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Duty to Fill? Threats to Pharmacists' Professional and Business Discretion

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Duty to Fill? Threats to Pharmacists' Professional and Business Discretion

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I. INTRODUCTION

Although the origin of the word pharmacy is often attributed to the Greek *pharmakon*, meaning remedy,¹ the art of combining and compounding agents existed long before the word came into use.² Despite the many changes pharmacy practice has gone through in its long history, the majority of which have occurred within the last fifty years,³ those in the profession consider it an intensely personal calling that is guided by basic human values and compassion.⁴ The role of the modern-day pharmacist is not that of a mere dispenser of legal medication⁵—that categorization undermines the pharmacist’s important role in the clinical process.⁶ Rather, pharmacists must achieve a certain expertise to practice their profession.⁷ They are independent health care professionals who serve important roles in their communities by acting as guardians, advisors, and protectors with respect to the products they dispense.⁸ This knowledge and sophistication earned them the 1930 slogan: “Your pharmacist is the scientist on the corner.”⁹ Recently however, the federal government has begun to consider a new regulatory scheme under a bill called the Access to Legal Pharmaceuticals Act (“ALPhA”)¹⁰ that would strictly limit pharmacists’ discretion by limiting their ability to refuse to fill prescriptions. This note will argue that the broad language of this bill disproportionately burdens small neighborhood drugstores over corporate chains and

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1. DAVID L. COWEN & WILLIAM H. HELFAND, *PHARMACY: AN ILLUSTRATED HISTORY* 17 (1990).
 2. *Id.*; ROBERT A. BUERKI & LOUIS D. VOTTERO, *ETHICAL RESPONSIBILITY IN PHARMACY PRACTICE* 1 (2d ed. 2002).
 3. *See* DOUGLAS J. PISANO, *ESSENTIALS OF PHARMACY LAW* 3–4 (2003) (discussing how the practice of pharmacy has changed since World War II).
 4. BUERKI & VOTTERO, *supra* note 2, at 1.
 5. *See* Gregory J. Higby, *The Continuing Evolution of American Pharmacy Practice, 1952–2002*, in *AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS* 11, 12–14 (Gregory J. Higby & Elaine C. Stroud eds. 2005) (discussing the shift from the era of ‘count and pour’ pharmaceutical practice in the 1950s to the birth of clinical pharmacy in the 1960s, which emphasized that the “function of pharmacy is clinical in nature . . . the sum total of knowledge, understanding, judgments, procedures, skills, controls, and ethics that assures optimal safety in the distribution and use of medication”).
 6. *See id.*; *Freedom of Conscience for Small Pharmacies: Hearing Before the H. Small Bus. Comm.*, 109th Cong. 64–66 (2005) (statement of Linda Garrelts MacLean, RPh, CDE, Member American Pharmacists Ass’n).
 7. *See* Robert A. Buerki, *American Pharmaceutical Education, 1852–1902*, in *AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS* 37–41 (Gregory J. Higby & Elaine C. Stroud eds. 2005) (discussing the higher standards implemented by pharmacy schools in training pharmacists from 1852–1902); Robert A. Buerki, *American Pharmaceutical Education, 1902–1952*, in *AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS* 43–47 (Gregory J. Higby & Elaine C. Stroud eds. 2005) (same standards as 1902–1952); Robert A. Buerki, *American Pharmaceutical Education, 1952–2002*, in *AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS* 49–52 (Gregory J. Higby & Elaine C. Stroud eds. 2005) (discussing the increased intensity and standards implemented by pharmacy schools in training pharmacists from 1952–2002); Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6.
 8. BUERKI & VOTTERO, *supra* note 2, at 2.
 9. *Id.* at 3.
 10. H.R. 1652, 109th Cong. (2005).

compels pharmacists to dispense prescriptions they may have ethical objections to filling.

Part II of this note briefly explores the history of pharmacy practice and its development as a regulated profession and business. Part III of this note explores the language of the ALPhA, and discusses the problems that the overly broad language of this statute will create for pharmacy practice. Finally, Part IV of this note proposes that the federal government look toward state regulations such as the guidelines adopted by the New York State Board of Pharmacy, for guidance in tailoring the language of the ALPhA more narrowly.

II. HISTORY AND DEVELOPMENT OF THE MODERN DAY PHARMACIST

At its essence, the practice of pharmacy is the “compounding and dispensing [of] medications directly to the public . . .”¹¹ and the pharmacist is the health professional trained to carry out that task.¹² However, the practice of pharmacy is much more than merely disseminating drugs to the masses.¹³ It is a profession, requiring years of study and expertise.¹⁴ Like many other professions, the practice of pharmacy is self-regulating, but pharmacists must also follow a regime of state and federal regulations.¹⁵ As the industry becomes more regulated, the issue of a pharmacist’s discretion to refuse to fill a prescription has become highly contested.¹⁶

A. Emergence of Pharmacy as a Profession

The fundamental roots of pharmaceutical practice can be traced back to ancient times.¹⁷ As far back as eighty thousand years ago, Paleolithic people began cultivating and depicting the plant life around them.¹⁸ Remains of Neolithic people from fifty thousand years ago were discovered with clusters of flowers and herbs, many of which possessed medicinal properties.¹⁹

11. BUERKI & VOTTERO, *supra* note 2, at 1.

12. *Id.* at 2.

13. *See generally* PISANO, *supra* note 3, at 3–4.

14. *See* Buerki, *American Pharmaceutical Education, 1852–1902*, *supra* note 7, at 37–41. *See generally* RICHARD ABOOD, *PHARMACY PRACTICE AND THE LAW* 279 (4th ed. 2005); PISANO, *supra* note 3, at 4–5.

15. *See generally* ABOOD, *supra* note 14, at 275–77.

16. *See* Jody Feder, *Federal and State Laws Regarding Pharmacists Who Refuse to Dispense Contraceptives*, CRS REPORT FOR CONGRESS 6 (2005); Cynthia Dailard, *Beyond the Issue of Pharmacist Refusals: Pharmacies that Won’t Sell Emergency Contraception*, 8 THE GUTTMACHER REPORT ON PUBLIC POLICY 3 (Guttmacher Inst. 2005).

17. *See generally* COWEN & HELFAND, *supra* note 1, at 17–26.

18. *Id.* at 17.

19. *Id.* (“As much as 80,000 years ago, people of the Paleolithic period were sufficiently interested in the flora around them to engrave a variety of plants and plant parts on bones and deer antlers, and 50,000 years

DUTY TO FILL?

In early human societies, the medicine man fulfilled the role of the pharmacist.²⁰ These men and women served the spiritual, medical, and medicinal needs of the sick and dying.²¹ It was their belief that disease could be caused by the presence of evil spirits, the violation of a taboo, an enemy's curse, or the departure of good spirits from the body.²² Once the cause of the disease was determined, the medicine men would fashion a remedy from various chants, magic objects, and drinking or smelling potions.²³

Artisans of ancient Mesopotamia were among the first recorded to use early forms of chemistry to produce medicines from natural ingredients.²⁴ Archaeologists have discovered thousands of clay tablets that recorded the ingredients and procedures used around 2100 B.C.E. to compound various medicines and remedies.²⁵ This early compounding was a specialized practice, and the medicines were offered to people in "drug stores" on the streets of ancient Babylonia.²⁶ The emergence of pharmaceutical practice as a separate and distinct profession originated in the Middle East in the ninth century, and coincided with the beginnings of professional licensure.²⁷ Educated pharmacists were given licenses to practice in Baghdad near army camps, while uneducated pharmacists were excluded from this privilege.²⁸

The art of compounding and making medicines further evolved in the Middle East, India, and China, and eventually spread throughout Europe after the fall of the Roman Empire.²⁹ Monks preserved ancient medicinal knowledge by translating early medicinal remedies and compounding techniques into several languages.³⁰ As chemistry became better understood in the mid-to-late Middle Ages, European alchemists were more able to develop and prepare medicines.³¹

ago a Neolithic man was buried in the Shanidar Cave in northern Iraq with clusters of flowers and herbs.”).

