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Volume 21
Number 1
2018

QHLJ

Table of Contents

Articles

- The Legal Origins of the New England Compounding
Center Crisis and the Future of Drug Compounding
Regulation
*Leo R. Takaoka, David P. M. Pleyne,
and Marc A. Rodwin* 1
- Reforming Quarantine: Moving Towards a More Ethical
and Effective Approach to Outbreak Management
Cara M. Passaro 57
- Refuah She'einah Bedukah: Jewish Medical Ethics and
Experimental Treatment
Antonio G. Tapia 83
- ### Notes
- Public Defenders: The Impossibility of Rule 1.14 and How
Mental Health First Aid Training Can Contribute to
Success
Kristin A. Chiriatti 103
- Selling Sex: The Costs of Criminalization
Candace N. Hill 131

THE LEGAL ORIGINS OF THE NEW ENGLAND COMPOUNDING CENTER CRISIS AND THE FUTURE OF DRUG COMPOUNDING REGULATION

Leo R. Takaoka, David P. M. Pleyne, and Marc A. Rodwin.*

ABSTRACT

The outbreak of fungal meningitis in 2012 that injured more than 750 people involved more than misconduct by the New England Compounding Center (NECC). It was due to the unclear legal status of compounding pharmacies, problems with the legal oversight, limited FDA authority, and overlapping and unclear federal and state jurisdiction. These conditions became hazardous when compounding pharmacies assumed functions that went beyond traditional compounding. This article explores the legal origins of the NECC crisis. It also examines how the state and federal government have responded, and it assesses the legislation enacted in 2013.

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I.	Introduction	3
II.	Compounding Pharmacy in American Medicine	5
III.	Federal Oversight of Compounding Pharmacies	9
	A. Before the Food and Drug Modernization Act of 1997	9
	B. The FDA Modernization Act § 503A Regulates Compounding, But Ninth Circuit Strikes It Down Because It Includes Unconstitutional Advertising Restrictions	16
	C. The Fifth Circuit Upholds § 503A except its Advertising Restrictions	19
	D. FDA Oversight After the Circuit Split	20
IV.	Obstacles to FDA Oversight and Calls for Greater FDA Regulation of Drug Compounding	23
	A. Limited FDA Inspection Authority	24
	B. The FDA's Limited Access to Relevant Information	25
	C. Drug Manufacturers Pressure the FDA to Act Against Compounding Pharmacies	27
	1. Wyeth's Citizen Petition	27
	2. KV Pharmaceutical Suit against the FDA	29
V.	The New England Compounding Center Crisis	30
	A. FDA Oversight of NECC	30
	B. FDA Oversight of Ameridose	35
	C. NECC Violates Legal and Quality Standards	39
VI.	State Response to the Crisis	41
	A. Hobbled State Oversight	41
	B. States' Response After the Fungal Meningitis Outbreak ...	42
VII.	The Drug Quality and Security Act of 2013	44
	A. The Compounding Quality Act	46
	1. Outsourcing Facilities for Certain Non-Traditional Compounding	46
	2. Labeling, Good Manufacturing Practices, Reporting Requirements, and Inspections	49
	3. Traditional Compounding	50
	4. Federal and State Coordination and Communication ...	52
	B. The Drug Supply Chain Security Act (DSCA)	53
VIII.	Key Unresolved Issues	54
	A. The Legal Status of Compounding Pharmacies Under Federal Law	54
	B. Conflicting Standards within Federal Law and Between Federal and State Law	55

I. Introduction

In 2012, an outbreak of fungal meningitis and other persistent fungal infections¹ both sickened more than 750 people and resulted in sixty-four deaths in twenty states, events that became known as the New England Compounding Center Crisis (NECC). Investigations revealed that the victims had been exposed to contaminated products compounded and distributed by NECC, a licensed pharmacy located in Framingham, Massachusetts, which was owned and managed by the same individuals who owned and managed Ameridose, a pharmaceutical manufacturer that also faced quality assurance problems that endangered patients.² The NECC outbreak ranks as one of the worst public health crises associated with contaminated drugs in the history of the United States, and it exposed fundamental failures in drug safety oversight.³ It illustrates the problems that can occur when pharmacies go beyond traditional drug compounding and produce large quantities of drugs without patient-specific prescriptions, and sell the drugs to health facilities in multiple states.⁴ In effect, these pharmacies manufacture drugs under the guise of drug compounding, thereby eluding the safety and effectiveness requirements under the 1938 Federal Food, Drug, and Cosmetics Act (FDCA).

Starting in the summer of 2012, NECC shipped over 17,000 contaminated vials of an injectable steroid solution into multiple states.⁵ The medication was often injected into the spinal columns of patients to relieve chronic pain. In September 2012, physicians at Vanderbilt University reported a case of fungal meningitis in a patient who had received

¹ Pontikes, R. G.; Gallagher, P. C.; Hart, E. L. *The Regulation of Pharmacy Compounding: FDA Authority and the Compounding Quality Act of 2013*, Food and Drug Law Institute, Washington, DC, 2014 [hereinafter Pontikes] (finding the states most affected by NECC's contaminated compounded drugs were Michigan, with 264 patients infected and nineteen deaths, and Tennessee, with fifteen patients infected and sixteen deaths).

² Committee on Energy and Commerce, 113th Cong. FDA'S OVERSIGHT OF NECC AND AMERIDOSE: A HISTORY OF MISSED OPPORTUNITIES? (2013), <http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD101.pdf> [hereinafter NECC AND AMERIDOSE].

³ NECC AND AMERIDOSE, *supra* note 2, at 1.

⁴ According to the U.S. Centers for Disease Control and Prevention, as of July 1, 2013, 749 individuals who received the contaminated steroid injections became ill with fungal meningitis or other types of infections and sixty-one of them have died. NECC AND AMERIDOSE, *supra* note 2, at 1.

⁵ NECC AND AMERIDOSE, *supra* note 2, at 1.

an injection of the compounded steroid methylprednisolone.⁶ Five additional complaints, also in Tennessee, were identified a few days later. All six cases were traced to methylprednisolone sterile injections compounded by NECC, which compelled the Tennessee Department of Health to contact the Massachusetts Department of Public Health (MDPH).⁷ Soon thereafter, Massachusetts conducted an on-site inspection of the NECC facilities, but NECC voluntarily recalled only three lots of the methylprednisolone sterile injections.⁸ A week later, officials from the Food and Drug Administration (FDA) were on site, at which time NECC voluntarily recalled all of its compounded products and surrendered its Massachusetts pharmacy license.⁹

FDA inspection of the NECC facility revealed that every vial of methylprednisolone that was tested contained microbial growth, with one vial even showing evidence of fungus.¹⁰ Despite NECC representing that the raw materials used for its injectable preparations were sterile, the FDA alleged that NECC used non-sterile active pharmaceutical ingredients (APIs) and raw materials for its injectable products.¹¹ Further tests showed bacterial and mold growth throughout the NECC facility, including in and on the surfaces of clean rooms, in gown rooms, on the tables and near the hoods where the drugs were compounded.

The NECC compounding crisis was a long time coming. It arose not only from the misconduct of one compounding center, but also from problems with legal oversight, weaknesses in federal legislation that limited the FDA's authority owed to overlapping and unclear federal and state jurisdiction, and the unclear legal status of compounding pharmacies. These conditions became critical when changes in the marketing of drugs allowed compounding pharmacies to take on functions that went beyond traditional compounding. This article explores the legal origins of the NECC crisis. It also examines how the state and federal government have responded, and it assesses the legislation that Congress enacted in 2013.

⁶ Kevin Outterson, *Regulating Compounding Pharmacies after NECC*, 367 NEW. ENG. J. MED. 1969, 1971 (2012); see Pontikes, *supra* note 1.

⁷ Outterson, *supra* note 6; see Pontikes, *supra* note 1.

⁸ Outterson, *supra* note 6; see Pontikes, *supra* note 1.

⁹ FDA Form 483 issued to New England Compounding Center on November 26, 2012. Pontikes, *supra* note 1; see Outterson, *supra* note 6.

¹⁰ Pontikes, *supra* note 1.

¹¹ Pontikes, *supra* note 1.

II. *Compounding Pharmacy in American Medicine*

Drug compounding comprises the process of combining, mixing, or altering ingredients to create a drug. Traditionally, drug compounding intended to create a drug tailored to the needs of an individual patient in response to a licensed medical practitioner's prescription.¹² Now, drug compounding also encompasses creating a drug without a prescription, based on order history – a practice known as anticipatory compounding.¹³ According to estimates, between thirty million to forty million prescriptions are compounded annually, comprising approximately one to three percent of the prescription drug market.¹⁴ Nevertheless, despite its small market share, pharmacy compounding plays an important role because it can provide a medication in a form better suited to the needs of an individual patient, e.g., by removing or replacing an excipient to which the patient is allergic or providing a liquid form of a tableted drug for a child who cannot swallow a tablet.¹⁵

Traditionally, the states have regulated compounding pharmacies.¹⁶ Over time, the activities of compounding pharmacies have expanded and some compounding pharmacies engage in activities that lie outside their traditional practice.¹⁷ In the 1990s and early 2000s, some compounding pharmacies started to resemble drug manufacturers.¹⁸ The FDA tried to respond to these changes but was hampered due to limited jurisdiction and challenges to its regulatory authority.¹⁹

Under the FDCA, compounded drugs are considered “new drugs,”²⁰ and are subject to FDA rules regarding manufacturing and market approval. However, traditional compounding pharmacies cannot

¹² U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-702, DRUG COMPOUNDING: CLEAR AUTHORITY AND MORE RELIABLE DATA NEEDED TO STRENGTHEN FDA OVERSIGHT (2013) [hereinafter GAO REPORT].

¹³ GAO REPORT, *supra* note 12, at 5.

¹⁴ Amanda Phillips, *The Role of Compounding in Tomorrow's Care of Patients: Personalized Pharmaceutical Care*, INT'L ACAD. OF COMPOUNDING PHARMACISTS (2011), <http://www.iacprx.org/displaycommon.cfm?an=1&subarticlenbr=1>; see Pontikes, *supra* note 1.

¹⁵ GAO REPORT, *supra* note 12, at 4.

¹⁶ Pontikes, *supra* note 1.

¹⁷ Pontikes, *supra* note 1.

¹⁸ Pontikes, *supra* note 1.

¹⁹ Pontikes, *supra* note 1.

²⁰ The FDCA defines “new drug” as “[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof” 21 U.S.C. § 321(p)(1) (2017). Drug manufacturers submit new drug applications (NDAs) to the FDA to seek

practically seek regulatory approval for each individualized drug that is compounded.²¹ As a result, the FDCA exempts compounding pharmacies from many of the stringent requirements imposed upon traditional drug manufacturers.²²

Free from the burden imposed on large-scale drug manufacturing under the FDCA, compounding pharmacies can sometimes sell medications at a lower price. The NECC crisis reflects an evolution to new business models that expand a pharmacist's role in patient care.²³ Healthcare providers such as hospitals or doctors' offices, sometimes, procured drugs from cheaper compounders rather than from manufacturers.

Prior to the NECC crisis, many pharmacies thought certain activities fell under FDA jurisdiction, and states generally believed that the FDA lacked the authority to regulate traditional compounding pharmacies. A split between the Fifth and Ninth Circuit Court of Appeals undermined the FDA's mandate, leaving the FDA hesitant to use its enforcement powers. This state of affairs created a false sense of security regarding compounded drugs and a dangerous situation for consumers. This NECC crisis paved the way for the Drug Quality and Security Act (DQSA), passed on November 27, 2013, providing the FDA more authority to regulate and monitor the manufacturing of compounding drugs.

Because some patients have a clinical need that cannot be met with existing pharmaceutical products, compounding pharmacies provide an important service to those patients. The growth in interest of customized products, including allergen-free drugs, single administration of multiple drugs, and individualized formulations of drugs (such as liquids instead of tablets) plays a major role in heightened demand for compounded drugs.²⁴ In addition, drug compounders also help supply

approval to market and sell new pharmaceutical drug products in the United States. 21 U.S.C. § 321(p) (2017). In addition, abbreviated new drug applications (ANDAs) are submitted to FDA to seek approval to market a generic version of a drug after the period of exclusivity and any patents for a brand-name drug expire. *Id.*

²¹ Pontikes, *supra* note 1.

²² Pontikes, *supra* note 1.

²³ See, e.g., Russell Redman, *2012 Retail Forecast: Chain Drug Eyes Broader Role*, CHAIN DRUG REVIEW (Dec. 29, 2011), <http://www.chaindrugreview.com/2012-retail-forecast-chain-drug-eyes-broader-role>; Council on Credentialing in Pharmacy, *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians*, J. AM. PHARM. ASS'N. 24 (2010).

²⁴ Carolyn Y. Johnson, *Compounding Pharmacies Fill Important Medical Niche*, BOSTON

medications that are produced by manufacturing firms when in short supply. Shortages of commercially-available drugs, especially shortages of generic sterile products, play a central role in the increased demand for drug compounding.²⁵

Pharmacists compound drugs using a variety of techniques, including compounding from bulk substances or APIs, which are generally defined as substances used in the manufacturing, processing or packaging of a drug which become a finished dosage form of the drug.²⁶ Compounded drugs fall into two categories: 1) sterile preparations, including intravenously administered fluids and injectable drugs, which pose special risks of contamination and require special safeguards to prevent injury or death; and 2) non-sterile preparations such as capsules, ointments, creams, gels, suppositories, and pills, which are considered to have lower production risk.²⁷

Drug compounding is a traditional component of the pharmacy profession,²⁸ and is practiced in hospital pharmacies, in community pharmacies, in chain drug store pharmacies, and in home infusion settings.²⁹ In 2012, nearly half of the 56,000 community-based pharmacies in the United States performed some type of compounding.³⁰ Precise statistics on the prevalence of pharmacies that compound drugs are beyond the scope of this article. However, there are also approximately 3,000 community-based pharmacies that specialize in the compounding of sterile

GLOBE (Nov. 3, 2012), <https://www.bostonglobe.com/metro/2012/11/02/compounding-pharmacies-filled-niche-for-major-hospitals/47MsPtBMEkT67TQmfNXF8O/story.html>.

²⁵ *Id.*; Kristina Fiore, *Drug Shortages Spark Use of Compounders*, MEDPAGE TODAY (Oct. 18, 2012), <http://www.medpagetoday.com/meetingcoverage/asa/35406>; T. Meyer, *Overseeing Outsourced Compounding During Shortages, Pharmacy Purchasing and Products*, PHARMACY PURCHASING & PRODUCTS (June 2012), http://www.pppmag.com/article/1141/June_2012/Overseeing_Outsourced_Compounding_during_Shortages/#.T9k83KBs1IQ.blogger; Katie Thomas, *Lapses at Big Drug Factories Add to Shortages and Danger*, N.Y. TIMES (Oct. 17, 2012), <http://www.nytimes.com/2012/10/18/business/drug-makers-stalled-in-a-cycle-of-quality-lapses-and-shortages.html>.

²⁶ 21 C.F.R. § 207.3(a)(4)(2017); *see also* 21 C.F.R. § 207.1(b)(2017).

²⁷ U.S. PHARMACOPEIAL CONVENTION, (795) PHARMACEUTICAL COMPOUNDING – NON-STERILE PREPARATIONS 1 (2014); *see also* Letter from Stuart Wright, Deputy Inspector Gen. for Evaluation and Inspections, to Dr. Margaret A. Hamburg, Comm’r of Food and Drugs (Apr. 10, 2013), <http://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf> [hereinafter *OIG Memorandum*].

²⁸ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008).

²⁹ GAO REPORT, *supra* note 12, at 5.

³⁰ *Public Hearing into Alleged Violations of Pharmacy Regulations at the New England Compounding Center and Associated Issues Concerning Oversight Capabilities at the Department of Public Health*, Mass. H.R. 3 (2012).

and non-sterile prescription drugs.³¹ Up to 26,000 community-based pharmacies engage in some form of compounding and 7500 specialize specifically in compounding.³² A 2013 report prepared for the FDA by the U.S. Department of Health and Human Services Office of the Inspector General revealed that 92 percent of acute-care hospitals surveyed used sterile compounded drugs administered via injection or infusion.³³ Of those acute-care hospitals, 85 percent outsourced at least some of the compounded drug products from extramural pharmacies.³⁴

The FDA regulates commercial pharmaceutical manufacturing activities. However, the states are the primary regulators of pharmacies and the practice of compounding. State laws generally require compounding pharmacies to receive a prescription order from a medical practitioner for an individually identified patient or a patient-specific prescription, before a drug can be compounded and sold.³⁵ Some states allow drugs to be compounded pursuant to a healthcare provider's order, in anticipation for use at the office.³⁶ The "office use" compounded drug can then be administered directly to a visiting patient at the provider's office.³⁷

State pharmacy laws typically require registration and licensing for pharmacies and pharmacists.³⁸ They also establish labeling and purity requirements for compounded drugs, and they set training and education

³¹ GAO REPORT, *supra* note 12, at 5.

³² GAO REPORT, *supra* note 12, at 5.

³³ The hospitals reported that drug shortages of commercially available products was "a very important factor when deciding whether to outsource" compounded sterile drugs. OIG Memorandum, *supra* note 27, at 6. The OIG went on to describe that "[a]ccording to pharmacists with whom we spoke, [compounded drugs] prepared onsite often have limited shelf lives or must be refrigerated." *Id.* "In many cases, outside pharmacies can provide products that have undergone stability testing and have extended shelf lives." *Id.* "Outsourcing these CSPs enables hospitals to have product on hand when needed with less waste." *Id.*; Pontikes, *supra* note 1.

³⁴ Pontikes, *supra* note 1.

³⁵ "A prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns." Ohio Admin. Code. Ann. § 4729-9-21(F) (repealed 2016).

³⁶ Compounding nonprescription drugs, however, would violate section 503A of the FDCA, since the compounded nonprescription drug would be misbranded, adulterated, and a new drug. Federal Food, Drug, and Cosmetic Act (FDCA) § 503(A) (2016); *see* Houck v. Iowa Bd. of Pharmacy Examiners, 752 N.W.2d 114 (Iowa 2008).

³⁷ "Nothing in this act is meant to limit a prescriber's ability under pre-existing law to order a compounded medication for use in the prescriber's practice, as permitted by State and federal law." N.J.S.A. § 45:14-41 (2000).

³⁸ N.Y. Educ. Law § 6803 (McKinney 2016).

requirements for compounding pharmacists.³⁹ State Pharmacy Boards oversee and enforce pharmacy compounding practices.⁴⁰ States typically require that pharmacists comply with United States Pharmacopeia (USP) and National Formulary (NF) standards.⁴¹ These standards are also incorporated into Federal law by the FDCA.⁴²

Under the FDCA, any drug that does not comply with federal quality standards violates the Act; there is no exception for compounded drugs. However, section 510(g) of the FDCA recognizes that traditional compounding by pharmacists, as regulated by state law, is not considered manufacturing and therefore exempts pharmacies from registering as manufacturers if they do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of dispensing or selling drugs or devices at retail.⁴³

III. Federal Oversight of Compounding Pharmacies

A. Before the Food and Drug Modernization Act of 1997

In 1906, Congress enacted the Pure Food and Drug Act to improve drug safety. The Act targeted false labeling of drugs but did not attempt to regulate the practice of drug compounding, which was traditionally a

³⁹ See, e.g., *id.*; Ga. Code. Ann. § 26-3-7 (2017).

⁴⁰ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 361 (2002); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008). *United States v. Franck's Lab, Inc.*, 816 F. Supp. 2d 1209, 1216 (M.D. Fla. 2011) (“Because the practice of pharmacy is state-governed, the states, including Florida, regulate compounding as part of their regulation of pharmacists.”); see, e.g., CALIFORNIA STATE BOARD OF PHARMACY, <http://www.pharmacy.ca.gov> (last visited Feb. 23, 2018); FLORIDA BOARD OF PHARMACY, <http://www.floridaspharmacy.gov> (last visited Feb. 23, 2018); TEXAS STATE BOARD OF PHARMACY, <http://www.tsbp.state.tx.us/> (last visited Feb. 23, 2018).

⁴¹ The USP and the NF are two compendia that set compounding standards that widely acknowledge scientifically sound procedures and best practices for the compounding of drugs, and that facilitate the delivery of consistent and good-quality compounding of drugs to patients. GAO REPORT, *supra* note 12. The USP and NF also provide monographs for drug articles, including ingredients used in compounded preparations, and monographs for the compounded preparations themselves, comprising standards of identity, quality, purity, strength, packaging, and labeling. *Id.*; see FDCA § 201(j) (2016) (designating the USP as the “official compendium” of the FDCA); U.S. PHARMACOPEIAL CONVENTION, (795), *supra* note 27 (defining “non-sterile drug compounding”); U.S. PHARMACOPEIAL CONVENTION, (797) PHARMACEUTICAL COMPOUNDING – STERILE PREPARATIONS 1 (2015) (defining “sterile drug compounding”).

⁴² Section 503A of the FDCA requires that drug products be compounded in compliance with USP Chapter 797 standards, if they are available. FDCA § 503(A) (2016). Many states require compounded drugs to comply with the USP and NF standards. See GAO REPORT, *supra* note 12, at 14.

⁴³ 21 U.S.C. § 360(g) (2017).

state function.⁴⁴ As long as a drug compounder made no false or misleading claims regarding the ingredients, they did not violate the statute.⁴⁵

The Pure Food and Drug Act established federal authority to interdict and penalize the interstate marketing of any drug that was adulterated or misbranded.⁴⁶ The FDCA, together with the 1962 Kefauver-Harris Drug Amendments to the FDCA, form the core of modern drug law in the United States.⁴⁷ The FDCA made the FDA a gate-keeper whose approval was necessary prior to the marketing of new drugs. The FDCA empowered the FDA to set official standards for strength, quality, purity, packaging, and labeling, to regulate the manufacture, marketing, and distribution of pharmaceutical products, and to enforce the Act.⁴⁸ Initially the FDA only reviewed drugs to ensure that they were not unsafe. The 1962 Amendments prohibited the marketing of new drugs if their sponsors failed to convince the FDA that the drugs were effective as well as safe.⁴⁹ While the FDCA does not explicitly regulate drug compounding, the statute does regulate the introduction of new drugs, as well as misbranding of drugs, adulteration of drugs, and production and distribution. The FDA has applied these standards to compounded drugs.⁵⁰

⁴⁴ Federal Food and Drug Act of 1906, Pub. L. 59-384, 21 U.S.C. Sec 1-15 (1906); *Joint Session of Am. Pharm. Ass'n, et al.*, 17 J. AM. PHARM. ASS'N 1000, 1010-13 (1938); *United States v. Antikamnia Chem. Co.*, 231 U.S. 654, 665 (1913); see also ANDREW NOLAN, FEDERAL AUTHORITY TO REGULATE THE COMPOUNDING OF HUMAN DRUGS, CRS REPORT R43038 at 13 (2013) [hereinafter CRS REPORT R43038].

⁴⁵ JAMES HARVEY YOUNG, THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION 9, 243-44 (1961); see also CRS REPORT R43038, *supra* note 44, at 2.

⁴⁶ Section 7 of the 1906 Act deemed a drug "adulterated" when: 1) it differs from the standard of strength, quality, or purity as determined by the test established by the USP or NF office and 2) the strength or purity falls below the professed standard or quality under which it is sold. Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906). Under section 8, a drug is "misbranded" if: 1) the drug is an imitation of or offered for sale under the name of another drug; 2) the terms of weight or measure are not correctly stated on the outside of the package; and 3) either (a) the label bears any false or misleading statements, or (b) the original package has been removed, or if the package fails to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of such substances contained. *Id.*

⁴⁷ John C. Krantz Jr., *New Drugs and the Kefauver-Harris Amendment*, J. NEW DRUGS, Mar-Apr. 1966, at 77; Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

⁴⁸ FDCA § 1003; 21 U.S.C. § 393 (2017); see, e.g., SUSAN THAUL, HOW FDA APPROVES DRUGS AND REGULATES THEIR SAFETY AND EFFECTIVENESS, CONG. RESEARCH SERV., R41983, at 4-5 (2013); see also CRS REPORT R43038, *supra* note 44, at 4.

⁴⁹ CRS REPORT R43038, *supra* note 44, at 3.

⁵⁰ CRS REPORT R43038, *supra* note 44, at 3.

Since 1938, the FDCA has regulated the introduction of new drugs. Specifically, section 201(p) of the FDCA defines a “new drug” as any drug that is not “generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.”⁵¹ To receive FDA approval, sponsors must submit data from well controlled studies that the FDA finds the drugs are “safe and effective” for their intended use prior to the products being marketed to the public, and transported or distributed in interstate commerce.⁵² The Act sets rules for testing new drugs under the Investigational New Drug (IND) program.⁵³ The process by which the FDA reviews evidence that a sponsor submits when seeking permission to market a new drug, is referred to as the New Drug Application (NDA) protocol.⁵⁴ Drug manufacturers must also ensure that its manufacturing site passes FDA Current Good Manufacturing Practices (cGMPs) inspection for production and packaging,⁵⁵ and obtain FDA approval for the drug’s labeling.⁵⁶

Section 502 of the FDCA prohibits misbranding.⁵⁷ The term “misbranding” applies to false or misleading information or packaging, lack of required information, lack of clear or conspicuous information, and improper or deficient packaging and labeling.⁵⁸ Section 502 also deems a drug misbranded if the labeling does not contain adequate direction for use.⁵⁹ Generally, “Adequate Direction for Use” means directions under

⁵¹ FDCA § 201(p)(1); *see* FDCA § 201(g)(1) (defining “drug” as a substance recognized by an official pharmacopeia or formulary that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease).

⁵² “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application [by the FDA] is effective with respect to such drug.” FDCA § 505(a).

⁵³ FDCA § 505.

⁵⁴ Generally, under the FDCA all “new chemical entity” (NCE) drugs were restricted by the FDA to prescription status and “new drug” requirements encompassed non-prescription drugs that had been converted from prescription status through a supplemental NDA protocol. FDCA § 505(b).

⁵⁵ FDCA § 520(f).

⁵⁶ FDCA § 502.

⁵⁷ FDCA § 301(b).

⁵⁸ FDCA § 502(i)(1).

⁵⁹ FDCA § 502(f).

which a layperson can understand the use of a drug and its intended purpose.⁶⁰ Drug labels must contain: 1) statements of all conditions, purposes, or uses for which such drug is intended, including warnings when the use, method or recommended dosage becomes unsafe, or when duration of administration or application may be dangerous to health; 2) general dose quantities for the drug's intended use by persons of different ages and physical conditions; 3) frequency, duration, time, and route of administration or application of the drug; and 4) any preparations for use that require shaking, dilution, adjustment of temperature, or other manipulation or processes.⁶¹

The FDCA also prohibits the transportation of adulterated drugs in interstate commerce.⁶² Section 501 explains that "adulteration" occurs when a drug becomes impure or unfit for human consumption due to an alteration in composition or formulation.⁶³ The FDCA deems a drug adulterated if: 1) it consists in whole or in part of any filthy, putrid, or decomposed substance whereby it may have been rendered injurious to health; 2) it purports to be or is represented as a drug name which is recognized in an official compendium (USP or NF), and its strength differs from, or its quality or purity falls below the standard set forth in such compendium; and 3) it has been mixed or re-packaged to reduce its quality or strength, or substituted wholly or in part.⁶⁴

The FDCA also deems a drug adulterated if it is manufactured, prepared, processed, packed, or stored in a facility under unsanitary conditions, or does not conform to the FDA's Current Good Manufacturing Practices (cGMPs).⁶⁵ The FDA's cGMPs set standards for the design, monitoring, and control of manufacturing processes in order to ensure the identity, strength, quality, and purity of the drug.⁶⁶ cGMPs cover all aspects of the drug manufacturing process including ventilation, air filtration and cooling, equipment maintenance, construction and design, production and processing controls, and the required records and reports by the pharmaceutical manufacturing entity for the facility.⁶⁷

⁶⁰ 21 C.F.R. § 201.5 (2017).

⁶¹ *Id.*

⁶² FDCA § 301(a).

⁶³ FDCA § 501.

⁶⁴ FDCA § 501(a)-(d).

⁶⁵ FDCA § 501(h).

⁶⁶ FDCA § 520(f)(1)(A).

⁶⁷ *See Facts About Current Good Manufacturing Practices (cGMPs)*, U.S. FOOD AND

Section 301 of the FDCA provides the FDA authority over compounded drugs under certain circumstances. For instance, the Act prohibits introducing or delivering into interstate commerce: 1) a “new drug” without prior FDA approval;⁶⁸ 2) an “adulterated” drug;⁶⁹ or 3) a “misbranded” drug.⁷⁰ It also prohibits the manufacturing of any adulterated or misbranded drug.⁷¹ Section 302 of the Act also authorizes the United States to seek injunctive relief in federal court to restrain any violations of Section 301,⁷² subjects those who have violated the FDCA’s prohibitions to civil fines and criminal penalties,⁷³ and allows the federal government to seize mislabeled or adulterated drugs or drug products.⁷⁴

Consequently, the FDA can take action over pharmaceutical compounders if the compounders introduce new drugs, misbrand drugs, or sell adulterated drugs in interstate commerce.⁷⁵ Initially, the FDA did not use these provisions to regulate compounding,⁷⁶ and deferred to the states for the regulation of drug compounding.⁷⁷ Also, the FDA did not require compounding pharmacists to file an NDA seeking “new drug” approval for compounded drugs.⁷⁸ The FDA has traditionally considered it important to allow pharmacies to provide medication tailored to the needs of individual patients.⁷⁹ The FDA also believed that it was impracticable for pharmacies to complete and obtain NDA approval for each compounded drug prepared for each patient-specific medication.⁸⁰

DRUG ADMIN. (Jan. 6, 2015), <http://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm169105.htm>. For additional guidance on the cGMP process, see FOOD AND DRUG LAW INSTITUTE, HOW TO COMPLY WITH cGMPs (2013); see also 21 C.F.R. §§ 211.46, 211.63-72, 211.100-113, 211.180-198 (2017).

⁶⁸ FDCA § 301; see CRS REPORT R43038, *supra* note 44, at 4; FDCA § 505 (new drugs).

⁶⁹ FDCA § 301; see CRS REPORT R43038, *supra* note 44, at 4; FDCA § 501(a)(2)(B) (adulteration).

⁷⁰ FDCA § 301; see CRS REPORT R43038, *supra* note 44, at 5; FDCA § 502(f)(1) (misbranding).

⁷¹ FDCA § 301; see CRS REPORT R43038, *supra* note 44, at 4.

⁷² FDCA § 302(a); see CRS REPORT R43038, *supra* note 44, at 4.

⁷³ FDCA § 301; see CRS REPORT R43038, *supra* note 44, at 4.

⁷⁴ FDCA § 304; see CRS REPORT R43038, *supra* note 44.

⁷⁵ See *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 395 (5th Cir. 2008) (noting the language of the FDCA’s new drug definition to be “both plain and expansive”); *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1237 (M.D. Fla. 2011) (noting that the FDCA’s provision, if “read literally,” would apply to bulk compounding); see CRS REPORT R43038, *supra* note 44, at 4.

⁷⁶ *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002).

⁷⁷ *Id.* at 361.

⁷⁸ *Mukasey*, 536 F.3d at 389.

⁷⁹ *Thompson*, 535 U.S. at 362.

⁸⁰ GAO REPORT, *supra* note 12, at 7. In fiscal year 2013, user fees for NDAs ranged from

Nevertheless, the FDA considers compounded drugs to be “new drugs” that are subject to FDA oversight to ensure that they are safe, effective and made in accordance with federal quality standards.⁸¹ However, because the FDA has limited resources to verify manufacturing quality prior to marketing, compounded drugs could potentially pose health risks should they be sub- or super-potent, contaminated, or otherwise adulterated.

For decades following the passage of the FDCA, regulation of drug compounding was generally left to the states because it was widely recognized that compounded drugs could not meet the FDCA’s drug approval requirements since compounded drugs were traditionally made in small amounts for an individual patient.⁸² Also, safety and efficacy trials were impracticable, since compounding pharmacies could not afford testing of the “new drugs” under the NDA approval process for each individual compounded drug.⁸³

In the late 1980s and early 1990s, the FDA became aware that some compounding pharmacies were engaging in activities that might have extended beyond “traditional” compounding; for example, by making drugs for interstate sale without a prescription for an individually identified patient.⁸⁴ In other instances, these pharmacies were competing with branded products by manufacturing and distributing interstate the generic versions of the branded drugs, which the FDA considers as unapproved “new drugs” in the absence of a completed abbreviated new drug application (ANDA).⁸⁵ In other instances, pharmacies were pro-

\$979,400 to \$1,958,800, depending on whether or not the application required clinical data, and were \$51,520 for ANDAs. See *Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients: Hearing Before the S. Comm. on Health, Educ., Labor and Pensions*, 108th Cong. 38 (2003) (statement of Steven K. Galson, Acting Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration), <https://www.gpo.gov/fdsys/pkg/CHRG-108shrg90129/html/CHRG-108shrg90129.htm> [hereinafter Statement of Steven K. Galson]. According to *Thompson*, 535 U.S. at 369,

[I]t would not make sense to require compounded drugs created to meet the unique needs of patients to undergo the testing required for the new drug approval process. Pharmacists do not make enough money from small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, so requiring such testing would force pharmacists to stop providing compounded drugs.

⁸¹ GAO REPORT, *supra* note 12, at 7.

⁸² *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002).

⁸³ Statement of Steven K. Galson, *supra* note 80.

⁸⁴ Pontikes, *supra* note 1.

⁸⁵ *Thompson*, 535 U.S. at 362 (“FDA eventually became concerned, however, that some pharmacists were manufacturing and selling drugs under the guise of compounding, thereby

moting compounded drugs directly to practitioners and patients, receiving and processing large quantities of bulk substances, and compounding drugs without patient-specific prescriptions.⁸⁶ The authority of the FDA to regulate compounded drugs did not become an issue until the early 1990s when the FDA became concerned that some pharmacists were engaged in large-scale bulk compounding that was, in the FDA's view, more akin to drug manufacturing and an attempt to circumvent the FDCA's new drug requirements.⁸⁷

There have been notable incidents of compounding pharmacies not producing drugs safely.⁸⁸ In response, the FDA published an Alert Letter and warned of enforcement action because some pharmacies were using incorrect procedures and controls when compounding sterile products.⁸⁹ The FDA emphasized that pharmacists who prepared batches of sterile drug products were responsible for conforming to current cGMP guidelines, and for using safe packaging to ensure continued sterility during use and warned pharmacists to balance the need to prepare batches of sterile products with their capacity for production.⁹⁰

avoiding the FDCA's new drug requirements."); *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 389-90 (5th Cir. 2008) ("Although [FDA] had long refrained from regulation compounding, it believed that pharmacies engaging in large-scale bulk compounding were . . . using the FDA's traditional lenience toward compounding as an end-run around the new drug approval, adulteration, and misbranding provisions of the FDCA.").

⁸⁶ U.S. FOOD & DRUG ADMIN., COMPLIANCE POLICY GUIDE 460.200, PHARMACY COMPOUNDING (1992) (rescinded upon the enactment of the Food and Drug Administration Modernization Act of 1997) [hereinafter CPG 1992].

⁸⁷ *Mukasey*, 536 F.3d at 389. The FDA's concern over the practice of compounding has also been, in large part, due to certain patient injuries caused by compounded drugs. See *The Special Risks of Pharmacy Compounding*, U.S. FOOD AND DRUG ADMIN. (Jan. 11, 2017), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm>. The Agency has asserted that it knows of more than 200 adverse events involving seventy-one compounded products since 1990, including certain instances with "devastating repercussions." *Id.*

⁸⁸ For example, in 1989, a pharmacist in Pittsburgh, Pennsylvania prepared indomethacin eye drops that caused severe eye infections in twelve patients – two female patients required removal of one eye. RICHARD R. ABOOD, *PHARMACY PRACTICE AND THE LAW* 134 (Jones and Bartlett Publishers, 6th ed. 2011). Indomethacin was an anti-inflammatory drug produced by the pharmaceutical manufacturer Merck, Sharp & Dohme. *Eye Drop Injuries Prompt an FDA Warning*, N.Y. TIMES, Dec. 9, 1990, at 39. Indomethacin was FDA-approved for pain relief and sold in capsule form. *Id.* The health investigators later determined that pseudomonas bacteria had contaminated an unknown number of the eye drop bottles. *Id.* While indomethacin had not been approved by the FDA for use in eye drop format, such use was not considered illegal. *Id.* Merck defended that it was not responsible for its drug since it had been altered from its FDA-approved capsule form. *Id.* Also in 1989, a hospital pharmacy in Lincoln, Nebraska, prepared surgical solutions that became microbially contaminated, resulting in patient deaths. *Id.*

⁸⁹ Marlene Z. Bloom, *Compounding in Today's Practice: Concern About Pharmacists' Right to Compound Has Heated Up Since Compounding Problems Occurred in Pittsburgh, Prompting Increased Interest by FDA*, AM. PHARMACY, Oct. 1991, at 31-32.

⁹⁰ *Id.*

The FDA also reviewed its authority to regulate drug compounding and published Compliance Policy Guide 7132.16 (CPG 1992), which attempted to clarify the distinction between drug compounding and drug manufacturing.⁹¹ The CPG 1992 emphasized that the FDA had no intention of regulating pharmacy's historic exemption on compounded drugs pursuant to a valid prescription. CPG 1992 also stated that pharmacists can engage in "anticipatory compounding" and produce limited quantities of drug when they "provide[d] a documented history of receiving valid prescriptions within an established professional relationship between the pharmacy, the practitioner and the patient."⁹² Still, the FDA declared that it would initiate enforcement actions when pharmacists went beyond "traditional" compounding and engaged in manufacturing, which would violate the FDCA's "new drug," "adulteration," or "misbranding" provisions.⁹³

B. The FDA Modernization Act § 503A Regulates Compounding, But Ninth Circuit Strikes It Down Because It Includes Unconstitutional Advertising Restrictions

In order to clarify the FDA's role regarding pharmacy compounding, as part of the Food and Drug Administration Modernization Act (FDAMA) of 1997, Congress added Section 503A⁹⁴ to the FDCA.⁹⁵

Section 503A distinguished manufacturing from compounding. It placed restrictions on the use of bulk substances in the compounding process,⁹⁶ and prohibited the compounding of copies of branded drugs.⁹⁷ Section 503A codified parts of the FDA's CPG 1992⁹⁸ and exempted

⁹¹ CPG 1992, *supra* note 86.

⁹² CPG 1992, *supra* note 86.

⁹³ CPG 1992, *supra* note 86.

⁹⁴ Food and Drug Admin. Modernization Act (FDAMA) of 1997, Pub. L. No. 105-115, §127, 111 Stat. 2296 (1997) (codified as amended at 21 U.S.C. § 353 (1997)).

⁹⁵ The FDAMA streamlined regulatory procedures to ensure the expedited availability of safe and effective drugs and devices to the public. *Id.* at § 503A. Informally known as the Modernization Act, the objective of the FDAMA was greater patient access to drugs and medical devices by accelerating review of significant new and novel medical products. *Id.*

⁹⁶ In November 1998, the FDA issued a Draft Guidance on the enforcement of Section 503A. U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: ENFORCEMENT POLICY DURING IMPLEMENTATION OF SECTION 503A OF THE FDCA (1998) [hereinafter 1998 DRAFT GUIDANCE]. The 1998 Draft Guidance primarily focused on Section 503A's limitations on compounding specific drugs including the bulk substances that could be used in compounding, and specific drugs that could not be compounded. *Id.*

⁹⁷ FDAMA § 503A.

⁹⁸ U.S. FED. FOOD AND DRUG ADMIN., *Guidance for FDA Staff and Industry, Compliance*

drug products compounded by a pharmacist from the FDA's NDA approval process, the requirements that the drug is manufactured in conformity with cGMP, and that the drug's labeling carry adequate directions for use.⁹⁹ However, to qualify for these exemptions, the compounding pharmacies had to refrain from advertising, promoting, or soliciting prescriptions.¹⁰⁰ The restrictions on advertising aimed to clamp down on compounding pharmacies promoting their services in a manner that would allow them to be manufacturers and supply drugs nationally.

Government restrictions on advertising are subject to court review to ensure they do not run afoul of the First Amendment guarantee of free speech. In *Central Hudson Gas v. Public Service Commission*, the Supreme Court held that for a regulation to be upheld, the government has the burden of showing that: 1) the government had a substantial interest in the regulation; 2) the regulation directly advanced the government interest; and 3) the burden on speech imposed by the regulation was not more extensive than is necessary to serve the government's interest.¹⁰¹

In 1998, in *Western States Medical Center et al. v. Shalala (Western States)*,¹⁰² seven pharmacies sued the FDA, challenging section 503A's restrictions on advertising, promotion, and solicitation, alleging that these restrictions represented an unconstitutional restriction on speech.¹⁰³ The U.S. District Court for the District of Nevada struck down section 503A's advertising restrictions.¹⁰⁴ In 2001, the Ninth Circuit Court of Appeals affirmed the holding but also held that these provisions were not severable from the rest of the section and therefore struck down section 503A in its entirety.¹⁰⁵ In 2002, in *Thompson v. Western States Medical Center*, the Supreme Court affirmed the lower court rulings, but because neither party petitioned for certiorari on the severability issue, the Court did not review that portion of the Court of Appeals' decision.¹⁰⁶

Policy Guides Manual, Sec. 460.200, Pharmacy Compounding (May 2002) [hereinafter CPG 2002].

⁹⁹ *Id.*

¹⁰⁰ FDAMA § 503A(c).

¹⁰¹ *Central Hudson Gas v. Public Service Commission*, 447 U.S. 557, 564 (1980).

¹⁰² *W. States Med. Ctr. v. Shalala*, 69 F. Supp. 2d 1288, 1292 (D. Nev. 1999).

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001), *aff'd sub nom. Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002).

¹⁰⁶ *Thompson v. W. States Med. Ctr.*, 535 U.S. at 360 (2002).

