All I Need is a Miracle and a Constitutional Right to Access It: The Rights of the Terminally Ill Reconsidered

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ALL I NEED IS A MIRACLE (AND A CONSTITUTIONAL RIGHT TO ACCESS IT): THE CONSTITUTIONAL RIGHTS OF THE TERMINALLY ILL RECONSIDERED

Abstract

In Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, Abigail Alliance sought to enjoin the FDA from preventing the sale of investigational drugs to terminally ill patients. The Alliance argued that terminally ill patients have a constitutional right to access investigational drugs under the Due Process Clause of Fifth Amendment.

In order to determine if a right to non-FDA approved drugs existed under the Due Process Clause, the court applied the test laid out in Washington v. Glucksberg. An en banc panel of the D.C. Circuit Court of Appeals held that terminally ill patients did not have a constitutional right to access non-FDA approved drugs.

This Note argues that the D.C. Circuit Court of Appeals correctly applied the Glucksberg test, but failed to consider how recent scientific discovery and changing societal views impact a Glucksberg analysis. With evolving technologies, the evidence of a “deeply rooted tradition” must be examined in terms of recent history, as the regulatory structure which defines the right at issue in this case did not exist until 1906. This Note asserts that the Glucksberg framework is not a viable analysis for emergent medical technologies, and that a more viable framework would be the framework used in Lawrence v. Texas, which emphasizes recent history and the evolution of society’s views towards a given topic.
“We are not dealing with a scientific problem. We are dealing with a political issue.”

~ Samuel Epstein, MD

When Dr. Epstein spoke these words, he was discussing cancer – a disease that kills over 1500 people per day. On June 9, 2001, Abigail Burroughs, a twenty-one year old honor student at the University of Virginia, became a statistic after losing her battle with squamous cell carcinoma. After receiving the diagnosis at age nineteen, Abigail vowed to fight the cancer and eventually help others facing the disease. Abigail and her family thought they found the miracle they searched for when Abigail’s oncologist informed them about two experimental drugs, Erbuitx and Iressa, which were undergoing clinical trials at the time.

Unfortunately, there would be no miracle for Abigail; she was denied admittance to the clinical trials for both of these drugs. Abigail’s story is not unique as clinical trials for non-FDA approved drugs have stringent requirements, which terminally ill patients often cannot meet. For people who cannot get admitted to an experimental drug clinical trial, the FDA has programs in place to allow early access to potentially life-saving drugs. Nevertheless, these programs are limited, and thus many terminally ill patients, like Abigail, are unable to qualify.

Frank Borroughs, Abigail’s father, founded an organization called Abigail Alliance for Better Access to Developmental Drugs seeking to increase access to experimental drugs for the terminally ill. Abigail Alliance asserts that the FDA approval process for a potentially life-saving drug is a virtual death sentence for terminally ill patients who do not have months, let alone years, to wait for FDA approval.
After failed attempts to lobby the FDA for regulatory change to access programs, Abigail Alliance turned to the legal system for relief. In Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, Abigail Alliance sought to enjoin the FDA from preventing the sale of investigational drugs to terminally ill patients. The Alliance argued that terminally ill patients have a constitutional right to access investigational drugs under the Due Process Clause of Fifth Amendment. People in medical need seeking to find redress within the form of a constitutional right is not new.

In order to determine if a right to non-FDA approved drugs existed under the Due Process Clause, the court applied the test laid out in Washington v. Glucksberg. An en banc panel of the D.C. Circuit Court of Appeals held that terminally ill patients did not have a constitutional right to access non-FDA approved drugs. The Court also indicated that earlier access to experimental drugs was ultimately a matter that should be handled by the legislature rather than the courts.

This Note argues that the D.C. Circuit Court of Appeals correctly applied the Glucksberg test, but failed to consider how recent scientific discovery and changing societal views impact a Glucksberg analysis. With new and evolving technologies, the evidence of a “deeply rooted tradition” must be examined in terms of recent history, as the regulatory structure which defines the right at issue in this case did not exist until 1906. Part II of this note provides a general overview of the FDA’s clinical trial process for a new drug. Part II also provides an overview of the FDA’s current programs that allow patients early access to experimental drugs outside of the clinical trial process. Part III discusses recent Supreme Court cases which have grappled with whether or not to recognize a new constitutional right. Part IV examines the D.C. Circuit Court’s reasoning in Abigail. Part V argues that when dealing with constitutional rights
involving scientific advancements, the Glucksberg analysis does not provide a viable framework.  