20. *Id.* at 18 (“In the medicine man’s collection and preparation of remedies lies the beginning of pharmacy. That a medication might possess powers beyond its effect on bodily function, and that medication was needed to exorcise evil spirits, were ideas that would affect pharmacy and medicine for ages to come.”).
21. *Id.* at 17.
22. *Id.*
23. *Id.*
24. *Id.* at 19–20.
25. *Id.*
26. *Id.* at 20 (stating that “[a]t least during the Babylonian period there was a special street in Sippur where retailers of drugs plied their trade”).
27. *Id.* at 46.
28. *Id.*; see also GEORGE EDWARD TREASE, PHARMACY IN HISTORY 13–14 (1964).
29. COWEN & HELFAND, *supra* note 1, at 49–52; see TREASE, *supra* note 28 (explaining the history of early alchemy).
30. COWEN & HELFAND, *supra* note 1, at 49–50.
31. See *id.* at 50.

Europe began to define the role of the alchemist and the role of the physician in 1180 with the emergence of pharmacy ordinances in France.³² In 1240, the *Constitutiones*, issued by Holy Roman Emperor Fredrick II, for the first time legally recognized pharmacy as a distinct profession from that of medicine, and required pharmacists in all of Western Europe to pledge that they would protect the public and make uniform quality goods.³³ The regulations in the *Constitutiones* promoted economic well-being and elevated the social status of trained and knowledgeable pharmacists.³⁴

In the United States, by contrast, the emergence of pharmacy as a profession, separate and distinct from that of physicians, evolved more slowly.³⁵ During the early colonization of America, colonists relied on medical books and kitchen remedies to aid them in compounding medicines and treating illnesses.³⁶ As the new settlements grew in population and became economically prosperous, apothecary shops owned and managed by physicians were established in some of the larger towns.³⁷

The Revolutionary War created, for the first time since the early colonization, a generalized need for locally-compounded medicine.³⁸ Because trade to America was cut off by Britain, physicians, their apprentices, and a new group of non-medical practitioners were forced to meet patients' needs by compounding their own medicines.³⁹ These non-medical practitioners were few in number and did not belong to any organized profession; they acted independently of each other.⁴⁰

It wasn't until the late eighteenth and early nineteenth centuries that American pharmacists began to be recognized as compounders and dispensers of medicine, fully distinct from physicians.⁴¹ This distinction can be partly attributed to the organization and popularization of medical schools in the United States during the early 1800s.⁴² With more physicians receiving formal training

32. *See id.* at 52–53. The ordinances adopted in France recognized pharmacy as a branch of medicine, regulating the practice of pharmacy under the medicinal police. *Id.*

33. *Id.* at 55. The *Constitutiones* was a series of edicts regulating the medical profession. *Id.*

34. *Id.*

35. *See supra* notes 32–34 and accompanying text; *infra* note 42 and accompanying text.

36. Gregory J. Higby, *Introduction: American Pharmacy Before 1852*, in *AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS ix–x* (Gregory J. Higby & Elaine C. Stroud eds. 2005).

37. *Id.*; *see also* GLENN SONNEDECKER, *KREMERS AND URDANG'S HISTORY OF PHARMACY* 152 (4th ed. 1976).

38. Higby, *supra* note 36, at ix.

39. *Id.*; *see also* SONNEDECKER, *supra* note 37, at 166–68 (explaining the new and growing responsibility of the American pharmacist).

40. Higby, *supra* note 36, at x.

41. *Id.* *See generally* SONNEDECKER, *supra* note 37, at 160–62.

42. Higby, *supra* note 36, at x.

DUTY TO FILL?

in medicine, prescription writing became common practice in the medical profession.⁴³ Once a prescription was written, the patient would be directed to the local druggist whom the doctor depended on to correctly compound and dispense the medicine according to the doctor's written instructions.⁴⁴ As physicians' reliance on druggists' services increased, physician-authorized books identifying drugs and detailed instructions on how to make them, called pharmacopoeias, began to circulate, allowing druggists to prepare a wider and more consistent range of medicines in line with their clients' needs.⁴⁵ Many physicians practicing between 1820 and 1860 believed that a separation of pharmaceutical and medical needs was a necessary division of labor.⁴⁶

In response to the increasing demand of separate pharmaceutical services, the first pharmacy school opened in Philadelphia in 1822.⁴⁷ In its early years there were no requirements for admission into the pharmacy school.⁴⁸ In order to graduate, individuals had to pass a written examination, provide proof of four years of satisfactory apprenticeship with a local druggist, and attend lectures given by the school two to three evenings a week for several months.⁴⁹ Even with these minimal requirements, encouraging druggists to receive formal training was difficult.⁵⁰ As of 1860, attendance at pharmacy schools remained small.⁵¹ Out of 11,031 practicing druggists in the nation at that time, only 514 had actually graduated from a pharmacy school.⁵² These statistics were not a cause for alarm because it was the general belief that formal instruction merely rounded off the valuable experience of an extended apprenticeship.⁵³ However, enrollment increased as states began to mandate formal training of pharmacists.⁵⁴

43. *Id.*

44. *Id.* Druggists, the title that pharmacists were referred by before the requirement of pharmacy schools, compounded and sold the drugs to patients. *Id.*

45. *Id.*; see also SONNEDECKER, *supra* note 37, at 260–75 (explaining the history and revision of the U.S. Pharmacopia).

46. Higby, *supra* note 36, at x.

47. See PISANO, *supra* note 3, at 4. See generally, SONNEDECKER, *supra* note 37, at 190–95 (discussing the history of the first pharmacy school).

48. Buerki, *American Pharmaceutical Education, 1852–1902*, *supra* note 7, at 38.

49. *Id.*

50. *Id.* See generally SONNEDECKER, *supra* note 37, at 227–28 (explaining the financial problems faced by pharmacy schools by optional education).

51. Buerki, *American Pharmaceutical Education, 1852–1902*, *supra* note 7, at 38.

52. *Id.*

53. *Id.* at 39. See generally SONNEDECKER, *supra* note 37, at 237–38 (discussing the importance of internships in the field).

54. See generally Buerki, *American Pharmaceutical Education, 1852–1902*, *supra* note 7, at 39–40 (stating that pharmacy practice laws that governed education and licensure of pharmacists emerged in the

In the nineteenth and twentieth centuries, in response to the exponential growth of the pharmaceutical industry, the number of pharmacy schools increased.⁵⁵ The development of new and complicated drugs at a faster and cheaper rate enhanced patient care but also increased the chances of injury.⁵⁶ Consequently, in addition to compounding and preparing certain medicines, pharmacists also had to hone their skills in therapeutic selection, drug regimen, drug monitoring, patient counseling, and patient education.⁵⁷ These developments created a need to ensure that pharmacy students graduated with high levels of expertise and professional skills.⁵⁸

Today, pharmacy schools in the United States require students to complete six years of study.⁵⁹ Part of the curriculum includes a hospital residency or a research fellowship to complement an intense academic training.⁶⁰ In addition, the curriculum and accreditation of pharmacy schools are monitored by the American Council on Pharmaceutical Education (“ACPE”).⁶¹ An applicant in the profession must also pass a licensure exam administered by a state board of pharmacy⁶² and the Multistate Pharmacy Jurisprudence Exam, which tests knowledge of relevant state and federal regulations.⁶³ Lastly, applicants must meet an age requirement, which varies from state to state, and demonstrate good moral character before receiving a license to practice.⁶⁴

B. Development of Pharmacy as a Business

Pharmacy is both a profession and a business.⁶⁵ The earliest pharmacy shops in history were established in the Middle East between 775 and 785 C.E.,

1880s and coincided with the increase in pharmacy schools). See also SONNEDECKER, *supra* note 37, at 214–17.

