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Dying to Wait: How the Abigail Court Got It Wrong

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DYING TO WAIT: HOW THE ABIGAIL COURT GOT IT WRONG

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I. INTRODUCTION

At age twenty-one, Abigail Kathleen Burroughs met a fate usually reserved for aged men who have spent much of their lives drinking and smoking.¹ Diagnosed

[†] To Professor Stephen W. Gard. Your encouragement and support inspired me toward excellence. Thank you for pushing me to write just “one more draft.”

To the memory of Abigail Kathleen Burroughs and to the Abigail Alliance for Better Access to Developmental Drugs. Your struggle has moved me.

To *mi madre*, who has patiently witnessed my growth and suffered the pain of a mother and the joy of a parent. Without you, I am not me. I thank you every day. To my father, *el toro*, who worked through life with his head down but never low. Your quiet dignity and your silent example continue to guide me toward personhood, manhood, and *paternidad*. To my maternal grandmother, Emilia, who resides in the memories of the ancestors and therefore is never still but moves in the darkness of my remembrance and has become my light. To all of those in *mi familia* who sometimes doubted but did not lose faith.

Thank you.

with cancer at age nineteen, Abigail battled the squamous cell carcinoma that invaded her body even as she struggled to maintain her characteristic optimism.²

Abigail struggled with more than her illness, however.³ In the last years of her life, Abigail and her family also wrestled with Food and Drug Administration (FDA) regulations that denied her access to medication that could have saved her life.⁴ The policy at issue was the FDA's practice of progressive testing, which requires that experimental drugs pass at least three testing phases before the FDA will grant approval for commercial marketing and public access to a drug.⁵ For Abigail, the process proved too long.⁶ This policy denied her the experimental drug, Erbitux, a cancer-fighting drug that Abigail's oncologist believed had a significant chance of saving her life.⁷ Despite her doctor's dedication and her family's continuing support, Abigail died in 2001—just two years after being diagnosed with the fast-moving cancer.⁸

Following Abigail's death, her father, Frank Burroughs, founded the *Abigail Alliance for Better Access to Developmental Drugs* (Abigail Alliance)⁹ which has dedicated itself to removing the “regulatory barriers currently preventing seriously ill patients from gaining access” to potentially life-saving drugs.¹⁰ Toward that end, the Abigail Alliance filed suit against the Secretary of the Department of Health and Human Services and the FDA Commissioner, seeking to enjoin enforcement of the ban on Phase I experimental drugs¹¹ that have been “deemed sufficiently safe for substantial human testing, but [have] not yet proven to be safe and effective [for commercial marketing].”¹²

On August 30, 2007, the D.C. Circuit dealt the Abigail Alliance a harsh blow when it held in *Abigail v. von Eschenbach* that terminally ill patients, such as Abigail, have no constitutional right of access to drugs that have not been proven

¹ See Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncaring Bureaucracy*, in LIFE EXTENSION 26 (Special Ed. 2007), available at <http://abigail-alliance.org/LEMSEP07pAbigailLR.pdf>.

² *Id.* at 26.

³ *Id.* at 26-28.

⁴ *Id.* at 26.

⁵ See *Abigail Alliance v. von Eschenbach*, 495 F.3d 695, 698 (D.C. Cir. 2007), *cert. denied* 128 S.Ct. 1069 (2008); see also *Abigail Alliance v. von Eschenbach*, 445 F.3d 470, 474 (D.C. Cir. 2006).

⁶ See Kovach, *supra* note 1, at 26-27.

⁷ *Id.* at 26.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.* at 25.

¹¹ See *Abigail Alliance*, 445 F.3d at 473-474, *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

¹² See *Abigail Alliance*, 445 F.3d at 473, 486 (quoting FDA counsel's oral arguments that “[i]t takes approximately one year to conduct Phase I testing”).

safe and effective by the FDA.¹³ Consequently, seriously ill patients seeking access to experimental drugs must either fit the FDA's stringent qualifications for experimental trials or wait for the drug to make its way through the FDA's burdensome approval process.¹⁴ For people, like Abigail, who are denied participation in experimental studies,¹⁵ the typical seven-year wait will end in a death made all the more bitter by the knowledge that the FDA withheld access to potentially life-saving medications.¹⁶ That the FDA eventually approved the very experimental drug Abigail sought to save her life must have been bitter medicine for her friends and family.¹⁷

This paper will argue that the D.C. Circuit's decision in *Abigail* rested on faulty conclusions. Specifically, the *Abigail* court's cursory examination of the history of drug¹⁸ regulation in the United States resulted in a mischaracterization of our nation's traditional attitude toward individual access to medicines. A close examination of the history of pharmacology in this country reveals the true tradition—a society accustomed to self-medicating and which implicitly assumed the government could not interfere with its personal choice to take certain medications.¹⁹

Section II of this paper examines the holding in *Abigail* with reference to *Washington v. Glucksberg*,²⁰ which set out the test for determining whether a

¹³ See *Abigail Alliance*, 495 F.3d at 697. The *Abigail* court also rejected the Abigail Alliance's arguments that application of the FDA policies is an intentional tort because it prevents a third party from rendering necessary aid to terminally ill patients and furthermore ruled that the common law doctrines of necessity and self-defense do not support the Abigail Alliance's claim of a fundamental right of access. *Id.*

¹⁴ See Kovach, *supra* note 1, at 27.

¹⁵ Sue Kovach writes that although the FDA was testing the efficacy of Erbitux in battling the type of cancer cells invading Abigail's body, the FDA denied her access to the experimental trials because those trials were designed to treat colon cancer. See Kovach, *supra* note 1, at 27. Because Abigail's cancer was located in her head and neck, the FDA considered her case irrelevant to the study. *Id.*

¹⁶ See *Abigail Alliance*, 495 F.3d at 698 (noting that the "testing process is an extremely lengthy one, requiring nearly seven years for the average experimental drug").

¹⁷ See Andrew Pollack, *Court Rejects Patient Right to Use Drugs Being Tested*, N.Y. TIMES, Aug. 8, 2007, at A12.

¹⁸ The 1828 edition of Webster's American Dictionary of the English Language defines "drug" as "[t]he general name of substances used in medicine, sold by the druggist, and compounded by apothecaries and physicians; any substance, vegetable, animal or mineral, which is used in the composition or preparation of medicines." *Webster's 1828 Dictionary*, CORNERSTONE BAPTIST TEMPLE, <http://www.cbministries.org/resources/webster1828.htm> (last visited Nov. 30, 2007).

¹⁹ See *infra* Part III.

²⁰ See *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1997). The Supreme Court in *Glucksberg* stated the test thusly:

"Our established method of substantive-due-process analysis has two primary features: First, we have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed . . . [s]econd, we have required

particular liberty interest is fundamental. Section III reveals the long-held American tradition of self-medication. Section IV surveys the American history of drug regulation and analyzes the text of several state and federal laws the *Abigail* court cited to support its holding. Section V proposes that application of the *Glucksberg* test to this country's long tradition of self-medication regulation renders the conclusion that there is in the United States a fundamental right of access to experimental drugs. Finally, Section VI concludes that courts should recognize the Abigail Alliance's fundamental right of access to experimental drugs.

II. ABIGAIL ALLIANCE V. VON ESCHENBACH

The Due Process Clause of the Fifth Amendment precludes the government from depriving persons of "life, liberty, or property, without due process of law."²¹ The Supreme Court has held that these rights warrant "heightened protection against governmental interference with certain fundamental rights and liberty interests."²² Therefore, if the government impinges on fundamental rights, such as privacy, marriage, abortion, or bodily integrity, its action must be necessary to fulfill some compelling governmental interest.²³

In *Abigail*, the D.C. Circuit held that terminally ill patients do not have a fundamental right of access to potentially life-saving drugs that have not been fully approved by the FDA.²⁴ The *Abigail* court relied heavily on *Washington v. Glucksberg*, which held that a right is fundamental under the due process clause if it is "objectively, deeply rooted in this nation's history and tradition...and implicit in the concept of ordered liberty."²⁵ The *Abigail* court concluded that there is no tradition in the United States to support a right of access to drugs that have not been proven safe.²⁶ Instead, the court stated that this country has a long history of drug regulation aimed at preventing access to unsafe drugs.²⁷ Accordingly, the court

in substantive-due-process cases a careful description of the asserted fundamental interest."

Id. at 720-21.

²¹ U.S. CONST. amend. V.

²² *Glucksberg*, 521 U.S. at 720.

²³ See *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Loving v. Virginia*, 388 U.S. 1 (1967); *Roe v. Wade*, 410 U.S. 113 (1973); and *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891) (concluding that "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law").

²⁴ See *Abigail Alliance*, 495 F.3d at 697.

²⁵ *Glucksberg*, 117 U.S. at 720-721 (1997). The *Glucksberg* test requires a showing that a liberty interest is deeply rooted in our nation's history and traditions, but also that the interest is "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if it were sacrificed." *Glucksberg*, 521 U.S. at 721. The *Abigail* court, however, did not reach the second prong because it concluded that the Abigail Alliance had failed to show their interest was deeply rooted in this nation's history and tradition. See *Abigail Alliance*, 495 F.3d at 697.

²⁶ See *Abigail Alliance*, 495 F.3d at 703.

²⁷ *Id.*

subjected FDA regulations prohibiting access to experimental drugs to the relatively undemanding test of rational basis scrutiny.²⁸ The court then concluded that FDA regulations limiting access to experimental drugs are rationally related to the state's legitimate interest in protecting the public from potentially unsafe drugs whose efficacy has not been established.²⁹ Had the *Abigail* court determined that terminally ill patients have a fundamental right of access to potentially life-saving experimental drugs, it would have then subjected the FDA policies at issue to strict scrutiny, a much higher constitutional standard.³⁰

To support its conclusions, the *Abigail* court offered a history of drug safety regulation dating back to 1736 and professed the existence of a long history of drug regulation in England.³¹ The court's treatment of the history, however, was cursory and resulted in premature assumptions based on a mischaracterization of the laws it blithely cited. The court failed to consider the vast historical material which reveals the real tradition in this country: the individual's unfettered choice to ingest drugs, even those not proven safe for human consumption.³² The true American tradition is one of self-medication, not government regulation.³³

III. THE AMERICAN TRADITION OF SELF-MEDICATION

A. Self-Medication in Early America

For centuries, Americans enjoyed the right to decide how to cure themselves—a tradition inherited from English culture.³⁴ American colonists treasured their medical self-help books and brought from their mother country the custom of self-medication.³⁵ As early as 1613, books, such as *The English Housewife* and the *English Husbandman*, guided colonists in cultivating and administering medicinal herbs and drugs.³⁶ More than a century later, John Tenant of Virginia published *Everyman His Own Doctor* (1734), which was translated into German and used by common farmers throughout Pennsylvania Dutch.³⁷

Medicinal decoctions were often administered by the earliest medical practitioners in colonial America—British housewives.³⁸ This American tradition is

²⁸ *Id.* at 712-13.

²⁹ *Id.* at 713.

³⁰ *Id.* at 711.

³¹ *Id.* at 704-06.

³² *See infra* Part III.

³³ *See infra* Parts III and IV.

³⁴ *See* EDWARD KREMERS & GEORGE URDANG, KREMERS AND URDANG'S HISTORY OF PHARMACY 153 (Glenn Sonnedecker ed., J.B. Lippincott) (4th ed. 1976).

³⁵ *Id.* at 153.

³⁶ *Id.*

³⁷ *See* DAVID L. COWEN, PHARMACOPOEIAS AND RELATED LITERATURE IN BRITAIN AND AMERICA, 1618-1847 at 269 (Ashgate 2001).

³⁸ *See* KREMERS, *supra* note 34, at 153.

reflected in Nicolas Culpeper's *The English Physician*, a book published in 1652 as a "Discourse of the Vulgar Herbs of this Nation; Containing a Compleat [sic] Method of Physick [sic]. Whereby a man may preserve his body in Health, or Cure Himself, being Sick, for three pence Charge with such things only as grow in England, they being most fit for English bodies."³⁹

The English settlers took advantage of their opportunity to experiment in their New World, a land that rendered new and diverse flora with immense curative potential.⁴⁰ Colonists learned to grow plants and indigenous herbs, and experimented with treatments learned from Native Americans⁴¹ despite repeated admonitions from medical doctors, who warned against the dangers of unknown therapies.⁴² For example, in his Centennial Address to the Massachusetts Medical Society in 1881, Dr. Samuel Abbott Green warned colleagues about the medical treatments colonists sought from Native Americans:

The Indians had no knowledge of medicine, but were accustomed to treat disease largely by incantations and powwows. There is, however, a popular belief to-day that the Indian doctor is skilled in botanical remedies, as he is wont to use the infusions and decoctions of various roots and herbs. While there is no ground for such an impression, *he will yet be consulted as long as the race of simpletons continues to exist—perhaps to the millennium.* The ravages of small-pox among the ignorant natives were fearful, as they had no knowledge of inoculation or vaccination; and thus a new danger opposed the *white settlers, who were already overburdened by their cares and trials.*⁴³

³⁹ Quoted in George E. Osborne, *Pharmacy in British Colonial America*, in AMERICAN PHARMACY IN THE COLONIAL REVOLUTIONARY PERIODS: A BICENTENNIAL SYMPOSIUM SPONSORED BY THE AMERICAN INSTITUTE OF THE HISTORY OF PHARMACY WITH THE CO-SPONSORSHIP OF THE AMERICAN PHARMACEUTICAL ASSOCIATION AND THE AMERICAN SOCIETY OF HOSPITAL PHARMACISTS, NEW ORLEANS, APRIL, 1976 at 8 (George A. Bender and John Parascandola, eds., American Inst. of the History of Pharmacy 1977).

