharmacy and the New Jersey Board of Medical Examiners. The committee could also, if deemed necessary, include outside members of both professions who have a significant interest in the regulations of compounding in general as well as physician in-office compounding. This committee would mainly serve an advisory role that would help guide regulatory changes of compounded medications. Regulatory boards often form outside committees in order to investigate in-depth issues that will affect the board and all of its licensees. It is important that concerns surrounding compounded medications be debated in the most collaborative way possible in order to establish regulations that work for pharmacists, physicians, and most importantly, the consumers.

Creating or changing regulations and legislation is a notoriously lengthy process that necessitates careful consideration. For example, it took almost a full year after the 2012 meningitis outbreak for new

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152 Carl Davis, *Tax Incentives: Costly for States, Drag on the Nation*, INST. ON TAX'N AND ECON. POL'Y (Aug. 12, 2013), https://itep.org/wp-content/uploads/taxincentiveeffectiveness.pdf.

153 *See id.*

federal statutes to be passed regarding human drug compounding.[154] Even today, seven years later, there is still a great amount of work to be done. The hybrid committee, while not a perfect solution, would allow an intense and necessary discussion of the issues surrounding physician compounding and could educate the New Jersey Legislature and other regulatory bodies who will ultimately have the final say in what the next steps will be for New Jersey. Additionally, both regulatory boards have an important stake in the issue and would benefit from working together to efficiently establish guideposts in order to protect consumer health. There can never be too much dialogue surrounding an important issue, especially one that affects the health of so many New Jersey residents.

C. *Counterarguments*

The potential for new restrictions on in-office compounding has already been widely contested by physicians.[155] Physicians claim that new FDA guidance requiring their facilities to comply with the same standards as compounding pharmacies would limit their ability to provide vital care to their patients.[156] Some physicians argue that stricter restrictions would severely limit a physician's ability to prepare sterile drug products to administer to patients.[157] Physicians claim that the reduced access to care will increase risks for patients because there will be fewer facilities providing theses sterile drugs.[158] Additionally, doctors claim that it would be extremely difficult for them to retrofit their offices with the new equipment and "clean rooms" that Ohio's guidance requires.[159] In order to comply with the potential requirements, such as implementing designated clean rooms or a vent hood, some offices would be required to make structural changes or find new spaces to operate.[160] Lastly, physicians argue that there is little to no evidence demonstrating a significant patient risk to necessitate a massive overhaul of the current in-office compounding system.[161]

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154 *2018 Compounding Priorities Plan*, *supra* note 114, at 1.

155 Brett Coldiron, *How To Explain Physician Compounding to Legis.*, MD EDGE (June 19, 2017), https://www.mdedge.com/dermatology/article/140696/business-medicine/how-explain-physician-compounding-legislators.

156 Coldiron, *supra* note 133.

157 *See* Coldiron, *supra* note 133.

158 Coldiron, *supra* note 133.

159 *See* Coldiron, *supra* note 133.

160 *See* Coldiron, *supra* note 133.

161 Coldiron, *supra* note 133.

Dermatologists in Ohio have been some of the strongest voices in opposition to this strict regulation.[162] In an article urging dermatologists and physicians nationwide to oppose such regulations, the executives of Ohio Dermatological Association state that they are "astounded by the intrusiveness of the Pharmacy board [*sic*]."[163] They go on to analyze the rules as applied to dermatology, stating that "mixing any prescription drug into another vehicle, such as a liquid gel, or ointment, for topical use is compounding" and "[w]hen you are compounding a prescription, you are compounding a dangerous drug."[164]

Recently, dermatologists in Ohio have attempted to outline how outrageous the TDDD licensing requirement is.[165] Whilst urging other dermatologists and compounding physicians across the country to persuade their local legislators that the restrictive Ohio compounding laws should not be enacted in other states, dermatologist Brett Coldiron created a demonstration that he believes illustrates the unnecessary restrictiveness of these regulations.[166] He suggests when a doctor quickly mixes epinephrine and bicarbonate in a syringe, a simple procedure to treat skin cancer patients, will no longer be able to be performed in Ohio without a TDDD license.[167]

Consumer health, however, should be the utmost priority for all healthcare providers, including compounding pharmacists and physicians who compound in their offices. Although stricter regulations, surprise office inspections, and additional registration materials (such as a TDDD license) may take some initial getting used to, it seems to be a small price to pay in order to ensure safer patient care.