55. PISANO, *supra* note 3, at 3–4; see also SONNEDECKER, *supra* note 37, at 333–35 (discussing the increase in production volume and industry research).

56. PISANO, *supra* note 3, at 3–4.

57. *Id.* at 3.

58. *Id.* at 3–4.

59. *Id.* at 4.

60. *Id.* at 4–5.

61. *Id.* at 5.

62. *Id.*

63. ABOOD, *supra* note 14, at 280.

64. *Id.* at 279.

65. See CHARLES L. HUISKING, HERBS TO HORMONES: THE EVOLUTION OF DRUGS AND CHEMICALS THAT REVOLUTIONIZED MEDICINE 13 (1968).

The American retail pharmacy has always been an omnibus store. The colonial druggist handled spices, herbs, condiments, dyes, tanstuffs and paint materials, all within the general category of ‘drugs.’ He also sold writing paper, candles and penknives . . . perfumes, rouge and white powder for wigs; tea, coffee and chocolate; rum, whisky and imported wines. Such merchandise was the historical forerunner of present-day stocks of paperbacks, greeting cards, records, cameras and photographic supplies. There has been no revolution in the

DUTY TO FILL?

where pharmacists privately owned and operated their businesses and performed a variety of functions as both owners and health professionals.⁶⁶ Physicians wrote prescriptions that were filled by both licensed and unlicensed pharmacists.⁶⁷ More importantly, at this time, codes of ethics, standards of cleanliness, delineation of duties, and standards of practice were developed to further aid the profession's business and advancement.⁶⁸ During the Middle Ages, early pharmacies in Western Europe reflected these Arab influences in both business and practice.⁶⁹ Additionally, pharmacies in Western Europe were characterized by their small shops that contained shelves of marked bottles, boxes, and leather bags.⁷⁰

During the colonization of America in the 1700s, the earliest pharmacies emerged as apothecary shops.⁷¹ These shops sold patented medicines, drugs, chemicals, spices, and medicines imported from England.⁷²

The early 1800s saw the emergence of what is traditionally thought of as the classic American drugstore,⁷³ and by 1830 the drugstore was already considered an American institution.⁷⁴ The typical American drugstore in the 1850s contained a front end that was considered the pharmacy work area for preparing medicines.⁷⁵ The druggist would not only compound and dispense, but also would supervise a staff of clerks and apprentices who attended to customers and did much of the hard labor.⁷⁶ A successful pharmacy practice required both knowledge of the chemistry of medicines and the business mechanics of owning a shop.⁷⁷

variety of goods sold in drugstores, only logical changes to accommodate new items and serve customers' new demands.

Id.; see also SONNEDECKER, *supra* note 37, at 311.

66. COWEN & HELFAND, *supra* note 1, at 46.

67. *See id.* at 46–49.

68. *Id.* at 49 (“The pharmacist must be certain to clean the balances and pans daily and keep all weights, measures, and vessels clean. The shop was to be kept well stocked and the display attractive; the inventory was to be watched carefully, and the deteriorated materials were to be replaced. Finally, the pharmacist was admonished to keep his profits moderate.”).

69. *Id.* at 55–56.

70. *Id.* at 56.

71. Higby, *supra* note 36, at ix; Gregory J. Higby, *American Pharmacy's First Great Transformation: Practice, 1852–1902*, in AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS 1 (Gregory J. Higby & Elaine C. Stroud eds. 2005).

72. Higby, *supra* note 36, at ix; see HUISKING, *supra* note 65.

73. Higby, *American Pharmacy's First Great Transformation: Practice, 1852–1902*, *supra* note 71, at 1.

74. *Id.*; see also SONNEDECKER, *supra* note 37, at 308–09 (discussing the soda fountain as an institution of the neighborhood pharmacy).

75. Higby, *American Pharmacy's First Great Transformation: Practice, 1852–1902*, *supra* note 71, at 1.

76. *Id.*

77. *Id.* at 1–2; see also SONNEDECKER, *supra* note 37, at 310–11 (discussing the variety of items sold).

In the early 1900s, pharmacy practice was considered “full-time employment, but only a part-time practice of pharmacy.”⁷⁸ The practice was attractive to American youth who liked the idea of owning a business while also practicing a profession.⁷⁹ By the mid-century, “[a]t least half of all pharmacists were owners or managers of the establishment in which they worked in a triple role as proprietor, professional pharmacist, and general salesperson.”⁸⁰ With the addition of soda fountains and general store items, drugstores became the social meeting place in both large and small communities alike.⁸¹

Around the same time, small and privately owned drugstores were being slowly replaced by large drugstore chains.⁸² These smaller drugstores found it difficult to compete with the economic efficiencies of large pharmacy chains like Walgreens, and the increased competition from sales of non-medical goods by supermarkets and department stores.⁸³ Large chains had the economic means to aggressively mass merchandise and commercialize retail pharmacy at a level with which small privately-owned pharmacies could not compete.⁸⁴

Today both private and corporate pharmacies continue to sell merchandise other than medicine. They have diversified their practices by also serving the general needs of clients by stocking food items, household goods, cosmetics, and recreational goods.⁸⁵ Nevertheless, pharmacies continue to play a crucial role in providing for the medical needs of their customers.

C. *Traditional Regulation of Pharmacy*

Pharmacy, for the most part, is a self-regulated profession.⁸⁶ At the beginning of the twentieth century, pharmacists chose to organize themselves in state-level systems to help regulate the emerging profession.⁸⁷ With the help of lawyer and pharmacist James Hartely Beal, and other pharmacy leaders, people within the industry influenced the development of national organizations to oversee the licensing, practice, and state regulation of pharmacy.⁸⁸ For example, ever since it was founded in 1852, the American Pharmacist Association (“APhA”) has been influential in regulating the education of pharmacists and adopting uniform

78. Glenn Sonnedecker, *The American Practice of Pharmacy, 1902–1952*, in AMERICAN PHARMACY: A COLLECTION OF HISTORICAL ESSAYS 5 (Gregory J. Higby & Elaine C. Stroud eds. 2005).

79. *Id.*

80. *Id.* at 6.

81. COWEN & HELFAND, *supra* note 1, at 188.

82. Sonnedecker, *supra* note 78, at 6–7. *See generally* SONNEDECKER, *supra* note 37, at 297–300.

83. Sonnedecker, *supra* note 78, at 6–7.

84. *Id.*

85. *See generally* COWEN & HELFAND, *supra* note 1, at 188.

86. ABOOD, *supra* note 14, at 275.

87. *See id.* at 275–76.

88. *See id.* at 276.