⁴⁰ See KREMERS, *supra* note 34, at 146-47.

⁴¹ Colonists' use of Native American drugs was extensive. See COLIN G. CALLOWAY, *NEW WORLDS FOR ALL: INDIANS, EUROPEANS, AND THE REMAKING OF EARLY AMERICA* 26-33 (Johns Hopkins 1997). In fact, about 170 drugs used by Native Americans in North and South America were included in the United States Pharmacopoeia or the National Formulary. See KREMERS, *supra* note 34, at 147. These two sources became the official standard used under the Federal Food and Drug Administration Act passed in 1906. See Glenn Sonnedeker, *Drug Standards Become Official*, in *THE EARLY YEARS OF FEDERAL FOOD AND DRUG CONTROL* 28-30 (Glenn Sonnedeker ed., Am. Inst. of the History of Pharmacy 1982).

⁴² See SAMUEL ABBOTT GREEN, *HISTORY OF MEDICINE IN MASSACHUSETTS: A CENTENNIAL ADDRESS DELIVERED BEFORE THE MASSACHUSETTS MEDICAL SOCIETY AT CAMBRIDGE* 13 (A. Williams and Co. 1881). Native Americans employed extensive knowledge of the healing properties of plants. They used leaves, roots, and bark to develop powerful remedies, many of which colonists consumed without ever discovering the secret to their curative powers. See CALLOWAY, *supra* note 41, at 26-27.

⁴³ GREEN, *supra* note 42, at 13 (emphasis added).

Dr. Green's words reflect Americans' faith in Native American medicine and the great extent to which early settlers relied on Native American treatments, despite medical officials' recriminations against such practices. That Dr. Green delivered this speech to the Massachusetts Medical society suggests that the medical establishment viewed Indian medicine as little more than attempts to heal by ceremony, incantation, and magic.

There seems to have been no consensus on this point among medical professionals. In colonial Virginia, for example, many English physicians and apothecaries dispatched their apprentices into the woods in search of herbal remedies.⁴⁴ Furthermore, the above excerpt reflects a determination among medical professionals to maintain their preeminence as doctors among a community of Americans accustomed to exercise what they had come to view as their right to self-medication.⁴⁵

Nevertheless, colonists' use of Native American drugs was extensive.⁴⁶ Many colonists, in fact, had great faith in the Native Americans' extensive knowledge of the healing properties of plants, and they consumed drugs⁴⁷ that Indian doctors decocted from leaves, roots, and bark, often without ever discovering the curative powers of these drugs.⁴⁸ Caught between official recriminations, such as those by Dr. Green,⁴⁹ and convictions held by those doctors who sought to replicate Indian remedies, many colonists chose to relieve their ills with Indian drugs, even though they often knew nothing about the nature of such medicines.⁵⁰ That government did not interfere with such decisions reflects how English tradition, the New World experience, and frontier living all combined to strengthen the American tradition of self-medication.⁵¹

The strength of this tradition, coupled with an increase in population, created a boom in the number of apothecary shops and drugstores that sold drugs to colonists

⁴⁴ See CALLOWAY, *supra* note 41, at 30-31.

⁴⁵ See KREMERS, *supra* note 34, at 159 (positing that London physicians sought to curb the ambitions of apothecaries, who also dispensed drugs to the public); *see also* text *infra* accompanying notes 80-83.

⁴⁶ See CALLOWAY, *supra* note 41, at 30-31.

⁴⁷ Although native treatments were decocted from plants, they were nonetheless drugs. In fact, the House Report on the Import Drug Act of 1848 specifically refers to plant derivatives as drugs. See H.R. Rep. No. 30-664. The Report refers to columbo and gentian roots as "important crude drugs" and enumerates plant derivatives, such as rhubarb root, jalap root, and sarsaparilla root, under the rubric of "some of the more important drugs." *Id.* at 4, 9. According to the report, Jalap root and Peruvian bark were "capital" medicines. *Id.* at 32, 29. Peruvian bark was used for quinine, which became an important drug for soldiers fighting in such wars as the American Revolution. See George B. Griffenhagen, *Medicines in the American Revolution*, in AMERICAN PHARMACY IN THE COLONIAL AND REVOLUTIONARY PERIODS 27 (George A. Bender & John Parascandola ed., American Institute of the History of Pharm. 1976).

⁴⁸ See CALLOWAY, *supra* note 41, at 26-27.

⁴⁹ See GREEN, *supra* note 42, at 13.

⁵⁰ See CALLOWAY, *supra* note 41, at 26-27.

⁵¹ See KREMERS, *supra* note 34, at 213.

over the counter.⁵² The increase led Dr. William Douglass to remark in 1722 that “[w]e abound with Practitioners, though no other graduate than myself, we have fourteen Apothecary shops in Boston; all our Practitioners dispense their own medicines.”⁵³ Whether run by physicians, pharmacists, apothecaries, or self-described purveyors of good health, these shops and drugstores dispensed myriad drugs, chemicals, and medicines directly to eager colonists.⁵⁴ In fact, in 1729 the revered Benjamin Franklin advertised in his *Pennsylvania Gazette* that his own store offered “powdered mustard, linseed oil, patent medicines and ‘seneca rattlesnake root, with directions how to use it in pleurisy.’”⁵⁵ Like many drug dispensers, it is unlikely that Franklin sold his wares by prescription to a community of colonists accustomed to self-medicating.⁵⁶

B. The Patent Medicine Boom

In the 1750s, English patent medicines⁵⁷ appeared in the colonies, and colonists began to dose themselves with large quantities of these “secret” medicines.⁵⁸ According to James Harvey Young, “Americans dosed themselves with galenicals and chymicals [sic], and swallowed complicated concoctions containing disgusting ingredients, in their efforts to drive away the ills” that afflicted them.⁵⁹ Known as “secret remedies” since the sixteenth century, patent medicines were concocted by anyone with a quest for knowledge and a bit of motivation.⁶⁰ Because the ingredients were secret, the patents issued covered only the shape of the bottles—not the contents,⁶¹ a policy that makes sense given that nobody really knew what was in

⁵² *Id.* at 155-57.

⁵³ *Id.* at 156.

⁵⁴ *Id.* at 157.

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ English patent medicines date back to the 1630s. The patent was a royal endowment given to makers of medicinal remedies that had become popular for their healing properties. Typically concocted from a multitude of unknown ingredients, patent medicines were marketed as cures for a wide variety of ailments. Eventually, the term “patent medicine” came to refer to any secret nostrum (patented or not) marketed as miracle remedies. *See generally* GEORGE B. GRIFFENHAGEN & JAMES HARVEY YOUNG, *Old English Patent Medicines in America*, in *CONTRIBUTIONS FROM THE MUSEUM OF HISTORY AND TECHNOLOGY, PAPERS 1-11*, 155 (Ernest E. Biebighauser ed., Smithsonian 1959).

⁵⁸ *See* JAMES HARVEY YOUNG, *THE TOADSTOOL MILLIONAIRES: A SOCIAL HISTORY OF PATENT MEDICINES IN AMERICA BEFORE FEDERAL REGULATION* 9, 67 (Princeton Univ. Press, 1961).

⁵⁹ *Id.* at 8.

⁶⁰ *See* Michael H. Jepson, *From Secret Remedies to Prescription Medicines: A Brief History of Medicine*, in *MAKING MEDICINES: A BRIEF HISTORY OF PHARMACY AND PHARMACEUTICALS* 224-26 (Stuart Anderson ed., Pharmaceutical Press 2005).

⁶¹ *See* YOUNG, *supra* note 58, at 40.

them. Thus, although the “ingredients might vary...,” the bottles were all shaped the same.⁶²

Countless advertisements testify to the wide acceptance and use of such medicines in American history.⁶³ By the time of the American Revolution, Americans had grown dependent on English patent medicines.⁶⁴ Because of non-importation policies during the war, English patent medicines had grown scarce, and Americans turned toward domestic production, which later boomed during the Civil War.⁶⁵ Americans replicated the English brands and packaged them inside the English bottles to give them the appearance of authenticity.⁶⁶ Although American patent medicines contained any number of ingredients, American consumers continued to purchase the “English” patent medicines because they recognized the bottles of their favorite brands.⁶⁷ In fact, the ability to market the medicines seems to have depended solely on the availability of authentic English bottles.⁶⁸ In short, it appears Americans continued to buy medicines concocted by their enterprising fellow citizens merely because they had grown to trust the bottles, not the ingredients.

The popularity of English patent medicines decreased dramatically by the end of the American Revolution.⁶⁹ This shift was not, however, due to Americans’ distaste for such medicines, but occurred because the domestic patent medicine industry had grown during the war and eventually supplanted its English antecedent.⁷⁰ The American patent medicine industry was then poised to reap huge potential benefits presented by a domestic market.

⁶² *Id.* at 12.

⁶³ James Harvey Young states:

Quackery was flagrant and brazen. No disease, however dire, if one believed advertising, could resist the potency of the promoter’s product. *Harper’s Weekly* possessed for its day a very large circulation and was considered one of the best advertising media in the nation. In leafing through the volume for 1876, the nation’s centennial year, I found in this most respectable publication promises for the certain cure of asthma, cancer, cholera, consumption, diabetes, diphtheria, epilepsy, rheumatism, gout, nervous ailments, and opium addiction. Although *Harper’s Weekly* was too genteel to accept abortifacient advertisements or promises to restore the prolapsed uterus or explicit cures for venereal disease and lost manhood, these bold claims could be found in other standard journals, including the religious press. In 1900 patent medicines stood as top category in money spent for national advertising.

JAMES HARVEY YOUNG, *AMERICAN HEALTH QUACKERY: COLLECTED ESSAYS* 91-92 (Princeton Univ. Press 1992).

⁶⁴ See YOUNG, *supra* note 58, at 14.

⁶⁵ *Id.* at 14-15, 93-110.

⁶⁶ *Id.* at 14-15.

⁶⁷ *Id.* at 14-15.

⁶⁸ *Id.* at 14-15.

⁶⁹ *Id.* at 15.

⁷⁰ *Id.*

During the Civil War era, the domestic patent medicine industry grew to extraordinary heights.⁷¹ Furthermore, Congress seemingly recognized the American culture of self-medication when in 1861 it taxed patent medicines for the purpose of raising revenue for the impending war.⁷² By 1905, one estimate put the number of patented medicines manufactured and sold in the U.S. at 28,000; the following year, a witness before Congress estimated that there were then 50,000.⁷³

Despite their immense popularity, patent medicines came under attack by American doctors.⁷⁴ In 1827, New York City created a “Committee of Quack Remedies” to condemn the practice of quackery,⁷⁵ and the following year a New York State medical society adopted its official opposition to patent medicines because it considered such medications anathema to the practice of medicine.⁷⁶ Yet the doctors did not rail against the manufacturing and sale of patent medicines in general but against their sale and use by non-physicians.⁷⁷ In fact, the New York City committee feared that allowing medical pretenders to sell patent medicines would lead to the degradation of the medical profession.⁷⁸ Referring to what it called “pretending empiric[s]” who sold such medicines, the committee report stated that “their partial successes will *confer upon their order, an importance and character that could not be otherwise obtained, to the serious detriment of the healing art.*”⁷⁹ Thus, it appears that the committee physicians, like those who fulminated against the use of Indian drugs, feared both the failures and the successes that resulted from the use of patent medicines.

Like doctors who had railed against the use of Native American drugs, physicians across the country admonished Americans against the use of patent medicines and

⁷¹ *Id.* at 93-110.

⁷² *Id.* at 107.

⁷³ *Id.* at 109.

⁷⁴ *Id.* at 63-67.

⁷⁵ The 1828 edition of Webster’s American Dictionary of the English Language defines “quackery” as “[t]he boastful pretensions or mean practice of an ignoramus, particularly in medicine.” *Webster’s 1828 Dictionary*, CORNERSTONE BAPTIST TEMPLE, <http://1828.mshaffer.com/d/search/word,quackery> (last visited Jan. 27, 2009); *see also* Peter M. Worling, *Pharmacy in the Early Modern World, 1617 to 1841 AD*, in *MAKING MEDICINES: A BRIEF HISTORY OF PHARMACY AND PHARMACEUTICALS* 60 (Stuart Anderson ed., Pharmaceutical Press 2005).

⁷⁶ YOUNG, *supra* note 58, at 66.

⁷⁷ *Id.* at 63-64.

⁷⁸ *Id.* at 63, 73. Physicians certainly pushed for the labeling of ingredients on patent medicines, an action which suggests that doctors feared patients would be harmed by unknown ingredients. Yet doctors were particularly concerned that Americans viewed patent salesmen as empiricists, practitioners who claim no scientific knowledge. By being forced to divulge ingredients, patent medicine manufacturers could make no claims of mystical knowledge or powers available only to them. They thus would be stripped of any enigmatic or mysterious pretensions, which doctors believed added to the popularity of their medicines. *Id.* at 63, 73.

⁷⁹ YOUNG, *supra* note 58, at 63-64 (emphasis added).

pushed for legislation to ban their sale.⁸⁰ They often warned Americans that buying medicines from unlicensed professionals was like employing “a blacksmith to repair a watch, a barber to shoe a horse, a ship-carpenter to make bonnets, or a milliner to build a church.”⁸¹ Meanwhile, others accused Congress of licensing the sale of patent medicines.⁸² Such legislative inaction, one doctor said in 1849, allowed deceitful men to prey on the American public.⁸³ Yet despite the efforts made by the medical establishment, Congress did nothing to regulate the inherent safety of drugs until well into the twentieth century.⁸⁴

Very real dangers certainly attended the consumption of patent medicines generally.⁸⁵ For example, a patent medicine caused the death of a young girl in 1805.⁸⁶ In addition, patent medicines often merely offered false and fleeting hope to patients who experienced temporary relief from those containing pain-numbing opiates.⁸⁷ Nonetheless, Americans eagerly consumed patent medicines containing such narcotics.