Because of the confusion regarding the extent of the FDA's authority to regulate compounding after this decision, the agency decided to issue guidance regarding the factors it would consider when determining whether to take enforcement action against compounding pharmacies for FDCA violations.¹⁰⁷ The FDA issued a Compliance Policy Guide in 2002 (CPG 2002), which was similar to its earlier compliance guide issued in 1992 (CPG 1992).¹⁰⁸ CPG 2002 distinguished between traditional compounding and what the FDA viewed as "manufacturing and distributing" under the guise of pharmacy compounding.¹⁰⁹ The guidance noted that the agency would continue to defer to state pharmacy authorities for "less significant" violations of the FDCA that were related to pharmacy compounding of human drugs.¹¹⁰ However, the agency would initiate enforcement action when a compounding pharmacy's activity resembled those of a drug manufacturer which results in violations of the "new drug," "adulteration," or "misbranding" provisions of the FDCA.¹¹¹

The CPG 2002 listed nine circumstances under which the FDA was likely to bring enforcement actions. These included: 1) compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities; 2) compounding drugs that were removed from the market due to safety reasons; 3) compounding finished drugs from bulk active ingredients that are not components of approved FDA drugs without an IND application; 4) receiving, storing, or using drug substances without obtaining written assurance from the supplier that each drug substance lot has been processed at FDA registered facilities; 5) receiving, storing, or using drug components that are not guaranteed or otherwise determined to meet official compendia requirements; 6) using commercial-scale manufacturing or testing equipment for drug compounding products; 7) compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state-licensed persons or commercial entities for resale; 8) compounding drug

¹⁰⁷ CPG 2002, *supra* note 98, at 1; FDAMA § 127.

¹⁰⁸ CPG 2002, *supra* note 98.

¹⁰⁹ For example, the FDA specifically identified the firms receiving and using large quantities of bulk drug substances to manufacture large quantities of unapproved drug products in advance of a valid prescription may be "far more consistent with drug manufacturers and wholesalers than with those of retail pharmacies." CPG 2002, *supra* note 98, at 3. The restrictions are included in 21 U.S.C. § 353a(c).

¹¹⁰ CPG 2002, *supra* note 98.

¹¹¹ CPG 2002, *supra* note 98.

products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products;¹¹² and 9) failing to operate in conformance with applicable state law.¹¹³

C. The Fifth Circuit Upholds § 503A except its Advertising Restrictions

In 2004, in *Medical Center Pharmacy v. Mukasey (Medical Center Pharmacy)*,¹¹⁴ ten pharmacies challenged the FDA's authority to regulate compounded drugs, particularly the CPG 2002 guidelines.¹¹⁵ The pharmacies asked the court to declare that: 1) compounded drugs are not subject to the FDCA "new drug" requirement; 2) the FDCA permits pharmacists to compound drugs from bulk ingredients for non-food producing animals; and 3) pharmacies that comply with certain provisions of the FDCA are exempt from the Act's records inspection provisions.¹¹⁶

The U.S. District Court for the Western District of Texas ruled in favor of the plaintiffs, holding that compounded drugs when created for an individual patient pursuant to a prescription from a licensed practitioner "are implicitly exempt" from the FDCA's "new drug" approval process.¹¹⁷ The court also declared that in light of *Western States*, the remainder of section 503A was severable.

The Fifth Circuit Court of Appeals, however, overturned the District Court and held that compounded drugs are subject to the new drug approval, adulteration, and misbranding requirements.¹¹⁸ The court reasoned that Congress would not have enacted the FDAMA's provisions

¹¹² In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA approved drug that is commercially available. CPG 2002, *supra* note 98. In these circumstances, the FDA will consider whether there is documentation of the medical need for the particular variation of the compounded drug for the particular patient. *Id.*

¹¹³ CPG 2002, *supra* note 98, at 4.

¹¹⁴ *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).

¹¹⁵ *Id.* at 391.

¹¹⁶ *Id.* at 392; *Pontikes*, *supra* note 1.

¹¹⁷ *Med. Ctr. Pharmacy v. Gonzales*, 451 F. Supp. 2d 854, 858 (W.D. Tex. 2006), *vacated in part sub nom. Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008).

¹¹⁸ *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 409 (5th Cir. 2008). The Fifth Circuit vacated the district court's judgment and remanded the case to the district court for further proceedings. *Id.*; see GAO REPORT, *supra* note 12, at 35.

exempting compounded drugs from the FDCA's "new drug" requirements had these provisions not applied to compounded drugs.¹¹⁹ The court also found, contrary to the Ninth Circuit, that the severability clause applied to section 503A.¹²⁰ The court explained that if Congress did not want the FDCA's severability clause to apply to section 503A, it would have specifically said so and that there was no strong evidence that Congress would not have enacted section 503A without the advertising provisions.¹²¹

As a result, in the Fifth Circuit, compounded drugs represented "new drugs" under the FDCA but were expressly exempt from the "new drug" requirements if the drug sponsor complied with section 503A, notwithstanding the provisions restricting advertising that the court held to be unconstitutional.¹²² The parties in *Medical Center Pharmacy* did not petition the Supreme Court for review; thus, uncertainty remains regarding the FDA's authority to regulate compounded drugs as "new drugs."

D. FDA Oversight After the Circuit Split

The *Western States* and *Medical Center Pharmacy* judicial decisions directly conflict regarding whether the non-speech provisions of section 503A are severable and remain in effect. As a result of the Fifth and Ninth Circuit split, the FDA developed distinct enforcement policies for different circuits.

The *Western States* decision invalidated all of section 503A, so the regulatory standards for quality, including those for compounding pharmacies, had no effect in the Ninth Circuit states (i.e., Alaska, Arizona, California, Hawaii, Idaho, Montana, Nevada, Oregon, and Washington).¹²³ In those states, the FDA adopted the approach that all compounded drugs were "new drugs" under the FDCA, and determined that

¹¹⁹ *Mukasey*, 536 F.3d at 400 ("In 1997, Congress enacted the FDAMA as an amendment to the FDCA. That amendment provides considerable evidence that Congress sought to address pharmacy compounding directly and that it did so with the assumption that the 'new drug' provision applies to drugs created through pharmacy compounding."); see also GAO REPORT, *supra* note 12, at 35.

¹²⁰ *Mukasey*, 536 F.3d at 401-02, 404-05 ("[W]e conclude that the invalidated portion of FDAMA is severable and that its surviving portions therefore remain in effect."); see GAO REPORT, *supra* note 12, at 35.

¹²¹ *Mukasey*, 536 F.3d at 401-02, 404-05; see GAO REPORT, *supra* note 12, at 35.

¹²² *Mukasey*, 536 F.3d at 405; see GAO REPORT, *supra* note 12, at 35.

¹²³ The Ninth Circuit Court of Appeals decision also applies to the FDA's authority over certain compounding pharmacies located in Colorado, New Jersey, Tennessee, Texas, and Wisconsin, as these pharmacies were party to the lawsuit. *Thompson v. W. States Med. Ctr.*, 535 U.S.

whether to take enforcement action against a compounding pharmacy would be based on whether the pharmacy had engaged in any of the activities outlined in the CPG 2002.¹²⁴ In any event, its compounded drug was still subject to all of the FDCA requirements for new drugs. The FDA continued to subject compounding pharmacies to the policies articulated in CPG 2002 for compounding pharmacies in the rest of the country, except in the Fifth Circuit.¹²⁵

In contrast, the *Medical Center Pharmacy* decision upheld all of section 503A, except the advertising, promotion, and solicitation restrictions, and so the regulatory standards for quality, including those for compounding pharmacies, had the force of law in the Fifth Circuit states (i.e., Louisiana, Mississippi, and Texas).¹²⁶ In those states, the FDA determined whether a compounded drug met the section 503A exemption from certain FDCA requirements that would preclude the agency from taking enforcement action against a drug compounder.

However, the FDA continued to assert regulatory authority over compounding pharmacies based on its “enforcement discretion” to regulate “new drugs.” In circumstances where the FDA believed that a pharmacy met the requirement of section 503A, it required strict compliance with cGMP regulations. For example, in a Warning Letter issued in 2001 to Professional Compounding Centers of America, the FDA found significant violations of cGMP regulations, including inadequate air-handling processes, and defective drug-testing and cleaning processes, resulting in a high risk potential for drug contamination.¹²⁷

The FDA subsequently discovered numerous other pharmacies in violation of cGMPs, and concluded that noncompliant pharmacies raised public health risks and dangers to human life.¹²⁸ The FDA also ex-

357, 360 (2002).

¹²⁴ *Id.* at 370.

¹²⁵ *Id.* Interestingly, however, the FDA did not issue any Warning Letters to compounding pharmacies in Texas, Louisiana or Mississippi applying section 503A. Warning Letter from U.S. Food and Drug Admin. to J & F Int'l. Inc. (Apr. 9, 2010), <https://web.archive.org/web/20110522122632/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm208772.htm>. Outside of the Fifth Circuit, FDA proceeded under its post-*Western States* policy. *Id.*

¹²⁶ Warning Letter from U.S. Food and Drug Admin. to Steven's Pharmacy (Nov. 12, 2008), <https://web.archive.org/web/20090709190819/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048074.htm>; Pontikes, *supra* note 1.

¹²⁷ Warning Letter from U.S. Food and Drug Admin. to Prof'l Compounding Ctr's. of America, Inc. (Jul. 27, 2001), <http://casewatch.org/fdawarning/comp/pcca.shtml>; Pontikes, *supra* note 1.

¹²⁸ Pontikes, *supra* note 1.

pressed concerns over public health risks associated with the compounding and distribution of drugs that had been withdrawn or removed from the market for safety or efficacy related reasons.¹²⁹ To qualify for the compounding exemption of section 503A, one of the conditions was to refrain from compounding drugs that were either withdrawn or removed from the market due to safety or efficacy reasons.

For instance, in 2001, the FDA issued a Warning Letter to Custom Care Pharmacy, which compounded strontium chloride SR-89, the active pharmaceutical ingredient found in the FDA-approved and commercially available drug Metastron.¹³⁰ The FDA considered this activity to lie outside “traditional” pharmacy compounding because Custom Care Pharmacy lacked documentation and data substantiating efficacy claims that the compounded product acted differently from the commercially available Metastron.¹³¹

Also in 2001, the FDA sent a Warning Letter to Unique Pharmaceuticals, a pharmacy that compounded injectable sterile drug products with equivalent dosage and strength similar to the commercially available product.¹³² The FDA expressed concerns of Unique Pharmaceuticals’ business structure regarding the quantities of compounded products that it sold to wholesalers. For example, during a three-month period, Unique Pharmaceuticals prepared and distributed 38,650 vials of dexamethasone and 38,400 vials of triamcinolone acetonide.¹³³ Unique Pharmaceuticals did not prepare compounded drugs for identified, individual patients based on prescription orders, but rather distributed the compounded drugs to wholesalers for further sale to hospitals, pharmacies, and physicians.¹³⁴ According to the FDA, Unique Pharmaceuticals op-

¹²⁹ Pontikes, *supra* note 1.

¹³⁰ Warning Letter from U.S. Food and Drug Admin. to Custom Care Pharmacy (Oct. 3, 2001), <https://web.archive.org/web/20111008013049/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178290.htm>; *see* Pontikes, *supra* note 1.

¹³¹ Pontikes, *supra* note 1.

¹³² Warning Letter from U.S. Food and Drug Admin. to Unique Pharmaceuticals, Ltd. (Oct. 10, 2001), <https://web.archive.org/web/20090827094727/http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178396.htm> [hereinafter Unique Pharmaceuticals Warning Letter]; *see* Pontikes, *supra* note 1.

¹³³ Pontikes, *supra* note 1, at n.80; Unique Pharmaceuticals Warning Letter, *supra* note 132 (“Of the 10 products identified by [the] FDA in the Warning Letter, only one of the products had a lower volume, with less than a thousand vials over a three-month period (650 vials of dicyclomine).”).

¹³⁴ Unique Pharmaceuticals Warning Letter, *supra* note 132. According to Pontikes, The same pharmacy also had received a Warning Letter from the Texas Department of

erated more like a manufacturer and distributor than a “traditional” compounding pharmacy.¹³⁵

To assess the qualification for a section 503A exemption for a compounding pharmacy, the FDA determined whether the pharmacy offered to sell drug products without a prescription, and whether the API was a component of an FDA-approved drug or was listed in an approved monograph in the USP or the NF. In 2002, the FDA initiated several enforcement actions when it found APIs that were ineligible for use in compounding. The FDA sent Warning Letters to three pharmacies that promoted nicotine lollipops and nicotine lip balm for smoking cessation and for reduction of nicotine addiction.¹³⁶ According to the FDA, the nicotine products were considered “new drugs” and did not qualify for the section 503A compounding exemption because they were sold without valid patient-specific prescriptions.¹³⁷ Additionally, the API nicotine salicylate was neither a component of an FDA-approved drug nor listed in a USP or NF monograph, and therefore was not a qualified bulk drug substance designated for compounding.¹³⁸

IV. Obstacles to FDA Oversight and Calls for Greater FDA Regulation of Drug Compounding

Prior to the NECC crisis, several factors limited FDA oversight of

Health on September 29, 2000, more than a year before the FDA’s October 10, 2001 Warning Letter. [The] FDA, Texas Department of Health, and Texas State Board of Pharmacy had conducted an inspection on August 2, 4, and 16, and [on] September 5, 2000. While the Texas Department of Health issued its Warning Letter about three weeks after the inspection, it took the FDA more than a year to prepare and send its Warning Letter, consistent with the findings of the Texas Department of Health.

Pontikes, *supra* note 1, at n.82.

¹³⁵ Pontikes, *supra* note 1, at n.79 (citing Unique Pharmaceuticals Warning Letter, *supra* note 132) (“For example, the FDA identified 10 compounded products that were made in the same dosage strengths as commercially available products that were sold to wholesale drug distributors for subsequent distribution to hospitals, pharmacies and physicians.”). The FDA acknowledged that some of the products may have been in short supply and not commercially available for a brief period of time. *Id.* However, in the FDA’s estimation, the large quantities of drugs prepared and distributed exceeded the limited quantities that may have been needed to meet demand during the temporary shortages. *Id.*

¹³⁶ Warning Letter from U.S. Food and Drug Admin. to Ashland Drug (Apr. 9, 2002), <https://web.archive.org/web/20090710114912/http://www.fda.gov/downloads/Drugs/Guidance-ComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeof-ViolationLetterstoPharmaceuticalCompanies/UCM164561.pdf>; Pontikes, *supra* note 1.

¹³⁷ Pontikes, *supra* note 1.

¹³⁸ Pontikes, *supra* note 1, at n.86 (“While nicotine and nicotine polacrilex were components of FDA-approved drugs that did not qualify for the different salt form, the nicotine salicylate used in the lollipops and lip balm [were] for use in compounding.”).

compounding pharmacies. The FDA has limited statutory authority. At the same time, some firms affected by compounding pharmacies requested that the FDA regulate compounding pharmacies, while compounding pharmacies resisted FDA oversight. As a result, the FDA was caught in the middle and subject to pressure to move in different directions.

A. Limited FDA Inspection Authority

The Fourth Amendment of the Constitution protects individuals from unreasonable search and seizures. Search warrants are issued to authorized law enforcement officers only after a court has found that there is probable cause.¹³⁹ Similarly, FDA inspections must comply with the Fourth Amendment requirements, as well as the FDCA requirements regarding inspections. Specifically, section 704 of the FDCA states that FDA inspectors may inspect facilities where drugs are held at reasonable times, within reasonable limits and a reasonable manner. It exempts from FDA inspections pharmacies that regularly dispense prescriptions, and do not manufacture, prepare, or compound drugs for sale other than in the regular course of the retail business.¹⁴⁰

Legal challenges to the FDA's authority to inspect compounding pharmacies undermine the agency's ability to identify problems and to take appropriate enforcement actions. Suspect entities often refuse to grant the FDA access to facilities and records unless the FDA has a warrant, citing the FDCA's provision which limits the agency's inspection authority over a pharmacy operating in compliance with state and local laws and with the Fourth Amendment.¹⁴¹

For example, in *Wedgewood Village Pharmacy, Inc. v. United States*, 421 F.3d 263, 265 (2005), concerned that the pharmacy was producing large quantities of drugs, the FDA obtained a search warrant to inspect the facility. The plaintiff challenged the FDA's authority to inspect the pharmacy for compounding violations, and filed a motion to

¹³⁹ U.S. Const. amend. IV. states:

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

¹⁴⁰ Robert M. Spiller, *How to Handle an FDA Inspection*, 33 FOOD DRUG COSM. L.J. 101 (1978); Eve E. Bachrach, *The Food and Drug Administration Cosmetic Inspection: An Industry Approach*, 38 FOOD DRUG COSM. L.J. 373 (1983).

¹⁴¹ 21 U.S.C. § 372 (2011).

dismiss the warrant on the grounds that pharmacies were exempt from FDA inspection due to the lack of jurisdiction over state-licensed pharmacies.¹⁴² The *Wedgewood* court held that Congress intended the FDA to be granted the authority to inspect pharmacies in order to determine whether the exemption applied.¹⁴³ The court also ruled that because the FDA had probable cause to believe that the pharmacy was manufacturing drugs, the FDA had the authority to also inspect the pharmacy records.¹⁴⁴ Nevertheless, FDA inspection authority is still limited by state statutes and the Fourth Amendment.¹⁴⁵

B. The FDA's Limited Access to Relevant Information

There is no requirement that compounders report adverse events to federal authorities, so the actual number of individuals harmed by compounded drugs is unknown,¹⁴⁶ and state reporting requirements vary.¹⁴⁷ Thus, the FDA often lacks timely and reliable data on compounding pharmacies, such as the types of drugs being compounded and the adverse events related to the use of compounded drugs.¹⁴⁸ Additionally, prior to the NECC crisis, the FDA was not able to collect timely and reliable data on compounded drugs and on the entities that produced

¹⁴² *Wedgewood Village Pharmacy, Inc. v. United States*, 421 F.3d 263, 266 (2005).

¹⁴³ *Id.* at 269.

¹⁴⁴ *Id.* at 275.

¹⁴⁵ *See generally id.*

¹⁴⁶ Generally, if a manufacturer receives drug- or certain device-related adverse event reports, it must send them to the FDA. 21 C.F.R. §§ 314.80(c), 803.30, 803.50. Health care professionals and consumers can voluntarily file adverse event reports with the FDA and may also report these events to the products' manufacturer. *Id.* User facilities (e.g., hospitals and nursing homes) must report certain device-related, but not drug-related-adverse events to the FDA as well. *Id.*; see also GAO REPORT, *supra* note 12, at 16; THAUL, *supra* note 48; AMALIA K. CORBY-EDWARDS, REGULATION OF DIETARY SUPPLEMENTS, CRS REPORT R43062, at 4 (2014); CTR. FOR DRUG EVALUATION AND RESEARCH, GUIDANCE FOR INDUSTRY (1997), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM299138.pdf>; *Questions and Answers on FDA's Adverse Event Reporting System (FAERS)*, U.S. FOOD AND DRUG ADMIN. (May 5, 2016), <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/default.htm>.

¹⁴⁷ A few, but not all, states require some form of reporting of adverse incidents from compounded drugs. See *A Legislative History and Summary of Laws*, NAT'L COUNCIL OF STATE LEGISLATORS (Oct. 1, 2014), <http://www.ncsl.org/issues-research/health/regulating-compounding-pharmacies.aspx>; see also Reporting about healthcare-associated infections and serious reportable events, and serious adverse drug events; charges or reimbursement for resulting services prohibiting, 190TH MASS. GEN. LEG. § 51H (Mass. 2015); Texas Food, Drug, And Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. tit. 6, ch. 431 (2016).

¹⁴⁸ U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-970, DRUG SAFETY: BETTER DATE MANAGEMENT AND MORE INSPECTIONS ARE NEEDED TO STRENGTHEN FDA'S FOREIGN DRUG INSPECTION PROGRAM (2008); see also GAO REPORT, *supra* note 12, at 15.

them, because under the FDCA compounding pharmacies were not required to register with the FDA or list the products that they produced.¹⁴⁹ In contrast, drug manufacturers are required to register with the FDA and provide information such as the company name, location, and the drugs that the company produces.¹⁵⁰ The FDA therefore could not routinely identify and inspect suspect compounding pharmacies.¹⁵¹ The FDA typically inspected compounding pharmacies only in response to complaints or adverse events.¹⁵² Furthermore, the agency's Field Accomplishments and Compliance Tracking System (FACTS) did not indicate the agency's final determination of an official action, or whether any action had been taken following an inspection, and could not even distinguish between the inspections of human or veterinary drug manufacturers.¹⁵³

Despite not being required to register, a few compounding pharmacies, such as Ameridose, voluntarily registered with the agency as manufacturers and marketed themselves as "FDA Registered" entities, which allowed them to appear as "registered manufacturers" in the FDA's drug registration database and listing system.¹⁵⁴ However, registering as a manufacturer did not give the FDA authority to require the pharmacy to comply with the FDA's cGMP requirements, which is normally applied to drug manufacturers.¹⁵⁵ In addition, some pharmacies that compounded drugs on large scale and marketed themselves as "FDA Registered" have led state officials, healthcare professionals and the public to assume they were in full compliance with FDA regulations.¹⁵⁶ Adding to the problem, states were also likely to mistakenly assume that "FDA Registered" pharmacies were actively regulated by the FDA and not subject to state oversight.¹⁵⁷

¹⁴⁹ Pharmacies are not required to register with the FDA if they follow any applicable local laws regulating the practice of pharmacy and medicine, regularly engage in dispensing drugs upon a prescription from a licensed practitioner, and do not manufacture, prepare, or compound drugs for sale other than during the regular course of their business of dispensing or selling drugs at retail. 21 U.S.C. § 360(g)(1); *see also* GAO REPORT, *supra* note 12, at 9.

¹⁵⁰ GAO REPORT, *supra* note 12, at 9.

¹⁵¹ GAO REPORT, *supra* note 12, at 14.

¹⁵² GAO REPORT, *supra* note 12, at 17.

¹⁵³ GAO REPORT, *supra* note 12, at 28.

¹⁵⁴ GAO REPORT, *supra* note 12, at 14.

¹⁵⁵ GAO REPORT, *supra* note 12, at 14.

¹⁵⁶ GAO REPORT, *supra* note 12, at 14.

¹⁵⁷ Memorandum from U.S. Drug and Food Admin. to Comm. staff, Timeline of FDA Interactions with NECC and Ameridose (Feb. 1, 2013) [hereinafter FDA Timeline]; *see also* NECC AND AMERIDOSE, *supra* note 2, at 21; GAO REPORT, *supra* note 12, at 27.

C. Drug Manufacturers Pressure the FDA to Act Against Compounding Pharmacies

Some drug manufacturers exerted pressure on the FDA to increase investigations of compounding pharmacies. For instance, in a citizen petition, Wyeth asked the FDA to initiate enforcement actions against pharmacies compounding “bioidentical” hormone replacement therapies.¹⁵⁸ Similarly, KV Pharmaceutical filed suit to force the FDA to initiate enforcement actions against pharmacies compounding hydroxyprogesterone caproate.¹⁵⁹ The FDA has often been pulled in different directions between manufacturers that want the agency to regulate compounding pharmacies more strictly and compounding pharmacies that resist FDA oversight.

1. Wyeth’s Citizen Petition

Wyeth’s 2005 citizen petition requested that the FDA initiate enforcement actions under CPG 2002 against pharmacies that were compounding “bioidentical” hormone replacement therapies.¹⁶⁰ Wyeth marketed the branded prescription medications Prempro, Premphase, and Premarin, estrogen-based hormone therapies used for the treatment of post-menopausal symptoms.¹⁶¹ According to Wyeth, compounding pharmacies were making unsubstantiated claims regarding the safety risks of using their compounded products without providing similar warning labels that Wyeth was required to include under the FDCA.¹⁶² Moreover, some of the compounded hormone therapies that the pharmacies advertised contained the estrogen analogue estriol, which was not a component of any FDA-approved drug.¹⁶³

In response, the pharmacies argued that estriol had been used as a component of compounded hormone replacement therapy for decades and compounding drugs containing estriol met the specific needs of

¹⁵⁸ Citizen Petition on Behalf of Wyeth, FDA Docket No. 2005-P-0411 (Oct. 6, 2005) [hereinafter Wyeth Citizen Petition].

¹⁵⁹ 17-hydroxyprogesterone caproate is commonly known as 17P. Press Release, U.S Food & Drug Admin., Updated FDA Statement on Compounded Versions of hydroxyprogesterone caproate (June 15, 2012), <https://web.archive.org/web/20120618021301/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308546.htm>.

¹⁶⁰ Wyeth Citizen Petition, *supra* note 158; Pontikes, *supra* note 1; CPG 2002, *supra* note 98.

¹⁶¹ Wyeth Citizen Petition, *supra* note 158, at 7.

¹⁶² Wyeth Citizen Petition, *supra* note 158, at 8-11.

¹⁶³ Wyeth Citizen Petition, *supra* note 158, at 9.

women needing hormone replacement therapy.¹⁶⁴ They also indicated that estriol was approved by the Boards of Pharmacies of all fifty states, allowed by the Pharmacy Compounding Accreditation Board, and had long been listed in the USP monograph.¹⁶⁵

In 2008, almost three years after Wyeth filed its citizen petition and after receiving more than 70,000 public comments, the FDA denied Wyeth's citizen petition request that the FDA take enforcement action against these compounding pharmacies, but on the same day, sent Warning Letters based on the CPG 2002 to seven compounding pharmacies regarding preparations containing estriol used for hormone replacement therapy.¹⁶⁶ The agency explained that enforcement was necessary because the API was not a component of an FDA-approved drug and that the compounding pharmacies made unsubstantiated claims that estriol was effective for hormone replacement therapy.¹⁶⁷ In response to the FDA Warning Letters, industry organizations supporting the compounding pharmacies¹⁶⁸ jointly wrote to the FDA to protest the agency's enforcement actions.¹⁶⁹ They argued that the FDA had overextended the authority of the CPG 2002 and insisted that the compliance policy guide was created without an opportunity for public comment.¹⁷⁰

Due to the split between the Fifth and Ninth Circuit, the FDA enforced different standards depending on the region. Hence, the compounding of estriol was legal for pharmacies in the Fifth Circuit states of Louisiana, Mississippi, and Texas, and based on the CPG 2002, the

¹⁶⁴ Wyeth Citizen Petition, *supra* note 158, at 9.

¹⁶⁵ J. Goodrum, *Estriol: Women's Choice vs. a Manufacturer's Greed*, 12 INT'L J. PHARM. COMPOUNDING 287 (2008); *see* Pontikes, *supra* note 1; *see also* FDA Response to Wyeth Citizen Petition, FDA Docket No. 2005P-0411/CPI & SUP1 (Jan. 9, 2008).

¹⁶⁶ Press Release, U.S. Food and Drug Admin., FDA Takes Action Against Compounded Menopause Therapy Drugs (Jan. 9, 2008); Warning Letter from U.S. Food and Drug Admin. to Pharmacy Compounding Specialties (Jan. 7, 2008).

¹⁶⁷ Pontikes, *supra* note 1. During the press conference held two days after the FDA denied Wyeth's citizen petition, FDA claimed that the actions taken in sending the Warning Letters were not as a result of the Wyeth citizen petition, that the issues raised in the Warning Letters predated Wyeth's petition, and that Wyeth's request of enforcement actions by a citizen petition was not an appropriate process. *Id.* Yet in sending the Warning Letters the same day it responded to the citizen petition, the FDA did exactly what Wyeth was asking it to do. *Id.*

¹⁶⁸ Pontikes, *supra* note 1. The industry organizations included the American Pharmacists Association, the International Academy of Compounding Pharmacists, the National Community Pharmacists Association, the National Alliance of State Pharmacy Associations, and the American College of Apothecaries. *Id.*

¹⁶⁹ Industry Letter to FDA Comm'r von Eschenbach (Nov. 17, 2008), <http://ncpa.co/pdf/letter-compoundingfdacores20081117.pdf>; Pontikes, *supra* note 1.

¹⁷⁰ Industry Letter to FDA Comm'r von Eschenbach, *supra* note 169.

FDA maintained enforcement actions against pharmacies outside the Fifth Circuit. The Warning Letters the FDA sent to pharmacies regarding hormone replacement compounded drugs highlighted the agency's inconsistent application of policy.

2. *KV Pharmaceutical Suit against the FDA*

In 2011, the FDA approved KV Pharmaceutical's NDA for Makena for use in reducing the risk of preterm birth.¹⁷¹ Makena was granted orphan drug status by the agency, a program that provides numerous development incentives, including seven years of marketing exclusivity and tax credits for qualified clinical research.¹⁷² In 2012, KV Pharmaceutical sought to force the FDA to take action against pharmacies compounding preparations of hydroxyprogesterone caproate, the API in its branded drug Makena. However, hydroxyprogesterone caproate had been previously available since 1956 under the trade name Delalutin, and pharmacies had compounded hydroxyprogesterone caproate for many years for use in gynecological disorders prior to KV Pharmaceutical's launching of Makena.¹⁷³ Seeking to enforce its market exclusivity, KV Pharmaceutical also sent letters to pharmacies compounding hydroxyprogesterone caproate advising them that Makena had been FDA-approved, and that the agency would no longer allow pharmacies to compound hydroxyprogesterone caproate.¹⁷⁴

KV Pharmaceutical also hired a corporate intelligence firm to obtain and test samples of the compounded version for potency and purity, and found that 80 percent of the compounded drug did not meet purity specifications established by cGMP.¹⁷⁵ KV Pharmaceutical alleged that the API hydroxyprogesterone caproate used in the compounded products

¹⁷¹ U.S. Food and Drug Admin., NDA No. 021945 (approved Feb. 3, 2011); Pontikes, *supra* note 1.

¹⁷² Patent & Exclusivity Information for Makena, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018190.htm> (search by "proprietary name"). Orphan drug status is granted for "new drugs" used to treat diseases that affects fewer than 200,000 people in the U.S., or affecting greater than 200,000 people with the expectation that the drug manufacturer is unlikely to recover the cost of drug discovery and development. See U.S. Food and Drug Admin., *Office of Orphan Products Development* (Jan. 5, 2017); Pontikes, *supra* note 1.

¹⁷³ *K-V Pharm. Co. v. Fed. Food and Drug Admin.*, 889 F. Supp. 2d 119, 124 (D.D.C. 2012).

¹⁷⁴ *Id.* at 125.

¹⁷⁵ Walt Bogdanich & Sabrina Tavernise, *U.S. Concern Over Compounders Predates Outbreak of Meningitis*, N.Y. TIMES, Oct. 22, 2012.

was imported in bulk by Chinese companies that were not registered with the FDA.¹⁷⁶ The FDA had been aware of compounders increasingly buying raw unapproved ingredients from foreign sources. The FDA subsequently conducted tests of both API and finished compounded products, but did not identify any major safety problem with the compounded hydroxyprogesterone caproate products.¹⁷⁷ In 2011, the FDA stated that it did not intend to take enforcement action against pharmacies compounding hydroxyprogesterone caproate for valid prescriptions, unless the compounder violated standards related to safety or efficacy.¹⁷⁸

Dissatisfied, KV Pharmaceutical sued the FDA seeking an injunction compelling the agency to take action against pharmacies compounding hydroxyprogesterone caproate.¹⁷⁹ The district court dismissed the complaint, holding that the FDA had discretion to initiate enforcement actions and that the courts lacked authority to review such decisions.¹⁸⁰ The courts also held that it could not direct FDA enforcement activities, particularly when the actions involve the FDA's expertise.¹⁸¹ However, the court did not discuss whether the statute allowed FDA enforcement discretion. Thus, the FDA continued to have the authority to regulate drug manufacturing and focused enforcement on compounding practices that it believed were akin to drug manufacturing.

V. *The New England Compounding Center Crisis*

A. *FDA Oversight of NECC*

NECC had been under FDA scrutiny since March 2002, when two adverse events were reported through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program. The FDA defines an adverse event as "any undesirable experience associated with the use of a medical product in a patient" and explains that such an event "should

¹⁷⁶ *Id.*

¹⁷⁷ Press Release, U.S. Food and Drug Admin., Statement on Compounded Versions of hydroxyprogesterone caproate (Feb. 3, 2011) [hereinafter FDA Statement on Makena]; see Pontikes, *supra* note 1.

¹⁷⁸ *K-V Pharm. Co.*, 889 F. Supp. 2d at 125. The FDA stated that it was taking this position in order to support access to hydroxyprogesterone caproate. Pontikes, *supra* note 1.

¹⁷⁹ *Id.* at 122-23; FDA Statement on Makena, *supra* note 177; Pontikes, *supra* note 1.

¹⁸⁰ *K-V Pharm. Co. v. Fed. Food and Drug Admin.*, 889 F. Supp. 2d 119, 144 (D.D.C. 2012); Pontikes, *supra* note 1.

¹⁸¹ *K-V Pharm. Co. v. Fed. Food and Drug Admin.*, 889 F. Supp. 2d at 134; see FDA Statement on Makena, *supra* note 177; Pontikes, *supra* note 1.

be reported when the patient outcome is death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, congenital anomaly or birth defect, or requires intervention to prevent permanent impairment or damage (devices), or any other serious important medical events.¹⁸²

Both adverse events involved patients suffering from meningitis symptoms after receiving betamethasone injections from a lot produced by NECC, which subsequently tested positive for contamination.¹⁸³ In response, the FDA and the MDPH inspected NECC and issued a Form 483 report, which noted conditions that may violate federal law.¹⁸⁴ The FDA sent NECC a Warning Letter on April 16, 2002, which focused on two violations: 1) the compounded betamethasone's failure to be sterile, and 2) NECC's failure to account for records related to the suspect lot of betamethasone.¹⁸⁵

In May 2002, hospital staff informed the FDA that vials of methylprednisolone acetate distributed by NECC were contaminated.¹⁸⁶ Methylprednisolone acetate is a steroid that is frequently injected into the spine to treat pain and swelling. By October 2002, Massachusetts and FDA inspectors had returned to NECC in response to three new MedWatch reports of patients hospitalized with meningitis symptoms following administration of methylprednisolone acetate made by NECC.¹⁸⁷

Prior to the FDA's issuance of a second Warning Letter to NECC, FDA and MDPH officials met in February 2003 to coordinate a joint response.¹⁸⁸ The meeting confirmed that NECC would be treated as a compounding pharmacy, and that Massachusetts would take the lead on further regulatory actions.¹⁸⁹ However, the FDA warned of potential se-

¹⁸² NECC AND AMERIDOSE, *supra* note 2, at 8.

¹⁸³ NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁸⁴ NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁸⁵ NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁸⁶ U.S. FOOD AND DRUG ADMIN., INSPECTION REPORT OF NEW ENG. COMPOUNDING CENTER (2013); *see also* NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁸⁷ *Id.*

¹⁸⁸ *See* Memorandum from Kristina Joyce, Consumer Safety Officer, New England Dist. Off., FDA & Mark Lookabaugh, Compliance Officer, New England Dist. Off., FDA, to Central File (Feb. 5, 2003) (referring to a meeting with Massachusetts Board of Pharmacy/Division of Professional Licensure at 239 Causeway Street, Boston, MA 02114 on Feb. 24, 2003) [hereinafter FDA Memorandum]; *see* NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁸⁹ FDA Memorandum, *supra* 188, at 1; *see* NECC AND AMERIDOSE, *supra* note 2, at 7.

rious harm if NECC's compounding practices were not improved, especially the practice relating to compounding sterile drug products.¹⁹⁰

Later, the FDA received additional information suggesting that the NECC was operating as a manufacturer, rather than a traditional compounding pharmacy. On February 27, 2004, the FDA received a complaint from a law firm representing a drug company regarding NECC's promotion of trypan blue, an ophthalmic dye product used for capsular staining during cataract surgery that the FDA had not approved, but which was similar to an FDA approved branded medication that the complainant produced.¹⁹¹ In May 2004, the Massachusetts Board of Registration in Pharmacy (MBRP) forwarded to the FDA a letter that it had received from a hospital pharmacist in Iowa which suggested that NECC manufactured trypan blue.¹⁹² The MBRP also forwarded a complaint from a pharmacist in Wisconsin regarding NECC's promotion of a potent topical anesthetic cream.¹⁹³

The trypan blue complaints prompted the FDA's Center for Drug Regulation and Research (CDER) to inspect NECC on June 2, 2004.¹⁹⁴ The FDA conducted the inspection in accordance with the CPG 2002; because Massachusetts is in the First Circuit, the Ninth Circuit decision in *Western States* was not binding. The investigations sought to determine if NECC's activities raised issues associated with a drug manufacturer rather than a traditional compounding pharmacy.¹⁹⁵

On December 4, 2006, the FDA sent NECC a Warning Letter listing several practices which indicated that NECC was operating as a manufacturer, and informing NECC's President and co-owner Barry Cadden that failure to promptly correct the violations could result in the FDA seizing its products, seeking injunctions, or taking other regulatory action.¹⁹⁶ The Warning Letter reveals that the FDA was aware that NECC operated outside the scope of a traditional compounding pharmacy.¹⁹⁷

The Warning Letter stated that NECC was: 1) compounding copies

¹⁹⁰ FDA Memorandum, *supra* 188, at 1; *see* NECC AND AMERIDOSE, *supra* note 2, at 7.

¹⁹¹ NECC AND AMERIDOSE, *supra* note 2, at 9; *see also* E-mail from Compliance Officer, New England Dist. Off., FDA, to Kathleen Anderson (Feb. 27, 2004, 10:49 EST).

¹⁹² NECC AND AMERIDOSE, *supra* note 2, at 9.

¹⁹³ NECC AND AMERIDOSE, *supra* note 2, at 9.

¹⁹⁴ NECC AND AMERIDOSE, *supra* note 2, at 10.

¹⁹⁵ CPG 2002, *supra* note 98, at 3.

¹⁹⁶ Warning Letter from Gail T. Costello, Dist. Dir., New England Dist. Office, FDA, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (Dec. 4, 2006) [hereinafter FDA Warning Letter]; *see also* NECC AND AMERIDOSE, *supra* note 2, at 10.

¹⁹⁷ NECC AND AMERIDOSE, *supra* note 2, at 10.

of commercially available products that were not components of FDA-approved products; 2) compounding standardized anesthetic drug products, which was outside the scope of traditional pharmacy compounding; 3) repackaging Avastin, a sterile injectable product used to treat macular degeneration; and 4) reportedly informing physicians that they could write a staff member, rather than the patient's name on the prescription.¹⁹⁸

In January 2007, NECC responded that the Warning Letter was based on an inspection started twenty-eight months earlier and that some assertions were no longer correct.¹⁹⁹ NECC argued that the FDA lacked authority over compounded drugs, that it did not need approved New Drug Applications (NDA) before dispensing compounded drugs, and that it did not introduce unapproved "new drugs" into interstate commerce because its medications were not misbranded.²⁰⁰ NECC insisted that it did not compound copies of commercially available drugs or process or repackage approved drugs in a manner that would subject it to FDA regulation. NECC claimed that it only dispensed compounded medications upon the receipt of valid patient-specific prescriptions.²⁰¹

On June 25, 2007, the FDA received an adverse event report which indicated that a patient had developed severe endophthalmitis and required emergency eye surgery after being administered Avastin, repackaged by NECC, to treat macular degeneration.²⁰² In its 2006 Warning Letter to NECC, the FDA had noted that splitting Avastin into multiple preservative-free doses created the potential for microbial contamination and could cause endophthalmitis and significant vision loss.²⁰³

The FDA continued to receive complaints regarding NECC products. In December 2007, a physician complained to the FDA that vials of betamethasone manufactured by NECC appeared to be discolored, with particles settling at the bottom of the vials.²⁰⁴ Patients complained

¹⁹⁸ FDA Warning Letter, *supra* note 196; *see also* NECC AND AMERIDOSE, *supra* note 2, at 10.

¹⁹⁹ NECC AND AMERIDOSE, *supra* note 2, at 12; *see also* Letter from Barry J. Cadden, Dir. of Pharmacy, NECC, to Compliance Officer, New England Dist. Off., FDA at 1 (Jan. 5, 2007).

²⁰⁰ NECC AND AMERIDOSE, *supra* note 2, at 12.

²⁰¹ NECC AND AMERIDOSE, *supra* note 2, at 5.

²⁰² NECC AND AMERIDOSE, *supra* note 2, at 13; *see also* U.S. FOOD AND DRUG ADMIN ADVERSE EVENT REPORTING SYSTEM (FAERS) (June 25, 2007).

²⁰³ NECC AND AMERIDOSE, *supra* note 2, at 13; *see also* FDA Warning Letter, *supra* note 197, at 13.

²⁰⁴ Memorandum from Consumer Safety Officer, New Orleans Dist. Off., FDA, to Supervisory Consumer Safety Officer (Jan. 9, 2008) (memorandum is accidentally dated 2007); *see also*

of increased fibromyalgia pain and suffered severe flu-like symptoms after receiving injections of the drug.²⁰⁵ By June 2008, the FDA had received additional complaints regarding betamethasone made by NECC.²⁰⁶

On October 9, 2008, while the FDA considered how to respond to NECC's January 2007 response letter, the FDA received a complaint stating that a patient had been hospitalized after intravenous administration of phosphatidylcholine made by NECC.²⁰⁷ The patient vomited, urinated blood, could not swallow food or liquid, and required emergency care for blood clots in his arm and hand.²⁰⁸ On October 31, 2008, the FDA replied to NECC's response letter according to CPG 2002, but did not return to inspect NECC until after the fungal meningitis crisis had erupted in 2012.²⁰⁹ Toward the end of 2009, the FDA received complaints regarding NECC's solicitation and distribution of erythromycin without patient-specific prescriptions,²¹⁰ as well as NECC's sale of sodium tetradecyl sulfate to a physician in North Carolina for use in treating varicose veins.²¹¹

Since February 2003, the FDA agreed that the state of Massachusetts would take the lead in overseeing the compounding issues associated with NECC. The FDA had long suspected that NECC was operating outside "traditional" compounding, and by 2011 the agency had evidence that NECC was operating more like a drug manufacturer and was convinced that it functioned as a drug manufacturer.²¹²

During this period, the FDA continued to grapple with the implications of the Circuit Court split. The FDA continued to assert that compounded drugs fell within the FDCA's definition of "new drugs" and subjected compounded drugs to the FDCA's new drug requirement by applying CPG 2002 outside of the Fifth Circuit. However, because of

NECC AND AMERIDOSE, *supra* note 2, at 14.

²⁰⁵ Memorandum to Consumer Safety Officer, *supra* note 204; *see also* NECC AND AMERIDOSE, *supra* note 2, at 14.

²⁰⁶ NECC AND AMERIDOSE, *supra* note 2, at 15.

²⁰⁷ U.S. FOOD AND DRUG ADMIN., CONSUMER COMPLAINT/INJURY REPORT at 1 (Oct. 9, 2008); NECC AND AMERIDOSE, *supra* note 2, at 17.

²⁰⁸ FDA CONSUMER COMPLAINT/INJURY REPORT, *supra* note 207.

²⁰⁹ NECC AND AMERIDOSE, *supra* note 2, at 17.

²¹⁰ E-mail from Kathleen R. Anderson to Samia Nasr, Div. of New Drugs and Labeling Compliance (Sept. 14, 2009, 3:26 EST); *see also* E-mail from Samia Nasr to Kathleen R. Anderson (Sept. 14, 2009, 3:34 EST); NECC AND AMERIDOSE, *supra* note 2, at 19.