DUTY TO FILL?

practices and standards.⁸⁹ Additionally, the National Association of Boards of Pharmacy (“NABP”)⁹⁰ provided a national forum that facilitated communication between state representatives and pharmacists to help develop professional policies, standards, and model legislation to better regulate the industry.⁹¹ It also developed the national licensure exam that each state administers to pharmacy candidates.⁹²

While the APhA and NABP are, for the most part, voluntary organizations, state legislatures have the power to regulate the practice of pharmacy by law.⁹³ This power is derived from the states’ police powers and the Tenth Amendment.⁹⁴ Most state regulation begins with the passage of state pharmacy practice acts or other regulatory schemes that establish each state’s board of pharmacy.⁹⁵ As an administrative agency, the purpose of the state board of pharmacy is to “protect the public health, safety, and welfare.”⁹⁶ Although the state board of pharmacy is usually comprised of practicing pharmacists, consumers, and other healthcare professionals,⁹⁷ the board is not meant to protect the profession of pharmacy but rather to protect the public.⁹⁸ In addition to issuing licenses to practitioners, the state board also oversees the licensure of pharmacies⁹⁹ and disciplinary actions against pharmacists and pharmacies.¹⁰⁰

In New York, for example, the state legislature created the State Education Department and the Board of Regents to jointly oversee all of the public health professions in the state.¹⁰¹ The Board of Regents prescribes the rules and regulations for all health professionals in New York.¹⁰² This agency created the State Board of Pharmacy, which ensures that pharmacists adhere to the rules of professional conduct.¹⁰³ Under Title VIII, Article 137, Section 6804 of the Education Law, the New York State Board of Pharmacy has the power to (1) regulate the

89. Higby, *supra* note 36, at xi.

90. The NABP was founded in 1904. SONNEDECKER, *supra* note 37, at 218.

91. ABOOD, *supra* note 14, at 278.

92. PISANO, *supra* note 3, at 5.

93. SONNEDECKER, *supra* note 37, at 214.

94. ABOOD, *supra* note 14, at 275.

95. SONNEDECKER, *supra* note 37, at 214.

96. ABOOD, *supra* note 14, at 278.

97. *See id.* These positions are politically appointed directly by the governor. *Id.*

98. *Id.*

99. *Id.* at 280 (“The state board will issue a license to operate a pharmacy only to those that meet established standards relating to structural matters (e.g., equipment), library, and assurance of pharmacist supervision.”).

100. *Id.* at 281.

101. *See* N.Y. COMP. CODES R. & REGS. tit. 8 §§ 3, 17.5 (2005).

102. *See id.* § 17.5.

103. *See id.*; *see also* N.Y. EDUC. LAW § 6804 (2005).

practice of pharmacy, (2) investigate alleged violations of the provisions of this article, and (3) conduct hearings and prescribe penalties when pharmacists are in violation of policies. The members of the State Board of Pharmacy are appointed by the Board of Regents on the recommendation of the New York State commissioner.¹⁰⁴

The federal government also regulates certain aspects of pharmaceutical practice, deriving its power from its interstate commerce powers.¹⁰⁵ This includes the enactment of practice-oriented drug laws that directly affect the dispensing of medicine.¹⁰⁶ These laws were enacted primarily to protect the public from the potential risks of abusing dangerous products.¹⁰⁷ The major practice-oriented drug law enacted in the United States is the Federal Controlled Substances Act of 1970 (“CSA”).¹⁰⁸ In addition to regulating the manufacture and distribution of controlled substances,¹⁰⁹ the CSA regulates the dispensing of controlled substances by pharmacists because controlled substances have a high potential to be abused by patients.¹¹⁰ The Drug Enforcement Administration (“DEA”) is the administrative agency in charge of controlling access to this class of medicines.¹¹¹ Among other regulations, the DEA placed prescription-dispensing limitations on these types of drugs.¹¹² States are otherwise free to regulate the dispensing of controlled substances as long as the state regulation is stricter than the federal regulation.¹¹³

D. A Pharmacist’s Discretion to Fill Prescriptions

In general, “[a] druggist (sic) is not obligated to fill any and all prescriptions, but may refuse to fill one for good reason”¹¹⁴ In practice, laws governing a pharmacist’s discretion to refuse to fill a prescription because it would violate his or her personal beliefs vary greatly from state to state.¹¹⁵ Some states, including

104. See N.Y. EDUC. LAW § 6804.

105. ABOOD, *supra* note 14, at 20; see also SONNEDECKER, *supra* note 37, at 219–20.

106. PISANO, *supra* note 3, at 29.

107. ABOOD, *supra* note 14, at 2–3.

108. PISANO, *supra* note 3, at 29.

109. Controlled substances are drugs that “are subject to, or have the potential for, abuse or physical or psychological dependence.” *Id.* Some examples include Percocet, Demerol, and Codeine. *Id.* at 42.

110. *Id.* at 29.

111. *Id.*

112. *Id.*

113. *Id.* at 30. For example, Massachusetts further regulates the dispensing of Schedule II controlled substances by mandating that the prescription be filled within five days after the date on which it was issued and limits the supply to a thirty-day supply per prescription only. *Id.*

114. STEVEN STRAUSS, THE PHARMACIST AND THE LAW 28 (1980) (citing 28 C.J.S., Supp., Drugs & Narcotics, § 43).

115. Feder, *supra* note 16, at 2.

DUTY TO FILL?

Georgia, Arkansas, South Dakota, and Mississippi, recognize pharmacists' rights to refuse to fill a prescription and place no affirmative duty on them to accommodate the consumer.¹¹⁶ By contrast, the State of Illinois has chosen to require the timely filling of any valid prescription—no matter what the circumstance.¹¹⁷ States such as North Carolina, Wisconsin, Texas, and Nevada have chosen a middle-of-the-road approach, allowing pharmacists to refuse to fill a prescription, but placing on them (or on their employer) a duty to have procedures in place to ensure that the patient can still get his medication filled at another pharmacy or by another pharmacist in the same pharmacy.¹¹⁸ And finally, some states, such as New York, remain silent on the issue.

In addition, drug product selection laws may also affect a pharmacist's discretion in certain narrow circumstances.¹¹⁹ The Food and Drug Administration ("FDA") oversees and keeps a list of suitable substitutions and equivalent generic drugs and allows pharmacists some latitude to dispense a different product without the doctor's consent.¹²⁰ In some situations, the pharmacist has the discretion to substitute the drug for its bioequivalent,¹²¹ and in others, the states have the option of allowing pharmacists the discretion to use it as an appropriate substitution.¹²²

A pharmacist's discretion to fill a prescription came to the forefront of political debate when the governor of Illinois, Rod Blagojevich, issued an executive order compelling all pharmacies to dispense the "morning after" birth control pill, even if the pharmacist objects to dispensing the medication on moral or religious grounds.¹²³ Within a month, six pharmacists refused to fill several prescriptions despite the governor's order.¹²⁴

116. *Id.* at 4.

117. *Id.* at 3 & n.6 (citations omitted).

118. *Id.* at 3–4; *see also id.* at 3 n.11 ("For example, Texas law provides that a pharmacist 'may not refuse to transfer original prescription information to another pharmacist,' and Oklahoma law specifies that '[n]o legally-competent practitioner of the healing arts shall refuse to honor the requests of his patient to have his prescription transferred to the registered pharmacist or pharmacy of the patient's choice.'") (citations omitted).

119. *See generally* PISANO, *supra* note 3, at 33–34.

120. *Id.* at 34.

121. *Id.*

122. *Id.* This is because B rated drugs may not be bioequivalent, just merely therapeutically equivalent.

123. *See* Molly McDonough, *Rx For Controversy*, 4 ABA J. EREPORT 23 (2005); Feder, *supra* note 16, at 3; Melissa Duvall, Comment, *Pharmacy Conscience Clause Statutes: Constitutional Religious "Accommodations" or Unconstitutional "Substantial Burdens" on Women?* 55 AM U. L. REV. 1485, 1488 n.12 (2006); Claire A. Smearman, *Drawing the Line: The Legal, Ethical and Public Policy Implications of Refusal Clauses for Pharmacists*, 48 ARIZ. L. REV. 469, 470–471 (2006).

124. *See* McDonough, *supra* note 123; Smearman, *supra* note 123, at 470–71; Kari Lydersen, *Pharmacies Required to Fill Prescriptions for Birth Control*, WASH. POST, Apr. 2, 2005, at A02; Dailard, *supra* note 16.