C. Americans and “Illicit” Drugs

Patent medicines containing opium were readily available. Sold under such innocuous names as “Mrs. Winslow’s Soothing Syrup” and “McMunn’s Elixir of Opium,” these drugs were widely marketed as treatments for dysentery, diarrhea, and “women’s trouble.”⁸⁸ Moreover, Americans considered opiate patent medicines so versatile that many mothers even used them to quiet teething babies.⁸⁹ In fact, patent medicine advertisements, which became ubiquitous,⁹⁰ proclaimed that these

⁸⁰ *Id.* at 71-72.

⁸¹ *Id.* at 72.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *See infra* Part IV.

⁸⁵ *See* YOUNG, *supra* note 58, at 69-71.

⁸⁶ *Id.* at 83.

⁸⁷ YOUNG, *supra* note 58, at 71. This danger was particularly acute when the illness was grave and time was of the essence. One critic described a hypothetical young man who upon discovering he has the initial symptoms of a dreadful disease, buys a patent medicine advertised as a cure: “His heart is cheered, his fears are in a measure dispelled, and with eagerness he procures and takes the medicine.” *Id.* (quoting 1809 address by Nicholas Romaine). Because, the critic continued, the medicine contains stimulants, he feels better, but then the disease progresses rapidly beyond cure and “with four-fold rapidity the poor victim is hurried into eternity.” *Id.*

⁸⁸ Edward M. Brecher, *Nineteenth-Century America: A Dope Fiend’s Paradise*, SHAFFER LIBRARY OF DRUG POLICY: THE CONSUMER UNION REPORT ON LICIT AND ILLICIT DRUGS (1972), <http://www.druglibrary.org/Schaffer/library/studies/cu/cu1.html> (last visited Dec. 1, 2007).

⁸⁹ *Id.*

⁹⁰ *See* YOUNG, *supra* note 58, at 104.

medicines could cure anything from anxiety to marital problems.⁹¹ Ultimately, however, these medicines were a legal supply of a narcotic which was readily accessible at the cost of a bottled concoction.⁹²

Patent medicines were not the sole legal source of opium.⁹³ By 1800, opium had become widely available in the U.S. and was a common ingredient even in prescription drugs.⁹⁴ Many doctors extolled the soothing, sedative effects of opium, which most doctors believed outweighed any potential harmful effects.⁹⁵ In fact, many physicians referred to opium as “G.O.M.”—“god’s own medicine”—not only because they allowed the patient to sleep during surgery⁹⁶ but also because it could be decocted into morphine and heroin—potent painkillers that could be used for a range of illnesses and ailments.⁹⁷

Morphine gained avid support among Americans after it was derived from opium in 1804.⁹⁸ Legally manufactured in the United States, morphine became a common ingredient in patent medicines, and its use soared during the 1870s. This marked increase in morphine use was due in great part to the invention of the hypodermic needle which greatly facilitated its consumption.⁹⁹ The proliferation of patent medicines and the wide acceptance of morphine to treat soldiers in the Civil War also added substantially to the drug’s popularity. In 1874, heroin was decocted from morphine and was eventually sold as “The Sedative for Coughs” by Bayer Pharmaceuticals in 1898.¹⁰⁰ Ironically, doctors prescribed heroin to wean morphine addicts off the drug, but they also used heroin to treat the great number of patients who suffered from pulmonary disorders, such as pneumonia and tuberculosis.¹⁰¹

Cocaine, too, became a common ingredient in patent medicines.¹⁰² First derived from the coca plant in 1844, cocaine became a common beverage ingredient throughout Europe and North America, the most recognizable of which was Coca-Cola. Many Americans consumed the drug to alleviate depression, treat morphine

⁹¹ See Elaine Casey, *History of Drug Use and Drugs User in the United States*, SCHAEFFER LIBRARY OF DRUG POLICY, Nov. 1978, <http://www.druglibrary.org/schaffer/History/CASEY1.htm>.

⁹² *Id.*

⁹³ See *Drugs and the Drug Laws: Historical and Cultural Contexts*, KING COUNTY BAR ASSOCIATION DRUG POLICY PROJECT 6 (Jan. 19, 2005), http://www.kcba.org/ScriptContent/KCBA/druglaw/proposal/report_hc.pdf.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ 1 VIDEOTAPE: HOOKED: ILLEGAL DRUGS AND HOW THEY GOT THAT WAY (Tera Media for the History Channel 2000) (on file with Cleveland-Marshall College of Law Library).

⁹⁷ *Id.*

⁹⁸ See *Drugs and the Drug Laws*, *supra* note 93, at 6-7.

⁹⁹ *Id.* at 6-7.

¹⁰⁰ *Id.* at 7

¹⁰¹ *Id.*

¹⁰² See HOOKED, *supra* note 96.

addiction, or merely to stimulate themselves.¹⁰³ Endorsed by the Surgeon-General of the U.S. Army for its medical properties, cocaine gained great popularity at the turn of the twentieth century when it became a common ingredient in tonics marketed to treat various respiratory illnesses and to overcome exhaustion and fatigue.¹⁰⁴ Altogether, Americans liberally consumed opiates, cocaine, and marijuana through the beginning of the twentieth century, and through the 1920s, doctors continued to prescribe heroin extensively.¹⁰⁵

Despite their popularity, opiates, cocaine, and marijuana did not gain complete social or medical acceptance.¹⁰⁶ Opiates in particular were not considered respectable and in some cases their use was thought immoral.¹⁰⁷ Many civic and religious leaders joined doctors to warn Americans of their potentially harmful effects.¹⁰⁸ Together, they preached moderation or espoused government control.¹⁰⁹ Yet despite warnings about the drugs' potentially harmful effects and their powerful addictive properties, there was scarcely any popular support for banning or even regulating them.¹¹⁰ Indeed, Americans legally engaged in large-scale, non-prescribed cannabis, cocaine and opium consumption well into the twentieth century.¹¹¹

Like Native American drugs and patent medicines in general, opiates came under fire from those warning of the dangers they posed to human health.¹¹² Yet Americans continued to use drugs from all these classes.¹¹³ The strength of this continued tradition lay in the potent contemporary institution of American individualism, an institution summarized by a New York doctor, who in 1856 lamented but accurately described the popular understanding of the time, stating, "The people regard it among their vested interests...to buy and swallow such physick [sic] as they in their sovereign will and pleasure shall determine; and in this free country, the democracy denounce all restrictions [on self-medication]."¹¹⁴ This

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *See Drugs and the Drug Laws*, *supra* note 93, at 8.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *See Brecher*, *supra* note 88.

¹¹¹ *HOOKED*, *supra* note 96. The federal Marihuana Tax Act of 1937 levied a tax on the importation, sale, and handling of cannabis. The Act required tax stamps for these activities, but the government had printed only a nominal amount of stamps. *Id.* Although the Act did not prohibit the sale or possession of marijuana, the act established government's authority over the regulation of "illicit" drugs. *Id.* The Harrison Act of 1914 taxed opium and cocaine to the point where it was available only for medicinal use. *See Drugs and the Drug Laws*, *supra* note 74, at 19, 25.

¹¹² *See YOUNG*, *supra* note 57, at 71.

¹¹³ *See HOOKED*, *supra* note 96.

¹¹⁴ *YOUNG*, *supra* note 58, at 52. According to Young, many doctors believed that American democracy and individualism had grown excessive and become misdirected. *Id.*

sentiment was echoed with passion by a New York Senator who, reacting sympathetically to a wheelbarrow full of signatures written on a petition¹¹⁵ that extended thirty-one yards, declared that “[t]he people of this state have been bled long enough in their bodies and pockets...and it [is] time they should do as the men of the Revolution did: resolve to set down and enjoy the freedom for which they bled.”¹¹⁶ In short, it seems Americans had come to view the democratization embodied in the Spirit of ’76 as encompassing individual personal choices. Among such choices was the right to self-medication.

Although the government has rightly prohibited the use of certain drugs deemed harmful to health and society, our nation’s history of marijuana, cocaine, and narcotics consumption epitomizes the American tradition of self-medication. For much of the nineteenth century, physicians, pharmacies, drugstores, groceries, and general stores all sold opiates legally and conveniently.¹¹⁷ Many Americans even bought opiates by mail-order,¹¹⁸ a testament to the permissive government attitude toward drug regulation. Until well into the twentieth century, self-indulgent Americans dosed themselves on these drugs¹¹⁹ just as much as they did on compounded medicines that were dispensed freely and sold to eager Americans.¹²⁰

To be sure, the government’s historically permissive approach to such drugs does not suggest that it should recognize Americans’ absolute right to ingest them. However, its laissez-faire approach does indicate that government has long recognized and accepted the citizenry’s choice in ingesting drugs generally.

IV. THE AMERICAN TRADITION OF LAISSEZ-FAIRE DRUG REGULATION

A. Consumer Protection in Early America

Government’s laissez-faire approach to drug regulation further testifies to the American tradition of self-medication, despite that the American tradition of self-medication certainly bred countless pseudo-healers.¹²¹ An Ohio editor lamented the

Rather than merely advocating political and social democracy, Americans were turning toward a self-destructive form of individualism—within which harm or death could result as the price of individual choice. *Id.*

¹¹⁵ *Id.* at 55. Although the petition was directed to the New York legislature and had the limited purpose of repealing laws criminalizing the practice of Thompsonian medicine, the tone of the petition and the senator’s response are indicative of contemporary popular sentiment. According to James Harvey Young, “[m]edical democracy, indeed, was what Americans seemed to desire.” *Id.* Furthermore, Thompsonian medicine “was the ultimate in the democratic approach to health” because it required no doctors and it left the choice of therapy completely to the patient. *Id.* at 54.

¹¹⁶ *Id.* at 55.

¹¹⁷ See HOOKED, *supra* note 96.

¹¹⁸ See Brecher, *supra* note 88.

¹¹⁹ See generally Casey, *supra* note 91.

¹²⁰ See YOUNG, *supra* note 58, at 56.

¹²¹ See YOUNG, *supra* note 63, at 44; see also Worling, *supra* note 75, at 60 (noting that poor, naive people seeking cures were regularly targeted by traveling salesmen who advertised panaceas that often had little or no remedial powers).

ease with which Americans could make such concoctions in the mid-nineteenth century.¹²² He described how the average person could easily get into the business of selling drugs:

[A]ny idle mechanic by chance gets a dispensatory, or some old receipt book, and poring over it, or having it read to him..., he finds that mercury is good for the itch, and old ulcers [sic]; that opium will give ease; and that a glass of antimony will vomit. Down goes the hammer, or saw, razor, awl, or shutter—and away to make electuaries, tinctures, elixirs, pills, plasters and poultices.¹²³

Yet government generally did little, if anything, to ensure that citizens would not be harmed by unsafe or ineffective medicines.¹²⁴

Before 1865, free competition and the honor system regulated drug safety.¹²⁵ Early British settlers and nineteenth-century Americans believed the pharmaceutical profession bore the sole responsibility for ensuring the purity of drugs.¹²⁶ According to FDA historian Wallace F. Janssen, the enormous popularity of patent medicines reflected contemporary “public acceptance of the doctrine that the buyer could and should look out for himself.”¹²⁷ This view likely sprung directly from the economic climate of the day, which emphasized laissez-faire capitalism and individualism.¹²⁸ Such opposition to drug legislation may be gleaned from the words of a Georgia Congressman, who drolly remarked that “[t]he Federal Government was not created for the purpose of cutting your toe nails or corns.”¹²⁹ While whimsical, his words reflect the popular sentiment that consumers would be protected by economic competition and freedom of enterprise, not by the intervention of government regulation.

Comprehensive legislation governing specific pharmaceutical activities did not become common in the United States until after 1870.¹³⁰ Before then, American

¹²² See YOUNG, *supra* note 58, at 41.

¹²³ *Id.*

¹²⁴ See text *infra* accompanying notes 122-243.

¹²⁵ See Glenn Sonnedecker, *Contribution of the Pharmaceutical Profession Toward Controlling the Quality of Drugs in the Nineteenth Century*, in *SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL* 97 (John B. Blake ed., Johns Hopkins Press 1970).

¹²⁶ See Wesley J. Heath, *America's First Drug Regulation Regime: The Rise and Fall of the Import Drug Act of 1848*, 59 *FOOD & DRUG L.J.* 170 (2004).

¹²⁷ Wallace F. Janssen, *The Story of the Laws Behind the Labels: 1906 Food and Drugs Act*, U.S. FOOD AND DRUG ADMINISTRATION, <http://vm.cfsan.fda.gov/~lrd/history1.html> (last visited Oct. 5, 2007).

¹²⁸ See *Social Darwinism and American Laissez-Faire Capitalism*, CONSTITUTIONAL RIGHTS FOUNDATION, <http://www.crf-usa.org/bill-of-rights-in-action/bria-19-2-b.html> (last visited Jan. 27, 2009).

¹²⁹ JAMES HARVEY YOUNG, *AMERICAN SELF-DOSAGE MEDICINES: AN HISTORICAL PERSPECTIVE* 5 (Coronado Press, 1974).