The physicians' main argument is that having fewer physicians to provide these vital medications will increase the costs to the consumer. This rationale is, at best, flawed. The new category of outsourcing facilities created by the FDA in 2013 could alleviate some of this pressure. These facilities are able to create large quantities of commonly compounded drugs and ship them to healthcare facilities around the country.[168] If the drugs were made in larger quantities and

162 Muennich, *supra* note 139.
163 Muennich, *supra* note 139 .
164 Muennich, *supra* note 139.
165 *See* Coldiron, *supra* note 155.
166 Coldiron, *supra* note 155.
167 Coldiron, *supra* note 155.
168 *2018 Compounding Priorities Plan*, *supra* note 114, at 2.

in safer facilities that are regulated directly by the FDA, it would not only be safer for the patient but also could lower prices.[169]

Additionally, allowing an exemption for physicians who conduct in-office compounding that permits them to be non-compliant with FDA regulations could inevitably create a loophole for compounding operations under the guise of a physician[170] Creative, profit-oriented physicians could potentially circumvent the regulations put in place, thereby weakening safeguards for patients across the country.[171] A loophole could certainly lead to another public health crisis, which could be even worse than the 2012 meningitis outbreak that seriously harmed thousands of people.[172]

IV. CONCLUSION

Drug compounding is a vital part of the medical landscape that provides patients with the ability to obtain custom drugs that fit their unique needs.[173] Without drug compounding, there are many patients who otherwise would be unable to obtain the medications necessary to most effectively treat their illnesses.[174] But, with all of the benefits associated with compounded medications, there are also many risks as well. The 2012 fungal meningitis outbreak sparked a wide range of federal and state-wide changes in compounding regulations. The outbreak also highlighted the many problems that existed within the field currently, including physician in-office compounding.[175] While drug compounding will always involve some risk, there are certainly ways for New Jersey to minimize them. It is in the state's best interest to take action to better regulate medical compounding to keep its residents safe, especially that which is done in physicians' offices.

New Jersey should first look to the Ohio regulations and use them as a guidepost for their own regulations. The Ohio regulations have undoubtedly made compounded drugs safer in the state but have also faced much criticism from physicians in the state and around the country, which should be taken into account as well. Finding a balance between the strict Ohio regulations and the complete lack of regulations in New Jersey is possible and crucial to protecting patients while still allowing them access to their medications. New Jersey may also want to

169 *See 2018 Compounding Priorities Plan*, *supra* note 114, at 3.
170 Coldiron, *supra* note 155.
171 Coldiron, *supra* note 155.
172 *NECC*, *supra* note 82.
173 *Compounding and the FDA*, *supra* note 1.
174 *Compounding and the FDA*, *supra* note 1.
175 *NECC*, *supra* note 82 .

experiment with other ways that can make compounded drugs safer, including creating incentives for Section 503B outsourcing facilities to operate in New Jersey. Forcing compounders into using more heavily regulated outsourcing facilities, through stricter regulations for physician compounders, will hopefully make drugs safer for the consumer. Additionally, New Jersey should also consider giving the New Jersey Board of Pharmacy jurisdiction over compounding physicians as well as consider creating a hybrid committee with pharmacists, physicians, and other members of the public in order to better investigate this issue and all of the various solutions.

While physician opposition to these measures may be strong at first, it is important to remember the backdrop that brought this issue to the forefront of medicine in the first place. The 2012 meningitis outbreak significantly affected nearly a thousand people, largely due to the lack of regulations regarding compounded drugs.[176] The protection of the consumer should be the ultimate priority, and by putting stricter regulations into effect, New Jersey will accomplish this.

[176] Staes, *supra* note 75, at 1, 8-9.