Part V suggests a more viable framework would be the framework used in Lawrence v. Texas, which emphasizes recent history and the evolution of society’s views towards a given topic. Part VI examines the larger implications of recognizing constitutional rights based on regulatory structures, exploring the areas of stem cell research and human cloning. Part VI also argues that ultimately constitutional rights cannot be based on a regulatory agency’s processes, and thus the claims of Abigail Alliance should be dealt with via legislative means.

II: The FDA and a History of Gate-Keeping

A. Drug Regulation in America

“From the beginnings of civilization, people have been concerned about the quality and safety of foods and medicines.” The movement towards federal regulation of drugs began in 1848, when Congress passed the Drug Importation Act. In 1862, Congress established the Bureau of Chemistry within the Department of Agriculture. In the wake of child deaths in response to smallpox and diphtheria vaccines, Congress passed the Biologics Control Act in 1902. Increasing fears over industrialization and its negative effect on safety of food and drugs in the United States spurred the passage of the 1906 Pure Food and Drugs Act (“PFDA”). The PFDA had serious flaws, which became evident to consumers over the next twenty-seven years.

Ultimately, the flaws of the PFDA were exposed when Elixir Sulfanilamide was given to the public purporting to cure infection, when in fact it was highly toxic. The distribution of Elixir Sulfanilamide to the public caused the deaths of over a hundred people in a few day period. In wake of this tragedy, Congress passed the 1938 Federal Food, Drug and Cosmetic
Act ("FDCA"). The 1938 FDCA stopped short of requiring premarket approval prior to the marketing of a new drug. The passage of the 1962 amendments to the FDCA, however, represented a key change in drug regulation as the amendments required FDA affirmative approval of a drug prior to approving the drug for sale. The 1962 Amendments to the FDCA raised the “safety and efficacy threshold . . . considerably” and placed the burden of proof “on the manufacturer to demonstrate that the drug was both safe and effective prior to its marketing.”

B. Clinical Trials: Testing New Drugs for Safety and Efficacy

Prior to the introduction of any new drug into the United States, a drug manufacture must obtain approval from the FDA. Before commencing the clinical trial process, a drug sponsor begins by isolating the drug and testing it on animals. If animal testing shows scientific promise, then the drug sponsor submits an Investigational New Drug Application ("IND") to the FDA to gain permission to conduct human clinical trials.

Once the IND is approved, the drug sponsor begins the first part of the three-part human testing protocol. In Phase I testing, the drug is given to a small group of people to evaluate drug safety, determine a safe dosage range, and indentify immediate side effects of the drug. Phase II trials involve giving the drug to a larger group of people to determine if the drug is effective and to further evaluate the drug’s safety. Phase III trials involve giving the drug to a larger group of people to determine drug’s effectiveness, monitor side effects, compare the drug to commonly used treatments, and collect information that will allow the experimental drug to be used safely. After Phase III is complete, the drug sponsor can file a New Drug Application (NDA) in order to gain approval to market the drug. The FDA will then approve the NDA if it
determines that the drug is safe and effective.\textsuperscript{50} After the NDA is approved, “the manufacturer may market the new drug for specific indications that the FDA approved.”\textsuperscript{51} Even after drug approval, the FDA continues to gather additional information about the drug’s risks, benefits, and optimal use.\textsuperscript{52}

The FDA has created some early access programs that allow patients to go beyond the clinical trial process in order to access potentially life-saving drugs.\textsuperscript{53} In creating these programs, the FDA recognized that patients with life-threatening diseases may not be able to wait the requisite number of years for a new drug to go through Phases I to III of testing.\textsuperscript{54} Compassionate use treatment INDs and disease-specific programs have made it possible for some seriously ill patients to gain access to experimental drugs.\textsuperscript{55} Nevertheless, terminally ill patients cannot always gain an investigational drug through existing protocols because early access programs are often restricted by disease type.\textsuperscript{56} An additional barrier to accessing drugs is getting the drug manufacturers to produce extra quantities of an investigational drug and agree to give the drug to patients outside the clinical trial process.\textsuperscript{57}

\textbf{III. Struggling to Define Medical Constitutional Rights: The Supreme Court’s Prescription for Autonomy and Patient Rights}