¹³⁰ See KREMERS, *supra* note 34, at 213.

ideology borne of democratic and laissez-faire economic principles combined with frontier living to preempt the development of comprehensive drug regulation.¹³¹ The United States does, however, have a long history of drug regulation aimed at protecting consumers from fraud or misrepresentation.¹³² Such regulations were intended to regulate the efficacy of drugs in order to ensure that unsuspecting Americans did not purchase drugs that came with false assurances.¹³³ In fact, most colonial regulation involved the structuring of fees,¹³⁴ not denial of access to potentially unsafe drugs.¹³⁵ In brief, most laws were designed to prevent quackery and the exorbitant fees¹³⁶ associated with that dubious though lucrative vocation.¹³⁷

This American tradition of protecting consumer confidence dates back to 1630 when Massachusetts Bay Colony authorities fined or whipped one Nicholas Knopp for “vending as a cure for scurvy ‘a water of no worth nor value,’ which he ‘solde att a very deare rate [sic].’”¹³⁸ The Massachusetts authorities were concerned that purveyors of drugs were deceiving colonists into paying high prices for drugs of “no worth nor value.”¹³⁹ As the *Abigail* court noted in a footnote, Knopp’s punishment was not an example of government regulation in the modern sense.¹⁴⁰ Yet the court failed to recognize that the incident reflects the importance that early Americans placed on protecting the confidence and pocketbooks of consumers who sought to self-medicate—a tradition Americans would carry into the twentieth century.¹⁴¹ Colonies, and later states, certainly have a history of regulating drugs, but such regulations reflect the community’s desire to condemn frauds, such as Knopp’s in Massachusetts.¹⁴² Rather than recognize that Knopp’s punishment reflected consumerist principles, the *Abigail* court cited the case to add flavor, credibility, and a sense of pedigree to what it viewed as a long-standing tradition of drug regulation in this country. Drug regulation certainly extends as far back as 1630 when Knopp was made to pay for his deception, but it is not a tradition of regulating the safety of drugs. History bears this out.

¹³¹ *Id.*

¹³² See LESLIE G. MATTHEWS, HISTORY OF PHARMACY IN BRITAIN 358 (E & S Livingstone Ltd. 1962). In 1604, James I of England issued an act designed to prevent fraud and the deceitful sale of adulterated hops, which foreign suppliers were apparently adulterating with a variety of plant matter. *Id.*

¹³³ See *infra* text accompanying notes 135-243.

¹³⁴ See HAROLD B. GILL, JR., THE APOTHECARY IN COLONIAL VIRGINIA 23 (Univ. Press of Virginia 1972).

¹³⁵ See *infra* text accompanying notes 140-243.

¹³⁶ *Id.*

¹³⁷ See Worling, *supra* note 75, at 60.

¹³⁸ YOUNG, *supra* note 58, at 16-17.

¹³⁹ *Id.*

¹⁴⁰ See *Abigail Alliance*, 495 F.3d at 704.

¹⁴¹ See *infra* text accompanying notes 122-243.

¹⁴² *Id.*

B. State Regulations

1. The Virginia Act of 1736

The *Abigail* court began its examination of history by stating that “[d]rug regulation in the United States began when the Colony of Virginia’s legislature passed an act in 1736 that addressed the dispensing of more drugs than was ‘necessary or useful’ because that practice had become ‘dangerous and intolerable.’”¹⁴³ These words certainly convey alarm, but such alarm could result only from a gross mischaracterization of the act, which in fact merely arranged a fee structure for the sale of drugs by surgeons and apothecaries.¹⁴⁴

The *Abigail* court cited the words “necessary and useful” out of context.¹⁴⁵ The 1736 statute reveals that the Virginia House of Burgesses merely sought to prevent surgeons and apothecaries from “padding” their bills.¹⁴⁶ Rather than regulate drug

¹⁴³ *Abigail Alliance*, 495 F.3d at 703-04.

¹⁴⁴ See WYNHAM H. BLANTON, *MEDICINE IN VIRGINIA IN THE EIGHTEENTH CENTURY* 399, 400 (Garrett & Massie 1931).

¹⁴⁵ *Abigail Alliance*, 495 F.3d at 703-04.

¹⁴⁶ See Hening: Statutes at Large, v. 4, 507-10, *quoted in* BLANTON, *supra*, note 144, at 399-400. The statute states in pertinent part:

I. WHEREAS the practice of phisic [sic] in this colony, is most commonly taken up and followed, by surgeons, apothecaries, or such as have only served apprenticeships to those trades, who often prove very unskilful [sic] in the art of a phisician [sic]; and yet do demand *excessive fees and exact unreasonable prices for the medicines which they administer*, and do too often, *for the sake of making up long and expensive bills, load their patients with greater quantities thereof, than are necessary or useful, concealing all their compositions*, as well to prevent the discovery of their practice, as of the *true value* of what they administer: which is *become a grievance, dangerous and intolerable, as well to the poorer sort of people*, as others, & doth require the most effectual remedy that the nature of the thing will admit (emphases added).

II. Be it therefore enacted...[that] no practicer [sic] in phisic [sic], in any action or suit whatsoever, hereafter to be commenced in any court in this colony, shall recover, for visiting any sick person, more than the rates hereafter to be commenced in any court of record in this colony, shall recover, for visiting any sick person, more than the rates hereafter mentioned: that is to say....

III. And to the end the true value of the medicines administered by any practicer [sic] in phisic [sic], may be better known, and judged of, *Be it further enacted, by the authority aforesaid*, That whenever any pills, bolus, portion, draught, electuary, decoction, or any medicines, in any form whatsoever, shall be administered to any sick person, the person administering [sic] the same shall, at the same time, deliver his bill, expressing every particular thing made up therein; or if the medicine administred [sic] be a simple, or compound, directed in the *dispensatories*, the true name thereof shall be expressed in the same bill, together with the quantities and prices, in both cases. And in failure thereof, such practicer [sic], or any apothecary, making up the prescription of another, shall be nonsuited, in any action or suit hereafter commenced, which shall be grounded upon such bill or bills: Nor shall any book, or account, of any practicer [sic] in phisic [sic] or any apothecary, be permitted to be given in evidence, before a court; unless the articles therein contained, be charged according to the directions of this act.

safety, the Burgesses were seeking to regulate pharmacy professionals who “for the sake of making up long and expensive bills, load their patients with greater quantities thereof, than are *necessary and useful*, concealing all their compositions, as well to prevent the discovery of their practice, as of the *true value* of what they administer.”¹⁴⁷ More importantly, the words “dangerous and intolerable” referred only to the fact that this practice of padding had “become a grievance, *dangerous and intolerable*, as well to the poorer sort of people, and others”—their customers.¹⁴⁸ By citing each phrase out of context and binding them together, the *Abigail* court conveyed the false impression that the Virginia legislature designed the act to regulate the sale of dangerous drugs, when in fact it merely sought to prevent the practice by which surgeons and apothecaries “padded” their bills by prescribing superfluous drugs to unsuspecting consumers.¹⁴⁹

Rather than a law designed to protect patients by promoting the safety of drugs, the 1736 legislation was designed to protect consumers from having to pay excessive fees¹⁵⁰ for the medicines they used in their self-medication regimes.¹⁵¹ Specifically, the law was created to ensure that those who had served only as apprentices would receive a lower rate of remuneration for their services,¹⁵² but its broader purpose was consumer protection.¹⁵³ In effect, the Virginia Act protected the consumer by setting fees for practitioners according to their level of education and training.¹⁵⁴ Although the law also provided that practitioners itemize all ingredients in the drugs they sold,¹⁵⁵ it appears the provision was intended to ensure that consumers knew the potency of the drugs they were buying. Whether or not to purchase particular drugs would have remained the consumer’s choice.

The Virginia Act was not a mechanism to prohibit unlicensed persons from dispensing drugs.¹⁵⁶ Indeed, the Act does not refer to licensing, but sets out a scheme by which educated dispensers could charge for their products.¹⁵⁷ The law’s title, which the *Abigail* court omitted, was “An Act for regulating the Fees and

IV. *And be it further enacted, by the authority aforesaid*, That this act shall continue and be in force, for and during two years, next after the passing thereof, and from thence to end of the next session of assembly.

Id. (emphases in the original unless otherwise stated)

¹⁴⁷ BLANTON, *supra* note 144, at 399-400 (emphasis added).

¹⁴⁸ *Id.* at 399-400 (emphases added).

¹⁴⁹ *See id.* at 399 (stating that by passing the Virginia Act, the House of Burgesses “sought to remedy the abuses of excessive fees and ‘unreasonable prices’ for medicines”).

¹⁵⁰ *See* BLANTON, *supra* note 144, at 399.

¹⁵¹ *See supra* Part III.

¹⁵² *See* BLANTON, *supra* note 144, at 399.

¹⁵³ *Id.*

¹⁵⁴ *Id.*; *see also* KREMERS, *supra* note 34, at 159 (stating that the act deprecated the abilities of apprentices).

¹⁵⁵ *See supra* note 146.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

Accounts of the Practicers in Phisic [sic].”¹⁵⁸ The title reflects the import of the law, which did not bar anyone not trained in pharmacy from continuing to concoct and dispense drugs in Virginia yet made it illegal for professionals to demand more than the value of their products.¹⁵⁹ To be sure, average Virginians and their colonial brothers continued to enjoy their notoriety for their ability to treat illness.¹⁶⁰ In short, although the *Abigail* court cited the Virginia Act as proof of government’s dedication to regulating drug safety,¹⁶¹ the 1736 law is better characterized as legislation designed to protect consumers from unscrupulous peddlers seeking to secure unreasonable fees for drugs. As such, its citation lends little support to the court’s holding in *Abigail*. Of note, the Virginia Act expired just two years after it was passed,¹⁶² and similar bills were defeated in 1748, 1761, and 1762.¹⁶³

2. The New Orleans Act of 1808

The *Abigail* court also relied on a law passed in the Territory of Orleans, Louisiana in 1808.¹⁶⁴ The court noted that the law, known as the “New Orleans

¹⁵⁸ BLANTON, *supra* note 144, at 399.

¹⁵⁹ See *supra* note 146.

¹⁶⁰ See GILL, *supra* note 134, at 23. On May 12, 1778, the *Virginia Gazette* reported that a woman, Constant Woodson, claimed she could cure cancer and even received acclaim from newspapers and physicians. *Id.* Also, the House of Burgesses voted to use 100 pounds in public funds to pay Mrs. Mary Johnson, who had offered to divulge to the public her cure for cancer—in exchange for a reward. The *Virginia Almanac* published her remedy in 1754. *Id.*; see also BLANTON, *supra* note 144, at 33 (describing how throughout the eighteenth century “the drug business [in Virginia] was actively conducted by physicians in their own shops as well as by those who combined the sale of drugs with that of other commodities.”).

¹⁶¹ See *Abigail Alliance*, 495 F.3d at 703-04.

¹⁶² See GILL, *supra* note 134, at 26.

¹⁶³ See BLANTON, *supra* note 144, at 400.

¹⁶⁴ See *Abigail Alliance*, 495 F.3d at 704. The statute states in pertinent part:

An Act Concerning Physicians, Surgeons and Apothecaries—

BE it enacted . . . That no person shall presume to practice, in the Territory of Orleans, as physician, surgeon or apothecary, without first exhibiting satisfactory proof of his having qualified himself as such, by previous studies, which shall be made to appear by a diploma of any university or school in which he may have pursued his studies. The candidate shall exhibit said diploma to the Mayor of the City of New-Orleans, who shall fix on a day, and shall appoint four physicians or surgeons from among the oldest practitioners, whose duty it shall be publicly to examine the candidate, and to give him a certificate of admission, if he should be admitted; which certificate shall be signed by the four examiners, and by the Mayor, who shall cause the seal of the city to be affixed to the same.

And be it further enacted, That every physician, surgeon or apothecary, who shall sell, or cause to be sold, remedies or drugs, which shall be proved to have been, at the time of selling the same, injured, moulded [sic], discomposed [sic], or sophisticated, shall, on conviction, forfeit and pay the sum of five hundred dollars, to the benefit of the hospital of the poor of New-Orleans.

And it be further enacted, That no physician, surgeon or apothecary, shall sell, give, or in any way, directly or indirectly, part with any suspicious or dangerous remedy, but on application in writing of heads of families of good reputation.—And it shall be the duty of said

Act,” “require[d] a diploma and an examination before permitting pharmacists to dispense drugs.”¹⁶⁵ More importantly, the New Orleans Act prohibited unlicensed practitioners from collecting fees,¹⁶⁶ a provision which certainly would have dampened the spirits of charlatans looking to make easy money by selling fraudulent medicines. Thus, on its face, the New Orleans Act supports the *Abigail* court’s conclusion that governmental regulation of drug safety is deeply rooted in American history and traditions.

The New Orleans Act, however, did not grow from American culture and tradition but from its Franco-Spanish tradition.¹⁶⁷ Louisiana did not become an American territory until 1804, just four years before the passage of the New Orleans Act.¹⁶⁸ Eighteenth-century French and Spanish legal traditions influenced the early development of drug regulation in American Louisiana and the passing of the 1804 New Orleans Act,¹⁶⁹ which world-renowned pharmacy historian David L. Cowen called “by far the outstanding enactment in the history of pharmaceutical legislation.”¹⁷⁰

Eighty years before the U.S. annexed Louisiana, French officials passed a law that mirrored the 1808 law.¹⁷¹ It is likely that the 1723 French law was a precursor

heads of families, in said application in writing, to state for what use said remedy is wanted, the day on which said remedy was delivered, and receive [sic] the name, the quality, and the quantity of said remedy. Said application in writing shall be the only means of defence [sic] allowed to the seller, in case said remedy should have been made use of with evil design; and should the seller prove unable to exhibit such a writing for his discharge, he shall be deprived of the exercise of his profession, and shall forfeit and pay the sum of one thousand dollars, to the benefit of the hospital of New-Orleans.

ACTS PASSED AT THE FIRST SESSION OF THE SECOND LEGISLATURE OF THE TERRITORY OF ORLEANS (New Orleans, 1808), at 24-31, *quoted in* David L. Cowen, *America’s First Pharmacy Laws*, 3 J. OF THE AM. PHARMACEUTICAL ASSOC. 162-63 (1942).

¹⁶⁵ *Abigail Alliance*, 495 F.3d at 704.