²¹¹ E-mail from Compliance Officer, New England Dist. Off., FDA (Sept. 24, 2009, 3:40 EST); *see also* NECC AND AMERIDOSE, *supra* note 2, at 19.

²¹² NECC AND AMERIDOSE, *supra* note 2, at 20.

uncertainty over the scope of federal authority, FDA oversight of compounded drugs remained minimal.²¹³

B. FDA Oversight of Ameridose

Ameridose, NECC's sister company, also had a checkered past. The common ownership and management of NECC and of Ameridose was a factor in the FDA's decision to take action against both. Ameridose was registered with the FDA—contrary to NECC—as a manufacturer since September 2006,²¹⁴ and advertised that it met both USP compounding standards and cGMP requirements.²¹⁵ In addition, Ameridose was also registered in Massachusetts as a retail pharmacy, and it had Drug Enforcement Administration (DEA) licenses as a manufacturer and as a retail pharmacy for controlled substances.²¹⁶

Within a year of Ameridose's registration, the FDA received a complaint through the MedWatch system alleging that Ameridose was manufacturing unapproved intravenous solutions that were dispensed without a valid prescription.²¹⁷ Prior to its first inspection in December 2007, the FDA noted Ameridose's connection with NECC, and it sought information regarding the business relationship and leadership structure of Ameridose and of NECC.²¹⁸

In July 2008, a second FDA inspection determined that Ameridose was a “high risk” facility that had significantly expanded its business operations since the first inspection.²¹⁹ The inspection found that Ameridose marketed over 600 products, including antibiotics, 15 Class II, one Class III, two Class IV, and many Class VI products.²²⁰ Ameridose's customers included approximately 500 hospital pharmacies located in

²¹³ NECC AND AMERIDOSE, *supra* note 2, at 21.

²¹⁴ FDA Timeline, *supra* note 157, at 2; *see* NECC AND AMERIDOSE, *supra* note 2, at 21.

²¹⁵ NECC AND AMERIDOSE, *supra* note 2, at 21.

²¹⁶ NECC AND AMERIDOSE, *supra* note 2, at 21; *see also* U.S. FOOD AND DRUG ADMIN., ESTABLISHMENT INSPECTION REPORT at 1 (Jan. 22, 2008) [hereinafter ESTABLISHMENT INSPECTION REPORT].

²¹⁷ Inspection Request from Staff Fellow, Compounding Team, DNDLC, Off. of Compliance, CDER, FDA, to Michael Kravchuk, Dir., Investigations Branch, New England Dist. Off., FDA at 1 (May 21, 2007); *see also* NECC AND AMERIDOSE, *supra* note 2, at 22.

²¹⁸ NECC AND AMERIDOSE, *supra* note 2, at 23.

²¹⁹ NECC AND AMERIDOSE, *supra* note 2, at 24.

²²⁰ NECC AND AMERIDOSE, *supra* note 2, at 24; *see also* U.S. FOOD AND DRUG ADMIN., ESTABLISHMENT INSPECTION REPORT at 4 (Aug. 22, 2008) (page numbers correspond with narrative report attachment).

forty-nine states.²²¹ Ameridose shipped 75 percent of its manufactured or repackaged products outside Massachusetts without patient-specific prescriptions.²²²

The second inspection included testing of fentanyl, an injectable narcotic more powerful than morphine.²²³ Test results showed that the product exceeded potency standards.²²⁴ The FDA informed Gregory Conigliaro, co-owner of Ameridose, that the compounded fentanyl product was “adulterated” because it had failed to meet federal potency standards.²²⁵ Nevertheless, the FDA did not issue a Warning Letter to Ameridose due to conflicting court holdings.²²⁶

In view of the Circuit split, the FDA debated how to enforce the law. It considered applying section 503A only in the Fifth Circuit and exercising enforcement discretion elsewhere. It also considered uniformly applying CPG 2002 nationwide, and exercising enforcement discretion regarding compounding pharmacies.²²⁷ Eventually, the FDA opted for the latter approach but decided that it needed to establish a clear framework and guidance document that distinguished between pharmacy compounding and drug manufacturing. Unfortunately, the FDA had not completed the framework and guidance before the NECC fungal meningitis outbreak.

As the FDA developed new compounding guidance, federal enforcement of Ameridose stalled. In October 2009, the FDA received an anonymous email alleging that Ameridose had directed a facility that was responsible for monitoring quality and testing the purity of its drugs to change the test reports and to force the employees to forge test results.²²⁸ In response, the FDA prepared to inspect Ameridose.²²⁹ In early June 2010, the agency received yet another complaint from a manufacturer related to Ameridose’s admixing and distribution of nicardipine IV injection products.²³⁰ Since the FDA could not determine whether

²²¹ NECC AND AMERIDOSE, *supra* note 2, at 5.

²²² NECC AND AMERIDOSE, *supra* note 2, at 3.

²²³ ESTABLISHMENT INSPECTION REPORT, *supra* note 216.

²²⁴ ESTABLISHMENT INSPECTION REPORT, *supra* note 216; *see* NECC AND AMERIDOSE, *supra* note 2, at 24.

²²⁵ NECC AND AMERIDOSE, *supra* note 2, at 25.

²²⁶ NECC AND AMERIDOSE, *supra* note 2, at 26.

²²⁷ NECC AND AMERIDOSE, *supra* note 2, at 27.

²²⁸ NECC AND AMERIDOSE, *supra* note 2, at 28.

²²⁹ NECC AND AMERIDOSE, *supra* note 2, at 28.

²³⁰ NECC AND AMERIDOSE, *supra* note 2, at 29.

Ameridose was operating outside of CPG 2002,²³¹ it did not take immediate action.²³²

In July 2010, the FDA received an anonymous complaint from an Ameridose pharmacist alleging that the firm had compounded contaminated batches of succinylcholine because it did not follow cGMP.²³³ The FDA also received a MedWatch report stating that a nurse, who had administered a syringe of dextrose that was 50 percent made by Ameridose, noticed a white precipitate along the plunger's base.²³⁴ In August 2010, the same Ameridose informant alleged that one of the clean rooms had mold growth.²³⁵ Four days later, the informant reported that mold was also found in the hood space where the operations took place.²³⁶ Without a warrant the FDA was unable to inspect the company and determine whether Ameridose was operating outside of CPG 2002.²³⁷

On January 14, 2011, the FDA was informed that a settlement had been reached between Ameridose and those who filed the commercial complainant in the nicardipine matter.²³⁸ One month later, the FDA received a medication error report about a photocopied Ameridose label of a sodium chloride product compounded and distributed by Ameridose. The Ameridose label did not indicate that the sodium chloride was sterile.²³⁹ The FDA did not conduct an inspection of Ameridose until the agency issued guidance asserting federal authority under CPG 2002.²⁴⁰ The agency also planned to re-inspect Ameridose after issuance of the new guidance.²⁴¹

²³¹ NECC AND AMERIDOSE, *supra* note 2, at 30.

²³² NECC AND AMERIDOSE, *supra* note 2, at 30.

²³³ Memorandum of Teleconference between Redaction and Compliance Officer, New England Dist. Off., FDA (Jul. 13, 2010); *see also* NECC AND AMERIDOSE, *supra* note 2, at 29.

²³⁴ NECC AND AMERIDOSE, *supra* note 2, at 30; *see also* U.S. FOOD AND DRUG ADMIN, MEDWATCH REPORT (Jul. 23, 2010).

²³⁵ Memorandum of Teleconference between Redaction and Compliance Officer, New England Dist. Off., FDA, at 1 (Aug. 16, 2010); *see also* NECC AND AMERIDOSE, *supra* note 2, at 30.

²³⁶ NECC AND AMERIDOSE, *supra* note 2, at 31.

²³⁷ NECC AND AMERIDOSE, *supra* note 2, at 31.

²³⁸ NECC AND AMERIDOSE, *supra* note 2, at 33.

²³⁹ NECC AND AMERIDOSE, *supra* note 2, at 33.

²⁴⁰ NECC AND AMERIDOSE, *supra* note 2, at 10.

²⁴¹ E-mail from Consumer Safety Officer, Compounding & Pharmacy Practices Team, Div. of Prescription Drugs, Off. of Unapproved Drugs & Labeling Compliance (OUDLC), Off. of Compliance, CDER, FDA, to Consumer Safety Technician, OUDLC (Sept. 15, 2011, 3:46 EST). By September 2011, the Office of Compliance appears to have been restructured, resulting in the Compounding Team, formerly within the Division of New Drugs and Labeling Compliance, being renamed the Compounding and Pharmacy Practices Team within the Office of Unapproved Drugs and Labeling Compliance, Division of Prescription Drugs. NECC AND AMERIDOSE, *supra* note

While the FDA focused on developing the new guidance, complaints regarding Ameridose continued to be reported. In November 2010, the California Health Department and Board of Pharmacy reported that Ameridose was shipping repackaged succinylcholine products without packaging inserts and with significantly different expiration dates than the branded products.²⁴² The FDA also received an adverse event report regarding Ameridose products in which three women complained of poor pain control after receiving epidural fentanyl injections while in labor.²⁴³

In January 2012, the FDA received additional reports indicating that fentanyl was distributed by Ameridose without clear labeling and almost resulted in a nurse administering 100 mcg of the drug instead of fifty mcg to a patient.²⁴⁴ The FDA also received an adverse event report involving an Ameridose heparin product. Hospital lab tests revealed that the heparin bags in fact did not contain heparin.²⁴⁵ Despite these complaints, the FDA delayed action until after it drafted the new guidelines.

By late September 2012, NECC had already shipped two of the three batches of contaminated methylprednisolone acetate to facilities across the country, leading to the fatal fungal meningitis outbreak.²⁴⁶ On October 10, 2012, after it was determined that NECC was at the epicenter of the crisis, the FDA, along with Massachusetts authorities began inspection of Ameridose.²⁴⁷

By November 1, 2012, the FDA announced that Ameridose was conducting a voluntary recall of all of its unexpired products in circulation based on the preliminary results of the FDA's ongoing inspection, which had documented a lack of sterility assurance.²⁴⁸ On November 9, 2012, the FDA sent Gregory Conigliaro a Warning Letter documenting problems the agency observed during the October 10 inspection.²⁴⁹ The

2, at 34.

²⁴² NECC AND AMERIDOSE, *supra* note 2, at 36.

²⁴³ U.S. FOOD AND DRUG ADMIN ADVERSE EVENT REPORTING SYSTEM (FAERS) (Nov. 17, 2011); *see also* NECC AND AMERIDOSE, *supra* note 2, at 36.

²⁴⁴ U.S. FOOD AND DRUG ADMIN ADVERSE EVENT REPORTING SYSTEM (FAERS), <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm> (last visited Feb. 26, 2018).

²⁴⁵ *Id.*

²⁴⁶ NECC AND AMERIDOSE, *supra* note 2, at 38

²⁴⁷ NECC AND AMERIDOSE, *supra* note 2, at 38.

²⁴⁸ Warning Letter from FDA Pub. Health Serv. to Barry J. Cadden, Director of Pharmacy and Owner NECC (Dec. 4, 2006).

²⁴⁹ U.S. FOOD AND DRUG ADMIN., DEP'T OF HEALTH AND HUM. SERVICES FORM 483 (Nov. 9, 2012).

Warning Letter stated that the firm failed: 1) to test finished products for potency; 2) to investigate complaints for ineffective products; 3) to investigate violations of their own environmental sampling plan; and 4) to adequately maintain equipment and facilities used to manufacture sterile drug products.²⁵⁰ FDA uncertainty over its legal authority prevented the agency from initiating enforcement actions sooner.²⁵¹ The FDA's legal authority for pharmacy compounding was limited, unclear, and untested.²⁵² These factors impeded the FDA's ability to act despite the activities of NECC and Ameridose creating mounting concerns for patient safety and for public health.²⁵³

C. NECC Violates Legal and Quality Standards

At the time of the NECC crisis, section 503A of the FDCA exempted drug products compounded by a pharmacist or physician on a customized basis for an individual patient from three key provisions of the FDCA: 1) the adulteration provision of section 501 (a)(2)(B) (concerning the cGMP requirements); 2) the misbranding provision of section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and 3) the new drug provision of section 505 (concerning the approval of drugs under NDAs or ANDAs). To qualify for these exemptions, section 503A requires that the medication be compounded by:

1) "a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed professional authorized by State law to prescribe drugs"; or

2) "a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient"; and centered "on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within

²⁵⁰ Elizabeth Weise, *FDA finds contamination at Ameridose*, USA TODAY (Nov. 13, 2012, 5:21 PM), <http://www.usatoday.com/story/news/nation/2012/11/12/fda-ameridose-meningitis/1700589/>; see also NECC AND AMERIDOSE, *supra* 2, at 39.

²⁵¹ *The Fungal Meningitis Outbreak: Could It Have Been Prevented? Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 112th Cong. 10 (Nov. 14, 2012) (statement of Margaret Hamburg, Comm. Of food and Drug Admin., Dep't of Health and Hum. Services) [hereinafter Hamburg Statement], <https://web.archive.org/web/20121203012007/https://www.fda.gov/NewsEvents/Testimony/ucm327664.htm>.

²⁵² *Id.* at 74; see generally *Energy and Commerce Committee*, <http://energycommerce.house.gov/hearing/fungal-meningitis-outbreak-could-it-have-been-prevented> (last visited Feb. 26, 2018).

²⁵³ NECC AND AMERIDOSE, *supra* note 2, at 39.

an established relationship” between the licensed professional and “such individual patient for whom the prescription order will be provided.”²⁵⁴

In legal filings, the government provided evidence that NECC engaged in fraudulent practice by using fake patient names, such as, the names of celebrities, fictional characters, doctors, and medical staff, to create fraudulent prescriptions for drugs.²⁵⁵ For instance, NECC used names, such as, Big Baby, Jesus, Fat Albert, Wonder Woman, Pee-wee Herman, Freddie Mae, Fannie Mac, Silver Surfer, Tony Tiger, Coco Puff, Harry Potter, Ned Flanders, Flash Gordon, Jimmy Carter, Bill Clinton, Jennifer Lopez, or Dale Earnhardt.²⁵⁶

In another instance, NECC used the names of patients supplied by NECC’s customers to create fraudulent prescriptions for drugs, or shipped drugs to NECC’s customers without any patient names, and then used the names of patients received after the drug shipments to create fraudulent prescriptions for those or subsequent orders.²⁵⁷ In one particular situation, NECC instructed staff to create 300 fraudulent prescriptions for the surgical patients of a Massachusetts hospital and later submitted a response to a Massachusetts Board of Pharmacy inquiry, by including in an attachment “[t]hree hundred patient-specific transcribed prescriptions #132023 7 -#1320536 which are retained per [NECC’s standard operating procedure].”²⁵⁸

Compounding pharmacies were also subject to the standards set by the USP Convention for drug purity, quality or identification.²⁵⁹ All compounding personnel had to comply with USP Chapter 797, which set standards to guarantee the sterility of drugs in order to ensure safety.²⁶⁰ Among many requirements, USP Chapter 797 required that

²⁵⁴ FDCA § 503A.

²⁵⁵ Grand Jury Charge at 42, *United States v. Cadden*, 1:14-cr-10363-RGS-1 (D. Mass.). Some fictitious names shared a common theme such as Bud Weiser, Richard Coors, Michael Keystone, Adam Foster, Samuel Adams, John Killian, or Raymond Rollingrock. *Id.* At one point, one of the defendants commented in an email to a sales representative that the “facility uses bogus patient names that are just ridiculous,” to which the sales representative acquiesced, “[t]hese are RIDICULOUS.” *Id.*

²⁵⁶ *Id.* at 44-46.

²⁵⁷ *Id.* at 39.

²⁵⁸ *Id.* at 47.

²⁵⁹ PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 4. This scientific organization publishes those standards in the USP. In Massachusetts, all licensed pharmacists are required to follow the standards set forth in the USP per section 9.01(3) of Title 247 of the Code of Massachusetts Regulations. CODE OF PROF’L CONDUCT; PROF’L STANDARDS FOR REGISTERED PHARMACISTS, PHARMACIES AND PHARMACY DEPARTMENTS § 9.01(3) (BD. OF REGISTRATION IN PHARMACY 2014).

²⁶⁰ PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 27.

the drugs be exposed to steam at 121°C under a pressure of one atmosphere for twenty to sixty minutes to ensure sterilization.²⁶¹ USP Chapter 797 further required that the sterilization process be verified through the use of a biological indicator and that compounding pharmacies document conditions and durations that specific drugs were sterilized.²⁶² NECC repeatedly failed to implement and strictly adhere to these procedures. For instance, NECC routinely autoclaved the drugs for fifteen to seventeen minutes instead of twenty to sixty minutes required by USP Chapter 797, and never verified the effectiveness of the sterilization.²⁶³ NECC violated USP Chapter 797 by using expired ingredients and stock solutions in compounding sterile drugs, mixing stock solutions from different drug batches, and failing to clean and disinfect clean rooms.²⁶⁴

VI. State Response to the Crisis

A. Hobbled State Oversight

Many states have insufficient resources or staff to adequately inspect and oversee licensed pharmacies, and this creates problems for their own citizens and citizens of the other states where compounding pharmacies sell medications.²⁶⁵ Until the NECC crisis, states typically relied on the jurisdictions where the pharmacies were located to license and regulate drug compounding.²⁶⁶

State Boards of Pharmacy have also lacked consistent inspection practices, thereby hampering state oversight.²⁶⁷ Pharmacy organizations have indicated that there is no assurance that non-resident pharmacies receive the same level of oversight as resident pharmacies since the frequency of pharmacy inspections and the qualifications of the inspectors can vary drastically among non-resident pharmacies.²⁶⁸

²⁶¹ PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 10.

²⁶² PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 10.

²⁶³ PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 13.

²⁶⁴ PHARMACOPEIAL CONVENTION, (797), *supra* note 41, at 12.

²⁶⁵ A discussion on the states' resource constraints and their ability to oversee drug compounding can also be found in GAO REPORT, *supra* note 12, at 25-26.

²⁶⁶ GAO REPORT, *supra* note 12, at 25.

²⁶⁷ GAO REPORT, *supra* note 12, at 25.

²⁶⁸ GAO REPORT, *supra* note 12, at 25. In response, some states are beginning to regulate nonresident pharmacies. *Id.* at 28. For instance, California, Florida, and Iowa require licensure or registration of nonresident pharmacies that provide services in the state. *Id.* These three states also require nonresident pharmacies applying for a license or registration to have a current license, permit, or registration issued by the regulatory body of the pharmacies' home state. *Id.*

State Boards of Pharmacy have also failed to make their inspection information readily available for review, thereby making it harder for state regulators to ensure safety, particularly for non-resident pharmacies.²⁶⁹ With a few exceptions,²⁷⁰ state enforcement records regarding safety have not been made public or readily accessible for review. Most State Boards of Pharmacy websites do not allow for keyword searches, which prevents the public from easily and efficiently locating or downloading enforcement records associated with violations regarding pharmacies or compounded drugs in a certain jurisdiction.²⁷¹ Moreover, publicly available information, such as state enforcement activities, only include traditional types of violations by individual pharmacies or pharmacists, such as billing violations, failure to have a licensed pharmacist onsite, or the distribution of controlled substances by the falsification of prescriptions.²⁷²

B. States' Response After the Fungal Meningitis Outbreak

Immediately after the NECC outbreak, the FDA convened a national meeting with the leaders of each state's Board of Pharmacy. The agency sought input regarding state oversight of compounding pharmacies.²⁷³

In collaboration with the National Association of Boards of Pharmacy (NABP) and other national pharmacy organizations, some states such as California, Florida, and Iowa have increased inspections.²⁷⁴ They developed a specific inspection program for sterile drug compounders located outside of the state that dispense drugs in the state. They also drafted legislation requiring their Boards of Pharmacy to conduct onsite inspections prior to licensing a pharmacy for exporting drug products.²⁷⁵

²⁶⁹ Office of Congressman Edward J. Markey (D-Mass.), *Compounding Pharmacies: Compounding Risk*, 10 (Oct. 29, 2012), https://www.snmni.org/files/docs/Compounding%20Pharmacies%20-%20Compounding%20Risk%20FINAL_0.pdf.

²⁷⁰ *Id.*

²⁷¹ Instead of keyword search capabilities, state enforcement action records relating to pharmacies are often limited to alphabetical or temporal lists, or summaries of violations that are not themselves searchable. *Id.* at 11. These lists in many instances lack sufficient information to understand the nature of the violation by pharmacies. *Id.*

²⁷² *Id.* at 3.

²⁷³ Open Letter from Dr. Hamburg, Commissioner of Fed. Food and Drug Admin., to State Boards of Pharmacy (Jan. 8, 2014) [hereinafter Hamburg Letter]; Pontikes, *supra* note 1, at 15.

²⁷⁴ See generally GAO REPORT, *supra* note 12.

²⁷⁵ GAO REPORT, *supra* note 12, at 20. The NABP instituted a Compounding Action Plan

California enacted legislation prohibiting resident and non-resident pharmacies from compounding or dispensing any sterile drugs in California unless they possess a sterile compounding pharmacy license; and it required the California State Board of Pharmacy to inspect pharmacies prior to granting such licenses.²⁷⁶ The license requires that: 1) resident and non-resident pharmacies report adverse events related to compounded drugs to both the California State Board of Pharmacy and the FDA's adverse event reporting system (MedWatch); and 2) all pharmacies submit a list of all sterile medications compounded during the previous twelve months.²⁷⁷

The California law exempts certain pharmacies accredited by a private accreditation agency approved by the California State Board of Pharmacy.²⁷⁸ Licensed pharmacies are subject to annual inspections prior to license renewal. Non-resident pharmacies must provide a copy of a recent inspection report issued by the pharmacy's licensing agency or a private accrediting agency approved by the California State Board of Pharmacy, demonstrating that the pharmacy complies with regulations regarding the compounding of injectable sterile drug products.

Florida's Board of Pharmacy issued an emergency rule following the NECC crisis, requiring resident and non-resident pharmacies to notify the State Board of Pharmacy of all compounding activities.²⁷⁹ Prior

(CAP) to identify and inspect compounding pharmacies. *Id.* at 24. Initially, the NABP drew on lists of pharmacies and inspection results obtained from the Iowa non-resident inspection program. *Id.* The NABP intends to collect data regarding the scope of compounding operations from all the states, and follow with inspections of the compounding pharmacies. *Id.* The NABP asked all states to identify any known or suspected compounding pharmacies in their state that are not on the Iowa list. *Id.*

²⁷⁶ Cal. Bus. & Prof. Code §§ 4127.1, 4127.2.

²⁷⁷ *Id.*; see GAO REPORT, *supra* note 12, at 20 (discussing California and other state law).

²⁷⁸ Cal. Bus. & Prof. Code §§ 4127.1-4127.2. Resident pharmacies operated by entities that are licensed by either the board or the California Department of Health and nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility are eligible for such exemption. *Id.* In contrast to current law, which imposes special licensure requirements only on pharmacies compounding injectable sterile drugs, this proposed legislation would require pharmacies compounding all types of sterile drugs to meet such requirements. *Id.*; GAO REPORT, *supra* note 12, at 21.

²⁷⁹ See Rule No. 64B16ER12-1, Immediate Notification of Compounding Status and Inspections, 38 Fla. Admin. Reg. 5183-5184 (Nov. 27, 2012). The GAO Report states:

Specifically, Florida's emergency rule required resident pharmacies with state pharmacy permits and nonresident pharmacies registered with the state to immediately notify the board of their sterile and non-sterile compounding activities, the types of drugs they compound, and whether they compound drugs in bulk. In addition, the emergency rule required Florida's board of pharmacy to use the information on compounding activities to place a high priority on inspecting high-risk pharmacies such as those that compound sterile drugs. The emergency rule also required all nonresident registered

to the emergency rule, the state did not know the number of resident pharmacies compounding drugs, or which non-resident pharmacies imported non-sterile or sterile compounded drugs. Following the emergency rule, the state learned that 12 percent of pharmacies compounded sterile products, such as injectable and ophthalmic solutions; 32 percent of pharmacies performing sterile compounding were non-resident pharmacies; and 55 percent of the responding pharmacies compounded non-sterile products, such as ointments or tablets.²⁸⁰ The Board of Pharmacy relied on this information to prioritize risk-based inspections.²⁸¹

The NABP has inspected drug compounders licensed by Iowa as non-resident pharmacies.²⁸² The inspections revealed that certain non-resident pharmacies compounded drugs that violated Iowa regulations.²⁸³ In response, the Iowa Board of Pharmacy initiated disciplinary actions against those out-of-state pharmacies.²⁸⁴

Other states have followed the lead of California, Florida, and Iowa. At least eighteen states have proposed or passed new legislation addressing compounded drugs or state oversight over compounding practices.²⁸⁵

VII. The Drug Quality and Security Act of 2013

Investigations of the NECC crisis identified several problems with industry practice and existing law.²⁸⁶ Federal and state responsibility

pharmacies to provide a copy of their last two inspection reports as provided by the state in which the pharmacies are physically located and licensed.

GAO Report, *supra* note 12, at 22 n.37.

²⁸⁰ GAO REPORT, *supra* note 12, at 22; *see also* DIV. OF MED. QUALITY ASSUR., FLA. DEP'T OF HEALTH, FLORIDA BOARD OF PHARMACY COMPOUNDING SURVEY REPORT (2013).

²⁸¹ DIV. OF MED. QUALITY ASSUR., FLA. DEP'T OF HEALTH, FLORIDA BOARD OF PHARMACY COMPOUNDING SURVEY REPORT (2013); *see also* Rule No. 64B16ER12-1, Immediate Notification of Compounding Status and Inspections, 38 Fla. Admin. Reg. 5183-5184 (Nov. 27, 2012).

²⁸² GAO REPORT, *supra* note 12, at 23.

²⁸³ GAO REPORT, *supra* note 12, at 23.

²⁸⁴ GAO REPORT, *supra* note 12, at 23.

²⁸⁵ *See 2014 State Compounding Legislation Tracker*, INT'L ACAD. COMPOUNDING PHARMACISTS (2014), <http://c.ymcdn.com/sites/www.iacprx.org/resource/resmgr/imported/%20Weekly%20of%20State%20Legislation%2001282014-1.pdf>. These efforts by the states were echoed by industry organizations, such as the NABP. Pontikes, *supra* note 1. For example, the NABP convened a meeting in November 2012 with executive directors of the State Boards of Pharmacy, and with a goal of developing a system to identify and correct the systemic failures that led to the NECC outbreak. *Id.*

²⁸⁶ PEW CHARITABLE TRUSTS, NATIONAL ASSESSMENT OF STATE OVERSIGHT OF STERILE DRUG COMPOUNDING (Feb. 2016), http://www.pewtrusts.org/~media//2016/02/national_assessment_of_state_of_sterile_drug_compounding.pdf.

regarding compounding pharmacies needed to be clarified. Inconsistent federal circuit court decisions had required the FDA to apply different standards across various regions.²⁸⁷ State oversight varied based on local law and state resources.²⁸⁸ The FDA also lacked timely and reliable information relayed from state inspections and enforcement.²⁸⁹ Furthermore, many states and purchasers incorrectly believed that the FDA had approved drugs and inspected facilities that advertised themselves as “FDA registered.”²⁹⁰ The result was regulatory gaps and inadequate public health protection.²⁹¹

Senate and House of Representatives hearings investigated ways to improve oversight of compounding pharmacies.²⁹² FDA officials testified in favor of legislation that granted the FDA explicit authority over “non-traditional” compounding.²⁹³ The statute does not define “traditional” compounding; however, FDA officials use the term to signify pharmacies that compound a drug “for an identified individual patient based on the receipt of a valid prescription order.”²⁹⁴

Non-traditional compounding falls between traditional compounding and manufacturing, particularly the production of sterile product produced in advance without an individual patient prescription that are shipped across state lines.²⁹⁵ Commissioner Hamburg testified that non-traditional compounding should be identified according to the FDA’s CPG 1992, CPG 2002, and based on four factors: 1) the type of product or compounding activity; 2) the volume compounded; 3) whether the compounding occurred prior to receipt of a “patient-specific” prescription; and 4) whether the medications were shipped into interstate commerce.²⁹⁶

²⁸⁷ *Id.* at 2-3

²⁸⁸ *Id.* at 1.

²⁸⁹ *See generally id.*

²⁹⁰ GAO REPORT, *supra* note 12, at 27.

²⁹¹ *See generally id.*

²⁹² CRS REPORT R43038, *supra* note 44, at 45.

²⁹³ Hamburg Letter, *supra* note 273.

²⁹⁴ GAO REPORT, *supra* note 12, at 37; *see also* Pontikes, *supra* note 1.

²⁹⁵ GAO REPORT, *supra* note 12, at 12; *see, e.g., Pharmaceutical Compounding: Proposed Legislative Solution: Hearing Before the S. Comm. on Health, Education, Labor & Pensions, 113th Cong. (2013)* (statement of Janet Woodcock, M.D., Director, Center for Drug Eval. & Research, Food & Drug Admin.); *see also* Hamburg Statement, *supra* note 251.

²⁹⁶ *A Continuing Investigation Into the Fungal Meningitis Outbreak and Whether it Could Have Been Prevented: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 113th Cong. (2013)* (statement of Dr. Margaret A. Hamburg, Comm’r, Food and Drug Admin.); *see also* Pontikes, *supra* note 1.

The Drug Quality and Security Act (DQSA), enacted in November 2013, includes two parts: Title I, the Compounding Quality Act (CQA); and Title II, the Drug Supply Chain Security Act (DSCSA).²⁹⁷

A. *The Compounding Quality Act*

The CQA authorizes the FDA to oversee non-traditional compounding pharmacies, those that compound and ship large quantities of sterile drugs that are willing to submit to its jurisdiction. However, under the CQA, compliance with the new standards apply only to pharmacies that voluntarily register as “outsourcing facilities.”²⁹⁸

1. *Outsourcing Facilities for Certain Non-Traditional Compounding*

The CQA creates the new legal category *outsourcing facilities* under section 503B to the FDCA.²⁹⁹ Qualifying pharmacies can register annually and be regulated as outsourcing facilities.³⁰⁰ Pharmacies that

²⁹⁷ Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587 (2013). Since Congress enacted the DQSA, sixty-seven compounding facilities have registered with the FDA as outsourcing facilities and are subject to increased quality standards and federal oversight. See U.S. FOOD AND DRUG ADMIN., FDA’S HUMAN DRUG COMPOUNDING PROGRESS REPORT (Jan. 2017), <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm536549.pdf>. The CQA has also enabled the FDA to increase its inspections of compounding facilities and permitted the agency to respond to compounders that violate the FDCA. FDA COMPOUNDING PROGRESS REPORT, *supra*, at 10. The FDA has issued seven final guidance documents, eighteen draft guidance documents, one final rule, two proposed rules, and a draft memorandum of understanding with the states. *Id.* The FDA has worked closely with the states to share information and coordinate regulatory efforts. *Id.* Since November 27, 2016, the FDA has: 1) conducted eighty-five inspections of outsourcing facilities—issuing many Form FDA 483s when it found violations of the FDCA; 2) issued more than 130 warning letters advising compounders of significant violations of sections 503A or 503B; 3) issued more than thirty letters related to inspectional findings to state regulatory agencies so that states could ensure that violators brought their activities into compliance; and 4) overseen the recall of up to 100 compounded drugs due to unsanitary facility conditions or sub- or super-potent drug products. *Id.* Compounders that do not come into compliance may be subject to enforcement action, such as seizure, injunction, or criminal prosecution. *Id.* In addition, the FDA has also worked with the Department of Justice on many civil and criminal enforcement actions regarding violations of the FDCA. These steps have reduced risks and improved safety. *Id.*; Drug Quality and Security Act (DQSA), tit. I, § 102; FDCA § 503B(a)(1) (2013); DQSA, tit. II, § 201.

²⁹⁸ DQSA, tit. I, § 102; FDCA § 503B.

²⁹⁹ DQSA, tit. I, § 102; FDCA § 503B(a)(1); see also U.S. FOOD AND DRUG ADMIN., REGISTERED OUTSOURCING FACILITIES (Feb. 10, 2017), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm.htm>.

³⁰⁰ DQSA, tit. I, § 102; FDCA § 503B. Under FDCA § 503B(b), the FDA can deem compounded drugs misbranded if they were produced by an outsourcing facility that has not registered and paid its annual registration fee. See FDCA § 503B(b)(1).

do not register must either meet the requirements for traditional pharmacies under section 503A, or for manufacturers under sections 502(f)(1), 505, and 582. They must inform the FDA of certain activities, most notably, if they intend in the following year to compound drugs appearing on the FDA's drug shortage list or compound sterile drugs from bulk substances.³⁰¹ Outsourcing facilities can also maintain a state pharmacy license.³⁰²

Outsourcing facilities compound sterile drugs under the direct supervision of a licensed pharmacist.³⁰³ They are not required to obtain prescriptions for individual patients, but they are only allowed to compound drugs that the FDA authorizes and must comply with cGMPs and certain reporting and labeling requirements.³⁰⁴ They are exempt from the FDCA standard for new drug approvals each time they compound a drug,³⁰⁵ as well as certain labeling requirements designed to ensure adequate directions for the drug's use.³⁰⁶

Section 503B restricts the drugs that outsourcing facilities can prepare, the bulk substances that they can use, and it regulates their operations.

There are five main restrictions:

- 1) Prohibition on compounding drugs withdrawn from the market for safety or efficacy reasons, or when the FDA indicates present demonstrable difficulties for compounding.³⁰⁷
- 2) Prohibition on compounded drugs that are "essentially a copy"

³⁰¹ Pontikes, *supra* note 1; *see* FDCA § 503B(b)(2). According to the FDA's Draft 503B Guidance, the registration process must be completed between October 1 and December 31 of each year and requires the outsourcing facility to provide the name, place of business, unique facility identifier, and a designated point of contact email address. U.S. FOOD AND DRUG ADMIN., DRAFT GUIDANCE: REGISTRATION FOR HUMAN DRUG COMPOUNDING OUTSOURCING FACILITIES UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, 3 (Dec. 2013), <https://www.fda.gov/downloads/guidances/ucm377051.pdf> [hereinafter DRAFT 503B REGISTRATION GUIDANCE]. "This guidance describes the process for submission of registration information for outsourcing facilities. The guidance is intended to facilitate registration as human drug compounding outsourcing facilities. A compounder can elect to register with the FDA as an outsourcing facility under section 503B of the FDCA, as added by the DQSA, Pub. Law No. 113-54 (November 27, 2013)." *Id.*; *see also* U.S. FOOD AND DRUG ADMIN., ELECTRONIC DRUG PRODUCT REPORTING FOR HUMAN DRUG COMPOUNDING OUTSOURCING FACILITIES UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (Dec. 2016).

³⁰² Pontikes, *supra* note 1; *see* FDCA § 503B(d).

³⁰³ DQSA, tit. I, § 102; FDCA § 503B(a).

³⁰⁴ Pontikes, *supra* note 1.

³⁰⁵ DQSA, tit. I, § 102; FDCA § 503B(a); 21 U.S.C. § 355 *et seq.*

³⁰⁶ DQSA, tit. I, § 102; FDCA § 503B(a).

³⁰⁷ Pontikes, *supra* note 1; *see* FDCA § 503B(a)(4), (a)(6).

of an FDA-approved drug,³⁰⁸ defined as: (i) a drug that is identical or nearly identical to an FDA-approved drug or a marketed drug not subject to premarket approval unless FDA finds there is a shortage of the drug at the time of compounding; or (ii) a drug, a component of which is a bulk drug substance that is a component of an approved drug, unless a change in the drug produces a clinical difference for an individual patient.³⁰⁹

3) Prohibition on using a bulk drug substance in compounding unless: (i) the bulk drug substance either appears on an FDA approved list or the drug compounded appears on the FDA's drug shortage list;³¹⁰ (ii) the bulk substance complies with an applicable USP or NF monograph, or another compendium or pharmacopeia recognized by the FDA;³¹¹ (iii) the bulk drug substance is manufactured by a FDA-registered facility;³¹² and (iv) the purity of the bulk drug substance is confirmed by a valid certificate of analysis reflecting purity.³¹³

4) Prohibition on acting as wholesalers or distributing compounded drugs for resale,³¹⁴ or transfer to other entities.³¹⁵

5) Prohibition on compounding drugs subject to a Risk Evaluation and Mitigation Strategy (REMS) unless the pharmacy has demonstrated to the FDA that it utilizes comparable controls.³¹⁶

The CQA also prohibits: 1) reselling compounded drugs that are labeled "not for resale"; 2) intentionally falsifying a prescription for a compounded drug; 3) failing to report drugs from an outsourcing facility or adverse events; and 4) using advertisements or promotions of compounded drugs that are false or misleading.³¹⁷

³⁰⁸ DQSA, tit. I, § 102; FDCA § 503B(a)(5)-(6).

³⁰⁹ Pontikes, *supra* note 1; *see* FDCA § 503B(d)(2).

³¹⁰ DQSA, tit. I, § 102; FDCA § 503B(a)(2)(A).

³¹¹ DQSA, tit. I, § 102; FDCA § 503B(a)(2)(B).

³¹² FDA has regulatory authority over facilities that manufacture bulk substances, including foreign facilities, under section 510 of the FDCA. *See generally* Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 355 *et seq.* (2010).

³¹³ DQSA, tit. I, § 102; FDCA § 503B(a)(2)(D).

³¹⁴ DQSA, tit. I, § 102; FDCA § 503B(a)(8).

³¹⁵ DQSA, tit. I, § 102; FDCA § 503B(a)(8).

³¹⁶ Pontikes, *supra* note 2. The FDA may require a proposed "risk evaluation and mitigation strategy" if it determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug. 21 U.S.C. § 355-1. REMS will generally include a time frame for assessing the drug at specified intervals after the drug obtains FDA approval, communication plans with health care providers, and development of patient medication inserts or other education materials. *Id.*; *see also* FDCA § 503B(a)(7).

³¹⁷ DQSA, tit. I, § 102; FDCA § 503B(a)(10).

2. *Labeling, Good Manufacturing Practices, Reporting Requirements, and Inspections*

Outsourcing facilities must comply with multiple requirements such as the following: 1) displaying detailed information on their labels that helps implement the track and trace provisions and reduces risk of improper use;³¹⁸ 2) complying with cGMPs;³¹⁹ 3) reporting to the FDA within 15 days of notice all serious and unexpected adverse events associated with their compounded drugs;³²⁰ 4) conducting a prompt investigation of all adverse events associated with their compounded drugs and report the findings to the FDA;³²¹ 5) maintaining records of correspondences relating to all adverse drug experiences for a period of ten years and allow FDA employees access to the records;³²² and 6) submitting semi-annual reports³²³ to the FDA identifying all drugs compounded during the preceding six-month period.³²⁴

Outsourcing facilities are subject to full inspections pursuant to section 704 of the FDCA.³²⁵ On written notice, the FDA can inspect equipment, finished and unfinished materials, containers, labeling, records, papers, files, processes, controls, and facilities.³²⁶ The FDA will inspect outsourcing facilities on a risk-based schedule according to

³¹⁸ *Id.* The labels of outsourcing facilities' drugs must include: 1) a statement that it is a compounded drug; 2) the name, address, and phone number of the outsourcing facility; 3) the lot or batch number of the drug; 4) the established name of the drug; 5) the quantity or volume of the drug; 6) the date the drug was compounded and the expiration date; 7) instructions for storage and handling; 8) the NDC number, if available; 9) a statement that the compounded drug is "not for resale" and/or for "office use only"; and 10) containers from which individual units of drugs are removed must also include information for adverse event reporting and directions for use. Pontikes, *supra* note 1.

³¹⁹ DQSA, tit. I, § 102; FDCA § 503B(a)(10).

³²⁰ DQSA, tit. I, § 102; FDCA § 503B(b)(5); 21 C.F.R. § 310.305 (setting forth the procedure for and scope of adverse event reporting).

³²¹ 21 C.F.R. § 310.305(c)(1).

³²² *Id.*; *see* 21 C.F.R. § 310.305(f).

³²³ DQSA, tit. I, § 102; FDCA § 503B(b). The FDA may grant waivers to the electronic reporting requirement if it finds that "use of electronic means is not reasonable for the person requesting the waiver." *See* FDCA § 503B(b)(3).

³²⁴ DQSA, tit. I, § 102; FDCA § 503B(b)(2). These reports will be due in June and December of each year. DRAFT 503B REGISTRATION GUIDANCE, *supra* note 301. The reports must include: 1) the API and strength of API per unit; 2) the source of the API such as bulk or finished drug; 3) the National Drug Code (NDC) number of the source drug or bulk active ingredient, if available; 4) the dosage form and route of administration; 5) the package description; 6) the number of individual units produced; and 7) the NDC number of the final product, if assigned. *Id.*

³²⁵ Pontikes, *supra* note 1; *see* FDCA § 503B(b)(4); 21 U.S.C. § 374(a) ("Inspection. (a) Right of agents to enter; scope of inspection; notice; promptness; exclusions.").

³²⁶ Pontikes, *supra* note 1.

“known safety risks” in the outsourcing facility, which the FDA determines based on the facility’s compliance, recall, and inspection history, and based on whether the facility intends to compound drugs on the FDA’s drug shortage list and on other criteria.³²⁷

3. *Traditional Compounding*

The revised FDCA section 503A regulates traditional compounding.³²⁸ It also exempts from the NDA approval process certain compounded drugs that include adequate directions for use, and that conform to the FDCA’s general labeling and cGMP requirements.³²⁹ In doing so, the CQA removes the option that the FDA, in theory, had to deem compounded drugs to be “new drugs” that must meet the same standards that apply to manufactures who seek to market new products.³³⁰ The CQA also deletes the provision of section 503A that the Court held unconstitutional in *Western States*.³³¹

Section 503A allows pharmacies to compound a drug “for an identified individual patient based on the unsolicited receipt of a valid prescription”³³² and a limited amount (undefined) of drugs before receiving a prescription, if based on historical ordering patterns.³³³ Permitted anticipatory compounding includes the preparation of syringes used in the operating room, epidurals, narcotic infusions, diluted and concentrated medications that are not commercially available, and medications unavailable due to supply shortages.³³⁴

Section 503A prohibits compounding drugs that the FDA has found unsafe or ineffective and withdrawn from the market,³³⁵ or that the FDA has determined are difficult to compound.³³⁶ It also prohibits routine

³²⁷ Pontikes, *supra* note 1.

³²⁸ Pontikes, *supra* note 1.

³²⁹ FDCA § 503A(a).

³³⁰ Pontikes, *supra* note 1.

³³¹ FDCA § 503A; DQSA, tit. I, § 102.

³³² FDCA § 503A(a).

³³³ FDCA § 503A(a)(2)(A).

³³⁴ Pew Charitable Trusts, American Society of Health-System Pharmacists, and American Hospital Association, Pharmacy Compounding Summit: Summary of a Stakeholder Meeting, at 4 Washington, DC (Feb. 6, 2013).