The Due Process Clause of the Fifth Amendment states the federal government must not infringe on an individual’s right to “life, liberty, and property, without due process of law.”\textsuperscript{58} Throughout history, the Supreme Court recognized various rights under the Due Process Clause.\textsuperscript{59} The Court also rejected attempts to expand the rights guaranteed under the Due Process Clause.\textsuperscript{60}
Due process jurisprudence reveals two distinctive tests to evaluate a potential right under the Due Process Clause.\textsuperscript{61} One test, announced in \textit{Washington v. Glucksberg}\textsuperscript{62}, requires that the asserted right is “deeply rooted in [the] Nation’s history and traditions and implicit in the concept of ordered liberty.”\textsuperscript{63} Conversely, in a different line of cases, the Supreme Court determined that a right may be deemed fundamental if the right involves “choices central to personal dignity and autonomy . . . .”\textsuperscript{64} The \textit{Glucksberg} test is the more restrictive test, and thus if a right would be found under the \textit{Glucksberg} test, then it would also be deemed fundamental under the autonomy test.\textsuperscript{65}

A. Historical Roots and Constitutional Rights

The \textit{Glucksberg} test recognizes only those rights that are narrowly defined and rooted in the underpinnings of American history as fundamental rights.\textsuperscript{66} In \textit{Glucksberg}, three terminally ill patients brought a lawsuit claiming a state statute that banned physician assisted suicide violated the patients’ liberty interests.\textsuperscript{67} The Supreme Court held that the patients had no constitutional right to commit physician assisted suicide.\textsuperscript{68} In assessing this purported right, the Court established a two-prong test.\textsuperscript{69}

Under the \textit{Glucksberg} analysis, the first prong requires a “careful description” of the asserted right.\textsuperscript{70} Second, a party seeking to establish that a right is fundamental under the \textit{Glucksberg} test must show that the asserted right is “deeply rooted in [the] Nation’s history and tradition . . . .” and “implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed.”\textsuperscript{71} The right to commit suicide failed the second prong of the test because historically society explicitly rejected such a right.\textsuperscript{72}
Years prior to Glucksberg, the Supreme Court addressed the right of a person to refuse unwanted medical treatment in Cruzan ex rel. Cruzan v. Missouri Department of Health.\(^73\) In Cruzan, the Supreme Court held there was a constitutional right to “refuse lifesaving hydration and nutrition.”\(^74\) In reaching this conclusion, Chief Justice Rehnquist opined that a person’s right to refuse lifesaving treatment was rooted in the common law doctrines of informed consent and battery.\(^75\)

B. A Broader Approach: Lawrence v. Texas

In Lawrence v. Texas\(^76\), the Supreme Court applied a drastically different historical assessment to evaluate if a state statute violated individuals’ due process rights.\(^77\) The Court in Lawrence determined a Texas statute, which made it a criminal act for two persons of the same sex to engage in consensual intimate contact, was unconstitutional.\(^78\) First, the Court discussed that there were prohibitions on sodomy in colonial times; however, the Court found that this was not detrimental to the petitioners’ case.\(^79\) Next, the Court determined that “our laws and traditions of the past half century are of most relevance” in assessing if the right to freely engage in sexual contact with the same sex was protected as a liberty interest.\(^80\) Examining recent history, the Court held that in fact society had recognized that people’s liberty interests are implicated when making autonomous choices of a private nature, such as sexual contact.\(^81\) Thus, Lawrence rejected the historical prong of the Glucksberg analysis and found a protected liberty interest by focusing on recent history and developments.\(^82\)

IV. Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach: Death Sentence for the Terminally Ill?
A. Facts and Procedure: Giving the Terminally Ill What They Are “Due” – A Fighting Chance

On July 28, 2003 Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance) filed a lawsuit against Mark B. McClellan, Commissioner of the FDA and Tommy G. Thompson, Secretary of Health and Human Services, in the D.C. District Court. The Alliance asserted that the FDA’s policy of barring the use of post-Phase I drugs by terminally ill patients, who were unable to gain access to clinical trials, violated the terminally ill patients’ due process rights.

Finding that the FDA’s early access programs were inadequate to meet the needs of the terminally ill patients, Abigail Alliance submitted a citizen’s petition to the FDA challenging the FDA policy which barred the sale of drugs that had passed through Phase I clinical testing. The FDA failed to respond to this petition within 180 days, and thus Abigail Alliance automatically had the right to judicial review. In response to the Alliance’s lawsuit, the FDA filed a motion to dismiss for failure to state a claim upon which relief could be granted. The D.C. Circuit Court granted this motion and dismissed the complaint.