¹⁶⁶ See RUDOLPH MATAS, *HISTORY OF MEDICINE IN LOUISIANA* 332 (John Duffy ed., La. State Univ. 1958).

¹⁶⁷ *Id.* at 64. From the days of early settlement, French officials engaged in “zealous supervision” of drugs, hospital facilities, and medical personnel, an enthusiasm reflected in French Louisiana laws. *Id.*

¹⁶⁸ *Id.* at xv-xvi. The area that is today Louisiana had been a French territory from 1699 to 1768, and had been a Spanish colony from 1769 to 1803. *Id.*

¹⁶⁹ See *id.* at 330 (stating that “the long tradition of regulation under the French and Spanish governments was bound to have had considerable influence” in early American attempts to regulate medicine in Louisiana); *but see* Cowen, *supra* note 164, at 219 (cautioning against assuming that Louisiana’s preeminence in the field for medical regulation should be ascribed to its Franco-Spanish tradition, because “at least ten of the twenty-six individuals associated with drug shops in 1822 New Orleans had last names that were not of French or Spanish origin,” and there is evidence that in the early 1800s “the medical profession in Louisiana was rather disreputable”).

¹⁷⁰ *In Memoriam*, DAVID L. COWEN, MEDICAL HISTORY SOCIETY OF NEW JERSEY, <http://www.mhsnj.org/> (last visited Nov. 30, 2007); *see also* David L. Cowen, *Louisiana, Pioneer in the Regulation of Pharmacy*, in LA. HIST. QUART. 331 (1943).

¹⁷¹ See MATAS, *supra* note 166, at 64. In 1723, Louisiana’s Superior Council became alarmed that “several ignorant persons were giving remedies and performing operations in

of the 1808 New Orleans Act, because the “relatively strong controls which French authorities had established over medical practice during the first half of the eighteenth century were continued and strengthened under the Spanish regime.”¹⁷² Louisiana also boasts what is likely the earliest American law designed to regulate drug quality.¹⁷³ The law was the prototype of the New Orleans Act,¹⁷⁴ but was only one of many Spanish laws that reflected a strong Spanish commitment to the regulation of drugs.¹⁷⁵ It is no wonder that in the area of drug regulation, Louisiana was far ahead of every other American state at the beginning of the nineteenth century.¹⁷⁶

Louisiana’s preeminence in this field would not last long under American rule. In 1816, the state passed a law repealing the New Orleans Act and made no new provision to prohibit the sale of drugs.¹⁷⁷ According to John Duffy, “[n]either the apothecaries nor the public apparently favored any such regulations, and a wide field was opened for unethical and unscrupulous individuals to profit at the expense of the sick.”¹⁷⁸ In 1820, the American tradition of self-medication made its way into Louisiana law when the legislature permitted unlicensed persons to sell “medicines which shall have been purchased from any legal apothecary, and which have been plainly labeled by said apothecary.”¹⁷⁹ While this law certainly regulated drugs, it did so by requiring that they be labeled,¹⁸⁰ a tactic that would have made it easier for the average citizen to choose his preferred medication.

By 1820, the American spirit of laissez-faire drug regulation had seemingly displaced the Franco-Spanish traditions, but the devolvement was not then complete.¹⁸¹ The most telling evidence of this shift in traditions is that in 1852 Louisiana succumbed to the American tradition and finally repealed all medical

New Orleans as well as the country.” *Id.* at 64. The council responded by declaring that unlicensed practitioners were “forbidden to meddle in the arts of medicine or surgery on penalty of being prosecuted by the Attorney General and punished with death.” *Id.*

¹⁷² *Id.* at 173.

¹⁷³ Cowen, *supra* note 170, at 331. Promulgated February 12, 1770 by Don Alexandre O’Reilly, Louisiana’s Spanish governor, the edict declared that, “[s]urgeons shall be always ready to open and show to the physician the place where they keep their remedies so that they may be inspected and thrown out if they are bad.” *Id.* The decree also forbade quackery by providing that “[a]ll pretended healers, who are not provided with documents and certificates, will be punished with imprisonment and arbitrary punishment if they are caught abusing the credulity of the people.” MATAS, *supra* note 166, at 178.

¹⁷⁴ MATAS, *supra* note 166, at 178.

¹⁷⁵ *Id.* at 186-92.

¹⁷⁶ Cowen, *supra* note 170, at 330.

¹⁷⁷ John Duffy, *Pharmacy in Franco-Spanish America*, in AMER. PHARMACY IN THE COLONIAL AND REVOL. PERIODS 15, 24-25 (George A. Bender & John Parascandola ed., Amer. Inst. of the History of Pharm., 1976).

¹⁷⁸ See MATAS, *supra* note 163, at 342.

¹⁷⁹ See Cowen, *supra* note 167, at 334.

¹⁸⁰ *Id.*

¹⁸¹ See KREMERS, *supra* note 34, at 214.

legislation.¹⁸² According to Cowen, this devolution demonstrated “Louisiana’s assimilation of the culture pattern of the rest of the country...[f]or the repeal of the legislation in 1852 came not from conditions peculiar to Louisiana, but from conditions characteristic of the entire American scene.”¹⁸³ If anything, the 1808 New Orleans Act marked the highpoint of the Franco-Spanish tradition and does not accurately reflect the American tradition of drug regulation. The *Abigail* court’s reference to the law therefore misrepresented the historical reality that the New Orleans Act reflected Franco-Spanish traditions, not laissez-faire American attitudes.

3. A Short Survey of State Regulations

Although by 1870 many American states and territories had passed drug regulations, it does not necessarily follow that such regulations were designed to ensure drug safety. The 1736 Virginia Act is merely an example of the various laws states passed to regulate the profession of pharmacy itself, not the access to unsafe drugs.¹⁸⁴ Meanwhile, the historical context surrounding the New Orleans Act illustrates the American tradition of self-medication, as well as the government’s accommodation of those who sold drugs without licenses.¹⁸⁵ To be sure, the

¹⁸² *Id.*

¹⁸³ Cowen, *supra* note 170, at 339.

¹⁸⁴ The Virginia Act “reflects the attitude of London physicians of this period toward the medical ambitions of the apothecaries.” KREMERS, *supra* note 34, at 159. The law grew from a territorial dispute in which physicians sought to maintain status by differentiating themselves from the growing number of apothecaries, who had limited education but who were nonetheless permitted to dispense drugs. The “Act for regulating fees and accounts” recognized the relative importance of the different professions by stamping each with specific rates associated with their differing levels of education. *Id.*

¹⁸⁵ The *Abigail* court noted that in 1817 South Carolina introduced legislation requiring the licensing of pharmacists. See *Abigail Alliance*, 495 F.3d at 704. To be sure, South Carolina was the first of the American colonies to require pharmacists to pass examinations (1818) and to require apothecaries to obtain their licenses by applying to the state’s medical society or board of physicians. See KREMERS, *supra* note 34, at 184. The 1817 Act contained a fatal flaw, however, at least from the point of view of those who assumed that the act was designed to eliminate the sale of medicines by non-professionals. It declared “[t]hat nothing herein contained, be construed to prevent merchants or shop-keepers from vending or exposing to sale medicines already prepared.” Cowen, *supra* note 164, at 166. Thus, while the South Carolina law required examinations and licensing of pharmacists and apothecaries, it did not preclude the common man from entering a shop and choosing the medication he felt was necessary to cure his ailments. In fact, the South Carolina legislation was intended to regulate the practice of medicine, not to curb the availability of drugs to the common man. Moreover, twenty years later, this legislation was further emasculated. In 1838, South Carolina repealed all of the penalty provisions relating to both pharmacists and apothecaries—which essentially eviscerated the entire legislation. *Id.* In 1825, Georgia passed a statute that closely tracked the language of the South Carolina Act passed in 1817. *Id.* at 167. Entitled, “An Act to regulate licensing of Physicians to practice in this state,” the act permitted physicians to sell drugs, required apothecaries to be licensed by the state, and prohibited “[m]erchants, shop keepers and all other persons from compounding and preparing drugs and medicines, or either.” *Id.* It is clear then, that the Georgia Act was designed to prohibit the manufacture of drugs by anyone other than a licensed professional. Eleven years later, however, Georgia repealed all of the penalty provisions of the 1825 act. *Id.* Although in 1839

language of the various state acts must be read in context and their terms understood within the purposes of the various acts.

The *Abigail* court failed to recognize this need to examine the particulars of each act.¹⁸⁶ It stated that “[b]y 1870, at least twenty-five American states or territories had statutes regulating drug adulteration (impure drugs), and a few others had laws addressing poisons.”¹⁸⁷ While this statement appears to support the court’s overall conclusion regarding drug safety regulation, it in fact reveals the court’s failure to recognize the intricacies and purposes of each of the twenty-five laws to which it referred.¹⁸⁸ For example, when it defined “drug adulteration” as the fabrication of “impure drugs,” the *Abigail* court implied that the twenty-five states barred the production of inherently dangerous drugs.¹⁸⁹ The word “impure” does not strictly mean dangerous, but it connotes danger, particularly when it is associated with the consumption of medications.¹⁹⁰ As we shall see, the term “adulterated”¹⁹¹ as used in government drug regulations typically referred to drugs whose impurity has rendered them largely ineffective or inert, a quality that made them dangerous¹⁹² in that they

and 1847 the state declared the Georgia Act to be in full force, it did not also reinstate laws that prohibited the practice of Thompsonian medicine. *Id.* Thompsonian medicine was premised on the idea that every man could be his own physician. *See* YOUNG, *supra* note 58, at 54.

¹⁸⁶ For the purposes of this paper, an exhaustive examination of each statute cited by the court is not necessary. The Virginia and New Orleans acts illustrate the *Abigail* court’s failure to examine closely the laws it cited to support its conclusion. *See supra* Sections IV.B.1-2. Moreover, that the court’s facile construction of the word “adulterated” strongly implies danger demonstrates its failure to scrutinize the language of the various acts. *See infra* Section IV.B.3.

¹⁸⁷ *Abigail Alliance*, 495 F.3d at 704.

¹⁸⁸ The *Abigail* court cited the work of Edward Kremers and George Urdang with regard to these twenty-five laws. *See Abigail Alliance*, 495 F.3d at 703-04; *see also supra* note 34. This author’s research into the sources used by Kremers and Urdang did not confirm the court’s assertion.

¹⁸⁹ *See Abigail Alliance*, 495 F.3d at 704.

¹⁹⁰ Merriam-Webster’s online dictionary defines “impure” as inter alia, “containing something unclean.” Merriam-Webster Online Dictionary, <http://www.merriam-webster.com/dictionary/impure> (last visited Mar. 10, 2008).

¹⁹¹ The 1828 edition of Webster’s American Dictionary of the English Language defines “adulterated” as “[c]orrupted; debased by a mixture with something of *less value*.” *Webster’s 1828 Dictionary*, CORNERSTONE BAPTIST TEMPLE, <http://www.cbtministries.org/resources/webster1828.htm> (last visited Nov. 30, 2007) (emphasis added); Merriam-Webster’s contemporary online dictionary defines “adulterate” as “to corrupt, debase, or make impure by the addition of a foreign or inferior substance or element; *especially* : to prepare for sale by replacing more valuable with less valuable or inert ingredients.” Merriam-Webster Online Dictionary, <http://www.m-w.com/dictionary/adulterated> (last visited Nov. 30, 2007) (emphasis added). Therefore, the term did not merely mean dangerously “impure,” but that which has been made less effective by corruption.

¹⁹² The danger associated with purchasing cheap drugs was that patients would forego more reliable medical treatment. If the patient’s condition worsened while on the inadequate treatment, it might become too late to administer life-saving medical therapy. *See* H.R. Rep. No. 30-664, at 20 (1848) (stating that physicians in the Mexican War administered “herculean

gave false hope to unsuspecting consumers who bought cheap, useless drugs from “quacks”¹⁹³ in their efforts to self-medicate.

In any event, “under the double impact of the growth of medical laissez-faire and of the Civil War,” state laws regulating access to drugs became dead letters on the books.¹⁹⁴ In fact, a survey of state pharmaceutical laws found that by 1931, twenty-three states had no restrictions on the sale of patent medicines by “general merchants”—that is, “anyone permitted to sell drugs and medicines who [was] not a registered pharmacist or assistant pharmacist.”¹⁹⁵ Furthermore, only three states—Colorado, Mississippi, and Nebraska—absolutely prohibited such sales.¹⁹⁶ Given the relatively lax state regulations of pharmacy, it would be difficult to conclude, as the *Abigail* court seems to have done,¹⁹⁷ that states maintained a strong commitment to regulating drug safety even by the time of the early twentieth century.

C. Federal Regulations

It was not until 1938 that Congress passed any federal legislation regulating drug safety.¹⁹⁸ The *Abigail* court, however, characterized three federal drug regulations as laws designed to prevent access to unsafe drugs—the Import Drug Act of 1848, the Biologics Controls Act of 1902, and the Pure Food and Drug Act of 1906.¹⁹⁹ While the court accurately described the Biologics Control Act as a safety regulation, it failed to consider the purpose behind it, which was to ensure that vaccinations being forced on American citizens were in fact safe.²⁰⁰ Indeed, that act had little to do with personal choice.²⁰¹ Meanwhile, the court failed to recognize the peculiar language of the Import Drug Act and the Pure Food and Drug Act, neither of which prohibited

portions of active medicines” of adulterated drugs purchased abroad). That such large portions of drugs had to be administered demonstrates the danger of adulterated drugs. The concern with such a danger as associated with fraud is evident in the variety of state laws dealing with drug adulteration. For example, by 1858, Tennessee law penalized any adulteration of drugs that would render the drugs less effective and thus dangerous to health. In fact, various states prohibited fraudulent adulteration, which would render drugs harmful. In 1839 and 1844, Vermont and Rhode Island each respectively passed such prohibitions. See Sonnedecker, *supra* note 125, at 97.