³³⁵ FDCA § 503A(b)(1)(C). The FDA has already identified nearly sixty drugs it does not allow to be compounded because it does not meet this criterion and it plans to update this list periodically. Pontikes, *supra* note 1.

³³⁶ FDCA § 503A(b)(3)(A).

compounding or compounding inordinate amounts of drugs that are “essentially copies” of commercially available products.³³⁷ Such copies do not include drugs that have undergone modification, such as transformation from tablet to liquid to produce an alternative for an individual patient, when the prescribing practitioner determines that the modification produces a significant benefit for the patient.³³⁸

Section 503A establishes requirements regarding compounding ingredients. Compounders must use bulk substances bearing valid certificates of analyses for purity and comply with USP or NF monographs on pharmacy compounding. If no monograph exists, then they must use bulk substances that are components of FDA-approved drugs or that appear on an FDA-approved list and manufactured by an FDA-registered facility.³³⁹ In addition, ingredients must meet standards of applicable USP or NF monographs and the USP Chapters on pharmacy compounding if ingredients are not bulk substances.³⁴⁰

Section 704(a) of the FDCA exempts pharmacies that do not engage in outsourcing activities from records inspection and registration requirements,³⁴¹ if they comply with local pharmacy and medicine regulations, regularly dispense drugs upon prescriptions of practitioners, and only manufacture or distribute drugs for sale in their retail business.³⁴²

³³⁷ FDCA § 503A(b)(1)(D). “Essentially copies” are defined differently under section 503A and section 503B. Section 503B defines essentially copies as: 1) a drug that is identical or nearly identical to an FDA-approved drug or a marketed drug not subject to premarket approval unless, in the case of an approved drug, the drug appears on an FDA-created drug shortage list in effect at the time of compounding, distribution, and dispensing; or 2) a drug, a component of which is a bulk drug substance that is a component of an approved drug, unless a change in the drug produces a clinical difference for an individual patient. *See* FDCA § 503B(d)(2).

³³⁸ *Id.*; Pontikes, *supra* note 1, at 20.

³³⁹ FDCA § 503A(b)(1)(A)(i). In its Draft 503A Guidance, the FDA has taken the position that until a bulk substances drug list is published, compounded human drug products should be restricted to bulk substances that are components of FDA-approved drugs or the subject of USP or NF monographs. U.S. FOOD AND DRUG ADMIN., ENFORCEMENT POLICY DURING IMPLEMENTATION OF SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (Nov. 1998) [hereinafter DRAFT 503A GUIDANCE].

³⁴⁰ FDCA § 503A(b)(1)(B).

³⁴¹ FDCA § 704(a); 21 U.S.C. § 360(g).

³⁴² FDCA § 704(a). In comparison, the FDA’s 1998 draft Memorandum of Understanding (MOU), issued to implement the FDAMA, set a twenty percent maximum limit for interstate dispensing and distribution of compounded drugs. *See* Pontikes, *supra* note 1.

4. *Federal and State Coordination and Communication*

Under the revised Section 503A, the states continue to license and regulate pharmacies, and have primary jurisdiction over them.³⁴³ However, the FDA maintains that compounded drugs are also subject to the FDCA unless specifically exempted.³⁴⁴ The FDA intends to enforce FDCA sections 501 and 502 which prohibit drugs that: 1) consist of filthy, putrid, or decomposed substances; 2) are prepared under unsanitary conditions; 3) differ in quality and purity from the recognized official compendium with which the drug purports to comply; or 4) are not packaged or labeled as set forth in the official compendium in which the drug purports to comply.³⁴⁵

Section 503A also requires the FDA to consult with the NABP and develop a Memorandum of Understanding (MOU) with the states,³⁴⁶ in order to respond to the interstate distribution of “inordinate amounts” of compounded drugs and facilitate state investigation of complaints concerning interstate distribution.³⁴⁷ The FDA’s 2015 draft MOU³⁴⁸ specified that if the states do not enter into the final MOU, section 503A will prevent the distribution of compounds in excess of five percent of the total prescription orders dispensed or distributed.³⁴⁹

Section 105 of the CQA is intended to improve the communication between the State Boards of Pharmacy and the FDA.³⁵⁰ The statute requires that the reporting mechanism be implemented in consultation with the NABP.³⁵¹ The State Boards of Pharmacy must notify the FDA when

³⁴³ U.S. FOOD AND DRUG ADMIN., *Compounding and the FDA: Questions & Answers* (Oct. 6, 2015), <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm>.

³⁴⁴ U.S. DEP’T OF HEALTH & HUMAN SERVICES, INTERIM POLICY ON COMPOUNDING USING BULK DRUG SUBSTANCES UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, GUIDANCE FOR INDUSTRY at 2 (2017), <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf>.

³⁴⁵ *Id.* at 6.

³⁴⁶ FDCA § 503A(3)(B)(i).

³⁴⁷ *Id.*

³⁴⁸ Draft Memorandum of Understanding Addressing Certain Distribution of Compounded Human Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration 2015, <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM434233.pdf> (last visited Feb. 26, 2018).

³⁴⁹ *Id.*; DRAFT 503A GUIDANCE, *supra* note 339; Pontikes, *supra* note 1.

³⁵⁰ FDA Implementation of the Compounding Quality Act (Sept. 14, 2016). The NECC crisis highlighted the lack of effective communication between State Boards of Pharmacy and the FDA. *See* Drug Quality Security Act, Hearing on HR3204 before the House (statement of Rep. Henry A. Waxman) (Sept. 28, 2013); Pontikes, *supra* note 1.

³⁵¹ Pontikes, *supra* note 1. The FDA is also to consult with the NABP on the creation of this

they: 1) issue a warning letter or impose any sanctions for violations of compounding pharmacy regulations; 2) suspend or revoke a compounding pharmacy license or registration; or 3) learn of any recall regarding the quality or purity of a compounded drug.³⁵² Moreover, the FDA must immediately notify the State Boards of Pharmacy if the agency determines that a pharmacy violated section 503A or if it receives any notifications from a State Board of Pharmacy for any state related violation.³⁵³

B. The Drug Supply Chain Security Act (DSCSA)

The DSCSA creates track and trace requirements for each package of medication in the pharmaceutical distribution chain as a means to facilitate detection and removal of contaminated or counterfeit products.³⁵⁴ The legislation outlines a ten-year plan to implement an electronic, interoperable system across the United States.³⁵⁵ The key provisions include these requirements for manufacturers, repackagers, and wholesalers.³⁵⁶

Product Identification. Each prescription drug package will have a unique product identifier, such as a bar code, that can be easily read electronically.

Product Tracing. All entities will provide information regarding a drug product and any personnel who handled the drug each time the product was sold.

Product Verification. All entities will have to establish systems and processes to verify the product identifier on certain prescription drug packages.

Detection and Response. All entities will have to quarantine and promptly investigate a drug that has been suspected of being counterfeit, unapproved, or dangerous.

Notification. All entities will have to establish processes to notify

mechanism for enhanced communication between the State Boards of Pharmacy and the FDA. See DQSA, tit. I, § 105.

³⁵² DQSA, tit. I, § 105(b)(1)-(3).

³⁵³ DQSA, tit. I, § 105(d).

³⁵⁴ Drug Supply Chain Security Act (DSCSA), <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct> (last updated Nov. 28, 2017).

³⁵⁵ See U.S. DEP'T. OF HEALTH & HUMAN SERVICES ET AL., DRUG SUPPLY CHAIN SECURITY ACT IMPLEMENTATION: IDENTIFICATION OF SUSPECT PRODUCT AND NOTIFICATION GUIDANCE FOR INDUSTRY (2016).

³⁵⁶ *Id.* The act requires manufacturers to serialize drugs by 2017, and mandates the use of an electronic product tracing system by 2023. *Id.*

the FDA and other parties if an illegitimate drug is identified.

Licensing of Wholesalers and Distributors. Wholesale drug distributors will have to report their licensing status and contact information to the FDA which will be made publicly available.

Third-Party Logistics Provider Licensing. Third-party logistic providers, i.e., those who provide storage and logistical operations related to drug distribution, will have to obtain a state or federal license.

VIII. Key Unresolved Issues

A. The Legal Status of Compounding Pharmacies Under Federal Law

The legal status of non-traditional compounding and outsourcing facilities remains unresolved. The plain language of the FDCA favors the interpretation that the FDA has authority over drug compounding if compounded drugs constitute new drugs.³⁵⁷ Specifically, the FDCA states that no person can “introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application [is] filed” with the FDA pursuant to the statute with respect to the drug.³⁵⁸ However, the legislative history of the FDCA supports the view that manufacturers were the intended target of the 1938 Act, not traditional compounding pharmacies.³⁵⁹ Therefore, it is unclear whether the FDCA deems certain “traditional” compounding unlawful.³⁶⁰

The FDA has declined to test the current limits of federal authority to regulate “traditional” compounding, and deferred to state governments for compounding regulation.³⁶¹ As a result, the limits of the FDA’s authority over drug compounding remains uncertain.³⁶² Courts might not support new FDA regulation of traditional compounding.

³⁵⁷ *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000). If a statute’s terms are “plain,” the Supreme Court has noted that a court should look no further and enforce the law “according to its terms.” *See id.* (citations omitted); CRS REPORT R43038, *supra* note 44, at 11.

³⁵⁸ 21 U.S.C. § 355(a).

³⁵⁹ *United States v. Franck’s Lab, Inc.*, 816 F. Supp. 2d 1209, 1245-46 (M.D. Fla. 2011).

³⁶⁰ *Id.* at 1239.

³⁶¹ CPG § 460.200 (May 29, 2002); CPG § 608.400 (July 14, 2003); CRS REPORT R43038, *supra* note 44, at 12.

³⁶² This lack of resolution burdens “traditional” compounders, whose conduct could be in violation of federal law. *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 399-400 (5th Cir. 2008). As one court noted, “it remains no small burden for compounding pharmacists . . . to ‘live in sin,’ [as] their livelihood [has] no greater assurance than the FDA’s good graces.” *Id.*

However, Congress could expand the scope of the FDCA to reach “traditional” compounding.³⁶³

In addition, the CQA does not authorize the FDA to regulate compounding pharmacies unless such pharmacies voluntarily register as outsourcing pharmacies and accept FDA oversight. Therefore, the new regulatory controls can work only if compounding pharmacies register and accept to work under the new regulatory system. Proponents of the voluntary system argue that market forces will cause larger compounders to register because hospitals and other providers will choose to do business with compounders subject to FDA quality standards, inspection requirements, and adverse event reporting. It remains to be seen how many large compounders will register and whether state regulatory agencies will improve facility inspections and share information.

B. Conflicting Standards within Federal Law and Between Federal and State Law

Outsourcing pharmacies, including federal and state-licensed compounding pharmacies, all compound and repackage drugs based on individualized prescriptions. However, the CQA applies different standards regarding labeling, quality, and adverse event reporting for facilities depending on whether they are outsourcing facilities, state-licensed or federally regulated. The DQSA’s definition of an outsourcing facility includes only facilities engaged in the compounding of “sterile” drug products. However, the FDCA’s definition of compounding applies to all drugs in general.³⁶⁴

The DQSA standards do not apply to 503A entities, such as traditional drug compounding pharmacies, and are not imposed consistently across all jurisdictions.³⁶⁵ Yet, the DQSA standards apply to section 503B entities, i.e., outsourcing facilities, which are federally regulated. However, the DQSA does not make clear what responsibility states bear

³⁶³ *Gonzales v. Raich*, 545 U.S. 1, 22 (2005) (holding that the authority under the Commerce Clause extends such that Congress can regulate activities when, taken in the aggregate, substantially affect interstate commerce); see CRS REPORT R43038, *supra* note 44, at 12.

³⁶⁴ See *generally* Drug Quality and Service Act (DQSA). In addition, the DQSA applies only to “human drugs” and not to drugs for animal use. *Id.*

³⁶⁵ U.S. FOOD AND DRUG ADMIN, FDA GUIDANCE, ADVERSE EVENT REPORTING FOR OUTSOURCING FACILITIES UNDER SECTION 503B OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT (2015), <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm434188.pdf>.

vis-à-vis outsourcing facilities, and the FDA has yet to clarify the relation between federal and state standards for outsourcing facilities. Furthermore, some states do not recognize federally regulated outsourcing facilities and require that such facilities be licensed by the State Boards of Pharmacy as a pharmacy or pharmaceutical distributor. Some states argue that outsourcing facilities must meet both federal and state standards because they can make medications, compound drugs, and market them around the country similar to a manufacturer, but also be engaged in filling prescriptions similar to a pharmacist.

It is unclear whether federal legislation will permit non-traditional compounding practices to thrive outside of the outsourcing facility category. If it does, the CQA will not have effectively addressed the problems that caused the NECC crisis, despite the FDA's best efforts.

REFORMING QUARANTINE: MOVING TOWARDS A MORE ETHICAL AND EFFECTIVE APPROACH TO OUTBREAK MANAGEMENT

Cara M. Passaro*

ABSTRACT

Quarantine is a public health intervention where asymptomatic people who have been exposed to a contagious disease are separated from the general population while they are monitored to see if they become sick. Critics have cited several potential ethical issues raised by quarantine in the United States. These concerns include whether quarantine is the least restrictive alternative intervention,

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whether due process protections are adequate, and whether safe, humane, and fair methods have been used when executing quarantines. In addition, quarantines may be punitive or even counter-productive because they can be stigmatizing and because they can discourage reporting of symptoms.¹ In addition, the effectiveness of this emergency tool may be weakened by America's deference to individual rights, federalism, fragmented legal authority, and neglected public health infrastructure.² This paper will assess the ethics and efficacy of quarantine and propose some recommendations for improvement.

I. Introduction	59
II. The Problem	60
III. Literature Review	62
A. Effectiveness of Quarantine.....	62
B. Public Satisfaction	66
IV. Legal History of Quarantine	67
V. Modern Legal and Ethical Framework.....	70
VI. Lack of Coordination and Stigma.....	74
VII. Policy Approaches	76
A. Mental Health Commitment Model.....	76
B. State Statutes.....	77
C. Connecticut Legislation	78
VIII. Conclusion and Policy Recommendations	81

¹ See, e.g., Wendy Parmet, *Dangerous Perspectives: The Perils of Individualizing Public Health Problems* 5, 8-9 (NE. U. SCH. OF LAW, WORKING PAPER NO. 31-20092009); AM. CIVIL LIBERTIES UNION & YALE GLOBAL HEALTH JUST. PARTNERSHIP, FEAR, POLITICS, AND EBOLA: HOW QUARANTINES HURT THE FIGHT AGAINST EBOLA AND VIOLATE THE CONSTITUTION 4, 32 (2015), https://www.aclu.org/sites/default/files/field_document/aclu-ebolareport.pdf [hereinafter AM. CIVIL LIBERTIES UNION].

² See David P. Fidler, *Legal Issues Surrounding Public Health Emergencies*, 116 PUB. HEALTH REP. 79, 81 (2001).

I. Introduction

Although I tested negative for Ebola, there is no sign I will be able to leave this plastic prison-tent. . . . I know I cannot give anyone Ebola because I do not have symptoms. My rights have been taken away as if they do not matter and the wrong people are making decisions, people without expertise in public health or medicine. . . . I am being held captive in a tent due to fear and politics. . . . What scares me the most is . . . what if they keep me here, alone in this tent, for the entire twenty-one days?³

Quarantine is a public health intervention where asymptomatic people who have been exposed to a contagious disease are separated from the general population and their movement is restricted while they are monitored to see if they become sick.⁴ The authority to quarantine is rooted in a state's authority to ensure the public's health under its general police powers,⁵ but it has been in use in the United States since before the drafting of the Constitution.⁶

³ Kaci Hickox, *Caught Between Civil Liberties and Public Safety Fears: Personal Reflections from a Healthcare Provider Treating Ebola*, 11 J. OF HEALTH & BIOMEDICAL L. 9, 9-10 (2015). Hickox, an American Nurse for Doctors without Borders who treated Ebola patients in Sierra Leone, was one of the most vocal critics of the 2014 Ebola quarantines. Steven H. Miles, *Kaci Hickox: Public Health and the Politics of Fear*, 15 AM. J. OF BIOETHICS 17, 17 (2015). Asymptomatic individuals cannot spread Ebola. Hickox, *supra*, at 16. Although Hickox was asymptomatic, she was held in an isolation tent inside a New Jersey hospital for days before being released and escorted to her home in Maine with few medical precautions. Miles, *supra*, at 17. The same day Hickox returned to Maine, that state released a quarantine protocol requiring returning health workers to quarantine at home. Maine Center for Disease Control and Prevention, *Maine Center for Disease Control and Prevention Press Release* (Oct. 2014), <http://www.maine.gov/dhhs/mecdc/press-release.shtml?id=630240>. However, a state court dismissed the state health department's petition to order Hickox quarantined because she was not infectious. Miles, *supra*, at 18; see *Maine Dep't of Health and Human Services v. Hickox*, No. CV-2014-36 (D. Me. Oct. 31, 2014).

⁴ *Quarantine and Isolation*, CENTERS FOR DISEASE CONTROL & PREVENTION (Aug. 2016), <https://www.cdc.gov/quarantine/> (distinguishing quarantine from isolation where individuals known to be sick are separated); AM. CIVIL LIBERTIES UNION, *supra* note 1, at 6.

⁵ See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) ("According to settled principles the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety."). Note that the federal government's quarantine authority is derived from the Public Health Service Act of 1944 (PHSA), which charges the Secretary of Health and Human Services with making and enforcing regulation to prevent the introduction and transmission of communicable diseases into or within the United States. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 456 (2nd ed. 2008).

⁶ LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT*, 438 (2nd ed. 2008).

Critics have cited several potential ethical issues raised by the implementation or enforcement of quarantine in the United States. These concerns include whether quarantine is the least restrictive alternative intervention, whether due process protections are adequate, and whether safe, humane, and fair methods have been used when executing quarantines. In addition, quarantines may be punitive and/or counter-productive because they are stigmatizing and they discourage reporting of symptoms.⁷ The public health efficacy of this tool in an emergency may be undercut by America's deference to individual rights and federalism, fragmented and outdated legal authority, and neglected public health infrastructure.⁸ This paper will assess the ethics and efficacy of quarantine, and will propose some recommendations for improvement.

II. *The Problem*

The power to quarantine is perhaps the most coercive tool in a public official's toolkit for managing disease outbreaks. The public may demand it at times when people are fearful and do not have a rational understanding of the risks of infection. But when used correctly, the public health practitioner assesses quarantine's utility based only on science, and uses other measures to educate the public and mitigate fear.

Numerous criticisms and legal claims have been levied at the constitutionality of the state quarantines imposed in response to the panic surrounding the Ebola outbreak in 2014.⁹ From policy and ethical perspectives, quarantines pose unique challenges. For example, one of the challenges of containing the 2014 Ebola outbreak in West Africa was the region's weak public health infrastructure, including the shortage of personnel trained in treating and managing patients when they were most infectious.¹⁰ Non-governmental organizations mobilized American volunteers, but their efforts were thwarted by the threat that state and local health authorities would confine volunteers for three weeks upon their return to the United States.¹¹

⁷ See, e.g., Parmet, *supra* note 1; AM. CIVIL LIBERTIES UNION, *supra* note 1.

⁸ See Fidler, *supra* note 2.

⁹ See, e.g., AM. CIVIL LIBERTIES UNION, *supra* note 1, at 8.

¹⁰ *Id.* at 7, 31.

¹¹ *Id.* at 31.

In addition to the threat of confinement, exaggerated fears and stigmatization of Ebola health workers when they returned to their communities likely discouraged potential volunteers.¹² Ironically, many returning health workers were Ebola experts, trained in precautions and self-monitoring, a daily requirement of protecting themselves and their colleagues from the spread of the disease in West Africa.¹³ Still, many health workers who were subjected to quarantines declined to challenge them because they wanted to protect their families from public and media scrutiny.¹⁴ In addition, West African immigrant communities were stigmatized during this period; children traveling to the United States from West Africa were separated from their parents and prevented from going to school.¹⁵

In general, interventions that are perceived as punitive “threaten to spark evasive and counterproductive behavior”; for example, persons at risk of quarantine may downplay exposures or symptoms in order to avoid confinement and stigma, putting the public at risk if they later turn out to be contagious.¹⁶ Quarantines are also expensive to administer and draw resources away from other public health priorities. For example, in some quarantine cases, police are present outside homes (reinforcing stigma) and public health officials make daily visits.¹⁷ Quarantine also imposes other costs on its subjects, including forgone wages, legal fees, housing, childcare and eldercare expenses, and the stress of isolation and perceived rejection.¹⁸

In some ways, the 2014 Ebola quarantine cases were unique, but quarantines for other diagnoses, such as severe acute respiratory syndrome (SARS) and new influenza strains, can be similarly counterproductive and vulnerable to abuse. Depending on the nature of the infectious disease, applying a quarantine to all exposed persons without an individual assessment of risk may do more to undermine public health than protect it. The people who could most likely be harmed by a quarantine order are from groups who are vulnerable because of their age,

¹² *Id.* at 7.

¹³ *Id.* at 32.

¹⁴ *Id.* at 31.

¹⁵ *Id.* at 8.

¹⁶ *Id.* at 32.

¹⁷ *Id.* at 18.

¹⁸ *Id.*

health or disability status, income, race, ethnicity, or national origin.¹⁹ In addition to stigmatizing groups who may already be socially isolated, placing these vulnerable individuals under quarantine may limit their access to health care and basic services, and it may subject them to further discrimination. While some states provide employment protections, low-income hourly workers without access to paid time off may struggle financially while under a quarantine order or find they have no job to return to.²⁰ For these reasons, quarantine should only be used when absolutely necessary and when sufficient safeguards are in place to ensure basic needs are met.

III. Literature Review

A. Effectiveness of Quarantine

The effectiveness of quarantine, like other interventions, depends on a number of factors.²¹ These include a microbe's behavior, pathogenicity, mode(s) of transmission, concentration in different age groups and susceptibility to drugs; the host's behavior, health status, when he or she becomes contagious with respect to onset of symptoms and the length of time the host remains contagious; and the risk level imposed by the environment.²² Microbes include bacteria, viruses, protozoa, fungi, and prions.²³ The characteristics of microbes that pose a public health threat are those that can cause serious or fatal disease in humans and are transmitted person to person, animal to person, and food or water to person.²⁴ The most concerning are those microbes that spread rapidly, through casual contact and during the pre-symptomatic stage of illness.²⁵

¹⁹ Mark A. Rothstein, *From SARS to Ebola, Legal and Ethical Considerations for Modern Quarantine*, 12 IND. L. REV. 227, 264 (2015).

²⁰ Mark A. Rothstein & Meghan K. Talbott, *Encouraging Compliance with Quarantine: A Proposal to Provide Job Security and Income Replacement*, 97 AM. J. OF PUB. HEALTH S49, S49-S50 (2007).

²¹ See WORLD HEALTH ORG., AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT 52 (2005).

²² *Id.*

²³ LAURA B. SIVITZ, KATHLEEN STRATTON & GEORGES C. BENJAMIN, QUARANTINE STATIONS AT PORTS OF ENTRY PROTECTING THE PUBLIC'S HEALTH 3 (2005).

²⁴ *Id.* at 3-4.

²⁵ *Id.* Officials with quarantine authority are also concerned with the spread of chemical, radiological, and biological substances other than microbes (such as microbial toxins) that may be related to terrorism. *Id.*

For quarantine to be effective, an outbreak must meet the following three criteria: (1) the people likely to be incubating the infection must be effectively and efficiently identified; (2) the subjects, once identified, must comply with conditions of quarantine; and (3) the disease at hand must be transmissible in its pre-symptomatic or early symptomatic stages.²⁶

Applying these criteria, the 2003 SARS quarantine in Toronto, which subjected 23,103 people to confinement, failed on all three counts.²⁷ First, the quarantine was too broad in scale; public health authorities quarantined approximately 100 people for each SARS case, when the United States Centers for Disease Control and Prevention (CDC) estimated that this could have been equally effective had it been reduced by two-thirds by focusing only on those individuals “who had contact with an actively ill SARS patient.”²⁸ Toronto authorities may have quarantined twenty-five times more people than was appropriate, while failing to identify those most at risk: “at least the first 50 cases in the second phase of the outbreak were not quarantined.”²⁹ Second, officials estimated the compliance rate was poor; only 57% of people quarantined followed guidance.³⁰ Third, SARS, like Ebola, is ill-suited for quarantine. There is evidence “showing SARS is not infectious during the preclinical phase and does not become significantly infectious until the symptomatic illness is well-established.”³¹ The Toronto mass quarantine consumed resources, created anxiety, and compromised public trust of health officials.³²

However, not everyone thinks the Toronto quarantine was ineffective. Some believe that prematurely declaring an end to the outbreak and relaxing the quarantine and other control measures contributed to the SARS resurgence in phase 2.³³ Reinstating these measures ultimately

²⁶ Richard Schabas, *Severe Acute Respiratory Syndrome: Did Quarantine Help?*, 15 CAN. J. INFECTIOUS DISEASES AND MED. MICROBIOLOGY 204, 204 (2004).

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ Tomislav Svoboda et al., *Public Health Measures to Control the Spread of the Severe Acute Respiratory Syndrome during the Outbreak in Toronto*, 350 NEW ENG. J. MED. 2352, 2359 (2004).

brought the outbreak to a close.³⁴ Further, “the number of persons who were exposed to SARS in nonhospital and non-household settings dropped from twenty (13%) before the control measures were instituted (phase 1) to zero afterward (phase 2).”³⁵ In addition, “community spread (the length of the chains of transmission outside of hospital settings) was significantly reduced in phase 2 of the outbreak.”³⁶

In addition to quarantining people based on an individualized risk assessment, health officials may broadly quarantine groups of people based on their location or on some other characteristic or category (i.e., “geographic” or “largescale” quarantines),³⁷ although a largescale quarantine has never been implemented in the United States.³⁸ Similar to the three criteria for invoking an individualized quarantine, public health officials should examine three key questions when deciding whether to invoke a largescale quarantine: “(1) Do public health and medical analyses warrant the imposition largescale quarantine?; (2) Are the implementation and maintenance of largescale quarantines feasible?; and (3) Do the potential benefits . . . outweigh the possible adverse consequences?”³⁹

With regard to the second question, officials must consider whether there is a way to determine who should be quarantined; whether there are resources (i.e., law enforcement) available to enforce an involuntary quarantine; and whether a group could be confined for the whole time period during which they could transmit the disease, as this would require the state to provide for the basic needs of those confined, including food, shelter, and medical care.⁴⁰ Failure to satisfy these considerations will undermine the effectiveness of the quarantine and confidence in the officials who administer it. With regard to the third question, health officials must evaluate whether there will be health risks to those quarantined (i.e., healthy family members quarantined with a sick relative); whether noncompliance and officials’ responses to it will undermine their authority; and whether there is an impact on the economy, as well

³⁴ *Id.*

³⁵ *Id.* at 2352.

³⁶ *Id.*

³⁷ Joseph Barbera et al., *Large-Scale Quarantine Following Biological Terrorism in the United States: Scientific Examination, Logistic and Legal Limits, and Possible Consequences*, 286 J. OF AM. MED. ASS’N 2711 (2001).

³⁸ *Id.*

³⁹ *Id.* at 2714.

⁴⁰ *Id.* at 2714-15.

as the availability of food, medicine, sanitation, and basic supplies if an area is under quarantine.⁴¹ If a quarantine is to be successful, decision makers need timely, accurate information about the potential spread of the disease and the interventions available, as well as effective communication tools.⁴² Officials should also build trust and offer incentives for compliance by, for example, allowing a family member to voluntarily remain with a sick loved one, but providing them with the information and tools to protect themselves.⁴³

Overall, the literature on quarantine shows mixed results in terms of efficacy. A 2013 study assessed the impact of quarantine on a measles outbreak that occurred in Geneva, Switzerland in 2011.⁴⁴ In the study, seventy-three exposed unvaccinated or non-immune persons were quarantined, while a similar group of 173 exposed persons were not quarantined.⁴⁵ The groups produced six and eighty-one secondary measles cases, respectively.⁴⁶ The secondary cases stemming from the quarantined population occurred only in household members and not others in the community.⁴⁷ Quarantine reduced the overall risk of transmission by 74%.⁴⁸

Similarly, a 2009 Swedish study simulated a hypothetical influenza outbreak and measured the impact of closing public schools, limiting the ability of children to mix with their peers.⁴⁹ Researchers found that social distancing interventions among only a minority of a population can have a decisive effect on the probability of an outbreak to spread.⁵⁰ This study points to the potential effectiveness of limited or voluntary social distancing in lieu of broad and/or mandatory quarantine orders.

Broad quarantines tend to both confine people who are not a real

⁴¹ *Id.* at 2715.

⁴² *Id.* at 2716.

⁴³ *Id.*

⁴⁴ E. Delaporte et al., *Large measles outbreak in Geneva, Switzerland, January to August 2011: descriptive epidemiology and demonstration of quarantine effectiveness*, SURVEILLANCE AND OUTBREAK REP. 1 (Feb. 2013).

⁴⁵ *Id.* at 5.

⁴⁶ *Id.*

⁴⁷ *Id.* at 7.

⁴⁸ *Id.*

⁴⁹ Joakim Ekberg et al., *Impact of Precautionary Behaviors During Outbreaks for Pandemic Influenza: Modeling of Regional Differences*, AM. MED. INFORMATICS ASS'N 2009 SYMPOSIUM PROCEEDINGS 163, 163 (2009).

⁵⁰ *Id.* at 165.

risk and miss people who are a risk. A 2007 study examined the impact of quarantining over 150,000 people in a 2003 outbreak of SARS in Taiwan.⁵¹ The study examined both Level A quarantines (impacting potentially exposed contacts of suspected SARS patients) and Level B quarantines, of travelers entering Taiwan from SARS affected areas.⁵² Researchers found the Level A quarantines prevented about 461 additional SARS cases (81%) and sixty-two additional deaths (63%), but the impact of the Level B quarantine was very minor, reducing cases and deaths only by about 5%.⁵³ When combined, these two interventions reduced the number of cases and deaths by nearly half.⁵⁴ Still, the authors concluded that daily, under the Level A quarantine, only one out of every twenty-one exposed persons who should have been quarantined was in fact quarantined, reflecting the need for more efficient contact tracing to better identify potentially infected subjects.⁵⁵

Beijing, China was also hit by a SARS epidemic in 2003 and approximately 30,000 residents were quarantined at home or at other sites.⁵⁶ Researchers found that only quarantined people who had a history of contact with a SARS patient acquired SARS during quarantine.⁵⁷ They concluded that as part of a SARS program, quarantine should be limited to subjects who have contact with an actively ill SARS patient, to better focus resources.⁵⁸

B. Public Satisfaction

Some studies have examined the emotional effects of quarantines on their subjects. For example, a 2005 study surveyed a small sample, twenty-one of the over 14,000 individuals quarantined at home in Toronto during the SARS outbreak in 2003.⁵⁹ At that time quarantine was

⁵¹ Ying-Hen Hsieh et al., *Impact of quarantine on the 2003 SARS outbreak: A retrospective modeling study*, 244 J. OF THEORETICAL BIO 729, 729 (2007).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* at 734

⁵⁵ *Id.*

⁵⁶ J. Ou et al., *Efficiency of quarantine during an epidemic of severe acute respiratory syndrome in Beijing, 2003*, U.S. NAT'L LIBR. OF MED. NAT'L INST. OF HEALTH (2003).

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Maureen E. Cava et al., *The Experience of Quarantine for Individuals Affected by SARS in Toronto*, 22 PUB. H. NURSING 398, 398 (2005).

chosen because it was unclear how SARS could be transmitted.⁶⁰ While in quarantine, subjects reported feelings of isolation, separation, rejection, and stigma.⁶¹ With regard to their experiences with public health officials, some of those quarantined expressed frustration with not receiving a quarantine order until several days after exposure, and while some appreciated health officials calling them to check in, others were annoyed and suspicious of the monitoring, and confused by the messages they received about the protocols they were to follow.⁶² Although the sample size precludes generalizing these results to a larger population, many of these same frustrations were reported during the 2014 Ebola scare. It is also worth noting that health officials may be able to mitigate this confusion and frustration by providing more support in the form of resources (i.e., masks, thermometers and instructions on when to use them) and accurate information about the quarantine, its purpose, and the important role of those quarantined in protecting the community.⁶³

IV. Legal History of Quarantine

Exclusion to protect the health of the community has been long-used and is increasingly controversial. Disease tends to provoke fear, and healthy members of society may feel justified in blaming, isolating, and ostracizing a disease's victims and potential victims.⁶⁴ Such was the case with leprosy and syphilis dating back to ancient times; yellow fever for centuries in the United States; and more recently tuberculosis, AIDS, SARS,⁶⁵ and Ebola. Quarantine is distinct from isolation, in that isolation separates people who are known to be sick.⁶⁶

The power to quarantine and isolate individuals is rooted in a state's authority to ensure the public's health under its general police

⁶⁰ *Id.*

⁶¹ *Id.* at 401-02.

⁶² *Id.* at 401-03; see also C. Collins, C. Upright & J. Aleksich, *Reverse isolation: What patients perceive*, ONCOLOGY NURSING FORUM 675-79 (1989); J. Gammon, *Analysis of the stressful effects of hospitalization and source isolation on coping and psychological constructs*, INT'L J. OF NURSING PRAC. 84-96 (1998); J. Gammon, *The psychological consequences of source isolation: A review of the literature*, 8 J. OF CLINICAL NURSING 13 (1999); Robert J. Blendon et al., *Attitudes Toward The Use Of Quarantine In A Public Health Emergency In Four Countries* (Jan. 24, 2006), <http://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w15>.

⁶³ Cava et al., *supra* note 59, at 403-04.

⁶⁴ GOSTIN, *supra* note 6, at 426.

⁶⁵ *Id.* at 423-29.

⁶⁶ *Id.*

powers.⁶⁷ But this authority has been used in the United States since before the drafting of the Constitution.⁶⁸ In the nineteenth and twentieth centuries, judicial action in the area of compulsory health measures, such as quarantine and isolation, was often spurred by disease outbreaks.⁶⁹ The courts typically were deferential to government authorities, generally subordinating an individual's liberty to the public interest,⁷⁰ with some limits. As early as 1824, in *Gibbons v. Ogden*, the Supreme Court found that states have the authority to quarantine under their police powers.⁷¹ Then in 1905 in *Jacobson v. Massachusetts*, the U.S. Supreme Court upheld compulsory vaccination but said that compulsory public health measures must be exercised in a manner "reasonably required for the safety of the public" and cannot be arbitrary.⁷² But since the civil rights era of the 1960s, the judicial balance has shifted somewhat to favor individual liberties.⁷³ However, state laws have not necessarily been updated to reflect either the evolution of the case law or public health science and management.⁷⁴

With increased concerns about bioterrorism in the early 2000s, there was an interest in updating and creating uniformity in quarantine laws across the states. Following the terrorism of September 11, 2001

⁶⁷ See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) ("According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.")

⁶⁸ GOSTIN, *supra* note 6, at 437.

⁶⁹ *Id.* at 442. Governments typically acted in response to venereal disease, tuberculosis, smallpox, scarlet fever, leprosy, cholera and bubonic plague. *Id.*

⁷⁰ See, e.g., *Mugler v. Kansas*, 123 U.S. 623, 660-61 (1887) (finding the authority to quarantine "so as to bind us all must exist somewhere else, society will be at the mercy of the few, who, regarding only their appetites or passions, may be willing to imperil the security of the many, provided only they are permitted to do as they please"); *Rudolphe v. City of New Orleans*, 11 La. Ann. 242 (1856) (upholding quarantine of a ship carrying passengers with cholera); *Haverty v. Bass*, 66 Me. 71 (1876) (upholding the seizure and quarantine of a child believed to have smallpox); *People ex rel. Barmore v. Robertson*, 134 N.E. 815 (Ill. 1922) (upholding quarantine and other restrictions of a typhoid carrier); *Ex Parte Brown*, 172 N.W. 522 (Neb. 1919) (finding that people detained to prevent transmission of venereal disease are not entitled to a writ of habeas corpus); *Highland v. Schlute*, 82 N.W. 62 (Mich. 1900) (upholding quarantine of a man whose roommate had smallpox); *In re Martin*, 188 P.2d 287 (Cal. Ct. App. 1948) (finding that quarantine of prostitutes was reasonable because they were likely to have venereal disease).

⁷¹ *Gibbons v. Ogden*, 22 U.S. 1, 205 (1824).

⁷² *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905).

⁷³ GOSTIN, *supra* note 6, at 444.

⁷⁴ See Lawrence O. Gostin, *The Model State Emergency Health Powers Act: Public Health and Civil Liberties in a Time of Terrorism*, 13 HEALTH MATRIX 3, 19 (2003).

and subsequent anthrax attacks,⁷⁵ the CDC enlisted the help of public health law experts in drafting the Model State Emergency Health Powers Act (MSEHPA), which was aimed at standardizing states' public health emergency powers and at modernizing related individual rights and due process safeguards.⁷⁶ The model act permits the exercise of coercive public health measures only after a governor has declared a state of emergency.⁷⁷ It also requires officials to obtain a court order when using these measures; provides detainees with a right to counsel; and requires officials to adhere to human rights principles when applying coercive measures, including selecting the least restrictive alternative, ensuring the subject of an order is housed in a safe and habitable environment and his or her basic needs are satisfied.⁷⁸ Despite being drafted by well-respected health law scholars, MSEHPA drew significant criticism from others in the field who questioned "the breathtakingly expansive scope of the definition of 'public health emergency' [T]he model act, as drafted, appears to allow the existence of any epidemic, whatever the cause, to trigger the emergency powers vested in state authorities—powers that include the ability to quarantine individuals and compel treatment"⁷⁹ The model law ultimately underwent some revisions, and nearly 40 states revised their statutes to adopt the model act or portions of it.⁸⁰

The federal government has a more limited power to quarantine than the states. The federal quarantine authority is derived from the Public Health Service Act of 1944 (PHSA), which charges the Secretary of Health and Human Services with making and enforcing regulation to prevent the introduction and transmission of communicable diseases into or within the United States in a relatively limited way.⁸¹ These rules were

⁷⁵ *Id.* at 4.

⁷⁶ *Id.*

⁷⁷ *Id.* at 17; see also GOSTIN, *supra* note 6, at 439 (discussing the Turning Point Model Act, which provides a framework for public health prevention and disease management, and which emphasizes seeking voluntary compliance before implementing mandatory quarantines and isolation).

⁷⁸ GOSTIN, *supra* note 6, at 439.

⁷⁹ George J. Annas, *Blinded by Bioterrorism: Public Health and Liberty in the 21st Century*, 13 HEALTH MATRIX 33, 48 (2013).

⁸⁰ Fidler, David P.; Gostin, Lawrence O; Markel, Howard, *Through the Quarantine Looking Glass: Drug-Resistant Tuberculosis and Public Health Governance, Law, and Ethics*, (2007). *Articles by Maureer Faculty*. Paper 371.

⁸¹ GOSTIN, *supra* note 6, at 441.

not significantly updated until 2017, when the CDC released a final set of regulations allowing the agency to detain people anywhere in the country without obtaining approval from state and local officials.⁸² Again, public health law experts disagree over whether the rule strikes the right balance between government authority and individual protections.⁸³

V. *Modern Legal and Ethical Framework*

Based on the development of common law in the area of quarantine and compulsory interventions since the 1960s, Georgetown Law Professor and health law expert Lawrence O. Gostin has identified four legal prerequisites to the use of quarantine: (1) it must satisfy a compelling state interest; (2) it must be a targeted intervention; (3) it must be the least restrictive alternative; and (4) it must include opportunities for procedural due process.⁸⁴ Unpacking these elements in order: First, the U.S. Supreme Court has adopted a “strict scrutiny” standard, requiring state laws to be “suitably tailored to serve a compelling state interest” if they impact personal rights protected by the Constitution.⁸⁵ Further, the Court has held that without providing treatment, a state cannot detain a non-dangerous person with mental illness who is capable of surviving in the community.⁸⁶ Some lower courts have extended this civil liberties protection by requiring a finding of dangerousness as a condition of confining a person with an infectious disease.⁸⁷ Second, because only persons

⁸² CDC Final Rule, 42 CFR § 70, 71 (2017), <https://www.federalregister.gov/documents/2017/01/19/2017-00615/control-of-communicable-diseases>.

⁸³ See Public Comments on Notice of Proposed Rulemaking, Control of Communicable Diseases, 81 Fed. Reg. 157; James G. Hodge, Jr., et al., *Federal Powers to Control Communicable Conditions: Call for Reforms to Assure National Preparedness and Promote Global Security*, 15 HEALTH SECURITY 1 (2017); Rob Stein, *CDC Seeks Controversial New Powers to Stop Outbreaks*, NPR (Feb. 2, 2017, 4:47 AM), www.npr.org/sections/health-shots/2017/02/02/512678115/cdc-seeks-controversial-new-quarantine-powers-to-stop-outbreaks.

⁸⁴ GOSTIN, *supra* note 6, at 444-45.

⁸⁵ *City of Cleburne v. Cleburne Living Center*, 473 U.S. 432, 440 (1985).

⁸⁶ *O'Connor v. Donaldson*, 422 U.S. 563, 576 (1975). Gostin has argued that the civil liberty protections around the involuntary civil commitment of those with mental illness, a severe form of restraint, should apply equally to isolation and quarantine because “[i]nvoluntary commitment for having communicable tuberculosis impinges on the right to liberty . . . no less than involuntary commitment for being mentally ill.” GOSTIN, *supra* note 6, at 444 (quoting *Greene v. Edwards*, 263 S.E.2d 661, 663 (W. Va. 1980)).

⁸⁷ *Contra: In re Halko*, 246 Cal.App.2d 553, 558 (1966); see *Moore v. Draper*, 57 So.2d 648, 650 (Fla. 1952).

who pose a significant risk of transmission can be confined,⁸⁸ broad interventions intended to confine large groups without individually demonstrated risk are constitutionally questionable.⁸⁹ Instead, quarantines should be targeted toward individuals who demonstrate a risk to public health. Third, some courts have required states to show that less restrictive alternative interventions would not protect the public's health.⁹⁰ Fourth, individuals subject to confinement are entitled to procedural due process because confinement is a deprivation of liberty under the Constitution.⁹¹ The type of process required depends on the nature and duration of the restraint.⁹² For example, the West Virginia Supreme Court held that individuals with infectious diseases are entitled to procedures similar to those of people facing civil commitment for mental illness, including an adequate notice, a right to counsel, a hearing, a demonstration by the state of the need for confinement by a high standard of proof (clear and convincing evidence), and a right to an appeal.⁹³

Given that under some circumstances, quarantine can be counterproductive and vulnerable to abuse, Gostin and colleagues lay out an ethical framework to mitigate its impact on individual liberties. They advocate for the restriction of individual rights only when necessary based on the precautionary principle.⁹⁴ The precautionary principle obligates governments to "protect populations against reasonably foreseeable threats, even under conditions of uncertainty."⁹⁵ Further, "given the potential costs of inaction, it is the failure to implement preventive measures that requires justification."⁹⁶ One of the goals of the precautionary principle is to guide decision-making in the face of incomplete knowledge.