On May 2, 2006, a divided panel of the D.C. Circuit Court of Appeals held “that where there are no alternative government-approved treatment options, a terminally ill patient’s right to access potentially life-saving investigational new drugs determined by the FDA after Phase I trials to be sufficiently safe for expanded human trials” warrants protection under the Due Process Clause. The 2006 panel of the D.C. Circuit Court deduced this right from America’s long tradition of protecting personal autonomy and self defense. In response to this verdict, the FDA filed a petition for re-hearing; the petition was granted, and the D.C. Circuit Court elected to rehear the case en banc. On August 7, 2007, the en banc D.C. Circuit Court of Appeals...
reversed the previous panel’s decision, and held that terminally ill patients did not have a constitutional right to access non FDA-approved drugs.\textsuperscript{92}

\textbf{B. Majority’s Reasoning: Safety First}

For the majority the issue was framed as “whether the liberty interest protected by the Due Process Clause embraces the right of a terminally ill patient with no remaining approved treatment options . . . to seek access to investigational medications that the FDA concedes are safe enough and promising for human testing.”\textsuperscript{93} The majority based its analysis and constitutional inquiry on the two-part test established in \textit{Glucksberg}.	extsuperscript{94} Without analysis, the court assumed that the asserted right met the requirement of being “carefully described.”\textsuperscript{95} After examining the history of drug regulation since colonial times, the court concluded that there was no tradition in the United States of allowing access to drugs that have not been proven safe or effective; conversely, there was a tradition of preventing access to unsafe drugs.\textsuperscript{96} The majority emphasized that drugs which had passed through Phase I testing were not deemed safe or effective.\textsuperscript{97}

Next, the Court considered the common-law doctrines of self defense, necessity, and interference with rescue to assess if these doctrines might give rise to a deeply rooted right of medical decision-making self defense.\textsuperscript{98} The court rejected the self defense argument, noting that Congress had statutorily eliminated this defense when it enacted the FDCA.\textsuperscript{99} The court rejected the idea of “necessity,” concluding drugs that have gone through Phase I testing are not safe or effective, thus such drugs could not be “necessary” to save a terminally patient’s life.\textsuperscript{100} Finally, the court rejected the Alliance’s argument that the right to access unapproved drugs could be rooted in the common law doctrine of self defense.\textsuperscript{101}
Concluding there was no fundamental right at issue, the court applied the rational basis scrutiny test.\textsuperscript{102} The court held that FDA regulations prohibiting access to drugs that are not deemed safe or effective were rationally related to the state’s legitimate interest in protecting the public health of its citizens.\textsuperscript{103} Although determining that there was no constitutional right, the majority invited Abigail’s Alliance to pursue their case in the legislature, which the court deemed was a more appropriate forum for this discussion.\textsuperscript{104} The majority stated that the holding “ensures that this debate among the FDA, the scientific and medical communities, and the public may continue through the democratic process.”\textsuperscript{105}

C. Dissent’s Focus on Broad Ideals and the Right to Life

The dissent framed the right at issue as “the attempt to preserve one’s life.”\textsuperscript{106} Thus, the dissent began by examining if the right to save one’s life could be found “in the Nation’s history and traditions”.\textsuperscript{107} Noting that the right to life is rooted in common law doctrines of self defense and necessity, the dissent refuted the majority’s trivialization of these arguments.\textsuperscript{108} Further, the dissent noted that the Supreme Court previously recognized the right of a pregnant woman to have a life-saving abortion when her health is in jeopardy.\textsuperscript{109} Finally, the dissent opined that there was “no merit” to the idea that “there can be no deeply rooted privilege to save one’s own life with medical advances because medical advances . . . are a relatively recent phenomenon.”\textsuperscript{110} Finally, the dissent emphasized that there was not a long history of regulating drugs based on efficacy.\textsuperscript{111}

V. When Regulatory Agencies, Scientific Advancements, and the Constitution Meet in Court: Due Process Rights Redefined
A. Glucksberg Framework is Not Viable to Evaluate Emerging Scientific Advancements

The Glucksberg test’s requirement that new constitutional rights must be deeply rooted in the history of our Nation unfairly creates a bias against any new scientific development. This bias is inherent in the historical focus of the test. In cases of emerging scientific technologies, often the regulatory agencies that promulgate regulations to govern such products were recently created, preventing deep historical roots of the agencies’ regulatory policies. Additionally, the Glucksberg test’s reliance on tradition immediately eliminates a new technology from constitutional recognition based on the fact that there was not scientific information available to create the technology until recent times.