III. THE ACCESS TO LEGAL PHARMACEUTICALS ACT

In the wake of the controversy over the “morning after” pill, proponents of patients’ rights proposed federal “duty to fill” legislation that would ensure the availability of legally prescribed medicines to all patients.¹²⁵ Proponents support the enactment of nationwide legislation to govern pharmacist conduct, reasoning that a patient has a right to acquire, without delay and no matter where he lives, all legally valid medicines prescribed by his doctor.¹²⁶ The major proposal being considered is called the Access to Legal Pharmaceuticals Act (“ALPhA”), which was introduced to the House of Representatives on April 14, 2005 by Representative Carolyn B. Maloney.¹²⁷ This legislation would prevent pharmacies from denying the sale of legal, physician-prescribed medicines because of a pharmacist’s religious beliefs.¹²⁸

This note contends that the language of the bill is far too broad. It could have the effect of taking away important pharmacist discretion when it comes to filling prescriptions and would allow patients to dictate the types of medication pharmacies order. Additionally, the strict conditions and harsh penalties prescribed by this act would disproportionately hurt small neighborhood pharmacies over large corporate ones. Finally, the act requires pharmacists to go above and beyond an ordinary duty of care. Because there are many states that have remained silent on this issue, federal legislation should be enacted, but with much

125. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6 (discussing the negative impact that the proposed duty to fill legislation would have on pharmacists); *see also* Feder, *supra* note 16 (summarizing state duty to fill laws).

126. Feder, *supra* note 16, at 2.

One bill, H.R. 1539 would require pharmacies to ensure that, if a pharmacist refused to fill a prescription on the basis of religious beliefs or moral convictions, then the prescription would be filled by another pharmacist employed by the pharmacy within four hours of such refusal. Likewise, companion bills H.R. 1652 and S. 809 would require pharmacies to ensure that prescriptions are filled without delay by another of their pharmacists if one pharmacist refuses and would also prohibit pharmacies from employing any pharmacist who acts with intent to prevent or deter a customer from filling a valid prescription. In addition, S. 778 would require pharmacies that receive Medicare or Medicaid payments to ensure that valid prescriptions are filled without unnecessary delay or interference.

Id.

127. Press Release, Rep. Carolyn Maloney, Lawmakers Introduce Legislation to Ensure Pharmacies Fill All Dr. Prescriptions (Apr. 14, 2004), *available at* <http://maloney.house.gov/index.php?option=content&task=view&id=113&Itemid=61>.

128. *Id.* In justifying the bill, Congressmen Christopher Shays insisted that “[p]harmacists are health professionals whom we trust to fulfill their professional responsibilities to their patients It is unacceptable for a pharmacist to withhold any safe, legal medication and it is time to put an end to this abuse of trust.” *Id.* Judy Waxman, VP of Health and Reproductive Rights at the National Women’s Law Center agreed, stating that “[t]his bill would ensure that every woman can walk into her local pharmacy with a valid prescription and leave with her medication in hand and her dignity intact [sic].” *Id.*; *see also* Duvall, *supra* note 123, at 1494–95; Smearman, *supra* note 123, at 539; Minh N. Nguyen, Comment, *Refusal Clauses & Pro-Life Pharmacists: How can we protect ourselves from them?*, 8 SCHOLAR 251, 272–73 (2006).

DUTY TO FILL?

narrower language to ensure that a pharmacist's professional and business discretion is preserved. Any legislation must also avoid placing affirmative duties on pharmacists, such as forced ordering of medication, forced filling of prescriptions, or forced hiring of extra pharmacists.

A. The broad language of ALPhA may force pharmacists to fill legally valid medications despite harm to the consumer

The purpose of ALPhA is "to establish certain duties for pharmacies when pharmacists employed by the pharmacies refuse to fill valid prescriptions for drugs or devices on the basis of personal beliefs, and for other purposes."¹²⁹ Legally valid prescriptions however, are not the same as therapeutically safe prescriptions,¹³⁰ and the language of this bill takes away the pharmacist's discretion in assessing whether medication is appropriate or safe.¹³¹

There are many legitimate reasons why a pharmacist might exercise his or her discretion not to fill a prescription, only one of which includes an objection based on personal belief. Pharmacists are experts on drug interactions, appropriate drug therapies, and patient care, especially in the realm of new or experimental drugs.¹³² They gain that expertise through six years of study, clinical experience, and continuing education.¹³³ Based on this training and expertise, it is not surprising that a pharmacist's opinion on appropriate drug therapy may differ from that of the doctor. Under ALPhA, when a "morally objectionable" drug such as Plan B¹³⁴ is legally prescribed by a doctor, but there are questions about whether the patient could be hurt by the therapy, a pharmacist who exercises his or her expert opinion in refusing to fill that prescription may still be susceptible to penalties. This is because the language of the bill fails to differentiate between therapeutically safe and legally valid prescriptions.¹³⁵ This bill irre-

129. H.R. 1652, 109th Cong. (2005).

130. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6.

Duty to fill legislation would require pharmacies or pharmacists to dispense legal prescriptions. When poorly crafted, such a requirement conflicts with the pharmacist's legal responsibility to assess the clinical safety and appropriateness of the prescription A prescription calling for a 10 fold overdose is lawful, but likely fatal to the patient A prescription calling for an oral contraceptive for a patient with a history of thromboembolic disease is lawful, but may result in patient harm.

Id. at 6.

131. Smearman, *supra* note 123, at 539.

132. *See supra* notes 59–64 and accompanying text.

133. *Id.*

134. The FDA has recently approved making Plan B, the "morning after" pill, available over the counter for women over the age of eighteen. Women under the age of eighteen still need a prescription. *See* Press Release, U.S. Food and Drug Admin., FDA Approves Over-the-Counter Access for Plan B for Women 18 and Older Prescription Remains Required for Those 17 and Under (Aug. 24, 2006), *available at* <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01436.html>.

135. H.R. 1652, 109th Cong. (2005).

sponsibly places an affirmative duty on pharmacists to fill legally prescribed medications,¹³⁶ despite possible harmful side effects that may result.¹³⁷ In addition, fear of penalties would greatly interfere with the pharmacist's clinical judgment and would work to decrease the quality of patient care.¹³⁸

B. The broad language of ALPhA subjects pharmacy policy and practice to patients consent

Section 249(a)(1) of the ALPhA governs pharmacy policy as to who must fill morally objectionable prescriptions when the medication is already in stock in the pharmacy.¹³⁹ It reads:

[T]he pharmacy ensures, *subject to the consent of the individual* presenting the prescription . . . that the prescription is . . . *filled by another pharmacist employed by the pharmacy.*¹⁴⁰

This language places an affirmative duty on the pharmacy to ensure that, at all times, there is a pharmacist available to fill prescriptions that another pharmacist refuses to fill because of a moral objection. It also takes away the option of transferring the prescription to another pharmacy, a normal and valid pharmacy practice, unless the patient consents.¹⁴¹ Without affording pharmacists the option of exercising the normal pharmacy practice of transferring prescriptions, pharmacy practice becomes subject to patient approval. The prohibition of transferring a prescription to another pharmacy is particularly troublesome. If a situation arose where another pharmacist could not be reached, the pharmacy would be subject to a fine if it refused to fill the prescription. Small pharmacies would be far more susceptible to these penalties because they lack the personnel and resources to which the larger chain drugstores have access.¹⁴²

The language of ALPhA would also force pharmacies to order medications that they might not ordinarily carry.¹⁴³ Section 249(a)(2) governs the ordering of medicine not normally carried by the pharmacy. It reads:

136. *Id.*

137. For example, although Plan B is an FDA approved drug, there are numerous side effects, drug-to-drug interactions, and long term use consequences that have not been officially assessed. Plan B additionally may not be safe for diabetic women to take because of the possible effects it may have on blood-glucose levels. See Prescribing information of Plan B provided by its provider, Duramed, *available at* <http://www.go2planb.com/PDF/PlanBPI.pdf>.