¹⁹³ Worling, *supra* note 75, at 60.

¹⁹⁴ KREMERS, *supra* note 34, at 215.

¹⁹⁵ *Id.*

¹⁹⁶ See Robert P. Fischelis, *A Survey of State Pharmacy Laws with Reference to the Sale of Drugs and Medicines by General Merchants*, in AM. PHARM. ASSOC. 1331, 1333-38 (Dec. 1931).

¹⁹⁷ See *Abigail Alliance*, 495 F.3d at 704.

¹⁹⁸ See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938); see also YOUNG, *supra* note 129, at 12.

¹⁹⁹ See *Abigail Alliance*, 495 F.3d at 704.

²⁰⁰ See *Henning Jacobson v. Commonwealth of Mass.*, 197 U.S. 11 (1905) (holding that the state may exercise its police power to mandate forced vaccinations because they are part of a wholesome practice of ensuring the public welfare).

²⁰¹ *Id.*

the sale of dangerous drugs.²⁰² In fact, these two laws are better characterized as attempts to provide consumer information to those choosing medications for themselves.²⁰³ Any regulation of drug safety under these two laws seems to have been an incidental effect subordinated to the larger purpose of achieving greater economic reliability for consumers.²⁰⁴

1. The Import Drug Act of 1848

In 1848, Congress passed the Import Drug Act.²⁰⁵ The Import Drug Act was the federal government's first attempt to regulate drugs and was passed because by 1848 the U.S. had become a virtual dumping ground for international adulterated drugs.²⁰⁶ In noting this disturbing trend, the *Abigail* court inferred a sense of alarm among Americans and Congress at the increasing presence of such drugs by 1848.²⁰⁷ Therefore, the court cited the Import Drug Act as though Congress had designed it to halt the importation of all inherently dangerous drugs.²⁰⁸ The Import Drug Act itself and its legislative history, however, tell another story. That is, Congress passed it to protect consumers, who deserved to get their money's worth when buying international drugs.²⁰⁹

Certainly, Section I of the Import Drug Act provided that the American custom-house would examine and appraise all medicines and drugs arriving at U.S. ports.²¹⁰

²⁰² See *infra* text accompanying notes 201-243.

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Import Drug Act, 30th Cong., ch. 70, 9 Stat. 237 (1848). The law was entitled "An Act to prevent the Importation of adulterated and spurious Drugs and Medicines. *Id.*

²⁰⁶ See Heath, *supra* note 126, at 169, 171-72. European countries such as France and England had already passed laws designed to curb the importation of such medicines; therefore, more and more adulterated drugs reached American shores. See Alex Berman, *Drug Control in Nineteenth-Century France: Antecedents and Directions*, in *SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL* at 9 (John B. Blake ed., Johns Hopkins Press 1970) (noting that in the early nineteenth century, France promulgated national laws to eradicate adulterated drugs); see also H.R. Rep. No. 30-664, at 4, 9 (recognizing London as the largest drug market in the world in 1848, and asserting that because of long-standing British laws against adulteration, England was likely shipping its inferior drugs to the U.S.).

²⁰⁷ See *Abigail Alliance*, 495 F.3d at 704.

²⁰⁸ *Id.* at 704. The court stated that the Act "banned 'imported adulterated drugs' after a Congressional committee concluded that 'this country had become the grand mart and receptacle of all the refuse [drugs] . . . not only from the European warehouses, but from the whole Eastern world.'" *Id.* Although the court quoted Heath, the Committee language appears in H.R. Rep. No. 30-664, at 3 (1848). *Id.* (quoting Heath, *supra* note 126, at 175).

²⁰⁹ See Angela Walch, *A Spurious Solution to a Genuine Problem: An In-Depth Look at the Import Drugs Act of 1848*, at 29, available at <http://leda.law.harvard.edu/leda/data/448/Walch.pdf>.

²¹⁰ Import Drug Act, *supra* note 205. The Act states in pertinent part:

[A]ll drugs, medicines, medicinal preparations, including medicinal essential oils, and chemical preparations used wholly or in part as medicine, imported into the United

The Import Drug Act, however, limited the examination and appraisal to an assessment of their “quality, purity, and fitness for medical purposes, *as to their value and identity specified in the invoice*.”²¹¹ A close reading of the act reveals that the “quality, purity, and fitness” of the drugs did not refer to any dangers that might

States from abroad, shall, before passing the custom-house, be examined and appraised, as well in reference to their quality, purity, and fitness for medical purposes, as to their value and identity specified in the invoice.

SEC. 2. And be it further enacted, That all medicinal preparations, whether chemical or otherwise, usually imported with the name of the manufacturer, shall have the true name of the manufacturer, and the place where they are prepared, permanently and legibly affixed to each parcel, by stamp, label, or otherwise; and all medicinal preparations imported without such names affixed as aforesaid, shall be adjudged to be forfeited.

SEC. 3. And be it further enacted, That if, on examination, any drugs, medicines, medicinal preparations, whether chemical or otherwise, including medicinal essential oils, are found, in the opinion of the examiner, to be so far adulterated, or in any manner deteriorated, as to render them inferior in strength and purity to the standard established by the United States, Edinburgh, London, French, and German pharmacopoeias and dispensatories, and thereby improper, unsafe, or dangers to be used for medicinal purposes, a return to that effect shall be made upon the invoice, and the articles so noted shall not pass the custom-house, unless, on reexamination of a strictly analytical character, called for by the owner or consignee, the return of the examiner shall be found erroneous; and it shall be declared as the result of such analysis, that the said articles may properly, safely, and without danger, be used for medicinal purposes.

SEC. 4. And be it further enacted, That the owner or consignee shall at all times, when dissatisfied with the examiner's return, have the privilege of calling, at his own expense, for a reexamination; and, on depositing with the collector such sum as the latter may deem sufficient to defray such expense, it shall be the duty of that officer to procure some competent analytical chemist possessing the confidence of the medical profession, as well as of the colleges of medicine and pharmacy, if any such institutions exist in the State in which the collection district is situated, a careful analysis of the articles included in said return, and a report upon the same under oath; and in case the report, which shall be final, shall declare the return of the examiner to be erroneous, and the said articles to be of the requisite strength and purity, according to the standards referred to in the next preceding section of this act, the entire invoice shall be passed without reservation, on payment of the customary duties; but, in case the examiner's return shall be sustained by the analysis and report, the said articles shall remain in charge of the collector, and the owner or consignee, on payment of the charges of storage, and other expenses necessarily incurred by the United States, shall have the privilege of reexporting them at any time within the six months after the report of the analysis; but if the said articles shall not be sent out of the United States within the time specified, it shall be the duty of the collector, at the expiration of said time, to cause the same to be destroyed, holding the owner or consignee responsible to the United States for payment of all charges, in the same manner as if said articles had been reexported.

Id.

²¹¹ *Id.* at § 1 (emphasis added).

be inherent in drugs.²¹² Instead, the phrase referred specifically to their economic valuation and their identification as reflected in the invoice accompanying the drugs.²¹³

To be sure, the words “strength and purity” reflect Congress’s apparent intent to exclude those drugs which were chemically ineffectual or laden with chemically inert materials,²¹⁴ so that American consumers could know how effective the drugs and medicines would be²¹⁵ when they self-medicated.²¹⁶ Congress would have been aware that the strength of a drug could be diminished by long storage or exposure to the elements and might therefore become deteriorated to the point of inertness.²¹⁷ Meanwhile, a drug’s purity could be degraded by inert fillers like vegetable matter, clay, sand, and water.²¹⁸ Consequently, a drug’s value could be manipulated dramatically without the requisite price adjustment on the shipping invoice, upon which the seller would nevertheless demand the price commensurate with unadulterated drugs.²¹⁹ Indeed, a close reading of H.R. Rep. No. 30-664 reveals that it was such sharp practices that were the target of the Import Drug Act.²²⁰ In short, it appears Congress designed this section of the Import Drug Act to prevent entry through U.S. ports of those drugs which, in fact, did not meet the professed specifications under which they were sold.²²¹ Those drugs which failed to meet the standards professed were thereby considered ineligible for importation.²²²

²¹² *Id.*

²¹³ *Id.*

²¹⁴ See H.R. Rep. No. 30-664, at 7 (1848); see also Walch, *supra* note 209, at 28.

²¹⁵ See H.R. Rep. No. 30-664, at 2 (1848).

²¹⁶ See *supra* Part III.

²¹⁷ See Omudhome Ogbru, *What You Should Know About Drugs*, <http://www.medicinenet.com/script/main/art.asp?articlekey=16667> (last visited Nov. 30, 2007).

²¹⁸ See H.R. Rep. No. 30-664, at 7 (1848).

²¹⁹ *Id.* at 11; see also Walch, *supra* 209, at 30 (stating that although the Committee noted that deteriorated, ineffectual drugs were often sold at a lower price than that charged for purer products, the Committee was outraged that such materials could be sold at all to an unsuspecting public that bought the cheaper drugs in reliance of promises that they would have some medicinal effect).

²²⁰ See H.R. Rep. No. 30-664, at 9-13 (1848). The general tenor of the report can be summed up by the words of the doctor commissioned to report on the problem of adulterated foreign drugs which stated:

Many of the foreign medicinal extracts are prepared and sold in reference to price rather than strength and purity. The foreign manufacturers prepare any quality called for. Compound extract of colocynth (as the label imports) comes to us in a manner well calculated to deceive, but, on examination, is found to contain not one particle of colocynth.

Id. at 11.

²²¹ See Sonnedecker, *supra* note 41, at 28-29.

²²² Import Drug Act, *supra* note 205.

An examination of Section III of the Import Drug Act also reveals that Congress's primary goal was to prevent misrepresentation of the value of drugs and medicines.²²³ American consumers could therefore know how effective the drugs and medicines would be when they self-medicated. Section III of the Import Drug Act provided that drugs and medicines would not clear customs if they were "so far adulterated, or in any manner deteriorated, as to render them inferior in *strength and purity* to the standard established by the United States, Edinburgh, London, French, and German pharmacopoeias²²⁴ and dispensatories, and *thereby* improper, unsafe, or dangerous to be used for medicinal purposes."²²⁵

The word "adulterated" is susceptible to various interpretations, but the meaning Congress ascribed to it in the Import Drug Act seems to reflect Congress's preoccupation with consumer protection, not patient protection.²²⁶ Congress assigned the term a broader meaning than that which the *Abigail* court ascribed to it when it described adulterated drugs merely as "impure," a word that allows the facile inference that the Import Drug Act was designed primarily to exclude drugs that were contaminated with inherently dangerous ingredients.²²⁷ A close reading of Section III reveals, however, that the word "adulterated" referred to those drugs and medicines which were so "inferior in strength and purity" that they did not meet the *efficacy* standards of the various international pharmacopoeias.²²⁸ In fact, the statute states that by not meeting these standards of strength and purity, the drugs were "*thereby* improper, unsafe, or dangerous to be used for medicinal purposes,"²²⁹ not that their quality was inherently dangerous.²³⁰ Therefore, rather than a law designed to ensure the inherent safety of drugs, the Import Drug Act appears to have been designed to ensure the efficacy of drugs so that consumers would know whether they were getting their money's worth. As such, the law gives little support to the *Abigail*

²²³ *Id.*; see also Walch, *supra* note 209 at 29 (stating that page after page of the House Committee's Report describes the importation of many worthless drugs, and averring that the Committee was concerned particularly with protecting Americans from paying high prices for worthless drugs).

²²⁴ In 1820, physicians and pharmacists convened at the United States Pharmacopeial Convention. HARRY F. DOWLING, *MEDICINES FOR MAN: THE DEVELOPMENT, REGULATION, AND USE OF PRESCRIPTION DRUGS* 139 (Knopf 1970). In an effort to set standards by which they could determine whether particular drugs were pure and effective, they published a set of standards which have become the basis for several federal laws. *Id.*

²²⁵ Import Drug Act, *supra* note 205, at § 3 (emphasis added).

²²⁶ See Walch, *supra* note 209, at 29 (stating that "economic concerns, rather than the safety, of the American people were persuasive to Congress.").

²²⁷ The Merriam-Webster's online dictionary defines "impure" as *inter alia*, "containing something unclean."

Merriam-Webster Online Dictionary, <http://www.merriam-webster.com/dictionary/impure> (last visited Mar. 10, 2008).

²²⁸ See Import Drug Act, *supra* note 205, at § 3 (emphasis added).

²²⁹ *Id.*

²³⁰ See Sonnedecker, *supra* note 41, at 28-30 (emphasis added).

court's stilted conclusion that the Import Drug Act represents the federal government's intent to regulate drug safety in nineteenth-century America.