Further, the careful description requirement of the Glucksberg test poses serious problems for scientific-based rights that are subject to government regulations because these regulations are constantly changing. The Abigail court noted that it had “serious doubt about whether the Alliance’s description of its proposed constitutional right could ever pass constitutional muster.” If fundamental rights are defined based on the scientific judgments of regulatory agencies, then one must question what would happen to such rights if the regulatory structure changes. Therefore, it is essential to define the right in such a way that it is not based on the specific procedural intricacies of a regulatory agency, but rather on the more expansive concept of regulatory agency’s judgments. Thus, in Abigail, the right was correctly defined as being based on the broad judgment of FDA about a drug’s safety and efficacy. Though broadly framed, any right based on an administrative agency’s judgments is doomed for failure if the second-prong of the Glucksberg test fails to emphasize recent regulatory developments.

B. Survival of the Fittest: Glucksberg Loses an Evolutionary Battle
Due process claims should not be subject to the rigid requirements of Glucksberg; a more fluid approach, one that recognizes the evolving ideas and technology of society, should be used. On occasion, the Supreme Court circumvented the Glucksberg careful description requirement by defining the right broadly, such that there would be historical precedence supporting its recognition. Additionally, in some cases where the Court found a fundamental right, the Court selectively examined America’s history and often ignored evidence of historical disapproval of an activity. In reality, with almost any issue, there is some history of approval and some history of disapproval; thus, the Glucksberg analysis allows courts to selectively highlight historical precedents that support a given point of view, without ever assessing if such a right is fundamentally rooted in tradition. The Supreme Court has seemingly disregarded employing the Glucksberg analysis in certain due process cases, formulating broader tests and ignoring the question of if such a right was rooted in our Nation’s traditions.

By their very nature, new emergent technologies cannot be deeply rooted within the history of our Nation. Clinical trial testing for both safety and efficacy of a drug was not even a requirement of the FDA protocol until recent times. Thus, the Abigail court’s emphasis on the regulation of drugs within the colony of Virginia seems to have slight relation to the complex scientific procedures used to develop and test today’s pharmaceuticals. C. The Flexibility of the Lawrence Analysis Gives the Terminally Ill a Fighting Chance

A more viable framework for evaluating if there is a history of regulation of safety and efficacy would be to examine the more recent history of the FDA’s regulation of drugs. The Supreme Court advanced such an approach in Lawrence v. Texas. The Lawrence approach is
a more balanced approach to examine a new technology or an area that is undergoing constant evolution.\textsuperscript{132}

Applying Lawrence to the constitutional right of giving the terminally ill access to non-FDA approved drugs allows for arguments to be made on both sides of the issue.\textsuperscript{133} An examination of the FDA’s protocols shows constant evolution in response to public crises and errors.\textsuperscript{134} It was not until 1962 that the FDA required proof of a drug’s efficacy of a drug, but this requirement reflected advancing scientific understanding of how to test for a drug’s effectiveness.\textsuperscript{135} Therefore, the FDA could argue the safety and efficacy of drugs that are FDA-approved has become a societal expectation.\textsuperscript{136} The Supreme Court recognized the importance of the FDA’s governance of drugs by imposing strict criminal liability for violation of FDA statutes; this illustrates societal acceptance of FDA regulation.\textsuperscript{137} Additionally, the Supreme Court has previously rejected people’s attempts to obtain access to medical treatment without government interference, which illustrates that there is not a deeply rooted right to be free from government regulation of medications.\textsuperscript{138} Finally, the Supreme Court recognized that terminally ill patients have no special rights of access to drugs simply due to their status as terminally ill.\textsuperscript{139} Thus, there is a strong argument that the public’s reliance on the FDA’s authority and increasing scope of FDA post-market surveillance refutes the existence of a fundamental right to access non-FDA approved drugs.\textsuperscript{140}