⁸⁸ See *Kansas v. Crane*, 534 U.S. 407, 413 (2002).

⁸⁹ GOSTIN, *supra* note 6, at 444; see also *Jew Ho v. Williamson*, 103 F. 10, 12 (N.D. Cal. 1900).

⁹⁰ See *City of New York v. Antoinette R.*, 630 N.Y.S.2d 1008, 1009 (N.Y. Sup. Ct. 1995) (upholding detention for tuberculosis treatment upon a showing that less restrictive means would not succeed).

⁹¹ See *O'Connor*, 422 U.S. at 580 (1975); *Vitek v. Jones*, 445 U.S. 480, 481 (1980).

⁹² *Washington v. Harper*, 494 U.S. 210, 235 (1990).

⁹³ *Greene v. Edwards*, 263 S.E.2d 661, 662 (W. Va. 1980).

⁹⁴ See generally Lawrence O. Gostin et al., *Ethical and Legal Challenges Posed by Severe Acute Respiratory Syndrome: Implications for the Control of Severe Infectious Disease Threats*, PUBLIC HEALTH ETHICS: THEORY, POLICY AND PRACTICE 266 (2007).

⁹⁵ *Id.* at 265 (citing John Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 HUM. ECOL. RISK ASSESS. 413, 420 (2000)).

⁹⁶ *Id.*

While the Gostin et al. framework advises policymakers to proactively intervene, it urges them to approach quarantine carefully by applying the following criteria to their decision-making in order to avoid burdening individual rights: (1) targeting restrictive measures; (2) ensuring a safe and humane environment; (3) providing for fair treatment and social justice; (4) ensuring procedural due process; (5) using quarantine only when it is the least restrictive alternative; and (6) engaging in a scientific assessment of risk.⁹⁷

First, restrictive measures should be targeted or limited to those known to be infectious.⁹⁸ This criterion can be applied to some diseases more easily than others. For example, Ebola patients are only infectious once they have symptoms and are most infectious at a time when they are likely to seek medical treatment because their symptoms are severe. While SARS is similar, this was not known during the early SARS outbreaks.⁹⁹

Second, because quarantine is not intended to be punitive, public health officials have an obligation to provide a safe and habitable environment, preferably in a person's own home, which is less restrictive than an institution or health facility and mitigates stigma.¹⁰⁰ Although this "sheltering in place" method assumes voluntary compliance, it may intrude on privacy, as health and law enforcement officials may want to monitor patients remotely or in person.¹⁰¹ This type of quarantine also cannot be used if it will impose health risks on housemates and neighbors.¹⁰² Whether the subject of quarantine is at home or elsewhere, officials must ensure that basic needs are met, including food, clothing, healthcare, and a means of communication.¹⁰³

⁹⁷ *Id.* at 269. Others have proposed similar approaches to the analysis, *see, e.g.*, Mark A. Rothstein, *From SARS to Ebola, Legal and Ethical Considerations for Modern Quarantine* 12 IND. L. REV. 227, 249-50 (2015) (proposing the following criteria: (1) necessity, effectiveness, and scientific rationale; (2) proportionality and least infringement; (3) humane supportive services; and (4) public justification); Ross E.G. Upshur, *Principles for the Justification of Public Health Intervention*, 93 CAN. J. PUB. HEALTH 101, 102-03 (2002) (proposing the following criteria: (1) necessity, (2) least restrictive means, (3) necessary support services, and (4) communication of reasons).

⁹⁸ Gostin, *supra* note 94, at 269-71.

⁹⁹ *Id.* at 269.

¹⁰⁰ Cava et al., *supra* note 59, at 398.

¹⁰¹ Gostin, *supra* note 94, at 270.

¹⁰² *Id.*

¹⁰³ *Id.*

Third, “[w]hen public health authorities require people to forgo their freedom for the common good, equity requires that the financial burden be borne by the community as a whole.”¹⁰⁴ Quarantines have a more significant economic impact on low income hourly workers than salaried workers with access to paid time off, but most states do not offer financial compensation to those it subjects to quarantine.¹⁰⁵

Fourth, states must ensure procedural due process, including the opportunity for a hearing by “an independent tribunal in a timely manner with representation by an attorney.”¹⁰⁶ In an emergency, the hearing may come after the confinement begins, but it should still be available.¹⁰⁷ Fifth, at the end of the day, even if all the previously mentioned criteria are satisfied, public health authorities should only implement quarantine if it is the least restrictive way of adequately protecting the public’s health—a last resort.¹⁰⁸

Finally, the sixth step in assessing risk involves cases that will range from those easily justifiable to those ethically problematic based on the certainty that the patient is infected and poses a risk to others.¹⁰⁹ Where there is a significant risk based on the probability of transmission, policymakers should err on the side of quarantine, even when there is medical uncertainty.¹¹⁰ On the one hand, quarantine and isolation are justified in a suspected Ebola case when symptoms are present prior to diagnostic testing and the patient is theoretically infected. On the other hand, if the subject has merely been exposed or is suspected of being exposed and is not showing symptoms, then less restrictive measures, such as travel restrictions and active monitoring for symptoms by a public health official, would be more appropriate.

¹⁰⁴ *Id.*

¹⁰⁵ Eugene Kontorovich, *Paying People for Quarantines*, WASH. POST (Oct. 30, 2014), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2014/10/30/paying-people-for-quarantines/?utm_term=.81f206608d8a.

¹⁰⁶ Gostin, *supra* note 94, at 271.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 269.

¹¹⁰ *Id.*

VI. Lack of Coordination and Stigma

According to Fidler, certain characteristics make societies vulnerable to disease outbreaks from bioterrorism.¹¹¹ Other than anthrax, none of the diseases described herein have emerged as a result of bioterrorism, but the characteristics Fidler describes also leave societies vulnerable to emerging diseases or epidemics of existing disease. These include deference to individual rights and federalism, fragmented and outdated legal authority, and neglected public health infrastructure.¹¹²

The issue of fragmented legal authority was illustrated by the Kaci Hickox case.¹¹³ When Hickox returned from Sierra Leone in fall 2014, the CDC's guidelines advised, but did not require, persons at risk for developing Ebola to distance themselves from others for twenty-one days.¹¹⁴ The federal government apparently did not believe Hickox's exposure was a significant risk to public health; it only issued advisory guidelines, imposing modest restrictions on her personal liberty.¹¹⁵ Several states, including New Jersey and Maine, which both attempted to quarantine Hickox, imposed their own stricter guidelines. New Jersey ultimately allowed Hickox to leave the state and Maine's quarantine petition was rejected by a state court in favor of an order for direct active monitoring.¹¹⁶ Still, Hickox was vilified by politicians and the media; her actions were not viewed as a legitimate challenge to the state's authority to restrict her rights, but instead as her willfully putting others at risk.

Another well-known case highlighting weaknesses in legal authority and government coordination was that of Andrew Speaker. Speaker was infected with tuberculosis (TB), which typically warrants isolation. Despite being advised by local health officials that he had multidrug resistant TB in March 2007, Speaker traveled to Europe for his wedding

¹¹¹ See Fidler, *supra* note 2, at 80-81.

¹¹² *Id.*

¹¹³ For discussion of the Hickox case, see *supra* note 4 and accompanying text.

¹¹⁴ Betsy McKay et al., *CDC Rejects Mandatory Ebola Quarantines*, WALL ST. J. (Oct. 27, 2014), <http://www.wsj.com/articles/federal-ebola-quarantine-guidelines-releasedby-cdc-1414443143>.

¹¹⁵ Roni Adil Elias, *Preventing Contagion and Protecting Civil Liberties: Problems in Quarantine & Isolation Law in the United States & Suggestions for Reform*, 7 CHARLOTTE L. REV. 135, 148 (2016).

¹¹⁶ See Hickox, *supra* note 3.

and honeymoon.¹¹⁷ While he was away, tests showed Speaker had a more dangerous, drug resistant form of the disease than previously thought. The CDC then asked him to stay in Europe until a plan was in place to get him home safely and protect the public, as TB can be transmitted during long flights.¹¹⁸ The CDC also had the U.S. Department of Homeland Security (DHS) add Speaker to the “no fly list.”¹¹⁹ But before this occurred, Speaker flew to Montreal and traveled by car to the U.S. border where a border patrol agent allowed him to enter the U.S., even though the agent had been warned by DHS. Once across the border, Speaker checked himself into a New York hospital where he was placed under a rarely issued federal order.¹²⁰ Medical officials later determined Speaker had the less severe form of multidrug resistant TB, consistent with his original diagnosis.¹²¹

While Fidler claims that deference to individual rights detracts from an effective system for managing disease outbreaks, subjects of confinement, such as quarantine and isolation, are not only victims of disease, but victims of stigmatizing policy. Like Hickox, the much-caricatured Typhoid Mary of one hundred years ago,¹²² and countless others, Speaker was also vilified by the press and politicians following the incident. At a congressional hearing on the topic, Congressman Christopher Shays said, “Now I don’t care, frankly, if it is a terrorist carrying the contagious disease or a citizen who doesn’t give a darn about anyone else. I would treat them frankly the same way because the result could be the same way.”¹²³

In contrast to the reaction of America’s public and politicians, a

¹¹⁷ Parmet, *supra* note 1, at 1.

¹¹⁸ *Id.* at 1-2.

¹¹⁹ *Id.* at 2.

¹²⁰ *Id.* at 1-2.

¹²¹ *Id.* at 2.

¹²² Mary Mallon was an Irish immigrant cook in New York City and asymptomatic carrier of the pathogen associated with typhoid fever. *Id.* at 6. She was initially quarantined by health officials and released on the condition that she would not work as a cook, but resumed her occupation and infected additional people. *Id.* She was then quarantined for almost thirty years until her death in 1938. *Id.* at 6-7 & n.32. Mallon was treated more harshly than others similarly situated. *See id.* at 6-8. She is believed to have infected forty-seven people, three of whom died. *Id.* at 7 & n.33. During that time, there were 3000 cases of the disease in New York City. *Id.*

¹²³ *The XDR Tuberculosis Incident: Poorly Coordinated Federal Response to an Incident with Homeland Security Implications, Hearing Before Comm. on Homeland Security, 110th Cong. 44* (Jun. 6, 2007) (statement of Christopher Shays, Congressman of Connecticut), https://archive.org/stream/gov.gpo.fdsys.CHRG-110hrg48919/CHRG-110hrg48919_djvu.txt.

more scientific assessment of Speaker's actual risk of transmission reveals it was small.¹²⁴ TB is typically not very infectious without prolonged contact.¹²⁵ Although long airplane flights do increase the risk of transmission,¹²⁶ it was a mere coincidence (a rib injury leading to a chest x-ray) that Speaker was even diagnosed before embarking on his trip, suggesting that he was never symptomatic and may not have been contagious.¹²⁷ Successfully detaining Speaker at any point would not have produced a major impact on public TB risk.¹²⁸ In fact, the enormous resources spent on tracking down Speaker would have been better spent addressing the root causes of the disease. These might include contributing factors to the spread of TB, including poverty, low body mass index, and poor indoor air quality, particularly in developing countries,¹²⁹ rather than on "the risks posed by one not-very-infectious man."¹³⁰

VII. Policy Approaches

States' authority to order quarantines stems from their police powers. However, state approaches vary. Although many states have adopted portions of MSEHPA, some statutes are still outdated, fragmented, and do not represent a modern public health approach. In some cases, state laws are disease-specific. In such cases, quarantine may be authorized for specified communicable diseases, for example, but leave health officials without the proper tools to address other conditions.¹³¹

A. Mental Health Commitment Model

The United States Supreme Court has never ruled on what specific type of due process quarantined individuals are entitled to, but it has held

¹²⁴ Parmet, *supra* note 1, at 3.

¹²⁵ *How TB Spreads*, CDC, <https://www.cdc.gov/tb/topic/basics/howtbspreads> (last updated Feb. 23, 2018).

¹²⁶ Thomas A. Kenyon et al., *Transmission of Multi-Drug Resistant Mycobacterium Tuberculosis During a Long Plane Flight*, 334 N. ENG. J.MED. 933, 933-38 (1996).

¹²⁷ Parmet, *supra* note 1, at 4.

¹²⁸ Parmet, *supra* note 1, at 4.

¹²⁹ See Olivia Oxlade & Megan Murray, *Tuberculosis and Poverty: Why are the Poor at Greater Risk in India?* PLOS ONE 1 (Nov. 2012).

¹³⁰ Parmet, *supra* note 1, at 5.

¹³¹ GOSTIN, *supra* note 6, at 437.

that involuntary confinement is a significant deprivation of liberty requiring due process protections.¹³² The Fifth and Fourteenth Amendment prohibit the federal and state governments, respectively, from depriving individuals of liberty without due process of law.¹³³ In the case of civil commitment for mental illness, however, the Court has established a relatively high standard: a state must show by “clear and convincing evidence” that an individual is ill and dangerous.¹³⁴ Some have argued that this higher standard should be applied to quarantine and isolation because “[i]nvoluntary commitment for having communicable tuberculosis impinges on the right to liberty . . . no less than involuntary commitment for being mentally ill.”¹³⁵ At least one state, Maine, has adopted the clear and convincing standard in its statute.¹³⁶ In fact, it was a Maine state court that overturned Kaci Hickox’s quarantine order, because the state health department did not meet this high standard of proof.¹³⁷

B. State Statutes

Each state and the District of Columbia have laws authorizing quarantine, usually through their public health authorities.¹³⁸ A 2009 survey of state statutes by the University of Michigan School of Public Health revealed inconsistencies across the states.¹³⁹ Among other characteristics, the survey examined how the statutes safeguarded individual rights, based on whether the statutes contain provisions for notice, right to a

¹³² Michelle A. Daubert, *Pandemic Fears and Contemporary Quarantine: Protecting Liberty Through a Continuum of Due Process Rights*, 54 BUFF. L. REV. 1299, 1333 (2007) (citing *Foucha v. Louisiana*, 504 U.S. 71, 80 (1992)); *Jones v. United States*, 463 U.S. 354, 361 (1983); *Addington v. Texas*, 441 U.S. 418, 425 (1979).

¹³³ U.S. Const. amends. V and XIV.

¹³⁴ *Addington v. Texas*, 441 U.S. 418, 433 (1979).

¹³⁵ GOSTIN, *supra* note 6, at 444 (quoting *Greene v. Edwards*, 263 S.E. 2d 661, 663 (W. Va. 1980)) (holding that due process protections required in cases of civil commitment for mental illness, including right to appointment of counsel should apply to quarantines).

¹³⁶ ME. Rev. Stat. Ann. Tit. 22, § 810 (2017).

¹³⁷ Miles, *supra* note 3, at 18.

¹³⁸ *State Quarantine and Isolation Statutes*, NAT. CONF. OF ST. LEGISLATURES, (Oct. 29, 2014.), <http://www.ncsl.org/research/health/state-quarantine-and-isolation-statutes.aspx>.

¹³⁹ *State Isolation and Quarantine Measures: A Survey of State Laws*, UNIV. OF MICH. SCH. OF PUB. HEALTH 1 (Oct. 12, 2010), <https://practice.sph.umich.edu/practice/files/StateLawSurvey.pdf>.

hearing, prior court approval, confidentiality, and religious protections.¹⁴⁰ It should be noted that the survey probably did not accurately capture each state's characteristics, because the law in this area may be articulated in regulations and case law in addition to the statute.

According to the survey, eighteen states provide notice of a quarantine order and most of these states also provide for a right to a hearing.¹⁴¹ Only seven states have provisions to protect privacy and confidentiality and only two states have statutes that contain religious protections.¹⁴² Ten states require prior court approval in most cases.¹⁴³

According to the National Conference of State Legislatures, most state statutes contain penalties for non-compliance.¹⁴⁴ These penalties range from a fine of up to \$50 and up to two years in prison, or both, in Rhode Island,¹⁴⁵ to felony offenses in Mississippi, New Hampshire, South Carolina, and Texas.¹⁴⁶ Mississippi levies the harshest penalty: a fine of up to \$5000, imprisonment for up to five years, or both.¹⁴⁷

C. Connecticut Legislation

Having experienced the problematic 2014 Ebola quarantines firsthand, some Connecticut advocates have attempted to apply the rigorous due process standards the courts have demanded for mental health commitments to Connecticut's quarantine law. In 2017, the Connecticut legislature considered a proposal to reform its quarantine statute. Senate Bill 37, *An Act Concerning Health Emergency Response Operations* (HERO), was developed by students in Yale Law School's Worker and Immigrant Rights Advocacy Clinic, who also represented members of the Liberian community who were affected by Connecticut's 2014 Ebola quarantine orders.¹⁴⁸ The proposal would add several protections for individual rights. First, it would eliminate Connecticut's current two-track

¹⁴⁰ *Id.* at 6.

¹⁴¹ *Id.* at 7.

¹⁴² *Id.*

¹⁴³ *Id.* at 9.

¹⁴⁴ NAT. CONF. OF ST. LEGISLATURES, *supra* note 138.

¹⁴⁵ 23 R.I. Gen. Laws Ann. § 23-8-21 (West 2017).

¹⁴⁶ Miss. Code Ann. § 41-23-2 (West 2017); N.H. Rev. Stat. Ann. § 141-C:21 (2017); S.C. Code Ann. § 44-4-530 (2017); Tex. Health and Pub. Safety Code Ann. § 81.085 (West 2017).

¹⁴⁷ Miss. Code Ann. § 41-23-2 (West 2017).

¹⁴⁸ *Testimony in Support of Modifying Current Quarantine Laws*, Proposed SB 37, An Act Concerning Health Emergency Response Operations, Before the Public Health Committee (2017)

system, which authorizes local health directors or, when the Governor has declared a public health emergency, the state Commissioner of Public Health, to order quarantines under certain circumstances.¹⁴⁹ This would be replaced with a new bifurcated system that treats cases differently depending on whether exigent circumstances are present.¹⁵⁰ Exigent circumstances” are defined by the bill as “any circumstance in which the relative threat to public health or safety is so immediate and severe that there is no time for the commissioner or local health director to secure a court order without jeopardizing the health or safety of others.”¹⁵¹

In the absence of exigent circumstances, the subject of a potential order is entitled to judicial oversight prior to the issuance of the order and detainment. The Commissioner or local health director must petition the superior court for a preliminary order by attesting that probable cause for the order exists and make an effort to notice the subject prior to filing the order.¹⁵² If the court decides that there is probable cause, then it must grant the petition, in which case the order becomes effective and the subjects of the order must be served with a copy of the order detailing their rights, including the right to a hearing.¹⁵³ Probable cause is the same standard required for police to obtain an arrest warrant in a criminal case. If there is no probable cause, then the court must deny the state’s petition for a quarantine order.¹⁵⁴

If there are exigent circumstances, the Commissioner or local health director may issue a preliminary order based on probable cause that the order is required to avoid a clear, immediate danger to others and that safety considerations do not allow him or her time to petition the superior court.¹⁵⁵ Within twelve hours of the issuance of the order, the subjects must be served with the order, which must include a notice of their rights, including the right to a hearing within seventy-two hours.¹⁵⁶ This robust notice requirement is important, as it was reported

(statement of Megha Ram).

¹⁴⁹ Conn. Gen. Stat. § 19a-131b (2017); Conn. Gen. Stat. § 19a-221 (2017).

¹⁵⁰ See S.B. 37, 2017 Gen. Assemb., Reg. Sess. (Conn. 2017), §4-5.

¹⁵¹ *Id.* at § 1.

¹⁵² *Id.* at § 4(a).

¹⁵³ *Id.* at § 4(b).

¹⁵⁴ *Id.* at § 4(a).

¹⁵⁵ *Id.* at § 5(a).

¹⁵⁶ *Id.* at §§ 5(c)-(d).

by some quarantine subjects during the Ebola epidemic that they were unaware of their rights.¹⁵⁷

Presently, when a due process hearing is held on a quarantine order, the public health official issuing the order must show that the order is the least restrictive means necessary to protect and preserve public health.¹⁵⁸ In doing so, the official must only meet the “preponderance of the evidence” standard,¹⁵⁹ which is the lower of the two typical standards applied in civil cases. Under the HERO proposal, public health officials would be required to meet the higher “clear and convincing” standard¹⁶⁰ to show that an order is the least restrictive means necessary and should be issued.

In addition to imposing more rigorous judicial review, the HERO proposal authorizes officials to order other less restrictive public health measures, such as active monitoring, social distancing, and travel, work, or school restrictions using the same processes as for quarantine.¹⁶¹ These less restrictive alternatives are not available to health officials under the current statutory scheme.

Further, the existing Connecticut statute includes provisions to ensure a safe and humane environment, including addressing subjects’ basic needs like food, clothing, shelter, communication with those outside, medical care, and keeping households together when it is safe to do so.¹⁶² It also asks that health officials accommodate cultural and religious beliefs to the extent possible. The present statute does not address financial compensation.

The HERO proposal goes further in these areas as well. It requires that those quarantined be provided the following: adequate food that accommodates dietary restrictions; medication and medical care; clothing appropriate for the environment; shelter with an adequate number of beds; a means of communication with others in quarantine and those

¹⁵⁷ See, e.g., AM. CIVIL LIBERTIES, *supra* note 1, at 19, 40.

¹⁵⁸ Conn. Gen. Stat. §§ 19a-131b(j), 19a-221(h).

¹⁵⁹ The preponderance of the evidence standard only requires a party to show that the order is more likely than not necessary.

¹⁶⁰ This burden of proof requires the party to prove that the order is substantially more likely than not to be necessary. It would likely require the health official to produce scientific evidence to support his or her claims.

¹⁶¹ S.B. 37, § 3(2).

¹⁶² Conn. Gen. Stat. §§ 19a-131b(b), 19a-221(b).

outside; and accommodations for cultural and religious beliefs.¹⁶³ The bill also bars employers from discriminating against employees because they have been subject to quarantine or a less restrictive public health order, and it enables employees to bring civil actions to recover lost wages.¹⁶⁴

Overall, the HERO proposal provides more protections for individuals and more robust due process rights while also allowing state and local officials to better tailor their response to public health crises by specifically authorizing orders aimed at less restrictive social distancing measures. This is a strong step forward and should be adopted.¹⁶⁵ It seems unlikely that many of Connecticut's 2014 Ebola quarantine orders would have survived the clear and convincing standard, given that asymptomatic people cannot spread Ebola and the quarantine subjects were either asymptomatic or briefly symptomatic but tested negative for Ebola. However, if a public health official had been able to order active monitoring, school or work restrictions, as are authorized under the bill, then maybe quarantine orders would never have been attempted.

VIII. Conclusion and Policy Recommendations

Quarantine should have a very limited and unique role in modern public health practice. As a foundation, state statutes should comply with the Gostin et al. framework for protecting individual rights: (1) targeting the restrictive measures; (2) ensuring a safe and humane environment; (3) providing for fair treatment and social justice; (4) ensuring procedural due process; (5) using quarantine only when it is the least restrictive alternative; and (6) engaging in a scientific assessment of risk.

Quarantine should be used only when there are no other alternatives for protecting the public's health and only when health officials justify it with scientific evidence. State laws should encourage health officials to utilize less restrictive means by providing specific authority to order active monitoring, travel restrictions, and other social distancing measures. Health officials should use narrowly targeted measures and avoid broad or geographic orders unless absolutely necessary. In gen-

¹⁶³ S.B. 37, § 7(b).

¹⁶⁴ S.B. 37, § 9(2)(b).

¹⁶⁵ The Connecticut legislature adjourned in 2017 without passing the HERO Act.

eral, there should always be an individualized risk analysis. Health authorities seeking a quarantine order should be required to present strong evidence to a court for that order to be granted. The clear and convincing standard used for mental health commitments is the appropriate standard in this case.

If it is impossible to obtain a court approval before issuing an order, the probable cause standard should apply. Probable cause is required under the Fourteenth Amendment and is the same standard that police officers must meet in order to obtain a search or seizure warrant. When there are exigent circumstances requiring police to act quickly, they may proceed with a search or seizure without a warrant, but they still must show probable cause.

Whether the order is issued before or after judicial review, the subjects of quarantine should always have notice of the order and the opportunity to be heard. The notice should be timely and served in person by a marshal or other appropriate process server, as is the case for other orders that restrict liberties, like restraining orders. The notice should be in plain language and outline the individual's rights, including the right to a hearing and the right to be represented by counsel.

A statute should include explicit provisions to ensure fair treatment, and to ensure a safe and humane environment, including addressing subjects' basic needs like food, clothing, shelter, communication both with those outside and others in quarantine, and medical care. These services should be paid for by the government and provided in a culturally competent manner. Additionally, to mitigate the stigma of quarantine, a quarantine statute should impose privacy and confidentiality requirements on public officials handling the quarantine, including health officials, courts, and police.

Given that a quarantine order is a type of court order and that every state imposes some penalties on those who violate these orders, a reasonable fine and/or prison time are appropriate penalties. These penalties should be in line with a state's penalties for violating similar court orders.

These recommendations provide a framework of best practices based on legal standards, ethical protocols, and models from states and other areas of law. They are designed to ensure quarantine is used rarely and only as a last resort, to promote respect, privacy, and human dignity, and to mitigate the stigma inherent in segregating individuals from their community.

REFUAH SHE'EINAH BEDUKAH: JEWISH MEDICAL ETHICS AND EXPERIMENTAL TREATMENT

Antonio G. Tapia*

ABSTRACT

Modern medical experimentation and practical doctrines such as informed consent prompt ethical tensions that test adherents and promulgators of religion and law. This article explores difficult questions and positions for followers of Halacha - the legal part of Talmudic literature including Jewish tenets and law - when faced with health care decisions in secular Western cultures. These concerns include the impact of the Halachic approach on the physician-patient relationship, informed consent, and even use of experimental techniques and the resultant data. Jewish medical ethics and Western secular law define different duties influencing the physician-patient relationship. The duty of care owed by secular American medical practice is based on contract, while Halachic tradition obligates the Jewish physician to heal the sick under a different paradigm. Also, while the secular tradition pays deference to patient autonomy, Halachic tradition mandates that the patient give consent for and undergo the best available medical treatment as custodians of G-d's creation. This paper illuminates the need for an integrative

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approach whereby secular law and medicine may advance in a manner that promotes innovation while respecting the dignity and uniqueness of the individual follower of important Halachic traditions.

I. Introduction: Jewish Medical Ethics and Experimental Treatment	85
II. Duties to Oneself and Others	86
A. What Are the Duties of Physicians?	86
1. Secular Law: Duty to Treat and the Physician-Patient Relationship	86
2. Jewish Law: Beneficence, Paternity, and Autonomy....	88
B. What Are the Duties of the Patient?	90
1. Secular Law: Autonomy and Informed Consent.....	90
2. Jewish Law: Custodians of G-d's Creation.....	92
III. Human Experimentation.....	93
A. Secular Law: Statutory and Case Law Bars	93
B. Jewish Law: Refuah She'einah Bedukah	96
IV. Synthesis – Past Results, Present Use, and Future Experimentation.....	98
A. Sins of Nazi Doctors: Reliance On or Banishment Of Existing Improperly Collected Data	98
B. Future Experimentation	99
V. Conclusion.....	101

I. *Introduction: Jewish Medical Ethics and Experimental Treatment*

Medical experimentation, like other hot topics, sparks much controversy and disharmony between religious and legal perspectives. Between and within each organized mode of thought, the tension arises out of the varied positions for and against the use of human subjects. For some the primary concern is philosophical; for others more empirical concerns prevail.

The Jewish legal tradition, which has been alive for millennia, is often at odds with the modern Western legal tradition. The same can be said for the body of medical ethics for both cultures. Mind you, this does not suggest that these modes of thought are mutually exclusive. Certainly, the Jewish perspective and the secular perspective have had some influence on each other over time. The lines blur as Jewish citizens of the West begin to look to outside sources for guidance in reconciling philosophical and legal tensions. Reconciliation of Jewish and secular law approaches to human experimentation will require an examination into the bodies of medical ethics and the duties that influence the physician-patient relationship.

“Jewish medical ethics can be defined as the resolution of bioethical problems based upon the application of philosophical principles in a manner that is consistent with the adhered tenets and traditions of Judaism.”¹ This Halachic approach, derived from divinely revealed law, informs the inquiry into complex questions in the medical realm. “The role of *Halacha* [(a comprehensive system of laws; literally – the way)] in Jewish tradition has been so central that all of classical Jewish philosophy and theology have been derived through its analysis and interpretation.”² This approach is distinct from the Western secular approach in that it “result[s] in interpretations that become normative and binding and ultimately constitute obligatory behavior.”³ The Western approach takes a more philosophical approach to tough bioethics questions, and when combined with a strong cultural emphasis on individual autonomy, it is often hard to discover or impose a unified cultural consensus.

This article will cast bioethical questions through a Jewish law lens and attempt to examine the influence of the Halachic approach on cases

¹ LOUIS FLANCAUM, “. . . AND YOU SHALL LIVE BY THEM”: CONTEMPORARY JEWISH APPROACHES TO MEDICAL ETHICS 4-5 (Mirkov Publications, 2001).

² *Id.* at 6.

³ *Id.* at 9.

of human experimentation in the medical arena. The reader will find, after a significant inquiry into the influencing medical ethics and duties, that both Jewish and secular law favor an absolute bar on experimentation on humans that is either non-consensual or not likely to yield more benefit than risk to the individual.

II. *Duties to Oneself and Others*

A. *What Are the Duties of Physicians?*

1. *Secular Law: Duty to Treat and the Physician-Patient Relationship*

It is important to understand the basic duties imposed on and held by physicians in the secular American environment. Generally, the physician's duty of care is based on contract.⁴ The offer occurs when a patient appears in the doctor's office.⁵ This may be a response to the doctor's advertisement of services.⁶ The acceptance occurs when an appointment is made and the doctor agrees to see the patient.⁷ This is an implied contract.⁸ Submitting materials may also create an implied contract.⁹ There can also be an express oral or written contract.¹⁰ Because often the terms of the contract are unclear, the specifics of the relationship matter on a case by case basis.¹¹

The physician-patient contract is voluntary.¹² Doctors do not have to accept new patients (not even in emergency situations).¹³ The doctor's motive of refusal is not relevant.¹⁴

The contract, and therefore, the duty of the physician to the patient may be terminated.¹⁵ A doctor may terminate the doctor patient relationship if there is a termination by mutual consent, an explicit dismissal

⁴ BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 201 (6th ed., West 2008).

⁵ *Id.* at 202.

⁶ *Id.* at 201.

⁷ *Id.* at 202.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.* at 201.

¹¹ *Id.* at 202.

¹² *Id.* at 201.

¹³ *Id.*

¹⁴ *Id.* at 627.

¹⁵ *Id.* at 201 (citing *Jewson v. Mayo Clinic*, 691 F.2d 405 (8th Cir. 1982)).

by the patient, a physician's withdrawal after reasonable notice, a cessation of the necessity that gave rise to the relationship,¹⁶ and a failure of the patient to cooperate with care.¹⁷

There are statutory exceptions that affect the common law duty. These are embodied in the Emergency Medical Treatment and Active Labor Act (EMTALA),¹⁸ the American's with Disabilities Act (ADA),¹⁹ § 701 of the Federal Rehabilitation Act (FRA),²⁰ and Title VI of the Civil Rights Act of 1964.²¹

EMTALA prohibits the denial of care to certain classes of patients.²² It was enacted in response to widespread "patient dumping."²³ It applies only to hospitals that accept payment from Medicare and have an emergency room.²⁴ This act had to be tied to Medicare to be effective.²⁵ The statute allows patients to bring civil suits for damages against a participating hospital, but not a treating physician.²⁶ Simply put, EMTALA places minimum standards for stabilization of a patient even when a voluntary contractual relationship does not exist.²⁷

The FRA, ADA, and Title VI of the Civil Rights Act of 1964 mandates and imposes a duty on physicians not to discriminate on the basis of disability²⁸ or race.²⁹ The ADA³⁰ prohibits discrimination against patients with disabilities from facilities that accept federal funds.

¹⁶ Weiss v. Rojanasathit, 975 S.W.2D 113, 119-120 (Mo. 1998).

¹⁷ Brumbalow v. Fritz, 358 S.E.2D 872, 873 (Ga. Ct. App. 1987).

¹⁸ Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2015).

¹⁹ Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101-12213 (LexisNexis, LEXIS through PL 115-39, approved 6/6/17).

²⁰ Federal Rehabilitation Act of 1973, 29 U.S.C. § 701 (LexisNexis, LEXIS through PL 115-39, approved 8/17/17).

²¹ 42 U.S.C. § 2000d (1964).

²² See generally Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd (2015).

²³ Gatewood v. Washington Healthcare Corp., 933 F.2d 1037, 1039 (D.C. Cir. 1991) (affirming district court's dismissal of widow's claims under the EMTALA, but alternatively holding that the widow failed to state a claim cognizable under the Act); see H.R. Rep. No. 241, 99th Cong. 1st Sess. Pt. 1, at 27 (1985)

²⁴ FURROW ET AL., *supra* note 4, at 610.

²⁵ James v. Sunrise Hosp., 86 F.3d 885, 886 (9th Cir. 1996) (quoting Eberhardt v. City of Los Angeles, 62 F.3d 1253, 1255 (9th Cir. 1995)).

²⁶ FURROW ET AL., *supra* note 4, at 610.

²⁷ 42 U.S.C.S. § 1395dd(b)(1)(A) (2015).

²⁸ 42 U.S.C.S. § 12112; 29 U.S.C.S. § 794.

²⁹ FURROW ET AL., *supra* note 4, at 634.

³⁰ Federal Rehabilitation Act of 1973, 29 U.S.C. § 701 (LexisNexis, LEXIS through PL 115-39, approved 8/17/17). Through Congressional measures, the FRA was transformed and incorporated into the ADA.

Title VI “prohibits discrimination on the basis of race, color or national origin by any program receiving federal financial assistance.”³¹ Hospitals that receive Medicare or Medicaid funding must not discriminate.³² In order to bring a private action under Title VI, only intentional discrimination is actionable.³³

2. *Jewish Law: Beneficence, Paternity, and Autonomy*

Jewish law takes a different approach. A cardinal principal of Judaism is that human life is of infinite value.³⁴ “In order to preserve human life, the Sabbath and even the Day of Atonement may be desecrated, and most other rules and laws are suspended.”³⁵ In fact, a physician is obligated to use his medical skills to heal the sick and does not consider contractual relationships.³⁶ The Halacha clearly states in the Shulchan Aruch that “a physician who withholds himself from healing is guilty of shedding blood.”³⁷

By studying the Israeli physicians’ strike of 1983, the reader may be able to extract the modern state of duties imposed upon physicians. Because physicians were on strike, a council of Rabbis and Jewish law experts issued a ruling on the matter.³⁸ At its simplest, the following principles were decreed: 1) physicians may not withhold treatment,³⁹ and 2) physicians may do no harm.⁴⁰

Lord Immanuel Jakobovits, former Chief Rabbi of Great Britain, delineates further principles governing the physician’s interaction with a patient.⁴¹ These principles attempt to establish a boundary and clarify the interaction between the concepts of autonomy, beneficence, and paternity.⁴² Of the six principles, the first, second, and sixth are similar to those already discussed. The first principle states that “[i]t is a religious

³¹ FURROW ET AL., *supra* note 4, at 634.

³² *Id.*

³³ *Id.*; Alexander v. Sandoval, 532 U.S. 275 (2001).

³⁴ See FRED ROSNER, BIOMEDICAL ETHICS AND JEWISH LAW 47 (KTAV Publishing House, Inc., 2001).

³⁵ *Id.*

³⁶ *Id.* at 44.

³⁷ *Id.*

³⁸ *Id.* at 43-44.

³⁹ See Yoreh Deah 336:1.

⁴⁰ ROSNER, *supra* note 34, at 44 (quoting Rambam, Chovel Umazik 8:1 that “it is prohibited for a person to wound either himself or his fellow man”).

⁴¹ FLANCAUM, *supra* note 1, at 84.

⁴² *Id.* at 85-86.

obligation to protect human life and health, incumbent upon a doctor as upon any other person in a position to do so.”⁴³ The second principle states that “[a] doctor is therefore never morally entitled to withhold or withdraw his services, whether or not a contractual relationship exists between him and his patient, unless a more competent doctor is available.”⁴⁴ “A refusal to render medical aid where required is deemed as tantamount to shedding blood.”⁴⁵ The third principles expounded by Jakobovits will be discussed later regarding the patient’s obligation not to refuse treatment. He states that “[a] patient has no right to refuse medical treatment deemed essential by competent medical opinion for the preservation of his or her life or health, and his or her consent need not be procured for such treatment.”⁴⁶

Lastly, the sixth principle states that “the onus of choosing between various alternative forms of medical treatment, or none at all, rests upon the doctor, and patients should never be expected to render what are purely medical decisions.”⁴⁷ These three principles reinforce the ideas regarding a doctor’s duty to treat and the obligation of a patient to act as a custodian.

Lord Jakobovits’ last three principles governing a physician’s duties are of special importance in regard to experimental treatments. The fourth principle states that “in the discharge of the doctor’s obligation to save life and limb, and in the absence of the patient’s consent, the doctor may even be required to expose himself to the risk of legal claims for unauthorized ‘assault and battery.’”⁴⁸ This is an especially important mandate in the realm of medical experiments. This creates a clear Halachic prohibition and relationship between harming a patient and consent.

The fifth principal is also significant in the analysis of Jewish law and experimentation. It states that “while the patient should always be informed of treatments and procedures to be applied, prior consent is required, and should be sought, only in cases of a) high risk treatments, b) doubtful or experimental cures, and c) differences of opinion among

⁴³ *Id.* at 84.

⁴⁴ *Id.*

⁴⁵ *Id.* at 84-85.

⁴⁶ *Id.* at 85.

⁴⁷ *Id.*

⁴⁸ *Id.*

equally competent medical experts.”⁴⁹ This is an express Halachic prohibition of performing experimental treatments without consent.

B. What Are the Duties of the Patient?

1. Secular Law: Autonomy and Informed Consent

The patient also exhibits a spectrum of duties regarding healthcare. In the Western secular tradition, it is hard to suggest that a patient has any duty at all with regard to their health. This largely stems from the emphasis on autonomy and individualism throughout the West. For the purposes of this article and comparison, I will limit my explanation to the American law principle of informed consent.

“Informed consent has developed out of a strong judicial deference to individual autonomy.”⁵⁰ Therefore, the individual has the “right to be free from nonconsensual interference with his or her person” and cannot be forced to “act against his or her own will.”⁵¹ Informed consent has six functions: “1) protect individual autonomy, 2) protect the patient’s status as a human being, 3) avoid fraud or duress, 4) encourage doctors to carefully consider their decisions, 5) foster rational decision-making by the patient and, 6) involve the public generally in medicine.”⁵²

There also exists a spectrum of informed consent standards in American law. They are: 1) legal consent, 2) professional disclosure, 3) the reasonable patient standard, and 4) full disclosure.⁵³ Legal consent is the least protective of all schemes in American law. It refers to the institutional practice of using a consent form or similar device.⁵⁴ For legal consent the law requires that institutions document consent in a patient’s record and obtain consent if experimental therapy is used. Under legal consent no experimental treatment is authorized.⁵⁵

⁴⁹ *Id.*

⁵⁰ FURROW ET AL., *supra* note 4, at 230; *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (1914)

⁵¹ FURROW ET AL., *supra* note 4, at 230.

⁵² *Id.* at 231; Alexander Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U.PENN.L.REV. 340, 365-76 (1974).

⁵³ BARRY R. FURROW ET AL., *HEALTH LAW: 123-24* (3rd ed., West 2015).

⁵⁴ FURROW ET AL., *supra* note 4, at 287.

⁵⁵ *Id.*

Professional disclosure was until recently the standard in England.⁵⁶ This standard requires more than just a form, but less than assessing all the alternatives. It focuses on what the doctor thinks is professionally required to be disclosed.⁵⁷ This standard exhibits high therapeutic privilege (i.e., the doctor has a lot to say about what goes on).⁵⁸ This approach is highly paternal and does not allow the patient to make an informed decision.⁵⁹

The reasonable patient standard offers the best middle ground between patient autonomy and medical paternalism. “The test for determining whether a particular peril must be divulged is its materiality to the patient’s decision; all risks potentially affecting the decision must be unmasked.”⁶⁰ This could include the patient’s psychological ability to handle a truthful disclosure.⁶¹ This is highly subjective.⁶²

Lastly, and the most autonomous, is the full disclosure standard. In this standard, low weight is given to what the physician thinks is relevant and grants high autonomy for the patient.⁶³ This too fails to mimic the standard imposed by Jewish law.

There are only two exceptions in American law to informed consent.⁶⁴ The doctor may act without consent if “the patient is unconscious or otherwise incapable of consenting, and harm from failure to treat is imminent and outweighs any harm threatened by the proposed treatment.”⁶⁵ The doctor may also withhold information if “risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contraindicated from a medical perspective.”⁶⁶ Either way, none of these standards integrate fully with the Jewish law perspective.

⁵⁶ Sarah W. Chan, Ed Tulloch, E Sarah Cooper, Andrew Smith, Wojtek Wojcik & Jane Norman, *Montgomery and informed consent: where are we now?*, THE BMJ (May 12, 2017), <http://www.bmj.com/content/357/bmj.j2224>.

⁵⁷ See, e.g., *Woolley v. Henderson*, 418 A.2d 1123 (Me. 1980).

⁵⁸ FURROW ET AL., *supra* note 4, at 287.

⁵⁹ See generally *id.*

⁶⁰ *Canterbury v. Spence*, 464 F.2d 772, 786-87 (D.C. Cir), *cert. denied*, 409 U.S. 1064 (1972).

⁶¹ *Id.* at 789.

⁶² *Id.* at 791.

⁶³ FURROW ET AL., *supra* note 4, at 1160.

⁶⁴ *Id.* at 283.