2. The Pure Food and Drugs Act of 1906

In 1906, Congress passed and President Theodore Roosevelt signed, the Pure Food and Drugs Act, also known as the Wiley Act.²³¹ In describing the Wiley Act, the *Abigail* court mischaracterized its purpose and effect when it stated that Congress "passed the Food and Drugs Act of 1906, which prohibited the manufacture of any drug that was 'adulterated.'"²³² The court mischaracterized the Wiley Act as a drug safety regulation, when, in the words of James Harvey Young, the law actually "provided only modest controls of self-dosage medications."²³³ In short, Congress passed the Wiley Act to protect consumers from fraud or misrepresentation. Rather than being concerned about drug safety, Congress sought to "ensure that fair value was received for money spent."²³⁴

The Wiley Act prohibited the manufacture and interstate trade of "adulterated" drugs.²³⁵ It also prescribed, however, a particular meaning for the term "adulterated" that the *Abigail* court failed to recognize.²³⁶ The Wiley Act set out two definitions for "adulterated."²³⁷ First, it stated that no drug "defined in the United States Pharmacopoeia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity *be plainly stated* upon the bottle, box, or other container thereof *although the standard may differ from that determined by the test* laid down in the United States Pharmacopoeia or National Formulary."²³⁸ Thus, a drug defined by the official pharmacopoeia could be of inferior "strength, quality, or purity," but its packaging would have to disclose that fact.²³⁹ If it did so, the drug would not be considered "adulterated"²⁴⁰ and could be manufactured and even transported interstate.²⁴¹ Second, the Wiley act stated that a drug would not be "adulterated" unless its "strength or purity [fell] below the

²³¹ See Pure Food and Drugs Act, 34 Stat. 768 (1906); see also YOUNG, *supra* note 129, at 12. The Wiley Act was named after Dr. Harvey Wiley, head of the Bureau of Chemistry of the U.S. Department of Agriculture. Wiley was a staunch advocate of pure food and drugs laws and is credited for leading the movement that led to the Pure Food and Drugs Act of 1906. See HERBERT BURKHOLZ, *THE FDA FOLLIES* 7-8 (Basicbooks 1994).

²³² *Abigail Alliance*, 495 F.3d at 705.

²³³ YOUNG, *supra* note 129, at 12.

²³⁴ PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 4 (Harvard Press 1980).

²³⁵ Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 at § 2 (1906).

²³⁶ See *Abigail Alliance*, 495 F.3d at 705; see also Pure Food and Drugs Act ch. 3915, 34 Stat. 768 at § 7 (1906).

²³⁷ Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 at § 7 (1906).

²³⁸ *Id.* (emphasis added).

²³⁹ Sonnedecker, *supra* note 41, at 37.

²⁴⁰ See Pure Food and Drugs Act, ch. 3915, 34 Stat. 768 at § 7.

²⁴¹ See *id.* at § 2; see also Sonnedecker, *supra* note 41, at 37.

professed standard or quality under which it [was] sold,”²⁴² a provision that referred to drugs not covered by the two pharmacopoeias mentioned above.²⁴³ As a result, any drug not officially recognized by the two pharmacopoeias would be considered unadulterated and could therefore be manufactured, transported, and sold as long as the seller did not misrepresent the value of the drug.²⁴⁴ In short, the term “adulterated” as used in the Wiley Act did not mean “dangerous” or even “impure,” which was the superficial definition assigned to it by the *Abigail* court.²⁴⁵

The Wiley Act did little to regulate access to drugs because it was not designed to do so.²⁴⁶ It is unlikely, however, that the *Abigail* court recognized this fact when it deemed the Act one of the “early examples of federal government intervention.”²⁴⁷ The federal government certainly intervened, but it did so to prevent fraud and misrepresentation; it did not do so to prevent access to unsafe drugs. While it did require disclosure of potentially dangerous substances, the Wiley Act did not “strike a blow against self-medication, but sought to make it safer.”²⁴⁸

3. The Food, Drug, and Cosmetic Act of 1938 and its 1962 Kefauver-Harris Amendments

As noted above, Congress passed the first federal law regulating drug safety in 1938, the Federal Food, Drug, and Cosmetic Act.²⁴⁹ Although the 1938 law did not regulate the efficacy of drugs,²⁵⁰ the new powers it bestowed on government agencies were far-reaching.²⁵¹ The new law provided four new safeguards when it: 1) commanded the use of prescriptions,²⁵² 2) required that drugs be labeled with

²⁴² Pure Food and Drugs Act, 34 ch. 3915. Stat. 768 §7 (1906).

²⁴³ *Id.*

²⁴⁴ *Id.*; see also Sonnedecker, *supra* note 41, at 29-30.

²⁴⁵ See *Abigail Alliance*, 495 F.3d at 704.

²⁴⁶ See YOUNG, *supra* note 58, at 244. Furthermore, the Wiley Act did not require drug manufacturers to name all the ingredients in a drug. As long as the drug compounder made no false or misleading claims with regard to the ingredients, he could sell his wares to willing Americans. *Id.* If he chose to name ingredients, however, those elements had to be present in the amount claimed. *Id.* The only ingredients that needed to be named were inherently suspect articles such as alcohol, poisons, and a variety of opiates. *Id.* at 243-44. Peter Temin described the situation succinctly when he said that “to avoid the scope of the law entirely, [a manufacturer] could produce a nonnarcotic preparation, give it a novel name, and say little definite about it.” TEMIN, *supra* note 234, at 30.

²⁴⁷ *Abigail Alliance*, 495 F.3d at 704.

²⁴⁸ YOUNG, *supra* note 58, at 244.

²⁴⁹ See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 (1938); see also YOUNG, *supra* note 129, at 12.

²⁵⁰ See TEMIN, *supra* note 234, at 125-26.

²⁵¹ *Id.* at 4, 127.

²⁵² See Wallace F. Janssen, *History of the FDA: The 1938 Food, Drug, and Cosmetic Act*, <http://www.fda.gov/oc/history/historyoffda/section2.html> (last visited Oct. 29, 2007). This law was passed in response to 100 deaths caused by the untested sulfa drug, Elixir Sulfanilamide. *Id.* The law arguably marks the beginning of the progressive testing that the

directions for safe use, 3) removed the scienter requirement for proving false therapeutic claims, and 4) mandated that all drugs be deemed safe before they could be marketed.²⁵³ Of note, the final provision regarding drug safety was introduced late into the proposed legislation for the 1938 law.²⁵⁴ That Congress included this crucial provision as a virtual afterthought reveals the federal government's ambiguous approach to drug safety regulation even in 1938 when it passed the first "safety" regulation.²⁵⁵ Still, the new controls were stringent²⁵⁶ relative to those laid out in the corpus of *laissez-faire* drug laws that had flourished since the early days of American settlement.²⁵⁷ In effect, the 1938 law was the first American law that could be called a drug safety regulation affecting the discretion Americans had long enjoyed when choosing medications. The law's new restrictions were such that James Harvey Young said, "self-medication was doomed."²⁵⁸

On October 10, 1962, Congress passed the Kefauver-Harris Amendments to the 1938 law.²⁵⁹ These amendments compelled drug makers to operate under procedures prescribed by the FDA and required that factories submit to inspections, present plans for prospective clinical trials, and continuously monitor the effects of their drugs on patients.²⁶⁰ In effect, the amendments strengthened dramatically the FDA's control over the regulation of drug manufacturing.

The 1962 amendments were the first federal regulations that purported²⁶¹ to require drug manufacturers to make a substantial showing that their drugs were

FDA now requires before experimental drugs may be marketed once they pass the final phase of testing. Also, in 1936 Ruth De Forest published her book *The American Chamber of Horrors*, which detailed the pervasiveness of useless and "dangerous" foods, cosmetics, and drugs. See ROBERT N. MAYER, *THE CONSUMER MOVEMENT: GUARDIANS OF THE MARKETPLACE* 24 (Twayne Publ. 1989). The book caused a public outcry, which pushed Congress to enact the 1938 law. *Id.*

²⁵³ See JAMES HARVEY YOUNG, *MEDICAL MESSIAHS: A SOCIAL HISTORY OF HEALTH AND QUACKERY IN TWENTIETH-CENTURY AMERICA* 189-90 (Princeton Univ. Press 1967).

²⁵⁴ See James Harvey Young, *Drugs and The 1906 Law*, in *SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL* 156 (John B. Blake ed., Johns Hopkins Press 1970).

²⁵⁵ *Id.*

²⁵⁶ *Id.*

²⁵⁷ See *supra* Part IV.

²⁵⁸ James Harvey Young, *The Government and the Consumer: Evolution of Food and Drug Laws, The 1938 Food, Drug and Cosmetic Act*, 13 J. PUB. L. 197, 201 (1964).

²⁵⁹ See YOUNG, *supra* note 253, at 418.

²⁶⁰ *Id.* at 420-21.

²⁶¹ The new amendments offered little guidance on how to gauge the "effectiveness" of a drug. TEMIN, *supra* note 234, at 127. The amendments of 1962 relied on a drug's label to determine its effectiveness. *Id.* Indeed, the law stated that experts would be employed "to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug *will have the effect it purports or is represented to have . . .*" *Id.* at 127 (emphasis added). Thus, a panel of experts would decide whether the drug's actual efficacy comported with its own claim, a requirement reminiscent of that found in the 1906 law.

efficacious, not merely safe.²⁶² This efficacy requirement prompted the *Abigail* court to state correctly, if tritely, that “even setting the safety issue to one side..., as a matter of history, at least some drug regulation prior to 1962 addressed efficacy.”²⁶³ The court failed, however, to elucidate on the question of why ensuring drug efficacy has historically been an important government interest. Its treatment ignores the fact that the history of drug regulation in the U.S. has been tied to the tradition of self-medication and the desire to protect consumers’ pocketbooks, not their health.²⁶⁴

Congress’s requirement that drug makers make a substantial showing that their drugs be effective suggests strongly that the 1962 law was also rooted in a desire to protect market consumers. According to Louis Lasagna, the committee hearings leading up to the passage of the 1962 law appeared to be primarily concerned with “excessive drug costs, inadequate competition, price control, and patent protections.”²⁶⁵ Robert N. Mayer adds that, “the amendments were primarily designed to save dollars, not lives.”²⁶⁶ If Lasagna and Mayer are correct, then the efficacy requirement was largely an extension of a tradition within which the government had long engaged—that is, the regulation of drugs with the intent to protect consumers from fraud or misrepresentation.²⁶⁷ Therefore, the *Abigail* court was correct in stating that the government has long regulated the efficacy of drugs, but its intimation that it did so to ensure the safety of drugs has little support from history. In fact, the court’s words reflect its misunderstanding of our country’s history and traditions regarding the consumption and regulation of medicines.

V. THE PROPOSAL

On January 14, 2008, the United States Supreme Court declined the *Abigail Alliance*’s petition for a writ of certiorari.²⁶⁸ By doing so, the Court failed to address the circuit split²⁶⁹ over which test courts should apply when determining whether a particular liberty interest is deeply rooted in our country’s history and tradition.²⁷⁰

²⁶² See YOUNG, *supra* note 253, at 418.

²⁶³ *Abigail Alliance*, 495 F.3d at 706.

²⁶⁴ See *supra* Parts III and IV.

²⁶⁵ Louis Lasagna, 1938-1968: *The FDA, the Drug Industry, the Medical Profession, and the Public*, in SAFEGUARDING THE PUBLIC: HISTORICAL ASPECTS OF MEDICINAL DRUG CONTROL 171, 173 (John B. Blake ed., Johns Hopkins Press 1970).

²⁶⁶ MAYER, *supra* note 252, at 123.

²⁶⁷ See *supra* Part IV.

²⁶⁸ *Abigail Alliance v. von Eschenbach*, 128 S.Ct. 1069 (2008).

²⁶⁹ See Lisa K. Parshall, *Redefining Due Process Analysis: Justice Anthony M. Kennedy and the Concept of*

Emergent Rights, 69 ALB. L. REV. 237 (2005-06); see also Brian Hawkins, *The Glucksberg Renaissance: Substantive Due Process Since Lawrence v. Texas*, 105 MICH. L. REV. 409 (2006).

²⁷⁰ By denying certiorari, the Court has also declined to address the circuit split over whether *Lawrence v. Texas* has superseded *Glucksberg v. Washington* with regard to the test the Court will consider when determining that a particular liberty interest is not deeply rooted in our country’s history and tradition. To be sure, *Lawrence* has called into question the

More apropos of this paper, the Court declined to answer the salient question of whether terminally ill patients with no medical alternatives have a fundamental right of access to experimental drugs that have been deemed safe enough by Phase I investigative trials to continue human testing. This refusal leaves in place a deeply flawed precedent.

To be sure, the *Abigail* court's mischaracterization of history reveals that its approach was almost wholly devoid of historical analysis. Because it ignored this country's history of self-medication and disregarded its duty to scrutinize the laws it cited in support of its decision, the *Abigail* court found no deeply-rooted tradition of access to experimental drugs. In short, because of its misappropriation of history, the *Abigail* court rendered a conclusion perfectly contrary to reality. Had the Supreme Court chosen to review this nation's true history under the *Glucksberg* test,²⁷¹ it would have found that access to experimental drugs had been an institution that for centuries was "deeply rooted in this nation's history and tradition."²⁷² This finding would have opened the door to further constitutional analysis and the

Supreme Court's analysis set out in *Glucksberg*. See generally Hawkins, *supra* note 269. In *Lawrence*, the Court held that the Due Process Clause grants consenting adults a liberty right to be free of government interference into homosexual sodomy practiced within the privacy of their own homes. See *Lawrence v. Texas*, 539 U.S. 558, 578 (2003). More importantly, for purposes of the issue at hand, the Court concluded that this country's recent history with regard to attitudes toward homosexuality weighed more heavily than the purported long-standing tradition of anti-homosexual sentiment. *Id.* at 559. Therefore, the Court concluded that "laws and traditions in the past half century are of most relevance" when determining whether the liberty interest in *Lawrence* should be given substantive constitutional protection. *Id.* In reaching its conclusion, the Court noted that many states in the latter half of the twentieth-century had repealed anti-sodomy laws as well as laws banning homosexual sex in general. *Id.* The Court interpreted this as a jurisprudential shift that reflected "emerging awareness" that certain liberties indeed exist. *Id.*

Given the Court's analysis in *Lawrence*, it is possible that courts faced with the issue presented here will eschew the test in *Glucksberg* for *Lawrence*'s "emerging awareness" analysis. If so, such courts may find that terminally ill patients have no fundamental right of access to experimental drugs because the federal government has clearly established safety regulations, which have been in place since 1938. It is important to note, however, that the *Lawrence* Court did not subject the Texas statute under strict scrutiny, but instead a rational basis scrutiny. *Id.* at 574. It merely found that the statute was irrational and arbitrary because it singled out homosexuals and invaded their substantive due process rights. *Id.* at 578-79. Yet, the Court stopped short of calling that right fundamental. More importantly, the Court did not say that history is irrelevant. *Id.* at 572. Instead, it stated that "[h]istory and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry." *Id.* Thus, rather than a repudiation of extended history, *Lawrence* appears to stand for the proposition that courts may look to recent social developments to decide whether to recognize the fundamental nature of a particular liberty interest. See generally Parshall, *supra* note 269.