Despite the strong recent history of FDA regulation of drugs, there are counterarguments that support recognition of a right of access.\textsuperscript{141} In recent years, the FDA has specifically chosen not to regulate the off-label use of various drugs.\textsuperscript{142} Off-label use involves using a previously FDA-approved drug for a use that it was not initially approved for.\textsuperscript{143} Off-label use is especially common with oncology drugs.\textsuperscript{144} The Supreme Court recognized the modern acceptance and
importance of off-label use.\textsuperscript{145} From the evidence of increasing off-label use, the argument could be made that the FDA’s gate-keeping role over ensuring the safety and efficacy of drugs may be diminishing.\textsuperscript{146} This argument is flawed in one fatal respect, however, as off-label use still initially requires the drug to be approved and deemed safe and effective for treatment of at least one condition.\textsuperscript{147}

Further, the arguments of necessity and medical self defense are not valid under the \textit{Lawrence} analysis. There is prevalent history of rejecting the idea that persons have a right to access treatments, even when physicians deem such treatments necessary for the patient.\textsuperscript{148} Additionally, there is no rooted right to self defense against disease in the form of affirmative access to medications.\textsuperscript{149}

Thus, if the Court applied the \textit{Lawrence} analysis to the Alliance’s claim, the result would ultimately be the same as that reached by the D.C. Circuit Court in \textit{Abigail}. Terminally ill patients do not have a constitutional right to access non-FDA approved drugs because there is a recent history of increasing emphasis on ensuring that the FDA ensure the safety and effectiveness of drugs.\textsuperscript{150} The public relies on FDA approval of drugs, and this idea is deeply rooted in the history of the FDA.\textsuperscript{151} Although recent history shows the FDA is expanding access protocols to ensure that the terminally ill and those desperately in need of life-saving treatments have a chance for early access, this illustrates that ultimately regulatory changes to the FDA policy are rooted in legislative reform, not in a constitutional right.\textsuperscript{152}

\textbf{VI. Impact: Breathing Life into Emerging Scientific Developments}

A. \textit{Lawrence} Analysis Prevents the Dead Hand of the Past from Limiting Constitutional Recognition of Technology-Based Rights
Applying a Lawrence analysis to new scientific technologies allows courts to focus on recent societal developments, without having to manufacture history that could not have existed in years prior to the evolution of the technology. Additionally, as scientific understanding about a given technology or medication increases, often society’s views undergo drastic changes. A test to determine if a right is deeply rooted in our Nation’s history should focus on the recent years when the most information about a purported right is available. If recent history is not emphasized, then there is no chance for a new scientific technology to ever gain constitutional approval as there could be no history of a right to access such technology prior to its creation. The Lawrence analysis, however, does not open the floodgates to recognition of new constitutional rights because a purported right still must be considered deeply rooted in the traditions of our society, at least within the past fifty years.

B. Recognition of a Constitutional Right to Circumvent FDA Regulations Sets Dangerous Precedent

If the court found that terminally ill patients had a constitutional right to access non-FDA approved drugs this would weaken the FDA’s regulatory authority. Making drugs available to patients outside the clinical trial process limits the ability of the FDA to quickly determine the safety and efficacy of drugs. If patients are given un-regulated access to experimental drugs, then there is no incentive to participate in clinical trials. Without patients willing to enroll in clinical trials, the FDA’s speed at granting approval for new drugs will decrease causing diminished consumer confidence in the agency. Additionally, providing access to drugs that have not yet proven safe or effective can have negative effects on the research process itself, as
researchers and the public develop bias with magical thinking that a drug has the power to cure a
disease even in the absence of proof.\textsuperscript{162}

Moreover, a constitutional right to access non-FDA approved drugs for the terminally ill
could lead to total erosion of FDA authority.\textsuperscript{163} Commentators and the Supreme Court have
noted that the rights of the terminally ill are not different than the rights of all people; thus, a
right to non-FDA approved drugs would likely extend beyond the class of terminally ill
patients.\textsuperscript{164} Therefore, if the court had found a constitutional right to access non-FDA approved
drugs then the American consumer would suffer via delayed drug approval times and lack of
knowledge about drug safety and efficacy.\textsuperscript{165} Ultimately, the court’s decision to ignore the FDA
procedures would set precedent to allow recognition of a constitutional right to therapeutic
cloning or to use one’s stem cells absent FDA governance.\textsuperscript{166}

C. One Last Hope: Legislative Action

The D.C. Circuit Court emphasized that the judicial decision was not the end of hope for
Abigail Alliance’s fight to gain earlier access to experimental drugs.\textsuperscript{167} The Access,
Compassion, Care, and Ethics for Seriously Ill Patients Act ("ACCESS Act") was introduced in
the Senate in November 2005.\textsuperscript{168} The Bill was introduced in the House of Representatives in
October 2006.\textsuperscript{169}