138. See Part III.B.

139. See H.R. 1652, 109th Cong. § 249(a)(1) (2005).

140. *Id.* § 249(a)(2)(B) (emphasis added).

141. See Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6 (stating that transferring prescriptions is a type of system that ensures patients receive access to care).

142. See Sonnedecker, *supra* note 78, at 299 (describing the earning and resource differences of individual and chain drugstores). See *generally* Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6.

143. See H.R. 1652, 109th Cong. § 249(a)(2); Press Release Rep. Carolyn Maloney, *supra* note 127.

DUTY TO FILL?

The *pharmacy ensures, subject to the consent of the individual, that the product is, without delay, ordered by another pharmacist employed by the pharmacy.*¹⁴⁴

While the Act does not expressly require that all types of birth control must be on hand at the pharmacy at all times, it does require that the pharmacy order that medication whenever a patron requests it.¹⁴⁵

In looking at the language of the statute, the ALPhA goes farther than regulating pharmacist conduct by affecting the business decisions of pharmacies with respect to ordering medications. The ALPhA “dictat[es] how a business must accommodate its [patients].”¹⁴⁶

[D]epending on the patient’s needs, how quickly the pharmacy can receive the drug, and how much more the drug may cost the pharmacy (special orders may cost the pharmacy more—and the pharmacy may not receive any payment to cover those additional costs), special-ordering the drug may not be a viable option.¹⁴⁷

On the business end of the profession, duty to fill legislation has the effect of:

[Compelling] health care providers and businesses to provide certain services. Decisions about what services to provide and by whom should be left up to individual health care providers. Decisions about which systems to implement and how to implement them should be left up to the pharmacy managers and pharmacists. Patients will choose the pharmacy and pharmacists who best serve their needs, and market forces will dictate what services the pharmacies provide.¹⁴⁸

Subject to a patient’s consent, and without allowing the pharmacy the option of transferring the prescription, pharmacists would be compelled to order medications at the patient’s demand. Medicines that patients use on a weekly or monthly basis would have to be ordered in advance and on a regular basis by the pharmacy, despite how the pharmacist may want to run his own business.¹⁴⁹ Pharmacy as a business enjoys the same freedom of contract as other businesses do; the owner has the right to decide what he or she wants to sell. This is no different whether the owner of the pharmacy is a licensed pharmacist or a lay person. The bill’s language improperly infringes on this freedom of contract.

144. H.R. 1652 § 249(a)(2) (emphasis added).

145. *See id.*; Press Release Rep. Carolyn Maloney, *supra* note 127.

146. *See generally* Press Release Rep. Carolyn Maloney, *supra* note 127.

147. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6.

148. *Id.*

149. *Id.*

C. The requirements and penalties established in the ALPhA are unduly harsh to small, independent pharmacies

Section 249(c) describes the civil and private penalties to which pharmacies will be subject for failing to follow the conditions set by the ALPhA.¹⁵⁰ These include “a civil penalty in an amount not exceeding \$5,000 per day of violation, not to exceed \$500,000 for all violations adjudicated in a single proceeding,”¹⁵¹ and a cause of action for any person injured as a result of a violation including, “actual and punitive damages, injunctive relief, and a reasonable attorney’s fee and cost.”¹⁵²

Small neighborhood pharmacies would bare the brunt of the ALPhA penalties.¹⁵³ As stated above, this legislation puts an affirmative duty on the pharmacy to guarantee that a pharmacist at that particular pharmacy will always be on hand to fill prescriptions that other pharmacists may have an objection to filling.¹⁵⁴ It also puts a strict timing duty on the pharmacy to fill such prescriptions.¹⁵⁵ The prescription must be filled without delay, which is defined in the act as “the amount of time it would take the pharmacy to fill a prescription that is not personally objectionable to the pharmacist.”¹⁵⁶ If the pharmacy usually takes one hour to fill a prescription, then that is the time frame to which the pharmacy must adhere in filling morally objectionable prescriptions.¹⁵⁷ In addition, placing special orders for medications costs more money—money that small pharmacies cannot afford to lose when competing with large corporate chains.¹⁵⁸ Small pharmacies simply do not have the same resources as large corporate pharmacies to adhere to the strict timing and ordering requirements of this act.¹⁵⁹ By re-

150. See H.R. 1652, 109th Cong., § 249(c).

151. *Id.*

152. *Id.*

153. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6; Dailard, *supra* note 16.

154. H.R. 1652 § 249(a)(1).

If a product is in stock and a pharmacist employed by the pharmacy refuses on the basis of a personal belief to fill a valid prescription for the product, the pharmacy ensures, subject to the consent of the individual presenting the prescription in any case in which the individual has reason to know of the refusal, that the prescription is, without delay, filled by another pharmacist employed by the pharmacy.

Id.; see also Press Release Rep. Carolyn Maloney, *supra* note 127.

155. Press Release Rep. Carolyn Maloney, *supra* note 127.

156. H.R. 1652, 109th Cong., § 249(d)(8) (“The term ‘without delay,’ with respect to a pharmacy filling a prescription for a product or ordering the product, means within the usual and customary timeframe at the pharmacy for filling prescriptions for products for the health condition involved or for ordering such products, respectively.”); see also Press Release Rep. Carolyn Maloney, *supra* note 127.

157. Press Release Rep. Carolyn Maloney, *supra* note 127.

158. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6; see also Dailard, *supra* note 16, at 11–12.

159. See Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6; Nguyen, *supra* note 128, at 272–73.

DUTY TO FILL?

moving the option of transferring the prescription to another area pharmacy, the small neighborhood pharmacy is particularly susceptible to fines under this act.¹⁶⁰

D. The ALPhA requires pharmacists to provide patients more than ordinary care

The act as a whole also requires pharmacists to carry out a set of actions that go above and beyond ordinary patient care. Traditionally, a pharmacist only owes a duty of ordinary care that reflects the “degree of knowledge, skill, and diligence exercised by other members of the profession” to their patients.¹⁶¹ New York requires that pharmacists meet this duty of ordinary care.¹⁶²

In *France v. State of New York*, for example, a prison pharmacist failed to fill an inmate’s prescription for an ointment to soothe a skin condition called atopic dermatitis for a full month.¹⁶³ As a result, the prisoner “suffered discomfort during this period, as his skin dried, cracked and scaled and he was unable to relieve any of his pain without the ointment.”¹⁶⁴ Because the state failed to provide “any evidence explaining why the druggist refused to fill the prescription,”¹⁶⁵ the pharmacist’s failure to fill the prescription was a breach of ordinary care which rendered him liable for the patient’s damages.¹⁶⁶

Ordinary care in reference to pharmacy practice was evaluated in this case as “the highest practicable degree of thoughtfulness and vigilance, and the most exact and reliable safeguards consistent with the reasonable conduct of the business.”¹⁶⁷ Ordinary care, therefore, is a rule of reason and only mandates that a pharmacist do what is reasonable under the circumstances in dealing with patrons.

In *McChonchie v. Wal-Mart Stores, Inc.*, the court held that refusing to fill an unprofitable prescription was neither a breach of ordinary care nor unpro-

160. Dailard, *supra* note 16.

161. Steven W. Huang, *The Omnibus Reconciliation Act of 1990: Redefining Pharmacists’ Legal Responsibilities*, 24 AM. J. L. & MED. 417, 421 (1998) (quoting David J. Marchitelli, Annotation, *Liability of Pharmacist who Accurately Fills Prescription for Harm Resulting to User*, 44 A.L.R. 393 (1996)); see also *Selected Recent Court Decisions: Pharmacy: Negligence in Filling Prescriptions—Hooks SuperX, Inc. v. McLaughlin*, 20 AM. J. L. & MED. 503, 508 (1994) (discussing legal standard of care for pharmacists).