²⁷¹ A finding that self-medication and laissez-faire government regulation of drugs was a deeply-rooted tradition of American history would not mean that the Abigail Alliance would have met its burden of showing that access to experimental drugs is a fundamental right. Whether a liberty interest rises to the level of a fundamental right involves a more complex analysis. See *Glucksberg*, 117 U.S. at 720-721; see also *infra* Section V.

²⁷² *Glucksberg*, 521 U.S. at 720-721.

prospect of subjecting FDA policies to strict scrutiny, a much higher standard than the rational basis standard the *Abigail* court used to deny terminally ill patients with no other alternatives a fundamental right of access to potentially life-saving drugs.

Of course, a finding that a particular liberty interest is “deeply-rooted” does not dispose of the question of whether that interest merits constitutional protection.²⁷³ Under *Glucksberg*, once a court determines that a particular interest is “deeply-rooted,” it must then decide whether that interest is “implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed.”²⁷⁴

Allowing terminally ill patients, such as Abigail, access to potentially life-saving drugs is a right of liberty that is “implicit in the concept of ordered liberty.”²⁷⁵ This facet of the *Glucksberg* test, despite its seemingly distinctive nature, is in fact closely related to the question of whether a liberty interest is “deeply rooted.” For example, when the *Glucksberg* Court held that there is no fundamental right to assisted suicide, the Court relied heavily on the fact that the government has throughout American history banned, and continues to ban, assisted suicide.²⁷⁶ While the Court recognized that a liberty interest in suicide may be characterized as a right “to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life,”²⁷⁷ it stressed that the mere fact that “rights and liberties...sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are [fundamental rights].”²⁷⁸ Thus, the Court recognized that a liberty interest is “implicit in the concept of ordered liberty” not because it involves personal autonomy deserving of protection from government intrusion, but because it involves a personal liberty that is grounded in history and tradition—a construction that supports the Abigail Alliance’s pursuit of access to experimental drugs. To be sure, American history reflects a long tradition in which Americans enjoyed personal access to drugs.²⁷⁹ More than that, Americans’ right of self-medication was recognized and furthered by government regulations intended to promote consumer confidence.²⁸⁰ As such, a court that establishes the fundamental liberty the Abigail Alliance seeks would be recognizing a liberty interest in personal autonomy, as well as the tradition that has for centuries supported this freedom.

Finally, under *Glucksberg*, the Abigail Alliance would also have to submit a “careful description of the asserted fundamental interest” it seeks to establish.²⁸¹ Although the *Abigail* court failed to reach this aspect of the *Glucksberg* test, the court asserted that the Abigail Alliance would likely be unable to make such a

²⁷³ *Id.* at 721.

²⁷⁴ *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.* at 728.

²⁷⁷ *Id.* at 726.

²⁷⁸ *Id.* at 727.

²⁷⁹ See *supra* Part III.

²⁸⁰ See *supra* Part IV.

²⁸¹ *Glucksberg*, 521 U.S. at 721 (internal quotations omitted).

showing because access to experimental drugs would depend on the FDA's regulatory determinations regarding the drug's safety and efficacy.²⁸² The court asked, "How can a constitutional right be defined by an administrative regulation that is subject to change?"²⁸³ In addition, the court found it "difficult to imagine how a right inextricably entangled with the details of shifting administrative regulations could be deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty."²⁸⁴

The *Abigail* court failed to recognize that fundamental interests such as the one the Abigail Alliance seeks have been carefully described with regard to medical experts' evolving understanding of medicine and pharmacology. In *Planned Parenthood v. Casey*,²⁸⁵ the Supreme Court upheld *Roe v. Wade*²⁸⁶ and recognized that a woman's right to choose to abort a pre-viable fetus shall not be unduly burdened by government interference.²⁸⁷ That the *Casey* Court did not grant an absolute right to abortion²⁸⁸ is instructive. While it recognized the fundamental right of access to an abortion, the *Casey* Court qualified that right by reference to medical principles surrounding the viability of the fetus and concerns over the mother's health.²⁸⁹ In short, the government's interests in potential life and in the mother's health are circumscribed by medical opinions regarding fetal viability and the health of the mother.²⁹⁰ That doctors make such determinations is indicative of their role in carefully describing the mother's liberty interest in having an abortion.

The fundamental right the Abigail Alliance seeks to establish is similar to the right recognized in *Casey*. That is, the right that terminally ill patients seek in gaining access to experimental drugs is analogous to a woman's right to choose abortion under certain circumstances. It is important to note that the Abigail Alliance does not advocate absolute access to all drugs not proven safe; it merely seeks access to post-Phase I drugs that have been deemed sufficiently safe for continued experimentation on humans. The determinations that the FDA's medical experts make with regard to a drug's safety and efficacy are analogous to that which medical experts make with regard to whether a woman's request for an abortion is medically advisable. More specifically, determinations over whether continued human testing of post-Phase I drugs is advisable are analogous to determinations over whether a fetus is viable, or whether a woman's health will be inadvisably compromised by an invasive abortion. Yet the fundamental right to government-fettered access to an abortion is widely-recognized, while the patient who is breathing her last breath is denied access to potentially life-saving post-Phase I

²⁸² See *Abigail Alliance*, 495 F.3d at 703 n.6.

²⁸³ *Id.*

²⁸⁴ *Id.* (internal quotations omitted).

²⁸⁵ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

²⁸⁶ *Roe v. Wade*, 410 U.S. 113 (1973).

²⁸⁷ *Casey*, 505 U.S. at 874.

²⁸⁸ *Id.*

²⁸⁹ *Id.* at 846.

²⁹⁰ *Id.*

drugs. Rather than resting on concerns surrounding patients' health, it appears this artificial distinction rests largely on administrative, bureaucratic, and economic reasons having little to do with the impact that a carefully described right of access might entail.²⁹¹

The Abigail Alliance does not seek a liberty interest for the general public in obtaining access to experimental drugs. Rather, it seeks to establish a liberty interest for those terminally ill patients who have no life-saving alternatives and who consent to consume post-Phase I experimental drugs.²⁹² Like patients who seek abortions, these patients would act under the direction of their personal physicians, who are best-situated to make the determination that under the circumstances post-Phase I experimental drugs are the best alternative to dying. Abigail's doctor made that determination for her.²⁹³ Had he had his way, she might be alive today.

Were a court to determine that the liberty interest the Abigail Alliance seeks is fundamental, it would still need to decide whether the FDA policy is constitutional. That is, it must strictly scrutinize the FDA's denial of access to terminally ill patients who seek to consume post-Phase I experimental drugs. Such an exercise would entail greater effort and analysis than that displayed by the court in *Abigail*.

To determine the constitutionality of the FDA regulations, the court must determine whether those policies are narrowly tailored to furthering a compelling government interest.²⁹⁴ Of course, the court may find the policies pass such constitutional muster by finding that the fundamental right of access to potentially life-saving drugs must yield to the state's interests in preserving public health. Applying the *Glucksberg* test to the true history and tradition regarding self-medication and the lack of drug safety regulations, however, would require a court to make that difficult determination by weighing terminally ill patients' weighty interest in survival against the government's interest in prohibiting *this particular group's* access to potential cures.

If the thrust of the FDA policy is to protect the general public health, then it sweeps too broadly. The FDA has the alternative to narrow its prohibition on post-Phase I experimental drugs to exclude those who are not both terminally ill and willing to undergo post-Phase I clinical trials, which are regularly made available to those patients the FDA has deemed suitable test subjects. That the FDA allows post-Phase I drugs to be administered to willing test subjects demonstrates its willingness to accept risks to patients who themselves knowingly assume the risks. As the Abigail Alliance has stated, all that it seeks is a

right for terminally ill patients with no remaining treatment options to fight for their own lives, by taking a drug that their doctors have concluded is justified by the available scientific evidence and that the

²⁹¹ See generally BURKHOLZ, *supra* note 231.

²⁹² Brief of Petitioner, *Abigail Alliance v. von Eschenbach*, 128 S.Ct. 1069 (2008) (No. 07-444), at 9.

²⁹³ See Kovach, *supra* note 1, at 26.

²⁹⁴ *Casey*, 505 U.S. at 929.

FDA itself would let them take it if they were lucky or well-connected enough to get a spot in the trial.²⁹⁵

This statement reflects the frustrations that patients, such as Abigail, feel when they are denied access to a drug that is indeed being administered to human test subjects. As Abigail's failure to be accepted as a subject indicates,²⁹⁶ many patients are understandably frustrated when they are excluded for reasons associated with a drug's marketability, not for an overweening concern for patient safety.

Finding that terminally ill patients have a fundamental right of access to experimental drugs would not mean a return to the days of governmental laissez-faire regulation of drugs. The government surely maintains strong interests in regulating the sale and ingestion of drugs generally. Its interests in regulating narcotics are surely compelling and would outweigh the public's interest in ingesting such substances without strict oversight. Similarly, the government's interests in withholding access to experimental drugs would outweigh the general public's right of access to them. Absent the strong interest in self-preservation, the interest in seeking access to experimental drugs would be outweighed by the government's concern for patient safety. Indeed, courts may justifiably deny such access even as they recognize that terminally ill patients have a fundamental right of access to potentially life-saving cures that have passed Phase-I of the FDA's testing regime.

VI. CONCLUSIONS

The *Abigail* court declared that to prove its claim, the Abigail Alliance would need to show "that there is a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe."²⁹⁷ American history bears proof of both—that is, a cultural institution of self-medication, as well as government's accommodation and protection of that tradition.

American history reveals that British colonists came to America with a wealth of personal medical knowledge, and the custom of medical self-treatment that had been and would for long continue to be their tradition.²⁹⁸ Such traditions flourished in the New World of frontier living, experimentation, and laissez-faire economics. Meanwhile, the American laissez-faire attitude strengthened the belief that Americans expected government would not interfere with their right to self-medication. It is perhaps true, as the *Abigail* court noted, that the "lack of prior governmental regulation of an activity tells us little about whether the activity merits constitutional protection."²⁹⁹ This statement assumes, however, that the Abigail Alliance's argument rests on the proposition that government assumed a *completely* laissez-faire approach to drug regulation. It did not. For the greater part of American history, government regulation of drugs rested on protectionist principles and was designed to guard against charlatans who preyed on unsuspecting Americans seeking potential cures. Early American state and federal governments

²⁹⁵ Brief of Petitioner, *supra* note 292, at 9.

²⁹⁶ See Kovach, *supra* note 1, at 26-28.

²⁹⁷ *Abigail Alliance*, 495 F.3d at 703.

²⁹⁸ See *supra* Part III.

²⁹⁹ *Abigail Alliance*, 495 F.3d at 707.

often stepped in to regulate medical fees and drug costs because they recognized that citizens regularly engaged in such choices. Therefore, the government's laissez-faire approach to drug regulation involved recognition of the right of self-medication.³⁰⁰ Drug safety regulation did not begin until 1938³⁰¹ and any regulations dealing with the efficacy of drugs were aimed at ensuring that Americans received fair value, that is, that they did not pay for fraudulent therapeutic claims.³⁰²

Despite this unmistakable history, the *Abigail* court found no "deeply rooted" tradition that would support the Abigail Alliance's position. It is therefore ironic that the court began its analysis by noting that, "the Supreme Court has directed courts to exercise the *utmost care* whenever we are asked to break new ground in this field."³⁰³ In short, courts exploring the expansion of substantive due process rights must exercise extraordinary caution. While it is natural for a court facing such a question to be wary of the consequences that attend the recognition of substantive rights, the caveat does not amount to a license to courts to abdicate their responsibility of carefully analyzing the issue and the facts at hand.

In summary, the *Abigail* court's holding was founded on faulty conclusions about American history. A court reviewing the Abigail Alliance's case under *Glucksberg* must apply an accurate account of our nation's history. By doing so, the court will be able to find that there is a deeply-rooted tradition of self-medication and laissez-faire drug regulation in this country, and will then be able to proceed with the appropriate constitutional analysis. Such an analysis would produce the conclusion that a particular group of persons indeed has a fundamental right of access to experimental drugs. These are terminally ill people who, having no life-saving options, consent to consume post-Phase I experimental drugs under the care of physicians trying to save their lives.

³⁰⁰ See *supra* Part IV.

³⁰¹ *Id.* at Part IV.C. The *Abigail* court noted that the lack of regulation does not presuppose that a right is historically rooted. See *Abigail Alliance*, 495 F.3d at 706. This paper, however, has illuminated the history of self-medication in the United States and has revealed government's accommodating, laissez-faire policy toward drug *safety* regulation. See *supra* Parts III and IV. Moreover, it has shown that state and local governments certainly passed drug regulations, but these were usually laws prohibiting pharmacists and apothecaries from charging exorbitant fees, selling mislabeled or unmarked products, or defrauding customers. See *id.* at Part IV. Thus, there is in the United States a long tradition of regulating drugs with regard to their marketability, not their safety. In short, the *Abigail* court was wrong to assume that there has been a lack of government drug regulation in general.

³⁰² See *supra* Part IV.

³⁰³ *Abigail Alliance*, 495 F.3d at 702 (internal quotations omitted) (emphasis added).