⁶⁵ *Id.*

⁶⁶ *Id.*

2. *Jewish Law: Custodians of G-d's Creation*

Unlike the secular informed consent doctrine, whereby a patient can refuse treatment altogether, Jewish law imposes an obligation on patients to undergo treatment.⁶⁷ The obligation is based on the Jewish law view that individuals are responsible for their bodies while on earth.⁶⁸ They are, in essence, custodians of G-d's creation.⁶⁹ The obvious conclusion becomes then, "if man is charged with being the prudent steward of his body, required to accept medical treatment," then there therefore can be no "meaningful concept of informed consent in Jewish Law."⁷⁰

In contrast, Daniel Eisenberg, M.D., in his article *Medical Informed Consent in Jewish Law – from the Patient's Side*, urges that this is not the case.⁷¹ Eisenberg argues that "Judaism requires a type of informed consent that, while not identical to the secular concept, in some ways is actually more stringent than its secular counterpart."⁷² To him, the key distinction between the secular and Jewish approaches centers on the "difference between rights and obligations."⁷³ The secular approach has a key focus on the autonomy of the patient.⁷⁴ The Jewish law approach takes a paternalistic approach whereby the patient has the duty to BOTH become informed AND give consent for the best available treatment.⁷⁵ "[A]s the prudent steward of one's body, one MUST acquaint oneself with all reasonable medical options, including inaction, before making a decision. But after evaluating all reasonable options, the Torah requires one to choose the sensible option, the one that the prudent steward would choose."⁷⁶ One may only refuse treatment until she is convinced that the proposed course of treatment is prudent.⁷⁷

The Jewish patient's decision on prudence of a procedure is based on two different medical treatments: "those about which the medical ef-

⁶⁷ FLANCAUM, *supra* note 1, at 65.

⁶⁸ *Id.*

⁶⁹ Daniel Eisenberg, *Medical Informed Consent in Jewish Law – from the Patient's Side*, JEWISH LAW, <http://www.jlaw.com/Articles/MedConsent.html> (last visited Feb. 23, 2018).

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

ficacy is known (refuah bedukah) and those where the efficacy is unproven (refuah she'einah bedukah).⁷⁸ In cases involving refuah bedukah, Jewish authorities have held that the patient "is obligated according to Halacha to undergo treatment."⁷⁹ In cases of refuah she'einah bedukah, the patient is generally given more autonomy.⁸⁰ This distinction will become very important later in this article during the discussion of experimental procedures.

III. *Human Experimentation*

A. *Secular Law: Statutory and Case Law Bars*

Law governing human experimentation is, with the exception of constitutional law, one of the only places in American law that expressly incorporates moral language into the statutory text.⁸¹ The Nuremberg Code is such an attempt to legislate the prevention of human experimentation.⁸² This code was borne of the tragedies perpetrated by Nazis on categories of "special" persons.⁸³ The ten concepts that inform decisions on human experiments under the Nuremberg Code require consent, and they address the balance of risks and benefits.⁸⁴

⁷⁸ FLANCAUM, *supra* note 1, at 69.

⁷⁹ *Id.*

⁸⁰ *Id.* at 70.

⁸¹ FURROW ET AL., *supra* note 4, at 1569.

⁸² *See generally id.*

⁸³ *Id.* at 1569-70.

⁸⁴ Nuremberg Code: Permissible Medical Experiments: 1) The voluntary consent of the human subject is absolutely essential. 2) The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. 3) The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment. 4) The experiment should be so conducted as to avoid all unnecessary physical suffering and injury. 5) No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur except, perhaps, in those experiments where the experimental physicians also serve as subjects. 6) The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. 7) Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death. 8) The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment by those who conduct or engage in the experiment. 9) During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible. 10) During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the

What is stunning for the new examiner of American law is that Americans too have been involved in experimentation on human subjects.⁸⁵ While the United States was prosecuting Nazi doctors, the U.S. government was conducting research on human radiation by injecting subjects (claimed to be terminally ill, and not informed as to the nature of their treatment) with plutonium or uranium.⁸⁶ Other instances of American violations of the Nuremberg Code include the Tuskegee Syphilis Study.⁸⁷ In this study many disenfranchised individuals were infected with syphilis so that the government could track the progress of the disease. Even though penicillin was available and shown to be a proper treatment, scientists prohibited and discouraged the infected subjects from seeking treatment.⁸⁸

Public disclosure of the Tuskegee Syphilis Study in 1974 led Congress to enact the National Research Act (“NRA”).⁸⁹ In turn, the NRA established the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research (“National Commission”).⁹⁰ The role of the National Commission was to “conduct a comprehensive investigation and study to identify basic ethical principles that should underlie the conduct of human subject research.”⁹¹ This report led to the creation of institutional review boards (“IRB”) in almost every university, medical school, and research hospital.⁹² These principles were eventually codified in the Code of Federal Regulations (“CFR”).⁹³ Within the CFR, issues such as to what the policy applies, IRB creation and regulation, informed consent, and use of federal funds, were addressed.⁹⁴ Similar steps have been taken abroad by the promulgation of the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects.⁹⁵

good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

⁸⁵ *Id.* at 1573.

⁸⁶ *Id.*

⁸⁷ *Id.* at 1574.

⁸⁸ *Id.*

⁸⁹ *Id.* at 1575.

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ See generally 45 C.F.R. §§ 46.101-46.124 (2017).

⁹⁴ *Id.*

⁹⁵ FURROW ET AL., *supra* note 4, at 1571.

Protecting vulnerable subjects is also accomplished through research regulation litigation. *Grimes v. Kennedy Krieger Institute, Inc.*⁹⁶ is a perfect case to consider. The Court of Appeals considered two distinct actions involving negligence of a corporation and children that “allegedly developed elevated levels of lead dust in their blood while participating in a research study” with Kennedy Krieger Corporation.⁹⁷ Both of the claims asserted that “the children were poisoned, or at least exposed to the risk of being poisoned, due to negligence on the part of the corporation.”⁹⁸

The trial court ruled that a corporation conducting a non-therapeutic scientific study of lead paint abatement did not have a duty to warn minor volunteer participants and/or their legal guardians regarding dangers present when the researcher had knowledge of the potential for harm and the subjects were unaware of the danger.⁹⁹ The appeals court disagreed.¹⁰⁰ The appeals court reasoned that research programs at issue in the case normally create special relationships and/or can be of a contractual nature which creates a duty.¹⁰¹ Breach of such duties could ultimately result in viable negligence actions.¹⁰² At the very least, there were viable and genuine disputes of material fact concerning whether a special relationship or other relationships arising out of agreements giving rise to duties existed between the corporation and both sets of appellants. Based on the record, no degree of parental consent and no degree of furnished information to the parents could have made the experiment at issue ethically or legally permissible.¹⁰³ It was wrong in the first instance. The appeals court held the trial court erred in granting summary judgment.¹⁰⁴

Overall, the combination of statute and litigation has created express and strict requirements in the American legal system against experimentation on vulnerable human subjects.

⁹⁶ *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001).

⁹⁷ *Id.*

⁹⁸ *Id.* at 818.

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 861.

¹⁰¹ *Id.* at 819.

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

B. Jewish Law: Refuah She'einah Bedukah

Risk-benefit analysis is extremely relevant in Jewish law analyses.¹⁰⁵ For any treatment, even those *refuah bedukah* whose risks are well known, a risk-benefit analysis still exists.¹⁰⁶ However, despite the real risk inherent in any medical procedure, *refuah bedukah* tends to favor treatment.¹⁰⁷ In cases of *refuah she'einah bedukah*, the risk-benefit analysis may not clearly favor treatment or non-treatment.¹⁰⁸ In these cases Jewish law grants the patient more autonomy, and in certain cases one can refuse treatment.¹⁰⁹ This still does not mirror the secular document of informed consent.

However, what is to be said for the experimental treatment that may achieve results such as a long term cure for the patient? It is important to stress that this question only concerns itself with curing the individual patient and not future individuals. Dr. Louis Flancbaum, an expert in general surgery, trauma surgery, gastrointestinal surgery, bariatric surgery, surgical critical care, and nutrition support with over 20 years of clinical experience, argues that in cases where risks and outcome of medical treatment are uncertain, the patient, as custodian of his body, still "retains the prerogative to subject himself to an increased short term risk of dying . . . in order to potentially achieve a cure or normal functioning."¹¹⁰ How does this apply to cases of medical experimentation?

The autonomy of a patient in circumstances of experimental treatment provides two options.¹¹¹ First, the patient may retain full autonomy.¹¹² As such, the patient may refuse experimental treatment.¹¹³ The corollary to refusal of course is the option to agree to undergo the experimental procedure.¹¹⁴ This too is allowed in these special cases.¹¹⁵

How does Jewish law address instances of human experimentation involving participation in a study or clinical trial? This question is altogether different than the one immediately above. In this case, the results

¹⁰⁵ FLANCBAUM, *supra* note 1, at 102.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 102-103.

¹¹¹ *Id.* at 103.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

will not necessarily benefit the participant, but may ultimately help others.¹¹⁶ Since there is a prohibition against placing oneself in danger,¹¹⁷ the permissibility of participating in human experiments depends upon the risks involved.¹¹⁸ If the risks to the participants or the side effects of the experiment are minimal, some say that it is permissible.¹¹⁹ This view is documented in the Tziz Eliezer,¹²⁰ the Lev Avraham,¹²¹ the Central Conference of American Rabbis,¹²² and the NARR¹²³. Prohibition of participation in experiments entailing high risk is reflected and recorded in the very same sources.¹²⁴

Jewish law also recognizes the fact that some individuals might feel that the potential to save other lives by participating in experiments outweighs any risk to themselves.¹²⁵ Jewish law responds to that notion of sacrifice and altruism by retorting, “Who knows that your blood is redder? Perhaps his blood is redder.”¹²⁶ It is important to remember that the sense of stewardship and custodianship of G-d’s creation supersedes all other factors.¹²⁷ Humans do not exert unrestricted proprietorship over their own bodies and may not sacrifice them in order to save others.¹²⁸ Arguably, the only permissible voluntary participation with experimental treatment is where there is a possibility for benefit to the patient and there is no other available alternative for treatment.¹²⁹ Only in this instance do medical experiments align themselves with the obligation to act as a custodian of G-d’s creation.¹³⁰

¹¹⁶ *Id.*

¹¹⁷ Babylonian Talmud, Shabbat 32a.

¹¹⁸ FLANCAUM, *supra* note 1, at 104.

¹¹⁹ *Id.*

¹²⁰ Tziz Eliezer (Responsa of R. Eliezer Waldenberg) XII, #101.

¹²¹ See generally Avraham Steinberg, *Medical Halachic Decisions of R. Shlomo Zalman Auerbach*, 3 ASSIA- JEWISH MED. ETHICS 30, 30-43 (Jan. 1997) (medical ethics work) (containing many responses of R. Shlomo Zalman Auerbach that were otherwise not published).

¹²² See generally Central Conference of American Rabbis, <http://ccarnet.org/about-us/> (referring to Responsa #17).

¹²³ See generally WALTER JACOB, CONTEMPORARY AMERICAN REFORM RESPONSA (Central Conference of American Rabbis, 1988). The Tziz Eliezer, the Lev Avraham, the Central Conference of American Rabbis, and the NARR are all significant as powerful and respected voices of Rabbinic thought in the religious life of the American and international Jewish communities.

¹²⁴ FLANCAUM, *supra* note 1, at 104.

¹²⁵ *Id.* at 103.

¹²⁶ Babylonian Talmud, Sanhedrin 74a.

¹²⁷ FLANCAUM, *supra* note 1, at 69-70.

¹²⁸ *Id.* at 104.

¹²⁹ *Id.*

¹³⁰ *Id.*

IV. Synthesis – Past Results, Present Use, and Future Experimentation

Since the advent of medical technology, more and more possibilities and attempts to conduct human experiments have surfaced. Because progress will never be stayed, nor should it ever be, the Jewish and secular law communities must now work to create a framework that determines the permissibility of future experimentation. How may existing and improperly collected data be used, if at all? What experiments on humans will be permissible in the future?

A. Sins of Nazi Doctors: Reliance On or Banishment Of Existing Improperly Collected Data

To Jewish and secular perspectives on human experimentation, it is clear that the procedures executed by Nazi doctors on unwilling participants violate all sense of morality and dignity. The only real tension present today regarding Nazi procedures is whether modern science can use the improperly collected data, and if so, how?

Some scientists believe that use of the Nazi's data would justify the horrors perpetrated, and dishonor the victims.¹³¹ Others believe that it would be a travesty not to use the Nazi data, considering that the damage is already done and lives can genuinely be saved through its use.¹³²

"The data should be taboo," said Dr. Benno Muller-Hill, a molecular biologist and director of the Institute for Genetics at the University of Cologne in West Germany.¹³³ "We should remember those who died. We should not try to squeeze a profit out of it."¹³⁴ Other scientists reject the use of the data on another basis.¹³⁵ According to Dr. Roger Berger, a heart surgeon at the Harvard Medical School, the Dachau freezing experiments had "all the ingredients of a scientific fraud."¹³⁶ Sigmund Rascher was trying to prove an idea of Himmler's.¹³⁷ In doing so he failed to record essential data, as required by scientific methods, and

¹³¹ Isabel Wilkerson, *Nazi Scientists and Ethics of Today*, N.Y. TIMES, May 21, 1989, § 1 at 34.

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* (internal quotations omitted).

¹³⁵ *Id.*

¹³⁶ Nicholas Wade, *The Errors of Nazi Science: Even in Dachau, an Urge to Falsify*, N.Y. TIMES, May 27, 1990, at E12.

¹³⁷ *Id.*

some of his results were so doubtful as to suggest fabrication.¹³⁸

Scientists supporting the use of Nazi data argue that it would serve no purpose to science to ignore data that could help people.¹³⁹ “We are talking of the use of the data, not participation in these heinous studies, not replication of the atrocities,” said Dr. Benjamin Freedman, a bioethicist at McGill University in Montreal.¹⁴⁰ “The wrongs perpetrated were monstrous; those wrongs are over and done. How could the provenance of the data serve to prohibit their use?”¹⁴¹

Dr. Robert Pozos, Director of the Hypothermia Laboratory at the University of Minnesota of Medicine at Duluth, and Dr. John Hayward, a Biology Professor at the Victoria University in Vancouver, Canada, who conducts hypothermia research, “see it criminal *not* to use the available data, no matter how tainted it may be.”¹⁴² Dr. Hayward justifies using the Nazi Hypothermia data in the following way:

I don't want to have to use the Nazi data, but there is no other and will be no other in the ethical world. I've rationalized it a bit. But not to use it would be equally bad. I'm trying to make something constructive out of it. I use it with my guard up, but it's useful.¹⁴³

Ultimately, there is a bright-line consensus among conservative Americans and Jewish law scholars. According to Attorney Baruch Cohen, “the moral climate in the Jewish community is unforgiving to those who find any redeeming merit from Nazi horrors.”¹⁴⁴ Even though there is a split within the secular school of thought, the fact that the data is being discredited and medical journals veto the publication of studies that incorporate Nazi data, implies that it is more likely that Nazi data will be discarded as a scientific tool.

B. Future Experimentation

Secular and Jewish law approaches to experimentation create an absolute bar to any experimentation on an unknowing or non-consenting

¹³⁸ *Id.*

¹³⁹ Wilkerson, *supra* note 131.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* (internal quotations omitted).

¹⁴² Baruch C. Cohen, *The Ethics of Using Medical Data From Nazi Experiments*, <http://www.jlaw.com/Articles/NaziMedEx.html> (last visited Feb. 26, 2018).

¹⁴³ *Id.*

¹⁴⁴ *Id.*

human, or in any case where the risks outweigh the potential benefit.¹⁴⁵ However, the question has been posed: What is the stance of Jewish law in cases where even though the participant is not aware of all aspects of his treatment, no major harm comes to the patient? An example of this may be an instance where a psychiatrist, Dr. Smith, selects a group of similarly situated patients to conduct an efficacy study without their knowledge. Throughout the course of this “study,” Dr. Smith prescribes a different dosage of medication so that he may monitor over time which yields the best result. One could argue that the psychiatrist is still fulfilling his duties under the physician-patient relationship contract. Each patient is getting the required attention and minimum dosage of medication. No patients are in deteriorating conditions. In essence the doctor is doing no harm, and aiding in treatment, even though still subversively experimenting on his human subjects.

Some optimists may say that this hypothetical is too contrived. This could never happen. However, it happens on a regular basis, as doctors attempt to respond to the constantly changing supply of available and new prescription drugs.

The “no harm, no foul” mentality does not excuse this doctor’s behavior. According to the secular law approach discussed above, this doctor is violating patients’ autonomy and not considering any accepted standard of informed consent. Of the functions of informed consent, the doctor 1) is not protecting individual autonomy, 2) is not protecting the patient’s status as a human being, 3) is committing fraud upon the patient, and 4) is not fostering rational decision-making by the patient.¹⁴⁶ These are clear violations of the policy behind informed consent requirements.

Of the standards of informed consent, only the reasonable patient standard and full disclosure would govern this situation. The reasonable patient standard, even though highly subjective, still suggests that experimentation involving unorthodox use of prescription drugs is material to the patient’s decision on treatment. Full disclosure is clearly violated here by Dr. Smith’s failure to notify the participants.

Dr. Smith also violates statutory and case law mandates. In this hypothetical, the psychiatrist violates Rules 1, 2, 3, 4, 9, and 10 of the Nuremberg Code.¹⁴⁷ Further, the precedent established in litigation also

¹⁴⁵ See generally FLANCAUM, *supra* note 1.

¹⁴⁶ See FURROW ET AL., *supra* note 4, at 231.

¹⁴⁷ See Nuremberg Code: Permissible Medical Experiments, *supra* note 84.

disfavors the doctor's conduct. In litigation, a court would likely compare the facts and apply the holding in *Hiser*.¹⁴⁸ In essence, the lack of information disclosed to the patient would make this particular experiment unethical.

The Jewish law approach would also bar this type of seemingly benign experimentation, but on different grounds. It is Halachic principle that a physician may do no harm to a patient.¹⁴⁹ None. There is no relativity to this mandate.

Further, Dr. Smith is avoiding Lord Jakobovits' principles in which he must inform the patient in cases of experimental cures, and is in fact committing assault and battery.¹⁵⁰ It is also a great moral wrong that Dr. Smith is interfering with the patients' duty to act as knowing and careful custodians of G-d's creation. Dr. Flancbaum argues that in cases where risks and outcomes of medical treatment are uncertain, the patient as custodian of his body, may retain full autonomy.¹⁵¹ Therefore, Dr. Smith has violated key tenets in both Jewish law and secular law, and in bioethics.

V. Conclusion

There is a formal absolute bar on experimentation on non-consenting and vulnerable human subjects. Even with consent of a lucid and informed subject, one is still hard pressed to find a morally unencumbered instance of human subject experimentation. However, it is realistic to expect that human experimentation will continue as medical technology blossoms.

Because the secular law approach heralds individualism and autonomy, it offers more leeway for the individual to consent and be a subject, and therefore fosters a human experiment-safe environment. One should take respite, however, in the fact that the requirements for the administrators of the experiments have been formalized in statute and impose considerable burdens, duties to disclose, and the ability for a subject to terminate at will.

Jewish law, having a more definite tradition in religious bases, takes a much more paternal view and as such sees the human body as G-

¹⁴⁸ *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 807 (Md. 2001).

¹⁴⁹ FLANCAUM, *supra* note 1, at 85.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

d's creation. Humans, therefore, do not have complete proprietorship over it. Humans, therefore, must not participate in experimental treatments, when other modes are available or the risks outweigh the benefits. All in all, as an observer of technology and humanity at large, one can hope that the law will develop alongside medical advances in a manner that aids innovation, and yet respects the dignity and uniqueness of the individual.

PUBLIC DEFENDERS: THE IMPOSSIBILITY OF RULE 1.14 AND HOW MENTAL HEALTH FIRST AID TRAINING CAN CONTRIBUTE TO SUCCESS

Kristin A. Chiriatti*

I. Introduction	104
II. Understanding the Public Defense Landscape	106
A. Heavy Caseloads.....	107
B. Lack of Funding and Resources	108
C. Disproportionate Number of Clients with Mental Health Issues	109
III. Ethical Obligations of Public Defenders Under Rule 1.14.....	114
IV. Proposed Solution.....	116
A. What is Mental Health First Aid?	117
B. Mental Health First Aid for Public Defenders.....	119
C. Will it Work?	121
V. Conclusion.....	128

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Client Warner is one of fifteen clients waiting to be seen by Attorney Stevens. Court starts in thirty minutes, so Attorney Stevens' patience is thin as he works quickly to get through his list of clients waiting to see him. Client Warner struggles with anger management and other mental health issues. Within minutes of entering Attorney Stevens' office, communication breaks down as Client Warner unleashes his frustration about his case onto his attorney, threatening to fire him and return to a life of violence. In response, Attorney Stevens refuses to speak with him while he is angry and kicks Client Warner out of his office. The next time they see each other is in front of the judge. Both are still angry and neither has communicated to the other information necessary for a successful court hearing.

After meeting with Client Warner, Attorney Stevens heads down to lock-up where he sees Client Brown asleep in her cell after being picked up overnight in a prostitution sting. Attorney Stevens needs to interview her and ten other clients before heading up to court in fifteen minutes where he will argue their bond. Client Brown is suffering from heroin withdrawal and is not providing coherent answers to Attorney Stevens' questions. Seeing the futility of spending any more time with Client Brown, Attorney Stevens moves on to his next client knowing he has no useful information upon which to make a successful bond argument.

I. Introduction

Model Rule of Professional Conduct 1.14 (“Rule 1.14”) requires all attorneys to “maintain a normal client-lawyer relationship with the

client”¹ as far as “reasonably possible”² when representing clients with diminished capacities due to mental impairment.³ For public defenders, Rule 1.14 casts its heavy shadow over the majority of client relationships since a disproportionate number of clients suffer from mental health issues.⁴ Maintaining normal relationships with these clients can be difficult for public defenders because communication is often strained or virtually non-existent.⁵

As part of maintaining a normal attorney-client relationship, public defenders must also ensure that they are providing effective counsel to their clients as required by the 6th Amendment of the United States Constitution and *Gideon v. Wainwright*.⁶ The lack of communication as a result of client mental health issues makes this a difficult challenge for public defenders. In addition, conditions such as heavy caseloads,⁷ limited resources,⁸ and a lack of mental health training⁹ further aggravate the attorney-client relationship so that meeting the ethical obligations of Rule 1.14 becomes next to impossible.

Because of these unique challenges, it is necessary to give public defenders the tools they need to cope with and communicate effectively with clients suffering from mental health issues if they are to be held to the requirements of Rule 1.14. Jurisdictions across the country are now testing various ways to handle the overwhelming number of criminal defendants with mental health issues, including the use of specialty mental health courts and mental health dockets.¹⁰ Unfortunately, these solutions do not address the public defender-client relationship.

¹ MODEL RULES OF PROF’L CONDUCT r. 1.14 (AM. BAR. ASS’N, 1983).

² *Id.*

³ *Id.*

⁴ Richard L. Frierson, Mary S. Boyd & Angela Harper, *Mental Illness and Mental Health Defenses: Perceptions of the Criminal. Bar*, 43 J. AM. ACAD. PSYCHIATRY L. 483, 491 (2015), <http://jaapl.org/content/jaapl/43/4/483.full.pdf>.

⁵ Chelsea Davis, Ayesha Delany-Brumsey & Jim Parsons, ‘A Little Communication Would Have Been Nice, Since This is My Life:’ *Defendant Views on the Attorney-Client Relationship*, 40 CHAMPION, 28, 28 (2016).

⁶ See *Gideon v. Wainwright*, 372 U.S. 335 (1963).

⁷ DONALD J. FAROLE, JR., *A National Assessment of Public Defender Office Caseloads*, BUREAU JUST. STAT. (Oct. 28, 2010), http://www.jrsa.org/events/conference/presentations-10/Donald_Farole.pdf.

⁸ NORMAN LEFSTEIN, *Securing Reasonable Caseloads: Ethics and Law in Public Defense* 24 (A.B.A., 2011), http://www.americanbar.org/content/dam/aba/publications/books/ls_sclaid_def_securing_reasonable_caseloads.authcheckdam.pdf.

⁹ Frierson et al., *supra* note 4, at 491.

¹⁰ Hon. Peggy Fulton Hora, *Courting New Solutions Using Problem-Solving Justice: Key Components, Guiding Principles, Strategies, Responses, Models, Approaches, Blueprints, and*

Currently, organizations exist that offer mental health first aid (MHFA) training for the general public.¹¹ This note explores using a modified version of these MHFA trainings as a simple, resourceful way to give public defenders the skills they need to communicate more effectively with their clients who suffer from mental health issues¹² and, consequently, to meet their ethical obligations under Rule 1.14. It begins with an overview of the existing working environment facing public defenders. The focus is on understanding how a heavy caseload, a lack of funding and resources, and a high number of clients with mental health issues affect how public defenders do their jobs. The note then takes a closer look at the ethical obligations required under Rule 1.14. Finally, the note discusses a possible solution, and potential drawbacks, to the difficulties facing public defenders as they try to meet their ethical obligations of Rule 1.14 while operating in an environment wrought with challenges.

II. *Understanding the Public Defense Landscape*

Public defender services have been in existence since the United States Supreme Court first ruled on the issue in 1963.¹³ In the seminal case *Gideon v. Wainwright*,¹⁴ the United States Supreme Court interpreted the 14th Amendment of the U.S. Constitution as requiring states to provide legal counsel to indigent defendants accused of serious

Tool Kits, 2 CHAP. J. CRIM. JUST. 7, 7 (2011).

¹¹ *Frequently Asked Questions*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/faq/> (last visited Feb. 19, 2018).

¹² This note, including the proposed solution, is aimed at addressing various common mental illnesses. The National Alliance on Mental Illness describes “mental illness” as “a condition that affects a person’s thinking, feeling, or mood.” Mental illness encompasses a wide range of specific mental disorders such as bipolar disorder, depression, anxiety disorder, autism, and schizophrenia, among others. By contrast, legal insanity is a legal term that describes “any mental disorder severe enough that it prevents a person from having legal capacity and it excuses the person from criminal or civil responsibility. “Diminished capacity” describes a condition in which a “client’s capacity to make adequately considered decisions in connection with a representation is diminished, whether because of minority, mental impairment or for some other reason.” Clients suffering from mental illness may have diminished capacity as defined in Rule 1.14. This note focuses on mental disorders that give rise to diminished capacity rather than legal insanity. It is meant to address cases when mental illness may not be easily detectable, but nevertheless require recognition by the public defender so that any ethical issues arising under Rule 1.14 can be addressed. *Mental Health Conditions*, N.A.M.I., <https://www.nami.org/Learn-More/Mental-Health-Conditions> (last visited Feb. 19, 2018); *Insanity*, BLACK’S LAW DICTIONARY (10th ed. 2014); AM. BAR ASS’N, *supra* note 1.

¹³ *Gideon*, 372 U.S. at 341.

¹⁴ *Id.*

crimes.¹⁵ Almost ten years later, the Supreme Court extended the right to counsel to all defendants facing a potential loss of liberty.¹⁶ Recognizing the importance of ensuring effective legal representation for indigent individuals, some states now go even further and extend the right to counsel to various other hearings that may result in a loss of liberty.¹⁷

The result is that public defender offices are responsible for a staggering percentage of all criminal cases. Those familiar with the field of public defense believe that as many as “80-90% of all defendants prosecuted in criminal cases throughout the country are represented by publicly funded counsel.”¹⁸ This makes meeting the ethical obligations of Rule 1.14 a daunting challenge for public defenders considering the current circumstances in which they operate. Heavy caseloads, a lack of funding and resources, and a disproportionately high number of clients with mental health issues all add to the challenge.

A. Heavy Caseloads

In 2007, the United States Department of Justice’s Bureau of Justice Statistics conducted a census of public defender offices (both state and county administered) across the nation revealing staggering caseloads in many jurisdictions.¹⁹ Based on data from 957 public defender offices principally funded by state or local governments, the results show that public defenders handled more than 5.5 million cases in 2007.²⁰

On average, individual public defenders in state-run programs carried a median of eighty-two felony and 217 misdemeanor cases.²¹ Those in county-run programs carried a median of 100 felony and 146 misdemeanor cases.²² One California law firm recognizes the impact that heavy caseloads have on the quality of representation and states this difference in caseloads as the number one reason for choosing a private criminal defense attorney over a public defender.²³ The firm advertises

¹⁵ Suzanne M. Strong, *State-Administered Indigent Defense Systems, 2013*, BUREAU JUST. STAT. (Nov. 2016), <http://www.bjs.gov/content/pub/pdf/saids13.pdf>.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Phyllis E. Mann, *Ethical Obligations of Indigent Defense Attorneys to Their Clients*, 75 MO. L. REV. 715, 727 (2010).

¹⁹ FAROLE, JR., *supra* note 7.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Private Criminal Defense Attorneys vs Public Defender – Top 8 Reasons*,

a more manageable average caseload of ten to fifty cases for each of its private criminal defense attorneys.²⁴

In an attempt to protect the quality of representation by public defenders, some states have set caseload limits.²⁵ In 2007, about 40% of state-run and 20% of county-run public defender programs set maximum caseload limits.²⁶ Conversely, 32% of state-run and over 50% of county-run programs had neither caseload limits nor allowed public defenders the ability to refuse cases.²⁷ It can be inferred that the remaining programs do not have caseload limits, but give public defenders the ability to refuse cases. Even with these limits, only four out of seventeen state-run public defender programs felt they had a sufficient number of attorneys to meet the standards in 2007.²⁸ Similarly, only one in four county-run programs felt they had a sufficient number of attorneys to meet the caseload standards.²⁹

In sum, when compared to their private criminal defense attorney counterparts, public defenders wrestle with an overwhelming amount of clients. In addition to excessive caseloads, quality of representation is further threatened by a lack of funding and resources, as well as the difficulty of working with a majority of clients with mental health issues.

B. Lack of Funding and Resources

A lack of government funding and resources go hand in hand with heavy caseloads. The American Bar Association recognizes the importance of adequate funding. In fact, in a 2011 report, the American Bar Association's Standing Committee on Legal and Indigent Defendants identified a lack of funding as the leading problem behind excessive caseloads.³⁰ The same report stated that two years earlier, in 2009, the National Right to Counsel Committee recommended that legislators "appropriate adequate funds so that quality indigent defense services can be provided."³¹ Similarly, the National Association of Criminal Defense

SCHWARTZBERG, LUTHER, APC (Aug. 22, 2016), <http://www.ielawoffice.com/private-criminal-defense-attorney-vs-public-defender-top-8-reasons/>.

²⁴ *Id.*

²⁵ FAROLE, JR., *supra* note 7.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ LEFSTEIN, *supra* note 8, at 20.

³¹ *Id.*

Lawyers urged public defender offices to “have sufficient attorneys to permit the maintenance of ethical standards.”³² However, public defense services remain drastically underfunded. The American Bar Association went so far as to say that “[f]unding for indigent defense is shamefully inadequate.”³³

The under-funding crisis exacerbates the difficulties associated with working with clients with mental health issues.³⁴ Public defenders are left without the time or resources to communicate and work effectively with these clients who often require more attention than a client without mental health issues.³⁵ As a result, the ability of public defenders to provide effective counsel to their clients with mental health issues is severely limited.³⁶

C. Disproportionate Number of Clients with Mental Health Issues

Adding to the complexities created by a lack of funding and heavy caseloads is the fact that public defenders often represent a disproportionate number of clients with mental health issues.³⁷ In 2009, roughly “2.2 million people with [mental health disorders] nationwide came into contact” with the criminal justice system.³⁸ Unfortunately, there are relatively few, if any, studies or statistics focusing on the number of defendants with mental health issues who are represented by public defenders. The Vera Institute of Justice is currently conducting a study regarding the role of public defenders when representing clients with mental health disorders.³⁹ While this study will likely provide valuable

³² *Id.*

³³ *Gideon’s Broken Promise: America’s Continuing Quest for Equal Justice*, AM. BAR ASS’N (Dec. 2004), http://www.americanbar.org/content/dam/aba/administrative/legal_aid_indigent_defendants/ls_sclaid_def_bp_right_to_counsel_in_criminal_proceedings.authcheckdam.pdf.

³⁴ Davis et al., *supra* note 5, at 28.

³⁵ *Id.*

³⁶ Olivia Sideman, *New Study Examines Indigent Defense for People with Mental Health Disorders*, VERA INST. JUST.: THINK JUST, BLOG (May 22, 2013), <http://archive.vera.org/blog/new-study-examines-indigent-defense-people-mental-health-disorders-0>.

³⁷ *Id.*

³⁸ *Id.*

³⁹ Ayesha Delaney-Brumsey, *The Role of Indigent Defense for Defendants with Mental Health Disorders*, VERA INST. JUST., <https://www.vera.org/projects/the-role-of-indigent-defense-for-defendants-with-mental-health-disorders> (last visited Feb. 21, 2018).

information and statistics regarding the current number of indigent defendants with mental health disorders, the study's findings are still only preliminary. Until the findings are finalized, it is necessary to draw inferences from more accessible information about the number of defendants with mental health issues, and from the relation between those defendants and indigency.

A 2005 study conducted by the Bureau of Justice Statistics revealed that "more than half of all prison and jail inmates had a mental health problem."⁴⁰ Of those in local jails, 64% were found to have a mental health problem.⁴¹ This figure is particularly relevant because jails are where individuals are held "pending arraignment, trial, conviction, or sentencing."⁴² Nearly 80% of local jail inmates were represented by public defenders.⁴³ The findings were similar when it came to state and federal prisons. About 56% of state prisoners and 45% of federal prisoners have mental health problems.⁴⁴ Public defenders were found to represent about 75% and 50% of state and federal prisoners respectively.⁴⁵

The data above supports what public defenders already know: the large majority of defendants they represent have mental health problems. The types and severity of these mental health problems vary. Some problems are severe enough to meet legally-recognized standards, thus allowing public defenders to access special resources for their clients.⁴⁶ For example, defendants who have diminished capacity due to severe mental health issues may be deemed legally incompetent by a medical doctor.⁴⁷ In that case, the defendant will receive treatment aimed at restoring them to competency before any further court proceedings. A

⁴⁰ Doris J. James & Lauren E. Glaze, *Mental Health Problems of Prison and Jail Inmates*, BUREAU JUST. STAT., 3 (2006), <https://www.bjs.gov/content/pub/pdf/mhppji.pdf> (defining "mental health problems" by two measures: a recent history (diagnoses) or symptoms (undiagnosed) of a mental health problem, and excluding from the study "[p]ersons who have been judged by a court to be *mentally incompetent to stand trial or not guilty by reason of insanity*").

⁴¹ *Id.*

⁴² *Id.*

⁴³ Steven K. Smith & Carol J. DeFrances, *Indigent Defense*, BUREAU JUST. STAT. (1996), <https://www.bjs.gov/content/pub/pdf/id.pdf>.

⁴⁴ James & Glaze, *supra* note 40.

⁴⁵ Smith & DeFrances, *supra* note 43.

⁴⁶ See Lukas Saunders, *Competency to Stand Trial*, NOLO, <http://www.nolo.com/legal-encyclopedia/competency-stand-trial.html> (last visited Feb. 19, 2018); see *Mental Health*, A.B.A., http://www.americanbar.org/publications/criminal_justice_section_archive/crimjust_standards_mentalhealth_blk.html (last visited Feb. 19, 2018).

⁴⁷ Sheena E. Arteta, *How to Legally Declare Someone as Mentally Incompetent?*, THE LAW

public defender may also motion the court to appoint a guardian ad litem, conservator, or guardian to represent defendants with severe mental health issues.⁴⁸ Some jurisdictions have other resources available, including mental health specialty courts or specially trained public defenders.⁴⁹ However, these resources are reserved only for defendants with severe mental health issues, and public defenders are left to struggle with defendants with less severe mental health problems.⁵⁰

Less severe, but far more common mental health issues usually get no special attention or treatment by public defenders or the court system, despite standards set forth by the American Bar Association calling them to do so.⁵¹ Considering that a large majority of a public defender's clients have some sort of mental health problem, it would be impossible, from both a time and financial standpoint, for each of those defendants to receive special treatment or services. They may go unrecognized by public defenders because public defenders are not trained to screen for mental health disorders.⁵²

The 2005 Bureau of Justice Statistics study mentioned above attempted to identify the number and types of both diagnosed and undiagnosed mental health problems most commonly suffered by prison and jail inmates.⁵³ Of the 64% of inmates in local jails who reported having a mental health problem, only 11% were actually diagnosed by a mental health professional.⁵⁴ For inmates in state prisons, the figure dropped to 9% and for federal prison inmates, it dropped to 5%.⁵⁵ The remaining inmates who reported mental health problems exhibited symptoms only or had some other mental health history that did not include an official

DICTIONARY, <http://thelawdictionary.org/article/how-to-legally-declare-someone-as-mentally-incompetent/> (last visited Feb. 19, 2018).

⁴⁸ MODEL RULES OF PROF'L CONDUCT r. 1.14 (AM. BAR ASS'N 1983), http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_1_14_client_with_diminished_capacity.html (last visited Feb. 21, 2018).

⁴⁹ Jeff Bouffard, Elizabeth Berger & Gaylene S. Armstrong, *The Effectiveness of Specialized Legal Counsel and Case Management Services for Indigent Offenders with Mental Illness*, HEALTH AND JUSTICE (July 11, 2016), <https://healthandjusticejournal.springeropen.com/articles/10.1186/s40352-016-0038-6>.

⁵⁰ *Id.*

⁵¹ See CRIMINAL JUSTICE STANDARDS ON MENTAL HEALTH STANDARD 7-1 (AM. BAR ASS'N 2016), http://www.americanbar.org/content/dam/aba/publications/criminal_justice_standards/mental_health_standards_2016.authcheckdam.pdf.

⁵² Frierson et al., *supra* note 4, at 491.

⁵³ See James & Glaze, *supra* note 40.

⁵⁴ *Id.*

⁵⁵ *Id.*

diagnosis.⁵⁶

In the study, symptoms of mental health problems were reflective of disorders such as major depression, mania, and psychotic disorders, and included behaviors such as “persistent sadness, loss of interest in activities, insomnia or hypersomnia, psychomotor agitation, and persistent anger or irritability.”⁵⁷ Moreover, “[i]nsomnia or hypersomnia and persistent anger were the most frequently reported” symptoms.⁵⁸

To further aggravate these mental health disorders, many inmates suffer from substance dependence or abuse.⁵⁹ Of the jail and state prison inmates who were found to have mental health problems, about 76% and 74%, respectively, were found to also have a substance abuse or dependence problem.⁶⁰

Similarly, the American Bar Association identified the most common mental disorders found in the criminal justice system as schizophrenia, bipolar disorder, major depressive disorders, developmental disabilities, and “substance abuse disorders that develop from repeated and extensive abuse of drugs or alcohol or some combination thereof.”⁶¹

For public defenders that have the majority of their clients exhibiting these types of symptoms, providing effective representation can be a difficult, if not impossible task. Each of these symptoms can adversely affect communication on both ends of the attorney-client relationship. Clients may provide little or no useful information to their attorney as a result of angry outbursts, irritability, or being under the influence of illegal substances. Attorneys may become so frustrated that they cut client meetings short or only share the bare minimum amount of information in an effort to move the meeting along.

When communication is adversely affected, it becomes more challenging for the public defender to represent the client’s interests effectively. Early findings in the study currently being conducted by the Vera Institute show that poor communication among public defenders and indigent clients with mental health issues hinders development of positive

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ See CRIMINAL JUSTICE STANDARDS ON MENTAL HEALTH STANDARD 7-1.1(a) (AM. BAR ASS’N 2016), http://www.americanbar.org/content/dam/aba/publications/criminal_justice_standards/mental_health_standards_2016.authcheckdam.pdf.

and trusting relationships.⁶² Indeed, “clients frequently reported that being able to communicate effectively with their attorney was integral to their experience of, and perceived quality of, legal representation.”⁶³ The same study found that poor communication can also lead to disagreements between the attorney and client.⁶⁴ While disagreements about key decisions were common, poor communication led to a marked difference in the time at which attorneys and clients perceived disagreements.⁶⁵ In addition, 36% of disagreements went unresolved.⁶⁶

The American Bar Association recognizes the difficulties of representing clients with mental health problems and has set forth numerous standards (the “Standards”) addressing the topic.⁶⁷ For example, Standard 7-1.2 reads:

Officials throughout the criminal justice system should recognize that people with mental disorders have special needs that must be reconciled with the goals of ensuring accountability for conduct, respect for civil liberties, and public safety.⁶⁸

Standard 7-1.4(b) goes so far as to warn attorneys of the difficulties that can arise when working with clients with mental disorders. It states that “[a]ttorneys should be prepared to deal with difficulties in communication that can result from the client’s mental disorder.”⁶⁹

In addition, the Standards specifically address the roles of the attorney representing a defendant with a mental disorder,⁷⁰ as well as the

⁶² Davis et al., *supra* note 5.

⁶³ *Id.* at 6.

⁶⁴ *Id.* at 4.

⁶⁵ *Id.* at 4.

⁶⁶ *Id.* at 5.

⁶⁷ See CRIMINAL JUSTICE STANDARDS ON MENTAL HEALTH STANDARD 7-1 (AM. BAR ASS’N 2016), http://www.americanbar.org/content/dam/aba/publications/criminal_justice_standards/mental_health_standards_2016.authcheckdam.pdf.

⁶⁸ *Id.* Standard 7-1.2 goes on to read:

Criminal justice officials should work with community mental health treatment providers and other experts to develop valid and reliable screening, assessment, diversion, and intervention strategies that identify and respond to the needs of individuals with mental disorder who come into contact with the justice system, diversion program, or post-adjudication supervision monitoring.

⁶⁹ *Id.* Standard 7-1.4.(b)

⁷⁰ *Id.* Standard 7-1.4.(a-b). Moreover,

Attorneys who represent defendants with mental health disorders should provide client-centered representation that is inter-disciplinary in nature. These attorneys should be familiar with local providers and programs that offer mental health and related services to which clients might be referred in lieu of incarceration, in the interest of reducing the likelihood of further involvement with the criminal

need for “programs offering advanced instruction on mental health . . . law”⁷¹ for public defenders.⁷²

The standards are, however, vague and do not offer concrete recommendations. Budget-conscious state court systems are left to figure out how to meet the standards when resources are already scarce. The result is that only the most severe cases receive attention and public defenders are forced to attempt to provide effective representation with very little assistance and with inadequate training.

III. *Ethical Obligations of Public Defenders Under Rule 1.14*

Most lawyers are held to the ethical standards presented in the ABA’s Model Rules of Professional Conduct.⁷³ For public defenders working with a significant number of clients with mental health issues, Rule 1.14 is particularly important. Rule 1.14(a) reads:

When a client’s capacity to make adequately considered decisions in connection with a representation is diminished, whether because of minority, mental impairment, or for some other reason, the lawyer shall, as far as reasonably possible, maintain a normal client-

justice system.