162. *Willson v. Faxon*, 208 N.Y. 108, 114 (1913) (“The negligence which must be established to render a druggist liable, in [a case based upon the sale of a poison to a person who called for a harmless drug], is measured by his duty; and while this is only to exercise ordinary care, the phrase ordinary care in reference to the business of a druggist must be held to signify the highest practicable degree of prudence, thoughtfulness and vigilance, and the most exact and reliable safeguards consistent with the reasonable conduct of the business.”).

163. 506 N.Y.S.2d 254, 254–55 (1986).

164. *Id.* at 255.

165. *Id.*

166. *Id.*

167. *Willson*, 208 N.Y. at 114.

fessional conduct.¹⁶⁸ *McConchie* involved a pharmacist who was fired for filling a prescription that his employer told him not to fill.¹⁶⁹ The major issue in the case was “whether, under New York law, an employer’s termination of a licensed pharmacist for disobeying a directive that the pharmacist believed to be unethical and illegal is actionable as a breach of contract based upon an implied-in-law obligation.”¹⁷⁰ The plaintiff pharmacist’s employer noticed that profit margins had been falling as a result of filling bulk prescriptions for a veterinarian, Dr. Prendergast.¹⁷¹ He therefore ordered the pharmacist to no longer fill any prescription written by Dr. Prendergast.¹⁷² The plaintiff informed his employer that he believed it would be “against the law and pharmaceutical ethics to refuse to fill or refill a prescription based on profit margin.”¹⁷³ His employer disagreed and insisted that the pharmacist not fill the prescriptions.¹⁷⁴ The pharmacist disobeyed his employer’s mandate and filled three more prescriptions for Dr. Prendergast.¹⁷⁵ As a result, the plaintiff pharmacist was fired.¹⁷⁶

The court ruled for the defendant and held that “[p]laintiff can point to no rule specifically covering the conduct in question, i.e., refusing to fill large volume prescriptions because of economic or licensing considerations.”¹⁷⁷ The court reasoned that “[n]one of the statements in defendant’s own internal policy upon which plaintiff relies, such as those requiring that Wal-Mart pharmacists are to ‘maintain high ethical standards’ and ‘perform the legal and moral responsibility to the profession and to the general public,’ render [the employer’s] mandate improper.”¹⁷⁸ The court found that in the absence of evidence showing that the pharmacist reasonably believed that the employer’s mandate was a violation of the Rules of the Board of Regents Section 29.2,¹⁷⁹ refusing to fill a prescription for a regular customer for economic reasons was not a violation of the ethics rules or a pharmacist’s duty of care.¹⁸⁰

168. 985 F. Supp. 273, 279 (N.D.N.Y. 1997).

169. *Id.* at 276.

170. *Id.* at 274.

171. *Id.* at 275.

172. *Id.*

173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.* at 275–76.

177. *Id.* at 279.

178. *Id.*

179. Section 29.2(a) states that “unprofessional conduct shall include: (1) abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care” N.Y. COMP. CODES R. & REGS. tit. 8 § 29.2(a) (2006).

180. *McConchie*, 985 F. Supp. at 280. The court also said that Prendergast was “able to fill the prescriptions at another pharmacy in the area” and that “Prendergast never told [the pharmacist] that the prescriptions were for medical emergencies.” *Id.*

DUTY TO FILL?

Under the ALPhA, pharmacists would presumably be held strictly liable for damages flowing from the failure to fill birth control and emergency contraceptives. This is because the act places an affirmative duty to fill all legally valid medications despite harm to the consumer.¹⁸¹ However, courts have traditionally been reluctant to hold pharmacists to a standard of strict liability.¹⁸² Although there is a duty to dispense medications properly,¹⁸³ there has been no corresponding duty to fill every prescription handed to a pharmacist.

IV. THE FEDERAL GOVERNMENT SHOULD REVISE THE ALPhA BASED ON THE NEW YORK STATE BOARD OF PHARMACY'S GUIDELINE

Laws that govern pharmacist conduct should recognize the importance of patients receiving legally prescribed medications, but must also preserve pharmacists' discretion.¹⁸⁴ Preserving pharmacist discretion is not an unusual consideration because many other federal and state regulations do just that.¹⁸⁵ While the ALPhA limits a pharmacist's discretion, other federal and state regulations such as the CSA and drug product selection laws are narrowly tailored to recognize that a pharmacist's expertise in clinical practice and the business of pharmacy are valuable and necessary safeguards of our healthcare system.¹⁸⁶ The ALPhA should be rewritten with these other regulations in mind. In particular, the federal government could look to language similar to that contained in the New York State Board of Pharmacy's *Policy Guideline Concerning Matters of Conscience*, to guide it in constructing a narrowly tailored regulation that achieves its goals without unduly burdening the business and practice of pharmacy.¹⁸⁷ The language of this policy balances the interests of pharmacists and patients by preserving pharmacist discretion, protecting the business of pharmacy, better protecting small neighborhood pharmacies, and better following other pharmacy practice acts that affect pharmacist discretion, while still respecting a patient's right to obtain legally prescribed medication. Additionally, it is important for the federal government to look toward state recommendations for guidance because states have more experience regulating pharmacy practice.

181. *See supra* Part II.A.

182. Huang, *supra* note 161, at 421–22.

183. *Id.* at 428.

184. *See generally* Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6; Dailard, *supra* note 16, at 10 (discussing the APhA's adopting a policy that both "recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal").

185. *See supra* Part III.A.

186. *See supra* notes 108–20 and accompanying text.

187. Memorandum from Lawrence H. Mokhiber, Executive Secretary, New York State Education Department, to Supervising Pharmacists (Nov. 18, 2005), *available at* <http://www.op.nysed.gov/pharm/conscienceguideline.htm>.

A. Federal and state statutes that regulate pharmacy are usually tailored to protect the public while keeping pharmacist discretion intact

Preserving pharmacist discretion in the regulation of pharmacy practice is an important consideration in tailoring both federal and state regulations. As stated above, the CSA regulates the dispensing of controlled substances by pharmacists because controlled substances have a high potential to be abused by patients.¹⁸⁸ The DEA placed prescription-dispensing limitations on these drugs by placing them in different categories, reflecting their addictiveness and danger to patients' health.¹⁸⁹ Depending on the category or schedule in which the drug is placed, the pharmacist does not have discretion to refill the prescription under certain circumstances.¹⁹⁰ For example, drugs that fall under Schedule II status such as Morphine, Percodan, Amphetamines, and Barbiturates cannot be refilled without a prescription, and if a partial quantity is dispensed, the remainder must be given to the patient within seventy-two hours.¹⁹¹ However, the pharmacist retains discretion to "dispense partial quantities of Schedule II medications to patients in long-term care facilities or who are terminally ill for up to sixty days from the original date of the prescription's issuance."¹⁹² Schedule II drugs also cannot be filled by a verbal prescription.¹⁹³ However, again, in an emergency situation, the CSA allows the pharmacist the discretion to dispense medications but only what is necessary to get the patient through the emergency and only upon oral notification by the prescribing physician.¹⁹⁴ Additionally, pharmacists retain discretion not to fill controlled substance prescriptions when they believe that the prescription was not dispensed in good faith or for a legitimate medical purpose.¹⁹⁵

Another type of regulation that preserves pharmacists' discretion is drug product selection laws.¹⁹⁶ These regulations involve a combination of federal and state laws.¹⁹⁷ These laws recognize that when a doctor writes a prescription for a drug, situations may arise where dispensing a different product that is either the bioequivalent or therapeutic equivalent to the prescribed medication is better

188. PISANO, *supra* note 3, at 29.

189. *Id.* at 30.

190. *Id.* at 30–33.

191. *Id.* at 31.

192. *Id.*

193. *Id.* at 32.

194. *Id.*

195. *Id.* at 39.

196. *See generally id.* at 33–34.

197. *Id.*

DUTY TO FILL?

or more economically feasible to the client.¹⁹⁸ The federal government, through the FDA, publishes a list of suitable substitution products called “Approved Drug Products with Therapeutic Equivalence Evaluations.”¹⁹⁹ These evaluations are prepared as a guide for healthcare professionals to evaluate feasible substitutes to a physician’s recommendation.²⁰⁰ If the FDA gives the drug an A rating, the pharmacist has discretion to substitute the drug for its bioequivalent.²⁰¹ If the drug receives a B rating, states have the option of allowing pharmacists the discretion to use it as an appropriate substitution.²⁰² Although these laws govern pharmacists’ conduct, they do so in a narrowly tailored way to preserve pharmacists’ discretion.

B. The federal government should consider adopting similar language to New York’s policy guideline

In response to pharmacists’ confusion as to what their obligations are to fill prescriptions to which they may object, New York’s State Board of Pharmacy issued a policy guideline. The *Policy Guideline Concerning Matters of Conscience* was adopted on November 18, 2005 and posted on the Office of the Professions official website in March 2006.²⁰³ The pertinent language of the recommendation reads as follows:

[I]f a pharmacy employs a pharmacist that has identified circumstances that would preclude the filling of prescriptions for particular products, the owner and supervising pharmacist should devise, within reason, accommodations that will respect the pharmacist’s choice while assuring delivery of services to patients in need. This may include special attention to scheduling of professionals to allow a pharmacist who has a religious, moral or ethical obligation to practice simultaneously with another pharmacist who will fill the requested prescription, entering into collaborative arrangements with pharmacies in close proximity, or other accommodations designed to protect the public²⁰⁴

This recommendation does not have the force of law. It does, however, help ensure that patients get their medications without infringing upon a pharmacist’s discretion. The language also protects business decisions and allows pharmacies the option to transfer a prescription or come up with other reasonable remedies without the fear of harsh penalties typical of the duty to fill legislation.

198. *Id.* at 33.

199. *Id.* at 34.

200. *Id.*

201. *Id.*

202. *Id.*

203. Mokhiber, *supra* note 187.

204. *Id.*

1. *The language protects business decisions*

The State Board of Pharmacy guideline provides:

When a pharmacist recognizes that his/her religious, moral, or ethical belief, or any other factor, will result in the refusal to fill a prescription that is *otherwise available in a pharmacy* the pharmacist has a professional obligation to take appropriate steps to avoid the possibility of abandoning or neglecting a patient.²⁰⁵

The *otherwise available in a pharmacy* language would appropriately protect pharmacies that choose not to carry certain medications for any reason. Unlike duty to fill legislation, there is no affirmative duty placed on pharmacies to keep in stock or to order certain medications.²⁰⁶ With the vast number of legal medications on the market today, it is an economic impossibility to carry them all and pharmacies, as business entities, should be allowed to choose for any reason why they would keep some medications in stock and not others.²⁰⁷ As such, pharmacies will develop reputations for carrying or not carrying certain items, allowing consumers to make an appropriate choice as to where they want to take their business.²⁰⁸

In instances where the medication is carried by the pharmacy, but the pharmacist on duty has an objection to filling it, the language also protects business by allowing the pharmacy, and not the legislature, to prescribe the most beneficial way to accommodate the patient in that local community. The language states:

[T]he *owner and supervising pharmacist should devise, within reason*, accommodations that will respect the pharmacist's choice while assuring delivery of services to patients in need. *This may include* special attention to scheduling of professionals to allow a pharmacist who has a religious, moral or ethical objection to practice simultaneously with another pharmacist who will fill the requested prescription, *entering into collaborative arrangements with pharmacies* in close proximity, or other accommodations designed to protect the public²⁰⁹

Unlike troublesome duty to fill legislation, the affirmative duty is on the pharmacy to do what is reasonable. Unlike with the ALPhA, transferring the prescription is an option. The language *this may include* expands the reasonable

205. *Id.* (emphasis added).

206. *See supra* notes 153–63 and accompanying text.

207. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6, at 7–8.

208. *Id.* For example, Wal-Mart is known nationally for not carrying Plan B. Holly Teliska, Note, *Recent Development: Obstacles to Access: How Pharmacist Refusal Clauses Undermine the Basic Health Care Needs of Rural and Low-Income Women*, 20 BERKELEY J. GENDER L. & JUST. 229, 240 n.88 (2005).

209. Mokhiber, *supra* note 187 (emphasis added).

DUTY TO FILL?

choice to possibilities not enumerated in the text.²¹⁰ It recognizes that every community is different and gives the pharmacy a range of accommodations it may be able to give to customers. This language is also better in tune with the tradition of holding pharmacists to an ordinary care standard and mimics the American Pharmacist Association's recommendations on the matter.²¹¹ The Association recommends that a pharmacist should never feel compelled to fill a prescription to which he objects, but to make it known to the employer preemptively so that measures can be reasonably devised to accommodate a patient in need of medication.²¹²

2. *The language keeps pharmacists' discretion and clinical duty intact*

The State Board of Pharmacy guideline provides:

Pharmacists have a professional responsibility to ensure that their patients obtain properly ordered and *therapeutically appropriate* medications in a timely manner with *appropriate counseling from a pharmacist* When a pharmacist recognizes that his/her religious, moral, or ethical belief, or any other factor, will result in the refusal to fill a prescription . . . the pharmacist has a professional obligation to take *appropriate steps* to avoid the possibility of abandoning or neglecting a patient²¹³

This language helps protect both the patient and the pharmacist. The “policy balances the needs of the patient and the individual needs of the pharmacist, as well as the pharmacist’s professional responsibility.”²¹⁴ Instead of looking at pharmacists as mere dispensers of medication, the language of the recommendation recognizes that pharmacists are independent thinking healthcare professionals, and does not mandate that all legally prescribed medications be filled in a timely manner. It recognizes that the issue to be resolved here is the filling of prescriptions to which pharmacists may morally object, and uses narrow definite language to achieve a resolution that could not be read to take pharmacists’ discretion away from filling prescriptions that they would otherwise deem as therapeutically dangerous.

210. *Id.*

211. See generally Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6; Dailard, *supra* note 16 (discussing the APhA’s policy supporting “the individual pharmacist’s right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist’s right of conscientious refusal.”). See also Teliska, *supra* note 208, at 238 n.68.

212. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6, at 1; see also Smearman, *supra* note 123, at 516.

213. Mokhiber, *supra* note 187 (emphasis added).

214. Statement of Linda Garrelts MacLean, RPh, CDE, *supra* note 6.

V. CONCLUSION

The artisans of Mesopotamia and the alchemists of the Middle Ages could never have foreseen how their independent practices could be so heavily regulated and monitored in the distant future. Even the druggists of the early nineteenth and twentieth centuries may not have foreseen any reason why their practices should be regulated. In this day of mass-produced, publicly available drugs and decreased need for handmade medicine, the professional world of the pharmacist is vastly different than it was fifty years ago. However, no matter the changes it undergoes, the practice of pharmacy is still the practice of a profession, and any laws prescribed to regulate that practice should recognize and respect pharmacists' discretion as well as their business. In contemplating legislation that will affect pharmacy practice, the federal government should choose much narrower language than that suggested by ALPhA to ensure a proper resolution to the problem it wants to resolve.