Id. Furthermore, “[a]ttorneys who represent defendants with mental disorders should work particularly close with their clients to ensure that the clients understand their options.” *Id.*

⁷¹ MENTAL HEALTH, MENTAL RETARDATION AND CRIMINAL JUSTICE: GENERAL PROFESSIONAL OBLIGATIONS STANDARD 7-1.3(b)(ii) (AM. BAR ASS’N, Criminal Justice Section Archive), http://www.americanbar.org/publications/criminal_justice_section_archive/crim-just_standards_mentalhealth_blk.html (last visited Feb. 21, 2018).

⁷² *Id.* (“Bar associations, law schools, and other organizations having responsibility for providing continuing legal education should develop and regularly conduct programs offering advanced instruction on mental health and mental retardation law and mental health and mental retardation professional participation in the criminal process. Prosecutors, public defenders, and other attorneys who specialize in, or regularly practice, criminal law should participate in these programs.”)

⁷³ MODEL RULES OF PROF’L CONDUCT r. 1.14 (Am. Bar Ass’n 1983), http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct.html (last visited Feb. 18, 2018). The *ABA Model Rules of Professional Conduct*, adopted by the ABA House of Delegates in 1983, serves as models for the ethics rules of most states. See *Variations of the ABA Model Rules of Professional Conduct*, A.B.A. (Sept. 15, 2016), http://www.americanbar.org/content/dam/aba/administrative/professional_responsibility/mrpc_1_14.authcheckdam.pdf. As of September 15, 2016, twenty-seven states follow the ABA’s version of Model Rule 1.14 verbatim. *Id.* Texas chose not to adopt any version of Model Rule 1.14 and California has its own set of professional conduct rules that are not structured after the *ABA’s Model Rules of Professional Conduct*. *Id.* The remaining states adopted a similar version of the ABA’s Model Rule 1.14 with only minor word changes. *Id.* For example, Alabama changes “capacity” to “ability” in section (a) and North Dakota replaces “diminished” with “limited” throughout the rule. *Id.*

lawyer relationship with the client.⁷⁴

However, maintaining a “normal relationship”⁷⁵ “as far as reasonably possible”⁷⁶ can be next to impossible for public defenders and defendants suffering from mental health issues.

It is necessary to examine the Sixth Amendment to the United States Constitution to determine what it means to “maintain a normal relationship.”⁷⁷ In *Gideon v. Wainwright* and subsequent cases, the Supreme Court has continued to interpret the Sixth Amendment as establishing the right to effective counsel for indigent criminal defendants.⁷⁸ This means that indigent clients need more than just an assigned attorney – “representation by counsel is a necessary but not sufficient condition to satisfy the *Gideon* right.”⁷⁹ In other words, “the right to counsel is only as strong as the underlying commitment to the quality of representation provided by attorneys for indigent defendants.”⁸⁰

In addition to needing more than just an assigned attorney, effective counsel has been interpreted by the United States Supreme Court to mean that “when a State brings its judicial power to bear on an indigent defendant in a criminal proceeding, it must take steps to assure that the defendant has a fair opportunity to present his case.”⁸¹ In essence, “the Due Process Clause requires states to provide indigent defendants with the ‘basic tools’ of an adequate defense.”⁸² Moreover, “[m]ost courts have interpreted ‘basic tools’ to mean an investigative or expert service that is absolutely necessary to the defense.”⁸³ Effective communication with one’s attorney is a basic tool that is absolutely necessary in creating an adequate defense.

As discussed above, communication is often strained between public defenders and their clients as a result of the clients’ mental health problems.⁸⁴ How are public defenders expected to be held to the same

⁷⁴ *Id.* r. 1.14.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ John H. Blume & Sheri Lynn Johnson, *Gideon Exceptionalism?*, 122 YALE L.J. 2126, 2137 (2013).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.* at 2143 (quoting *Ake v. Oklahoma*, 470 U.S. 68, 76 (1985)).

⁸² *Id.*

⁸³ *Id.* at 2144.

⁸⁴ See Davis et al., *supra* note 5.

“effective counsel” standards as other attorneys when they have significantly more barriers to providing quality legal representation and very few, if any, resources to assist them?

IV. Proposed Solution

Any proposed solution to the difficulty that public defenders face when it comes to fulfilling Rule 1.14 must take into account the current working environment and ongoing funding crisis facing public defender services. As such, this note proposes a simple, cost-effective solution to provide public defenders with the basic tools needed to communicate more effectively with clients suffering from mental health issues. The proposed solution is not meant to take the place of mental health services for seriously ill indigent defendants. Rather, it is meant to give public defenders skills that can help them identify clients who suffer from mental health issues that may or may not be easily identifiable and interact with them more effectively.

One of the challenges for public defenders working with mentally ill clients is that they are not necessarily qualified to recognize signs of mental health disorders even though they work with more mentally ill clients than all other law occupations.⁸⁵ Many times, public defenders may mistake clients with mental health issues as just being uncooperative. If public defenders cannot recognize the symptoms of a mental health disorder, they are unable to effectively screen clients for social services, mental health dockets, or other mental health services. As the ABA’s Criminal Justice Mental Health Standards state, a public defender has an obligation to connect mentally ill defendants with the services they need.⁸⁶ This means public defenders need to be able to quickly recognize when a client is in need of additional services. This can be difficult when the defender has an excessive caseload and not

⁸⁵ See Frierson et al., *supra* note 4 (finding that attorneys may have little experience working with mentally ill clients due to inadequate training in law school based on a survey of 492 members of the criminal bar in South Carolina).

⁸⁶ AM. BAR ASS’N, *supra* note 51. Moreover,

Attorneys who represent defendants with mental health disorders should provide client-centered representation that is inter-disciplinary in nature. These attorneys should be familiar with local providers and programs that offer mental health and related services to which clients might be referred in lieu of incarceration, in the interest of reducing the likelihood of further involvement with the criminal justice system.

Id. Furthermore, “[a]ttorneys who represent defendants with mental disorders should work particularly close with their clients to ensure that the clients understand their options.” *Id.*

much time to evaluate the client. As a solution to this problem, this note proposes that public defenders be required to participate in mental health first aid courses specifically tailored to fit the needs and challenges of public defenders.

A. What is Mental Health First Aid?

Mental health first aid, such as those produced by Mental Health First Aid USA,⁸⁷ is designed to “give[] people the skills to help someone who is developing a mental health problem or experiencing a mental health crisis.”⁸⁸ First developed in 2001 by Tony Jorm and his wife, Betty Kitchener,⁸⁹ the “groundbreaking public education program . . . introduces participants to risk factors and warning signs of mental health problems, builds understanding of their impact, and overviews common treatments.”⁹⁰ Similar to a CPR or physical first aid course which teaches participants to give immediate medical attention in emergency situations, and then follow up with professional help, mental health first aid courses are meant to give participants the basic tools they need to assist individuals experiencing a mental health crisis.⁹¹ In fact, “[t]he training gives [participants] the skills [they] need to reach out and pro-

⁸⁷ See Rebecca A. Clay, *Mental Health First Aid: A Growing Movement Trains Laypeople to Spot Mental Health Concerns. What Does it Mean for Psychologists?*, MONITOR ON PSYCHOL., July–Aug. 2013. Organizations similar to Mental Health First Aid USA were already in the United States when the program was brought over from Australia. *Id.* For example, the National Coalition for Mental Health Recovery’s Emotional CPR program also teaches participants how to assist those in crisis, while Psychological First Aid trains American Red Cross workers to assist people in the wake of disasters. *Id.* This note focuses on the model created by Mental Health First Aid because of its increasing popularity, simple structure, and accessibility to the general public. *Id.*

⁸⁸ MENTAL HEALTH FIRST AID USA, *supra* note 11.

⁸⁹ Clay, *supra* note 87, at 33. Jorm, a mental health literacy professor, and Kitchener, a nurse, first thought of the idea while on a walk conversing about her history of depression and suicide attempt at fifteen years old. *Mental Health First Aid*, NAT’L COUNCIL BEHAV. HEALTH, <https://www.thenationalcouncil.org/training-courses/mental-health-first-aid/> (last visited Feb. 19, 2017). Kitchener had never received professional help and sought to help others with similar problems. *Id.* The first course was developed over a period of five years during which expert clinicians, consumer advocates, and caregiver advocates created guidelines and response protocols to address common mental health issues. *Id.* By 2001, the first class was being tested. *Id.* In 2008, Mental Health First Aid was brought to the United States by the National Council for Behavioral Health. See MENTAL HEALTH FIRST AID USA, *supra* note 11.

⁹⁰ *Mental Health First Aid*, NAT’L COUNCIL BEHAV. HEALTH, <https://www.thenationalcouncil.org/training-courses/mental-health-first-aid/> (last visited Feb. 21, 2018).

⁹¹ *About*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/about/> (last visited Feb. 21, 2018).

vide *initial* help and support to someone who may be developing a mental health or substance use problem or experiencing a crisis.”⁹²

Typically courses are eight-hours in length and cost anywhere from \$0-100 depending on the class size, instructor, and venue.⁹³ In addition, each course results in a three-year certification, which can be renewed by taking a ninety-minute online refresher course.⁹⁴ Courses address a variety of topics, including depression and mood disorders, anxiety disorders, trauma, psychosis, and substance abuse disorders.⁹⁵ Participants learn to recognize the signs, symptoms, and risk factors of each disorder, as well as how to implement a five-step action plan in both crisis and non-crisis situations based on which disorder is involved.⁹⁶ In addition, they learn interventions such as how to assist an individual experiencing a panic attack, suicidal thoughts or behaviors, non-suicidal self-injury, acute psychosis, overdose or withdrawal from alcohol or drug use, or reaction to a traumatic event.⁹⁷ During these live-training courses, participants simulate various situations that involve assessing a mental health crisis.⁹⁸ For example, in one simulation, a participant uses his mental health first aid skills to assist a neighbor who seems to be suffering from paranoia as a result of discontinuing her medications.⁹⁹

In addition to its general adult course, Mental Health First Aid USA offers a variety of other curriculums targeting various fields that may benefit from tailored action plans. Currently, it offers specialized courses for those working in higher education, law enforcement, and public safety, as well as those working with members of the military, veterans, youth, or the elderly population.¹⁰⁰ The program tailored for

⁹² *Id.* (emphasis added).

⁹³ *Find a Course*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/take-a-course/find-a-course/> (last visited Feb. 21, 2018).

⁹⁴ *Mental Health First Aid Re-Certification*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/re-certification/> (last visited Feb. 21, 2018) (advertising the cost of online recertification at \$29.95).

⁹⁵ *What You Learn*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/take-a-course/what-you-learn/> (last visited Feb. 21, 2018).

⁹⁶ MENTAL HEALTH FIRST AID USA, *YOUTH MENTAL HEALTH FIRST AID USA FOR ADULTS ASSISTING YOUNG PEOPLE 5* (Mental Health Ass'n Md. 2012).

⁹⁷ *Id.*

⁹⁸ NAT'L COUNCIL BEHAV. HEALTH, *supra* note 90.

⁹⁹ MENTAL HEALTH FIRST AID USA, *supra* note 95.

¹⁰⁰ *Course Types*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/more-information/> (last visited Feb. 21, 2018).

public safety is especially relevant because it is designed to give participants the tools they need to de-escalate tense situations¹⁰¹ – something public defenders find themselves doing.

Mental Health First Aid USA states that the public safety program is especially useful for police, corrections officers, and other public safety officials¹⁰² – essentially, groups that deal with the same individuals as public defenders. In September 2016, the House of Representatives approved an amended version of H.S. 1877, the Mental Health First Aid Act of 2015, which authorizes grants for mental health and substance abuse awareness training to emergency response personnel, law enforcement, and various other groups who work with individuals with mental health issues.¹⁰³ The rising popularity of mental health first aid is evidenced by the fact that more than 780,000 people across the United States have been trained so far.¹⁰⁴

B. Mental Health First Aid for Public Defenders

The pre-packaged course that currently exists can be easily adapted to fit the needs of public defenders. While similar skills will be taught, the purpose of the course will be slightly different when geared towards public defenders. As mentioned above, the regular course is designed to empower participants so that they may provide initial support for someone developing a mental health problem or experiencing a mental health crisis.¹⁰⁵ By contrast, the purpose of a course for public defenders will be to provide attorneys with the skills needed to be able to identify clients with mental health disorders and to give them the tools needed to aid communication, increase patience, and enhance understanding so that attorneys will be able to fulfill their Rule 1.14 obligations.

In addition to teaching about unique risk factors, common disor-

¹⁰¹ *Mental Health First Aid for Public Safety*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/wp-content/uploads/2016/01/Public-Safety-Overview-2.pdf> (last visited Feb. 21, 2018).

¹⁰² *Id.*

¹⁰³ Rebecca Farley, *House Passes Mental Health First Aid Act*, MENTAL HEALTH FIRST AID USA (Sept. 29, 2016), <https://www.mentalhealthfirstaid.org/cs/external/2016/09/house-passes-mental-health-first-aid-act/>; *see also* Mental Health First Aid Act of 2016, H.R. 1877, 114th Cong. (2d Sess. 2016), <https://www.congress.gov/bill/114th-congress/housebill/1877/text?q=%7B%22search%22%3A%5B%22HR+1877%22%5D%7D>.

¹⁰⁴ MENTAL HEALTH FIRST AID USA, *supra* note 91.

¹⁰⁵ *Id.*

ders, warning signs, and helpful action plans, a course for public defenders should focus on teaching skills geared toward specific situations commonly faced by public defenders, such as delivering bad news to clients with anger issues. Another focus of the course should be on teaching public defenders to recognize when clients are suffering from mental illness so that the clients can be recommended for mental health services. This is especially important in cases where a client's mental illness is not readily apparent to an untrained individual.

The purpose of the course will not be to teach public defenders to be mental health providers and is not meant as a substitute for appropriate mental health care. Likewise, the course will not be geared towards working with clients with severe mental health issues. Those clients will likely be easily identified by attorneys and quickly screened for appropriate available mental health services. While the tools learned in the specialized course may assist attorneys in communicating with those clients, the focus will be on situations in which clients suffer from milder mental health conditions. Addressing these goals, including the most common problems and disorders among clients of public defenders, such as depression, anxiety, acute psychosis, bipolar disorder, substance abuse, and aggression, would require little change to the current curriculum.

A program teaching the following skills has the potential to positively impact the attorney-client relationship:

- De-escalate tense and stressful situations
- Manage violent and aggressive behavior
- Use appropriate body language and vocabulary to avoid triggers that may create or enhance problematic situations
- Communicate bad news and manage resulting client behavior
- Communicate with clients under the influence of drugs or alcohol
- Communicate with clients experiencing withdrawals from drugs or alcohol
- Recognize the existence of a mental health disorder in order to screen for specialized services, such as placement on a mental health docket or assistance of a social worker
- Recognize mental health disorders that may be more difficult to identify in isolated meetings because symptoms are often sporadic

- Strategies for maintaining composure and patience in stressful situations involving mentally ill clients
- Self-care strategies for public defenders

During the course, public defenders can practice using these skills in simulations designed after common workplace experiences. For example, participants can role-play a situation in which a new client is exhibiting angry and aggressive behavior after just being brought into custody by police. The public defender can use her mental health first aid skills to de-escalate the situation, while working to gather information for the public defender services application. In another scenario, participants can simulate a client meeting where the attorney needs to convey unwelcome news regarding a bleak pretrial offer. The attorney will need to use his skills to handle the situation with care by avoiding trigger words or behavior so that the client remains calm and the meeting is ultimately productive.

Possessing and practicing these skills will empower public defenders to deal more efficiently, effectively, and compassionately with mentally ill clients, and will result in more trusting lawyer-client relationships and increased communication. In turn, better communication will lead to more effective representation allowing public defenders to fulfill their ethical obligations under Rule 1.14.

Like other mental health first aid courses, the program for public defenders will result in a three-year certification, which will need to be renewed every three years. Similar to the recertification course provided by Mental Health First Aid USA,¹⁰⁶ public defenders will be able to take the recertification course online in just ninety minutes and for a minimal cost.¹⁰⁷ Because knowledge about brain science and mental health is constantly expanding, this structure ensures public defenders will be equipped with the latest, most effective strategies and tools for dealing with clients with mental health issues.

C. Will it Work?

Considering the relatively low financial investment and time commitment, this simple program contains big promises for changing the way public defenders do their job. The question is: *Will it actually work?*

¹⁰⁶ See MENTAL HEALTH FIRST AID USA, *supra* note 94.

¹⁰⁷ See *id.* (advertising the cost of online recertification at \$29.95).

A Pennsylvania corrections officer, who works in the female mental health unit and as part of the Crisis Intervention Team, claims it has changed the way he does his job:¹⁰⁸

Working in the mental health unit of a state correctional institution is stressful and challenging at times. . . . In the past, we might not have recognized the signs of a mental health crisis An inmate that refused to cooperate with instructions may have been seen as simply being non-compliant An inmate that is hallucinating or experiencing psychosis, for example, may not be in a position to follow orders. . . . Our officers are trained to tell the difference between non-compliance and an inmate who cannot follow orders because they are in crisis. . . . We de-escalate [] situation[s] so they do not feel threatened. Doing so reduces the need for force, which is better for everyone.¹⁰⁹

Recently, the Rhode Island Police Department became one of the first to require all new police recruits to complete mental health first aid training.¹¹⁰ Retired West Warwick Police Captain Joe Coffey facilitates the trainings¹¹¹ because, considering the prevalence of mental illness related calls, he recognizes the need to equip all of his officers with the tools necessary to safely de-escalate crisis involving mentally ill individuals.¹¹² Coffey estimates that as many as 7-15% of the calls they go on involve some sort of mental health crisis.¹¹³ He now offers his testimonial in support of mental health first aid training on the Mental Health First Aid USA website.¹¹⁴

An article about the new Rhode Island training requirement recounts a story about an officer trained in mental health first aid who responds to a call involving a suicidal woman.¹¹⁵ The woman in the story

¹⁰⁸ Virgil Meyer, *Mental Health First Aid Has Changed the Way We Do Our Job*, MENTAL HEALTH FIRST AID USA (June 28, 2016), <https://www.mentalhealthfirstaid.org/cs/success-stories/mental-health-first-aid-changed-way-job/>.

¹⁰⁹ *Id.*

¹¹⁰ Kristin Gourlay, *Rhode Island Police Learn How to Respond to People Struggling With Mental Illness*, W.B.U.R. (Dec. 27, 2016), <http://www.wbur.org/morningedition/2016/12/27/mental-health-police-training>.

¹¹¹ *Id.*

¹¹² Joseph Coffey, *I Was Able to Save a Life*, MENTAL HEALTH FIRST AID USA (Dec. 4, 2013), <https://www.mentalhealthfirstaid.org/cs/success-stories/we-were-able-to-save-a-life/>.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ Gourlay, *supra* note 110.

shares that “[the officer] treated her like a human being.”¹¹⁶ In the same article, Coffey’s co-facilitator, Trisha Brouwer, equates mental health first aid skills with those learned for the purpose of conducting CPR or other physical first aid:¹¹⁷ Indeed, “mental health first aid is similar and just as critical. That’s because someone in crisis might not behave the way officers expect. Knowing how to respond can mean the difference between life and death – between making an arrest or helping the person get into treatment.”¹¹⁸ Finally, more pervasive training by police departments can ultimately “help divert more people from an overburdened criminal justice system . . . into treatment.”¹¹⁹

Like the Rhode Island Police Department, other organizations are recognizing the value of mental health first aid training and are working to incorporate it into their organizations. Recently, the New York City Department of Correction (“NYC DOC”) received a \$250,000 grant from the U.S. Department of Justice, which it will share with other organizations to set up clinic and intake support teams to assist inmates “through [an] emphasis on mental-health first aid and de-escalation.”¹²⁰ These teams “will help conduct mental health interventions, expedite clinic cases, educate individuals on the resources available to them, and identify individuals with mental illness who may have gone undiagnosed during intake, the process by which inmates enter the DOC facilities.”¹²¹ In addition, the teams will “offer support to correctional staff by providing skill refreshers and reinforcement of Mental Health First Aid training and techniques.”¹²² The goal is for the teams to use mental health first aid and de-escalation to “strengthen the efforts of the agency’s 14-Point Anti-Violence Agenda”¹²³ and ultimately reduce use of force.¹²⁴ NYC DOC Commissioner, Joseph Ponte, estimates that about 42% of the

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Danielle Poole, *NY DOC Receives Grant to Help Mentally Ill Inmates* (Feb. 8, 2017), <https://www.mentalhealthfirstaid.org/cs/external/2017/02/ny-doc-receives-grant-help-mentally-ill-inmates/>. The grant will be shared among the NYC DOC, NYC DOC’s health provider, NYC Health + Hospitals, and the Vera Institute of Justice. *Id.* The NYC DOC hopes to have all DOC facilities staffed by clinic and intake support teams trained in mental health first aid by July 30, 2019. *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

DOC's inmate population has mental health issues.¹²⁵ As such, New York City First Lady Chirlane McCray, who leads mental health and substance misuse efforts in New York City, feels "it is essential to tailor resources to meet the needs of both inmates and correction officers so they can respond [to situations] responsibly and compassionately."¹²⁶

These first-hand stories and testimonials are promising in that they provide some early support that mental health first aid training can be used by public defenders to increase the quality of the communication and the overall relationship with clients. Police officers, corrections officers, and public defenders all deal with the same clientele, just at different points in the criminal justice system. With increasing numbers of police and corrections officers taking advantage of mental health first aid training,¹²⁷ it seems to follow that public defenders should be given the same advantage. In fact, for public defenders who have an ethical obligation to maintain as normal a relationship as possible with clients who suffer from mental health issues, it is even more important that they be given the tools they need to do just that. While police officers only interact with an individual for a brief period of time, attorneys often work with clients over the course of months or years. Because of the necessity of having a trusting, confidential relationship with clients, public defenders should have access to practical tools that can help them succeed in building and maintaining that relationship.

With mental health first aid being a relatively new concept, the quantitative evidence supporting its effectiveness is limited.¹²⁸ The studies that do exist, however, show promising results.¹²⁹ Perhaps one of the most comprehensive sources of quantitative evidence regarding mental health first aid is a 2014 analysis performed by the National Centre for Suicide Research and Prevention of Mental Ill-Health.¹³⁰ This source

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ See Gourlay, *supra* note 110.

¹²⁸ *Mental Health First Aid Efficacy: A Compilation of Research Efforts*, MENTAL HEALTH FIRST AID USA, <https://www.mentalhealthfirstaid.org/cs/wp-content/uploads/2013/10/MHFA-Research-Summary-UPDATED.pdf> (last visited Feb. 21, 2018). MHFA keeps a running list of studies undertaken to evaluate the effectiveness of mental health first aid. Currently, there are only thirty-three studies on the list with several listed as still in progress. The studies listed were undertaken by a variety of organizations. *Id.* Some of the earliest ones were conducted by MHFA founders Kitchener and Jorm. *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

provides an overview of the effectiveness of mental health first aid.¹³¹ The study consisted of a meta-analysis of fifteen other mental health first aid studies and resulted in a collective evaluation of the results obtained by each study.¹³² The fifteen studies that were used were quantitative in nature and evaluated both adult and youth mental health first aid.¹³³ The meta-analysis showed that mental health first aid “increases participants’ knowledge regarding mental health, decreases their negative attitudes, and increases supportive [behaviors] toward individuals with mental health problems.”¹³⁴ In addition, it concluded that the mental health first aid program appeared “recommendable for public health action.”¹³⁵ These results have been interpreted as ““reasonably strong””¹³⁶ evidence that “individuals trained in [mental health first aid] experience improvements in knowledge, attitudes, and help-provision behaviors.”¹³⁷

As promising as the results of the meta-analysis are, they should be read cautiously. Of the fifteen studies included in the analysis, twelve were conducted in Australia (where mental health first aid originated), two were conducted in Sweden, and one in Canada.¹³⁸ Therefore, the results do not necessarily reflect the responses of any participants from the United States.¹³⁹ This means that results will likely only show the effectiveness of mental health first aid in the United States to the extent that the foreign participants and participants living in American are similar.¹⁴⁰

In another study, the effects of mental health first aid in multicultural communities were examined.¹⁴¹ The findings of this study “sug-

¹³¹ *Id.*

¹³² *Id.*; see Eunice C. Wong, Rebecca L. Collins & Jennifer L. Cerully, *Reviewing the Evidence Base for Mental Health First Aid* (July 15, 2015), http://www.rand.org/content/dam/rand/pubs/research_reports/RR900/RR972/RAND_RR972.pdf. Meta-analysis is a statistical method that “provides a rigorous systematic process for quantifying the overall effect of a treatment or program by summarizing findings across independent studies.” *Id.*

¹³³ Wong et al., *supra* note 132, at 1.

¹³⁴ Gergö Hadlaczky et al., *Mental Health First Aid is an Effective Public Health Intervention for Improving Knowledge, Attitudes, and Behaviour: A Meta-Analysis*, 26 INT’L REV. PSYCHIATRY 467, 467 (2014), <https://www.ncbi.nlm.nih.gov/pubmed/25137113>.

¹³⁵ *Id.*

¹³⁶ Wong et al., *supra* note 132, at 2.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ MENTAL HEALTH FIRST AID USA, *supra* note 128.

gested that [mental health first aid training] increased participant recognition of mental illnesses, concordance with primary care physicians about treatments, confidence in providing first aid, actual help provided to others, and a reduction in stigmatizing attitudes.”¹⁴² In addition, a six-month follow up demonstrated long-term effects of mental health first aid.¹⁴³ This study is significant because it attempted to study the effects of mental health first aid on diverse communities. Since this note is recommending that mental health first aid would be beneficial to public defenders throughout the country, this study suggests that the program would not need to be individually tailored to account for the diversity within each jurisdiction or community.

In 2005, mental health first aid founders, Betty Kitchener and Anthony Jorm, along with Stephen Mugford, performed a study, which consisted of compiling stories from participants about their subsequent use of mental health first aid.¹⁴⁴ The study found that participants reported increased empathy and confidence, and felt better able to handle a mental health crisis.¹⁴⁵ In addition, participants felt the course was very useful, and felt enthusiastic about seeing it repeated and extended.¹⁴⁶ The other significant finding that came out of this study was that “there was no evidence that the [participants were] over-reaching themselves because of over-confidence.”¹⁴⁷

One of the limitations of the previously mentioned studies is that they reveal little information about the effects of mental health first aid on the recipients.¹⁴⁸ A recent study, whose results have not yet been published, attempted to draw inferences about the impact on recipients based on information provided by past participants of mental health first aid training courses.¹⁴⁹ The qualitative study revealed that participants “described gaining knowledge, skill and confidence to help someone in

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ Anthony F. Jorm et al., *Experiences in Applying Skills Learned in a Mental Health First Aid Training Course: A Qualitative Study of Participants' Stories*, BMC PSYCHIATRY (Nov. 9, 2005), <https://bmcp psychiatry.biomedcentral.com/articles/10.1186/1471-244X-5-43>. The study analyzed stores of ninety-four former mental health first aid course participants anywhere from nineteen to twenty-one months after they completed the course training. *Id.* Of the ninety-four participants, 78% had utilized their first aid training skills. *Id.*; see also MENTAL HEALTH FIRST AID USA, *supra* note 128.

¹⁴⁵ Jorm, *supra* note 144.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ MENTAL HEALTH FIRST AID USA, *supra* note 128.

¹⁴⁹ *Id.*

distress, empathy for people with mental illness, and developing a sense of responsibility and permission to try to help when needed.”¹⁵⁰ Participants also shared that they used their new skills on clients, among others, and in a variety of situations, which suggests mental health first aid can have positive effects in a workplace setting.¹⁵¹

Another study worth looking at is currently being undertaken at the University of Kansas.¹⁵² Similar to other studies, the preliminary results indicate that mental health first aid courses can “provide a solid base of knowledge for people with a limited mental health background who are taking it for the first time, and can even act as a useful refresher for individuals with previous mental health education or experience.”¹⁵³ It is possible that some public defenders will not see the value in a mental health first aid course because they are confident that they can recognize when a client has mental health issues. This study points out that even for people who may have experience with or knowledge about mental health disorders, mental health first aid training can serve as a valuable refresher tool. In addition, it ensures that all employees have the opportunity to acquire the same knowledge and skills so that clients are not at a disadvantage if represented by someone with fewer skills.

With a growing number of success stories and testimonials, as well as increasing amounts of relevant research attesting to the effectiveness of mental health first aid training, it seems promising that a simple course can help public defenders improve their communication skills and better fulfill their Rule 1.14 ethical obligations to “maintain a normal client-lawyer relationship with the client”¹⁵⁴ as far as “reasonably possible.”¹⁵⁵ That said, there are possible barriers and drawbacks that should be taken into consideration.

For example, some public defenders may not recognize the value of the course and will perceive it as simply another requirement to fit into their busy schedules. As discussed above, public defenders struggle with overwhelming caseloads¹⁵⁶ and may believe they do not have the

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

¹⁵⁴ *Rule 1.14: Client with Diminished Capacity*, A.B.A., http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_1_14_client_with_diminished_capacity.html (last visited Feb. 21, 2018).

¹⁵⁵ *Id.*

¹⁵⁶ FAROLE, JR., *supra* note 7.

time to take the class. Similarly, supervisors of public defenders may not be receptive to the idea of carving out time for the class for each of the defenders. In addition, public defenders may not recognize the need for the course. Depending on each defender's experience, the attorney may believe she already possesses the skills needed to recognize clients with mental health issues and to adequately work with these individuals. There will also be an administrative burden imposed on public defender offices since they will need to keep records of which attorneys have taken the class and subsequent refresher courses. Finally, there is also a funding concern. As discussed above, public defender services are in the midst of a funding crisis.¹⁵⁷ Offices may be unable to pay the fee required to take the course.

To overcome these burdens, the value and potential benefits of the course will need to be clear to administrators, supervisors, and public defenders. This can be done by providing data from other organizations utilizing similar courses and by hearing testimonials and positive first-hand accounts from past participants. For those defenders who believe they already possess the tools to recognize mental health illness in their clients, a mental health first aid course can serve as a useful refresher course.¹⁵⁸ While there may be an added administrative burden and slight cost, these administrative burdens need to be weighed against the benefit that public defenders will receive. Hopefully, most jurisdictions will see that providing public defenders with the tools needed to successfully fulfill their Rule 1.14 ethical obligations outweighs the burdens imposed.

V. Conclusion

Client Warner is one of fifteen clients waiting to be seen by Attorney Stevens. Court starts in thirty minutes, so Attorney Stevens' patience is thin as he works quickly to get through his list of clients waiting to see him. Client Warner struggles with anger management and other mental health issues. Within minutes of entering Attorney Stevens' office, communication breaks down as Client Warner unleashes his frustration

¹⁵⁷ LEFSTEIN, *supra* note 8, at 20.

¹⁵⁸ MENTAL HEALTH FIRST AID USA, *supra* note 128.

about his case onto his attorney, threatening to fire him and return to a life of violence. In response, Attorney Stevens remains calm and attempts to de-escalate the situation. He speaks slowly, confidently, and in a caring tone of voice as he tells Client Warner to calm down. He stops shuffling the papers on his desk as he remembers that he should avoid projecting nervous behavior. He redirects the conversation until Client Warner is sufficiently calm, at which point they are then able to finish the meeting productively. When they see each other in court, they both feel confident in what will be presented to the judge and are ready for the hearing to begin.

After meeting with Client Warner, Attorney Stevens heads down to lock-up where he sees Client Brown asleep in her cell after being picked up overnight in a prostitution sting. Attorney Stevens needs to interview her and ten other clients before heading up to court in fifteen minutes where he will argue their bonds. Client Brown is suffering from heroin withdrawals and is not providing coherent answers to Attorney Stevens' questions. Attorney Stevens reminds himself to slow down and be respectful to Client Brown. He then focuses on using simple, clear language in an effort to make things easier for her to understand. Attorney Stevens takes the time to calmly repeat his questions several times, which seems to help because Client Brown becomes more responsive. Once he has the information he needs, Attorney Stevens moves on to his next client feeling confident that he has enough information to make a successful bond argument for Client Brown.

Public defenders operate in an extremely challenging environment. While the call is a noble one, finding its genesis in the wake of *Gideon*

v. Wainwright,¹⁵⁹ the attorneys who answer and dedicate their careers to representing indigent clients face seemingly insurmountable obstacles to providing quality representation.

In particular, public defenders face overwhelming caseloads, inadequate funding, and a high number of clients suffering from mental illness. When clients have severe mental illness, attorneys will likely recognize the client's condition and will seek social services or competency hearings for their clients. On the other hand, when a client's mental illness presents itself in a milder form, it may be difficult for the attorney to recognize even though it still interferes with the attorney-client relationship.

Poor communication and a lack of trust are the result, leaving the attorney feeling frustrated and impatient. With little time and few resources to assist them in these cases, public defenders are left to struggle as best they can. Unfortunately, the result is that it can be next to impossible for public defenders to fulfill their ethical obligation under Rule 1.14.

Keeping in mind the limited resources available to public defender services in remedying this problem, a possible solution to assist public defenders in better fulfilling their Rule 1.14 obligations is to require them to participate in a mental health first aid course geared toward the unique challenges presented by their job. A mental health first aid course tailored for public defenders would give them the skills they need to communicate more effectively with clients who suffer from mental illness.

While there are some barriers to implementing this type of program and further research is needed, the potential benefits likely outweigh the potential burdens. Mental health first aid is relatively new, but the preliminary results, both quantitative evidence and personal testimonies, are promising. As the mental health first aid movement gains traction and recognition among lawmakers, employers, and community members, public defender offices around the country should take notice and consider taking advantage of its benefits as a way to give these attorneys the tools they need to do their job effectively and ethically.

¹⁵⁹ *Gideon v. Wainwright*, 372 U.S. 335 (1963).

SELLING SEX: THE COSTS OF CRIMINALIZATION

Candace N. Hill

I. Introduction	132
II. History of Prostitution in the United States.....	136
A. Prostitution in Early America	136
B. Early Efforts to Punish Women Engaged in Prostitution .	137
C. Criminalization	138
III. Health Implications of Criminalization	139
A. Violence.....	139
B. Drug Abuse.....	140
C. Psychological Health	141
IV. Financial and Other Implications of Criminalization	143
V. Existing Models.....	144
A. Models for Legalized Prostitution	144
1. The Swedish Model	144
2. Nevada’s Brothel System.....	146
3. The Dutch Model	148
4. The New Zealand Model.....	149
B. Other Ways of Handling Prostitution	151
1. Seattle’s LEAD Program	151
2. Texas’ STAR Program.....	153
3. Baltimore City’s SPD Program.....	153
VI. Discussion.....	154
VII. Conclusion.....	156

I. Introduction

Georgina Spelvin, originally Shelley Bob Graham, is no stranger to the business of selling sex.¹ As a young adult in the 1950s, Spelvin was paid to dance in the chorus of Dallas State Fair Musicals, the Latin Quarter supper club, and finally in the chorus of the Broadway musical *Pajama Game*.² Spelvin's greatest work came in the early 1970s, during the height of the pornographic film industry in the United States, as the character of Miss Jones in Gerard Domiano's adult film, *The Devil in Miss Jones*.³ The film went on to become one of the most widely known and celebrated films in the history of pornographic cinema.⁴ Although it was also Spelvin's most well-known foray into the industry, it was not her only experience with sex work.⁵

Spelvin contributed the story of her first, and only, expedition into the world of prostitution to an anthology of stories about the lives of various sex workers released in 2009.⁶ In her contribution, Spelvin discusses her own financial issues as well as her inability to find work in the more "legitimate" field of pornographic film after the success of *The Devil in Miss Jones* because she was considered too old for that profession.⁷ Spelvin's description of her experience with prostitution was somewhat uneventful. She had another woman with experience in the industry book her appointments.⁸ She was considered something of a "Boutique item" as a result of her former work in the porn industry, was able to make a little money towards her rent, and the "Johns"⁹ that she encountered were not unpleasant towards her.¹⁰ Nonetheless, Spelvin determined after one day that prostitution was not for her.¹¹ She did, however, make clear that she "hold[s] the firm belief that prostitution

¹ *Bio*, GEORGINA SPELVIN STAR OF THE DEVIL IN MISS JONES, <http://georgiespelvin.com/page10/page10.html> (last visited Feb. 25, 2018).

² *Id.*

³ *Id.*

⁴ *See id.*

⁵ DAVID HENRY STERRY ET AL., *HOS, HOOKERS, CALL GIRLS AND RENT BOYS: PROFESSIONAL WRITING ON LIFE, LOVE, MONEY AND SEX* 38 (David Henry Sterry & R.J. Martin, Jr. eds., Soft Skull Press 2009).

⁶ *Id.* at 41-43.

⁷ *Id.* at 41.

⁸ *Id.* at 42.

⁹ *Id.* at 42-43. "Johns" refers to the men who procure, or purchase, services from prostitutes. *Id.*

¹⁰ *Id.* at 43.

¹¹ *Id.*

should not only be legal, but deserves some respect for its ineradicable place in society. The ‘working girl’ who makes a proper business of her business is as deserving of success as an entrepreneur.”¹²

Georgina Spelvin’s experience with prostitution is not universal. Many women who have engaged in prostitution have had different experiences and, as a result, feel differently about legalization and decriminalization efforts. Still, Spelvin’s instinct that legalization or decriminalization would be beneficial to women engaged in this work has substantial support within the industry. For example, organizations like the Sex Worker’s Outreach Project have shown support for the legalization of prostitution.¹³

Discussions of prostitution in the United States have often been hindered by strict adherence to a singular narrative. Prostitution is linked heavily with moral depravity, drug use, disease, human trafficking, and the exploitation and abuse of women.¹⁴ Women who engage in prostitution are often deemed victims of violence and coercion.¹⁵ This narrative, which is complicated by the nation’s almost universal insistence on prosecuting the women engaged in prostitution,¹⁶ ignores the fact that prostitutes in the United States are often willing participants in the work that they do.¹⁷ While many women who engage in prostitution are indeed victims of male violence,¹⁸ characterizing all women as victims is overly inclusive and ignores diverse points of view amongst the women themselves.

The victimization narrative also ignores how criminalization contributes to the harms that are often associated with prostitution. Nina Hartley, a well-known porn star and sex worker’s rights activist, insists

¹² *Id.*

¹³ Andrew Breiner, *These 3 Graphs Could Change Your Mind About Legalizing Sex Work*, THINKPROGRESS (July 31, 2015, 6:01 PM), <https://thinkprogress.org/these-3-graphs-could-change-your-mind-about-legalizing-sex-work-346ea00c8037#.ieg1vdr1c>; see also Liva Gershon, *What Sex Workers Want*, BOSTON MAGAZINE (Nov. 24, 2015, 2:52 PM), www.bostonmagazine.com/news/blog/2015/11/24/sex-workers/.

¹⁴ See Naima Karp, *Exposing the Top 11 Stereotypes of Sex Workers*, PUCKER MOB, <https://web.archive.org/web/20160617224855/www.puckermob.com/lifestyle/exposing-the-top-12-stereotypes-about-sex-workers> (last visited Feb. 25, 2018).

¹⁵ *Id.*

¹⁶ *US Federal and State Prostitution Laws and Related Punishments*, PROCON.ORG (July 14, 2016, 9:44 PM), <https://prostitution.procon.org/view.resource.php?resourceID=000119>.

¹⁷ STERRY ET AL., *supra* note 5 at 41–42.

¹⁸ See Melissa Farley & Howard Barkan, *Prostitution, Violence, and Posttraumatic Stress Disorder*, 27(3) WOMEN AND HEALTH 37, 40–41 (1998), <http://www.prostitutionresearch.com/Farley%26Barkan%201998.pdf>.

that “the negative effects of sex work come from society’s judgments and prejudices.”¹⁹ It is not difficult to see how criminalization²⁰ contributes to those judgments and prejudices.²¹

Whatever the reason a particular woman chooses to engage in prostitution in the United States, that choice is accompanied by a range of issues specific to the industry. Stigmatization, as well as the lack of access to health care and the criminal justice system, makes women engaged in prostitution particularly susceptible to untreated drug issues, mental health disorders, and other health issues, including physical and mental abuse. This note will discuss how these issues are affecting women engaged in prostitution and explain how criminalization is a contributing factor in perpetuating these problems. This note will further explain how current models of legalization and decriminalization have both succeeded and failed to address these issues. This note will conclude with an alternative to the current models for prostitution laws, as well as an explanation for how that alternative would benefit the health care needs of women engaged in prostitution. The conclusion will also offer a suggestion for how to fund health related services for women who are engaged in prostitution in a way that makes better use of tax payer funds.

The discussions in this note will be limited to a particular subset of individuals who are engaged in prostitution. Specifically, this note will focus on the health issues of women who are consensual participants in prostitution. While the importance of, and need for, meaningful discussion of human trafficking in the United States is undeniable, the particular issues associated with trafficked women are beyond the scope of this note. Additionally, while a certain percentage of prostitutes in the United States are men,²² they too are beyond the scope of this note.

Any meaningful conversation about the legalization of prostitution in the United States requires an acknowledgment that prostitution has not always been considered a criminal offense in the United States.²³ In

¹⁹ STERRY ET AL., *supra* note 5, at 221-222.

²⁰ Criminalization refers to the act of making something illegal, turning something into criminal conduct, or a person into a criminal. *Criminalize*, MERIAM-WEBSTER (11th ed. 2003).

²¹ TREENA ORCHARD, TIAN TIAN ZHENG & SUSAN DEWEY, SEX WORKERS AND CRIMINALIZATION IN NORTH AMERICA AND CHINA ETHICAL AND LEGAL ISSUES IN EXCLUSIONARY REGIMES 3 (Springer International Publishing 2016).

²² *Prostitution in the United States-The Statistics*, PROSTITUTION EDUCATION NETWORK, <http://www.bayswan.org/stats.html> (last visited Feb. 25, 2018).

²³ Melissa Gira Grant, *When Prostitution Wasn't a Crime: The Fascinating History of Sex*

fact, anti-prostitution laws are relatively new developments, first appearing in the 20th century.²⁴ Part II of this note will provide a short history of prostitution and prostitution laws, allowing for a more informed understanding of the historical, social, and political policies and justifications behind the current system.

Part III will discuss specific health issues that disproportionately impact women who are engaged in prostitution in the United States. The link between criminalization and both physical and mental abuse will be discussed, as well as how the stress of stigmatization has contributed to the link between drug abuse and poor mental health with prostitution. Most importantly, the impact criminalization has on the ability of women who engage in prostitution to both seek healthcare and gain access to the criminal justice system will be demonstrated and explained.

Part IV will discuss the financial costs of criminalizing prostitution. A lone study conducted in the 1980s remains the only large scale exploration of the costs of prostitution in the United States.²⁵ The results of that study indicated that the monetary costs of criminalization to taxpayers were staggering.²⁶ Smaller scale studies in various places across the United States indicate that monetary costs on taxpayers have not improved since the 1980s. This section will also provide some discussion on the non-monetary costs to the general public of criminalization of prostitution.

Part V will focus on current models of prostitution legalization and decriminalization from around the world. The Swedish model, currently the most celebrated model²⁷ for prostitution laws in the world, because of its focus on protecting women while still condemning the purchase of a prostitute's services,²⁸ will be discussed in depth to reveal where the model has both succeeded and failed to address the needs of women who engage in prostitution. The current model being utilized in Nevada will also be discussed, along with several other well-known models from

Work in America, ALTERNET (Feb. 18, 2013, 9:43 AM), <http://www.alternet.org/news-amp-politics/when-prostitution-wasnt-crime-fascinating-history-sex-work-america>.

²⁴ *Id.*

²⁵ See Julie Pearl, *The Highest Paying Customers: America's Cities and the Costs of Prostitution Control*, 38 HASTINGS L. J. 769 (1986).

²⁶ *Id.* at 769.

²⁷ Michelle Goldberg, *Swedish Prostitution Law is Spreading Worldwide – Here's How to Improve It*, THE GUARDIAN (Aug. 8, 2014), <https://www.theguardian.com/commentisfree/2014/aug/08/criminalise-buying-not-selling-sex>.

²⁸ *Id.*

around the world. Part V will also discuss diversionary programs,²⁹ which have become popular for handling drug offenses in the United States, and how these programs have been applied to prostitution offenses.

Part VI will discuss the differing viewpoints about legalization, the identity of the prostitute, and the competing suggestions for shaping prostitution laws and regulations in the future. Finally, Part VII will include suggestions for state, federal, or municipal legislation moving forward.

II. *History of Prostitution in the United States*

A. *Prostitution in Early America*

In 1721, there were fewer than 700 free men living in what would later become the state of Louisiana.³⁰ In an effort to prevent these men from engaging in relationships with the Native American women in the area, the French government sent eighty women by ship to the colony in the hopes that these women would marry the male colonists.³¹ These women were chosen from prisons across France, most of them having served time for the offense of prostitution.³² When these women arrived in the colony, most began to take up prostitution again, finding that it paid more than being married to one of the men that inhabited the colony.³³ These men would have to wait for different women to arrive if they wanted wives.³⁴

This was largely the story of prostitution in the early days of the colonies and then the United States. Women arrived from all over the world to work in American brothels and streets, selling sex to the overabundance of men who occupied the land at that time.³⁵ California, especially during the gold rush, was filled with women working in parlors,

²⁹ See *Pretrial Diversion Programs in Connecticut*, OFFICE OF GOVERNMENTAL ACCOUNTABILITY (Jan. 25, 2007, 9:43 PM), <http://www.ct.gov/ova/cwp/view.asp?a=2661&q=321094> (providing an overview of what kinds of diversion programs are offered in one state, who those programs are for, and what they consist of).

³⁰ Grant, *supra* note 23.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

dives, and gambling houses.³⁶ In 1933, one journalist, Herbert Asbury, stated that “[i]t has been said that by the end of 1852, there was no country in the world that was not represented in San Francisco by at least one prostitute.”³⁷

The largest red light district in the United States appeared in New Orleans in 1897.³⁸ The red light districts, which centralized the sale of prostitution into a single area of the city, allowed the working women to develop more formal governance structures.³⁹ Consisting mainly of brothels, the red light districts provided women with safer working environments.⁴⁰ They also provided a range of employment opportunities for non-prostitutes in maintenance and as performers.⁴¹

Particularly striking about this time period was the lack of regulation surrounding prostitution. Women in many cases were able to run their own businesses with little intervention from the legal system.⁴² This freedom, however, was not to remain a permanent part of the story of prostitution in the United States.

B. Early Efforts to Punish Women Engaged in Prostitution

Prior to criminalization, there were some efforts on behalf of law enforcement and government officials to both control and punish women who were engaged in prostitution. Even though their particular way of earning money was legal, these women were still viewed as social outcasts.⁴³ These women were viewed as immoral because they had sex outside of marriage, they were economically independent, and they lived without the control of men.⁴⁴ This made them targets for police harassment.⁴⁵

Many of these women were charged with crimes that, while not

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

technically punishing the act of selling sex, were designed to punish certain behaviors that were associated with the act of selling sex.⁴⁶ For example, many cities and states adopted vagrancy laws that punished people for being in public at restricted hours of the night.⁴⁷ Most charges made against these women were intended to keep them off the streets and out of the public eye rather than to actually keep them from engaging in prostitution. Notably, because prostitution was legal, these women were more likely to challenge their charges and were more successful at securing their own release from prison.⁴⁸

C. Criminalization

The 20th century saw a rise in efforts to end prostitution nationwide. Social reformers took up the cause of reframing prostitution as a “social disease” in and of itself.⁴⁹ New policies were adopted that sought to obstruct and end the red light districts.⁵⁰ These laws targeted brothels by making owners criminally liable for prostitution on their property.⁵¹ By 1916, at least forty-seven cities had closed their red light districts.⁵² The start of the First World War brought new laws targeting prostitution near military bases.⁵³ These laws, a direct response to the growing public view of prostitution as inherently dirty, proposed to protect military men from sexually transmitted infections.⁵⁴

Much of the push for eliminating prostitution in the United States came from early women’s rights activists who viewed prostitution as degrading and harmful for women.⁵⁵ Notably, some of the strongest opposition to criminalization efforts came from the prostitutes themselves.⁵⁶ In a group letter sent to the New York Evening Journal, Washington D.C.-area prostitutes wrote:

Knowing that public opinion is against us, and that the passing of

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *See id.*

⁵⁶ *Id.*

the Kenyon 'red Light' Bill is certain, we, the inmates of the underworld, want to know how the public expects to provide for us in the future? We don't want 'homes.' All we ask is that positions be provided for us. The majority will accept them. We must live somehow. We are human."⁵⁷

It is clear that these women could see problems with the public's call for the end of their trade. Without other options, how would these women provide for themselves?

Anti-prostitution legislation passed,⁵⁸ but it did not succeed in ending prostitution. Instead, it created a more dangerous work environment and additional health hazards for women engaged in prostitution.⁵⁹

III. *Health Implications of Criminalization*

Prostitution has always been a dangerous profession for women.⁶⁰ Unfortunately, it seems as if the hazards of being a sex worker have increased overtime, despite increasing social awareness and lessened stigma.⁶¹ Women who engage in prostitution suffer from a range of issues, from physical and mental abuse by clients, to issues with access, and willingness to access, health care.⁶² These issues are aggravated as a result of criminalization.⁶³

A. *Violence*

One of the issues impacting the health of women engaged in prostitution is violence. One study that included questionnaires and interviews with women who engaged in prostitution in San Francisco revealed that 82% of women who responded had been physically assaulted.⁶⁴ Of those women, 55% reported that they had been assaulted by customers⁶⁵ and 8% reported that their attacks resulted in serious

⁵⁷ *Id.*; see generally William Leavitt Stoddard, *Red Lights of Washington D.C.*, PEARSON'S MAGAZINE, Feb. 1914, 233, at 234.

⁵⁸ Grant, *supra* note 23.

⁵⁹ See Manpreet Abrol, *The Criminalization of Prostitution: Putting Women's Lives at Risk*, 3 THE J. OF HIST. STUD. 1, 1 (2014), <http://jps.library.utoronto.ca/index.php/prandium/article/viewFile/21843/17744>.

⁶⁰ *Id.*

⁶¹ *Id.* at 3, 6-7, 9.

⁶² *Id.* at 9.

⁶³ *Id.*

⁶⁴ Farley, *supra* note 18, at 40.

⁶⁵ *Id.* at 40-41.

physical injury, such as knife and gunshot wounds.⁶⁶

Equally terrifying is the prevalence of sexual assault amongst these women, with 68% reporting having been raped since entering into prostitution.⁶⁷ Among those women, many reported having been raped more than five times.⁶⁸ Many women reported incidents where customers recorded their interactions without permission.⁶⁹

Homicide rates among women who engage in prostitution tend to be higher than among women not engaged in prostitution. One study conducted in Colorado Springs, Colorado showed that between 1967 and 1999 the mortality rate of homicide for women who engaged in prostitution was 229 out of every 100,000 active prostitutes.⁷⁰ This rate was 17.7% higher than the standardized mortality rate for non-prostituting women.⁷¹

There are indications that decriminalization or legalization of prostitution could have positive effects on these numbers. Women who are engaged in prostitution in a system that criminalizes their actions are less likely to seek the assistance of police when they are assaulted or victimized.⁷² Their status as prostitutes exposes them to the possibility of prosecution if they draw attention to their work. It is unlikely that women will risk being arrested to make a complaint to the police.⁷³ Criminalization also means that these women are limited to unsafe working conditions. Without legal status, these women are not able to conduct their business in a way that would prevent abuse.

B. Drug Abuse

Prostitution is often associated with drug use – many stereotypes suggest that women who engage in prostitution do so to fund their drug habits.⁷⁴ In reality, the link between prostitution and drug use is much

⁶⁶ *Id.* at 41.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ John J. Potterat et al., *Mortality in a Long-term Open Cohort of Prostitute Women*, 159 AM. J. OF EPIDEMIOLOGY 778, 778 (Apr. 15, 2004), <http://aje.oxfordjournals.org/content/159/8/778.full>; see Abrol, *supra* note 59, at 2 (discussing the mortality rate among prostitutes in Canada).

⁷¹ Potterat, *supra* note 70.

⁷² Valeriya Metla, *Prostitution: Should it be Legalized or Criminalized?*, LAW STREET (Feb. 25, 2015), <http://lawstreetmedia.com/issues/law-and-politics/prostitution-legalized-criminalized/>.

⁷³ *Id.*

⁷⁴ Stefania Morozini, *The Real Link Between Drug Use and Sex Work*, TALKING DRUGS

more complex.⁷⁵ One study conducted in Portland, Oregon showed that while many prostitutes were addicted to drugs prior to their first experience with prostitution, it was equally likely that a woman would become addicted to drugs as a consequence of her work as a prostitute.⁷⁶ A separate study conducted in Connecticut demonstrated that many prostitutes⁷⁷ begin using drugs to escape from the difficulties of the industry, such as abuse from clients.⁷⁸ Criminal laws against prostitution contribute to this by making it more difficult for prostitutes to seek assistance when there is abuse and by perpetuating negative stereotypes about prostitutes by criminalizing their conduct.

C. Psychological Health

Opponents of prostitution legalization often focus on the psychological state of women who are engaged in prostitution. One study found that 88% of 315 prostitutes surveyed in Canada, Colombia, and Mexico in 2003, described verbal assaults being prevalent throughout the trade.⁷⁹ The frequency of rape and other abuses causes many prostitutes to suffer from posttraumatic stress disorder (PTSD).⁸⁰ One study found a PTSD prevalence rate of 68% among prostitutes from nine countries.⁸¹ A separate study conducted in 2008 found that 52.9% of the 278 street-based Miami prostitutes who were examined had symptoms of moderate to severe depression.⁸²

Other psychological problems that have been found amongst women who engage in prostitution are sexual dysfunction and disassociation.⁸³ Some women have lost the ability to view their chosen sexual

(Dec. 3, 2011), <http://www.talkingdrugs.org/drug-use-and-sex-work-what-is-the-real-link-between-them>.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ The survey in question was careful to highlight that drug use as escapism is not unique to prostitutes. Morozini, *supra* note 74. There are women and men in all careers who rely on drugs as a coping mechanism. *Id.* The correlation between prostitution and drug addiction is not causal. *Id.*

⁷⁸ *Id.*

⁷⁹ Melissa Farley, "Bad for the Body, Bad for the Heart": Prostitution Harms Women Even if Legalized or Decriminalized, 10 VIOLENCE AGAINST WOMEN 1087, 1104 (2004).

⁸⁰ *Id.*

⁸¹ *Id.* at 1105.

⁸² Hilary L. Surratt et al., *The Connections of Mental Health Problems, Violent Life Experiences, and the Social Milieu of the "Stroll" with the HIV Risk Behaviors of Female Street Workers*, 17 J. OF PSYCHOL. AND HUM. SEXUALITY 23, 23-4 (2008).

⁸³ Farley, *supra* note 79, at 1105.

partners separately from the “johns” that they have worked for, leading to an inability to experience normal human relationships.⁸⁴ Other women reported feeling disconnected from their own bodies, and being unable to view themselves as more than a product.⁸⁵

Other studies examining the mental health of sex workers found that there is little to no difference between the psychological condition of prostitutes and non-prostituting women. One study was conducted using surveys of prostitutes and non-prostituting women in New Zealand.⁸⁶ Both sets of women were asked to reflect on their experiences with their work.⁸⁷ The study found no statistical difference between levels of relationship satisfaction expressed by the women in both groups.⁸⁸ The study also found no statistical difference between the self-esteem reported by prostituting and non-prostituting women.⁸⁹ Overall, the study concluded that women who engage in prostitution are not guaranteed to have mental health outcomes substantially different from women who engage in other trades.⁹⁰

A separate study conducted in the early 2000s sought to analyze the level of emotional exhaustion faced by active prostitutes.⁹¹ This study surveyed women engaged in prostitution as well as women engaged in high stress healthcare professions, such as nursing.⁹² The study indicated that the level of emotional exhaustion suffered by prostitutes did not differ significantly from that experienced by women in the healthcare professions.⁹³

While it is possible that there is a connection between prostitution and poor mental health, that is not itself a reason for criminalizing prostitution. There is the possibility that many women have mental health issues prior to the decision to engage in prostitution, which is a problem entirely separate from the issue of prostitution itself.⁹⁴ Also, if women

⁸⁴ *Id.*

⁸⁵ *Id.* at 1106.

⁸⁶ Sarah E. Romans et al., *The mental and physical health of female sex workers: A comparative study*, 35 AUSTRALIAN AND N.Z. J. OF PSYCHIATRY 75 (2001).

⁸⁷ *Id.*

⁸⁸ *Id.* at 77.

⁸⁹ *Id.* at 78.

⁹⁰ *Id.* at 79-80.

⁹¹ Ine Vanwesenbeeck, *Burnout Among Female Indoor Sex Workers*, 34 ARCHIVES OF SEXUAL BEHAVIOR 627 (2006).

⁹² *Id.*

⁹³ *Id.* at 633.

⁹⁴ If there are women who are entering prostitution as a result of the barriers that mental

who develop mental health issues after engaging in prostitution do so because of the prevalence of abuse within the trade, that is a valid reason for legalizing or decriminalizing the profession so that these women will have recourse when abuses occur or will be able to conduct their business in a way that makes abuse less common.

IV. Financial and Other Implications of Criminalization

While the main issue with the criminalization of prostitution is its impact on women actually engaged in prostitution, criminalization also carries consequences for the general public. In 2006, there were an estimated 79,700 individuals in the United States arrested on charges of prostitution.⁹⁵ That number has decreased slightly each year since 2016, with an estimated 56,600 arrests made for prostitution in 2012.⁹⁶ These numbers have financial consequences for tax payers whose money is used to fund the monitoring, arrest, and prosecution of individuals who are engaged in prostitution.⁹⁷

There have been few studies conducted on the financial costs of prostitution criminalization in the United States. One study conducted in 1985 included a “detailed cost analyses for sixteen of the nation’s largest cities.”⁹⁸ The study concluded that those sixteen cities spent an average of \$7.5 million enforcing prostitution laws.⁹⁹ This was more than half of what the cities spent on either education or public healthcare.¹⁰⁰ One of the cities, Dallas, Texas, spent over \$10 million on prostitution control that year.¹⁰¹

While large scale studies on the financial cost of anti-prostitution laws are scarce, there are some reports for individual jurisdictions. In 2011, Texas spent roughly \$8 million on enforcing the state’s strict anti-prostitution laws.¹⁰² Harris County, in Texas, spent \$2.3 million alone

health problems create in seeking employment, there is an issue of access to mental health care and resources that would allow these women to have other options beyond prostitution.

⁹⁵ *Estimated arrests of all persons in the United States*, EASY ACCESS TO FBI ARREST STATISTICS: 1994-2012, https://www.ojjdp.gov/ojstatbb/ezaucr/asp/ucr_display.asp (last visited Feb. 25, 2018).

⁹⁶ *Id.*

⁹⁷ Pearl, *supra* note 25, at 769.

⁹⁸ *Id.* at 772.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 769.

¹⁰² Mark Lisher, *Strict Texas Prostitution Laws Cost Taxpayers \$8 Million a Year*, TX. WATCHDOG (Jan. 28, 2011), <http://www.texaswatchdog.org/2011/01/strict-texas-prostitution->

on housing, care, and food for individuals arrested for prostitution per year.¹⁰³ The costs amounted to slightly less than \$50 per person held on prostitution charges.¹⁰⁴

Financial costs are not the only losses suffered by taxpayers as a result of the criminalization of prostitution. Enforcement of anti-prostitution laws requires the efforts of law enforcement. If police officers are preoccupied investigating and arresting individuals for prostitution, there is less time reserved for the investigation of violent crimes. In 1985, prostitution arrests cost taxpayers “300 hours daily, or 2,170 hours weekly, of precious police man-hours.”¹⁰⁵ Of a reported 15,000 violent crimes in that year, only 2,665 resulted in arrests.¹⁰⁶ In comparison, there were 7280 prostitution arrests made in that year.¹⁰⁷

V. *Existing Models*

Legalization and decriminalization efforts have been made in other countries, as well as in individual jurisdictions within the United States. Some of these efforts have been, in some ways, successful at protecting and empowering the women engaged in prostitution. Some efforts have created new risks for these women, as well as patronized them. The successes and failures of existing programs can, and should, be analyzed for the purpose of developing new policies that would reflect the needs of the women that they impact in addition to the needs of the general public.

A. *Models for Legalized Prostitution*

1. *The Swedish Model*

In 1999, Sweden overhauled its existing prostitution laws with the passing of the Sex Purchase Law.¹⁰⁸ At the time, this law was revolutionary in that it decriminalized prostitution.¹⁰⁹ Women who engage in prostitution in Sweden are now offered a range of services, such as drug

laws-cost-taxpayers-8-million-a/1296228148.column.

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ Pearl, *supra* note 25, at 769.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ Kelsey Fleharty, *Targeting the Tricks of the Trade: A Comparative Analysis of Prostitution Laws in Sweden and the United States*, 15 OR. REV. INT’L L. 443, 445 (2013).

¹⁰⁹ Goldberg, *supra* note 27.

treatment and career planning.¹¹⁰ However, Sweden's Sex Purchase Law is not without some element of criminalization. Men who purchase sex can be held criminally liable if they are caught doing so.¹¹¹

The rationale behind Sweden's prostitution model is simple. The Sex Purchase Law is premised on the notion "that a legalized sex trade is fundamentally irreconcilable with gender equality and that legalization leads to undesirable consequences."¹¹² The law relies on the theory that prostitutes are "victims of male violence" and that the belief that these women can engage in prostitution willingly is based on an illusion of autonomy.¹¹³ The Swedish government determined that, if prostitutes are to be viewed as the victims of sexual violence, it is inconsistent with that narrative to continue prosecuting them.¹¹⁴

What the Swedish Sex Purchase Law does is remove the fear of prosecution from the prostitute's daily life, but it does not go far enough to optimize conditions for these women. Many women who are engaged in prostitution in Sweden argue that Sweden's new laws have only succeeded in pushing prostitution further underground.¹¹⁵ Men who purchase sex, because of fear of arrest and prosecution, now insist that these encounters happen in more secluded areas where violence is more likely to occur.¹¹⁶ Prostitutes in Sweden also reported a change in their client base.¹¹⁷ The ideal clients, well-off family men, were less likely to seek out prostitutes, increasing the risk that any particular client the prostitute had would be more aggressive.¹¹⁸

Another argument against the Swedish model for prostitution legislation is that it severely restricts the autonomy of those women that engage in prostitution willingly. Supporters of the Swedish model argue that "[p]rostitutes are not independent actors but rather victims of a society that forces women to submit their bodies to male domination under the pretense of basic economic theory."¹¹⁹ While it cannot be denied that

¹¹⁰ Fleharty, *supra* note 108, at 447.

¹¹¹ *Id.* at 446.

¹¹² *Id.* at 447.

¹¹³ *Id.* at 448.

¹¹⁴ *Id.* at 447.

¹¹⁵ *Id.* at 451; *see also* Breiner, *supra* note 13.

¹¹⁶ Fleharty, *supra* note 108, at 451.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.* at 453.

there are many prostitutes who are victims of male coercion and domination, the fact that there are prostitutes willing to stand in opposition to this characterization of prostitution demonstrates that not all prostitutes fall within this narrative of victimization.¹²⁰

Pye Jacobson, a Swedish sex worker, has argued that “[t]here are a lot of occupations that we take because we need to survive” but that does not make prostitutes victims.¹²¹ Jacobson argues that in many ways the Swedish legislation has worked to hurt prostitutes.¹²² Not only has the legislation resulted in more dangerous working conditions overall, it has also led to an increase in stigmatization.¹²³ Jacobson says that “you are a victim until you say that this is not a problem for me, and if you insist on working, and insist on continuing doing this, then you are ‘bad’ and will be punished.”¹²⁴ Jacobson indicates that the stereotypes placed on prostitutes and their clients have had a negative impact on those individuals’ mental health.¹²⁵ She states that “[t]he more stereotyped that you are, the more dehumanized that you are.”¹²⁶

While supporters of the Swedish model of prostitution legislation have ignored the concerns of prostitutes while arguing in support of that legislation, it is arguable that ignoring the concerns of the Swedish Sex Purchase Law’s target population is a form of victimization in itself. Legislatures should take into consideration the concerns of the population that they seek to regulate, because that population has a deeper understanding of the issues involved. To seek to protect women who are engaged in prostitution while ignoring the voices and the concerns of women that you seek to protect, appears misguided and patronizing as well as inconsistent with Sweden’s stated goal of gender equality.¹²⁷

2. Nevada’s Brothel System

Nevada provides a model for prostitution legalization and regulation.¹²⁸ Brothels are only permitted in counties with a population of less

¹²⁰ *Id.* at 452-3.

¹²¹ ALIYA, *Sweden: “We Want to Save You. And if You Don’t Appreciate It, We Will Punish You!”*, SEX WORKERS’ RIGHTS ADVOC. NETWORK (June 22, 2009), <http://swannet.org/node/1512>.

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ Fleharty, *supra* note 108, at 447.

¹²⁸ Nev. Rev. Stat. Ann. § 201.354.

than 400,000 people.¹²⁹ The women who are employed as prostitutes must be twenty-one years old in most counties, and eighteen in a minority of counties.¹³⁰ In 2015, there were around 500 prostitutes working in thirty brothels across Nevada.¹³¹

A recent study of these brothels indicated favorable results for the women who lived and worked in them. Among the surveyed workers, 84% felt that their jobs were safe.¹³² They also indicated that they were “free to come and go, and [were] bound only by their contract.”¹³³ These workers indicated that the reason they felt safe working in these brothels is that “the police, employers and co-workers were there to protect them.”¹³⁴ This study also revealed no evidence of trafficking in Nevada’s legal brothels.¹³⁵

There is a lot that Nevada’s model for prostitution legislation does right. Women in these brothels are afforded a level of safety and security that other women engaged in prostitution are not. With that said, Nevada’s system is not without its flaws. Because prostitution is limited only to areas with fewer than 400,000 people, the opportunity for women who wish to enter into legal sex work to find employment in a brothel is limited. Women who are not able to enter into work in one of these legal brothels often resort to street-prostitution, which is not legal in Nevada.¹³⁶ This involves all of the typical risks associated with prostitution, including the risk of prosecution. Nevada has made street-prostitution a misdemeanor criminal offense, thereby separating prostitutes into two categories: (1) those that are legally employed as sex workers and (2) those that are criminals.¹³⁷

¹²⁹ Vivian Giang, *Everything You Ever Wanted To Know About Prostitution in Nevada*, BUS. INSIDER (Dec. 14, 2011, 4:30 PM), <http://www.businessinsider.com/prostitution-legal-nevada-prostitutes-brothels-sex-2011-12?op=1/#x-workers-are-considered-independent-contractors-and-dont-receive-unemployment-retirement-or-health-care-benefits-11>.

¹³⁰ *Id.*

¹³¹ Metla, *supra* note 72.

¹³² Barbara G. Brents, *Nevada’s Legal Brothels Make Workers Feel Safer*, THE NEW YORK TIMES (Jan. 23, 2014), <http://www.nytimes.com/roomfordebate/2012/04/19/is-legalized-prostitution-safer/nevadas-legal-brothels-make-workers-feel-safer>.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ Giang, *supra* note 129.

¹³⁷ *Id.*

3. *The Dutch Model*

The Dutch Model for prostitution legislation is one of legalization with government regulation. Brothels were banned in the Netherlands in 1911.¹³⁸ In order to end abuses in the sex work industry, in 2011, “the Netherlands decided to change the law to reflect everyday reality.”¹³⁹ The Netherlands now issues licenses to control brothels that force business owners to ensure health and safety conditions for prostitutes.¹⁴⁰ Prostitution is considered a legitimate occupation and prostitutes are entitled to the same rights and obligations as workers in other professions.¹⁴¹ Prostitutes in these brothels must be over the age of consent and do the work voluntarily.¹⁴² The Dutch legislation allows the government to “exercise more control over the sex industry and counter abuses.”¹⁴³ There are between 3,500 and 4,000 prostitutes employed in 600-700 clubs and private brothels across the Netherlands.¹⁴⁴

Prostitutes also have the option to work for escort agencies or as self-employed workers from home.¹⁴⁵ Self-employed prostitutes must be registered and the Netherlands intends to subject all forms of commercial sex work to licensing in the future.¹⁴⁶ The Netherlands also wants to make the act of soliciting illegal prostitution an offense.¹⁴⁷ Street prostitution is allowed in ten Dutch cities, where an estimated 320 prostitutes work daily.¹⁴⁸

Prostitutes in the Netherlands receive many benefits from this system. Because prostitution is considered a legitimate trade, prostitutes are able to form their own unions.¹⁴⁹ Local authorities are able to establish

¹³⁸ *FAQ-Prostitution in the Netherlands*, RNW MEDIA, <https://www.rnw.org/archive/faq-prostitution-netherlands> (last visited Feb. 25, 2018) [hereinafter FAQ].

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ FAQ, *supra* note 138.

¹⁴⁹ *Id.*

by-laws governing safety, hygiene, and working conditions in brothels.¹⁵⁰ Brothels can also be prevented from forcing prostitutes to consume alcohol or engage in unsafe sex. Brothels can also be compelled to allow health services or interest groups unrestricted access to their premises.¹⁵¹ Pamphlets are distributed to brothel owners, as well as to prostitutes, to make them aware of the social and health services that are available to them.¹⁵² One of the greatest benefits provided by the Dutch prostitution laws is the ability to rely on law enforcement to ensure safety.¹⁵³

The Dutch model of legislation has resulted in some concerns about human trafficking and underage prostitution.¹⁵⁴ To combat this issue, the Netherlands has taken several steps to ensure that the women engaged in prostitution do so consensually and legally.¹⁵⁵ While police are generally not allowed to keep a registry of prostitutes, they are allowed to keep a temporary registry for the purpose of tracking and investigating the possibility of trafficking.¹⁵⁶ A special phone line has been established so that members of the public can anonymously report suspicious activity.¹⁵⁷ Prostitutes and clients are more likely to report suspicious activity or abuse because they are not at risk of prosecution. Brothel owners found to have employed either a minor or any person who is under coercion are subject to the loss of their license and the closing of their business.¹⁵⁸ These measures are taken to help ensure the safety of the profession, as well as to make it easier for law enforcement to track and to investigate incidents of abuse and trafficking.

4. *The New Zealand Model*

New Zealand passed The Prostitution Reform Act in 2003 to replace laws that criminalized prostitution.¹⁵⁹ The purpose of the act in-

¹⁵⁰ *Id.*; see Abrol, *supra* note 59, at 4.

¹⁵¹ FAQ, *supra* note 138.

¹⁵² *Id.*

¹⁵³ *See id.*

¹⁵⁴ *See id.*

¹⁵⁵ *See id.*

¹⁵⁶ FAQ, *supra* note 138.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ The Prostitution Reform Act (Act No. 28/2003) (N.Z.), <http://www.legislation.govt.nz/act/public/2003/0028/latest/DLM197815.html>.

cluded a framework for (1) safeguarding the human rights of sex workers, (2) promoting the welfare and the occupational health and safety of sex workers, (3) ensuring public health, (4) prohibiting the use of persons under eighteen years of age in prostitution, and (5) implementing related reforms.¹⁶⁰ New Zealand brothels require licenses and permits.¹⁶¹ They are also subject to health inspections.¹⁶² Police are utilized to ensure the safety of workers and managers.¹⁶³

The Prostitution Reform Act (PRA) resulted in the formation of the Prostitution Law Review Committee (PLRC).¹⁶⁴ This committee includes current and former government officials, members from various non-governmental organizations, and representatives from the sex worker community.¹⁶⁵ The function of this committee is to “review and critique the impact of the laws in place, and if need be, make recommendations to institute new laws and legislations which better the lives of sex workers in New Zealand.”¹⁶⁶ New Zealand has taken the approach of including the voices of prostitutes in the process of designing legislation intended to regulate and protect them.¹⁶⁷

The benefits of New Zealand’s system are major. Prostitutes can choose their own working conditions, including where they work, who they work with, and who their clients are.¹⁶⁸ Forcing prostitutes to have sex with a client, even after that client has paid, is a violation of the PRA.¹⁶⁹ Prostitutes have complete control over who they accept as clients and when they accept them.¹⁷⁰ Prostitutes are required to take steps to ensure safe sex, such as the use of condoms.¹⁷¹ Prostitutes also have access to Work and Income New Zealand, which provides financial assistance and employment services if they wish to leave the sex work industry.¹⁷² The New Zealand government is not allowed to deny them

¹⁶⁰ *Id.* at § 3.

¹⁶¹ Abrol, *supra* note 59, at 5.

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.* at 6

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *See* The Prostitution Reform Act (Act No. 28/2003) (N.Z.).

¹⁶⁹ *Id.* at § 17.

¹⁷⁰ *See id.* at § 16-17.

¹⁷¹ *Id.* at § 9.

¹⁷² *Id.*; *see also* *Work and Income*, MINISTRY OF SOCIAL DEVELOPMENT, <https://www.workandincome.govt.nz/> (last visited Feb. 25, 2018)

access to assistance because they quit their jobs or insist that they continue working as a sex worker.¹⁷³

In 2008, the PLRC conducted a report on the impact that the PRA has had on the lives of prostitutes in New Zealand.¹⁷⁴ That report concluded that “[o]n the whole, the PRA has been effective in achieving its purpose and . . . the vast majority of people involved in the sex industry are better off under the PRA than they were previously.”¹⁷⁵ The report did indicate that improvements in some areas still needed to be made and that “many sex workers were still vulnerable to exploitative employment conditions.”¹⁷⁶ The PLRC stated that “an assessment of the PRA’s impact should be undertaken at a later date to evaluate whether the [PRA] is achieving its purpose, if any unintended consequences have arisen, and if the PRA needs amendment.”¹⁷⁷ The PLRC indicated that the impact of the PRA would become clearer by 2018.¹⁷⁸

B. Other Ways of Handling Prostitution

Several American jurisdictions have begun to adopt a different way of addressing the issue of prostitution criminalization. These jurisdictions have passed legislation adopting diversionary programs for certain non-violent offenders. While this does not legalize prostitution, it provides a way for women arrested for prostitution to avoid prosecution and, in many cases, jail time. Although these programs are designed to offer help to vulnerable populations and decrease the jail population, they are not always effective at addressing the overall needs of the people.

1. Seattle’s LEAD Program

In 2011, Seattle established a pilot program known as Law Enforcement Assisted Diversion (LEAD).¹⁷⁹ This program opened a new

¹⁷³ The Prostitution Reform Act (Act No. 28/2003), § 18 (N.Z.).

¹⁷⁴ *Prostitution Law Reform in New Zealand*, NEW ZEALAND PARLIAMENT (July 10, 2012), <https://www.parliament.nz/en/pb/research-papers/document/00PLSocRP12051/prostitution-law-reform-in-new-zealand>.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Seattle LEAD’s on Law Enforcement Diversion*, COPS (Apr. 2013), https://cops.usdoj.gov/html/dispatch/04-2013/seattle_leads.asp.

avenue for police officers to handle low level drug and prostitution offenses. After a police officer makes an arrest, he has the opportunity to divert the individual to a community-based treatment program or to other support services rather than having that person jailed and prosecuted.¹⁸⁰ The officers have standards that they must follow in determining who to divert, but also are given substantial discretion.¹⁸¹ Those who enroll in LEAD¹⁸² are assigned a caseworker who helps them develop an individualized service plan.¹⁸³ This can mean anything from finding mental health treatment and drug counseling to finding suitable housing and job training.¹⁸⁴ If the individual completes the LEAD program, their charge is thrown out and they no longer face potential prosecution as a result of that charge.¹⁸⁵

A 2016 evaluation of LEAD indicated favorable results. People in LEAD were 60% less likely than the people in the control group to be rearrested within the first six months of the evaluation, and 58% less likely over the course of the entire evaluation period.¹⁸⁶ Unfortunately, the evaluation does not provide the recidivism rates for individual crimes. There is no way of knowing how many of those evaluated were originally arrested on prostitution charges.

The LEAD program is a success in that it makes social and health services available to women who are engaged in prostitution. Unfortunately, because those services are being offered only to individuals hand-picked by officers, and only as a method for avoiding jail time, this program does not go far enough in its goals of lowering recidivism and the jail population, and of assisting vulnerable populations. Many women who desire to engage in these programs will inevitably be shut out by officer discretion, while women who have no interest in leaving the sex work industry will be forced into these programs in order to avoid being prosecuted.

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.* The LEAD program is marketed as voluntary. *Id.* Those selected for the program are given the choice between participation and jail time. *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *LEAD Evaluation, LEAD LAW ENFORCEMENT ASSISTED DIVERSION* (Nov. 2016), <http://leadkingcounty.org/lead-evaluation/>.

2. *Texas' STAR Program*

Success Through Addiction Recovery (STAR) is a program established in 2003 in Texas to divert low level drug offenders and prostitutes out of the criminal justice system.¹⁸⁷ Similar to LEAD, STAR provides individualized supervision.¹⁸⁸ Individuals are referred to as clients and receive access to rehabilitative treatment facilities, social services, health care providers, and other programs.¹⁸⁹ The program focuses primarily on eliminating drug addiction, and for prostitutes to be able to take advantage of the program they must be a first offender with a documented history of drug or drug and alcohol dependency.¹⁹⁰ Prostitutes without drug addictions are excluded, as the program seems to be targeted primarily at drug addiction issues and offenses. Between 2003 and 2011 only a small number of women arrested for prostitution have qualified for the program, meaning that most arrested prostitutes faced criminal prosecution and jail sentences.¹⁹¹

3. *Baltimore City's SPD Program*

Baltimore's Specialized Prostitution Diversion (SPD) program was launched in 2009.¹⁹² Between the date that the program started and March 2011, the program accommodated 278 individuals.¹⁹³ The program was developed in response to public recognition that the revolving door of incarceration was not a solution to the issue of prostitution.¹⁹⁴ The program offers women who are arrested for prostitution, and who are not on probation or parole, the opportunity to participate in an individualized program run by social workers that are hired by the Office of

¹⁸⁷ See Lisher, *supra* note 102.

¹⁸⁸ *Overview*, HARRIS COUNTY DISTRICT COURTS, <https://www.justex.net/courts/drug/adult/ProgramOverview.aspx> (last visited Feb. 25, 2018).

¹⁸⁹ *Id.*

¹⁹⁰ *Eligibility*, HARRIS COUNTY DISTRICT COURTS, <https://www.justex.net/courts/drug/adult/Eligibility.aspx> (last visited Feb. 25, 2018).

¹⁹¹ Lisher, *supra* note 102.

¹⁹² *Abell Grant Enables SAO to Double Capacity of Prostitution Diversion Program*, OFFICE OF THE STATE'S ATTORNEY FOR BALTIMORE CITY (Oct. 27, 2011), <https://www.stattorney.org/central/189-102711-abel-grant-enables-sao-to-double-capacity-of-prostitution-diversion-program.html> [hereinafter Abell].

¹⁹³ *Id.*

¹⁹⁴ Corey S. Shdaimah & Shelly A. Wiechelt, *Converging on Empathy: Perspectives on Baltimore City's Specialized Prostitution Diversion Program*, 22 WOMEN AND CRIM. JUST. 156, 157 (April 2012).

the State's Attorney for Baltimore City.¹⁹⁵ Women that successfully complete the program have their charges dropped.¹⁹⁶

A study conducted on SPD revealed that the program is viewed favorably amongst women who have used it.¹⁹⁷ These women indicated that they saw SPD as something separate from the traditional criminal justice system, and that the program was "a sign of greater empathy and understanding of what drives women to engage in prostitution."¹⁹⁸ These women also seemed to embrace SPD as a way of obtaining services that they were otherwise cut off from.¹⁹⁹

While the program has the support of the women who have used it, there are still issues that must be addressed. Between August 2009 and March 2011, there were 545 women who were identified as being eligible for SPD.²⁰⁰ Only half of these women were admitted to the program as a result of budget issues.²⁰¹ This means that women who may have been interested in the program and the services that it offers were cut off as a result of funding. It has also been indicated that only 75% of participants successfully completed the program.²⁰² This lends evidence to the concern that some participants may not have an interest in leaving prostitution, or in taking advantage of the services provided through the program, and only enter the program because it is the only way to avoid jail time once arrested.²⁰³

VI. Discussion

The issue of prostitution has created a rift amongst feminist academics. While nearly all feminists have come to believe that the act of selling sex should never be criminalized and that the use of coercion or force to bring women into prostitution should always be criminalized, they differ as to how to characterize prostitution generally and whether or not it should be legalized entirely or only decriminalized.²⁰⁴ One

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* at 159.

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ Abell, *supra* note 192.

²⁰¹ *Id.*

²⁰² *Id.*

²⁰³ Shdaimah et al., *supra* note 194, at 163.

²⁰⁴ Barbara Havelkova, *Using Gender Equality Analysis to Improve the Wellbeing of Prostitutes*, 18 CARDOZO J.L. GENDER 55, 63 (2011). Systems that legalize prostitution impose no

group of feminists “conceptualizes prostitution as sex work and speaks about sex workers, clients, and procurers.”²⁰⁵ Sex worker proponents argue that “the inherent problem is not the nature of sex work but rather with the conditions that such work exists in today. It is the laws criminalizing sex workers and repressing their migration that need changing, not prostitution itself.”²⁰⁶ The other group sees prostitution as “sexual domination and the essence of women’s oppression.”²⁰⁷

Some sex workers have pushed back against the narrative of objectification that is advanced by opponents of prostitution.²⁰⁸ Kitty Winter,²⁰⁹ founding member of a newly re-established sex workers rights group in Boston, has stated that sex work is “not just having stuff being done to you,” but that it is “doing stuff” as well.²¹⁰ Winter, also a graduate student, emphasizes that she “could live without doing sex work, but it just makes [her] life easier.”²¹¹ She states that “people need a way to support themselves.”²¹² Winter does not paint prostitution as being the perfect choice for everyone, or even an easy choice, but acknowledges that it is a choice that women often make in order to provide for themselves and their families.²¹³ Winter argues that her organization wants “to be able to do [their] jobs safely and not be hunted down by the police, and not have stigma for [themselves] and for [their] clients too.”²¹⁴

Regardless of the stance that one takes with respect to what the inherent nature of prostitution is, legislation targeting the issue of prostitution should be concerned primarily with enhancing and optimizing the health of women who are engaged in it, ensuring that women have the

legal sanctions on the buying or selling of sex as long as those transactions fit within certain parameters. For example, the systems in place in New Zealand and Nevada are legalization models. Decriminalization, on the other hand, does not allow or regulate the selling of sex, but makes it low priority for law enforcement. One example is the Swedish model, which does not allow women to be prosecuted for the selling of sex, but instead actively sanctions men who are found purchasing or soliciting sex for money.

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 64.

²⁰⁷ *Id.* at 63.

²⁰⁸ See Livia Gershon, *What Sex Workers Want*, BOSTON MAGAZINE (Nov. 24, 2015), <https://www.bostonmagazine.com/news/blog/2015/11/24/sex-workers/>.

²⁰⁹ *Id.* Winter is considered a “high class” prostitute, as she does mostly escort work and “sugaring,” which is when typically younger women establish sexual relationships with mostly older men and receive some compensation in return.

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *Id.*

ability to make decisions for themselves about whether to engage in sex work, and optimizing the use of funds for the benefit of taxpayers. A system must be established that serves these purposes, and that also better serves the financial needs of the general public. A system of criminalization serves only to create further harms for women who are engaged in prostitution and is not cost effective for the taxpayers that fund such a system.

VII. Conclusion

The existing models for prostitution legislation provide an opportunity for legislatures to pick and choose between what does and does not work for the women engaged in prostitution. While Sweden has made great strides in decriminalizing the sale of sex, criminalizing the purchase of sex has increased risks for prostitutes in that country. Nevada's partial legalization works for many women that are able to access jobs in the brothels, but the limited number of positions means that many women have no opportunity to work in those brothels. Overall, the model of full legalization and strict regulation used by New Zealand and the Netherlands are most likely to benefit women that are engaged in prostitution, as well as to further the needs of society.

Legislatures should consider legalizing prostitution and setting in place regulations that will ensure that brothel owners provide necessary health care for women who work in those establishments. Access to health care for women who decide to work independently should also be ensured. All sex workers should have access to social programs that are available to workers in other professions. This system will also ensure that women who experience abuse will be able to seek the assistance of law enforcement. Moreover, the ability to rely on law enforcement will discourage violence against women who are engaged in sex work. Hotlines can be established to encourage others to report abuse without the fear of prosecution.

Additionally, diversionary programs can still be established to enable women who wish to leave sex work to do so. These programs should make addiction and mental health treatment available, as well as offer access to job training and recruitment programs. These programs should not be mandatory as a way to avoid jail time or other sanctions, but as a way for individuals who have had few options to gain access to new options. This would help to lower the number of women who are engaged in the unlicensed selling of sex and make it easier to target the

most vulnerable populations, such as drug addicted women and women who have been victims of trafficking or coercion. The enormous financial costs of criminalization can be diverted to fund such programs, which is far more cost effective for the public than the revolving door of incarceration that currently traps many prostitutes.

Prostitution criminalization enhances the risks faced by women who engage in prostitution. These women suffer increased physical and psychological harms, as well as the danger of arrest and prosecution. Furthermore, criminalization creates massive costs to the public in both taxes and law enforcement resources. Legalization can decrease the risks faced by prostitutes, as well as result in a reallocation of resources to drug treatment programs, mental health programs, job training and recruitment programs, and programs aimed at combating violent crime.

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