The ACCESS Act was created directly in response to findings that present FDA regulations
do not meet the needs of terminally-ill patients.\textsuperscript{170} The ACCESS Act created a three-tiered
approval system for new drugs.\textsuperscript{171} Tier I approval deems drugs available for sell on a limited
basis, enabling the drug companies to make profits.\textsuperscript{172} Tier I allows a drug sponsor to submit a
New Drug Application for approval to market and sell the drug with information solely from
Phase I testing. The Tier I requirements insist that a patient has exhausted all other options, including clinical trials. Although the ACCESS Act has not been passed by either the House or Senate, it represents a step towards an open dialogue about how to help terminally ill patients gain earlier access to drugs.

D. Conclusion: Lawrence Leaves the Door Open to Changes in Society’s Views

Society’s views and knowledge about a given issue often evolve over time, which creates a dilemma for recognition of constitutional rights that must be “deeply rooted” in our Nation’s ancient history. In Lawrence v. Texas, the Supreme Court established a new framework for a fundamental rights analysis, which examined not only our Nation’s history, but also the evolution of society’s views on a topic. Thus, the Lawrence framework should be used to examine emerging technologies, which by their very nature, cannot be rooted in the Nation’s traditions, as the technology could not even have been contemplated hundreds of years ago.

Ultimately, a constitutional right to access non-FDA approved drugs does not pass constitutional muster as there is a long-standing history of the FDA’s authority to regulate drugs and ensure that pharmaceuticals are safe and effective before being sold to consumers. Although the terminally ill are in a unique position, the FDA promulgates regulations to ensure the safety of drugs for all people; a broad exception allowing the terminally ill to circumvent the FDA approval process would weaken the system for everyone. Under the Lawrence analysis, there is not a deeply rooted right to access drugs that have not been proven safe or effective because recent history shows the FDA’s regulatory authority is increasing. Thus, the D.C. Circuit Court correctly held that there was no constitutional right of access to non-FDA approved
drugs. The Abigail Alliance should seek redress within the legislature and lobby the FDA to expand current early access programs so that others don’t need to needlessly die while waiting for FDA approval of a drug that may have saved them.

2 See Ahmedin Jemal et al., Cancer Statistics, 2009, 59 CA Cancer J. for Clinicians 225, 299 (2009) available at http://caonline.amcancersoc.org/cgi/content/full/59/4/ (noting that estimated 1.5 million new cancer cases “does not include basal-cell and squamous-cell cancers of the skin”). In 2009, there are expected to be more than one million additional cases of basal-cell and squamous-cell skin cancers diagnosed. See id. (discussing study findings about expected cancer cases in 2009).


4 See Kovach, supra note 3, at 26 (stating that one day after going through chemotherapy, Abigail said to her father, “Dad, if I make it, I’d like you and I to devote our lives to helping people with cancer”).

5 See Susan Okie, Access Before Approval – A Right to Take Experimental Drugs?, 355 New Eng. J. Med. 437, 438 (2006), available at http://content.nejm.org/cgi/content/full/355/5/437 (noting that Erbitux and Iressa were not being tested specifically for head and neck cancer, but were shown to inhibit epidermal growth factor receptors, which were prevalent in Abigail’s tumor). Erbitux gained FDA approval in 2006, and is now approved to treat head and neck cancer. See Medical News Today, FDA Approves Erbitux (Cetuximab) for Treatment of Head and Neck Cancer, March 2, 2006, www.medicalnewstoday.com/articles/38678.php (announcing FDA approval); Bristol-Myers Squibb, Erbitux Package Insert, http://packageinserts.bms.com/pi/pi_erbitux.pdf (last visited October 12, 2009) (listing one of indicated uses for Erbitux as treatment of head and neck cancer). It was the FDA’s initial rejection of Erbitux that lead to the federal indictment of Martha Stewart and others regarding insider trading of ImClone stock. See Allan

6 See Dave Visel, Living with Cancer: A Practical Guide 257 (2006) (noting that Abigail could not gain admission to ongoing clinical trials because both drugs were being targeted for treatment of other types of cancers).

7 See generally U.S. National Institutes of Health, Understanding Clinical Trials, http://www.clinicaltrials.gov/ct2/info/understand (last visited October 12, 2009) (noting that inclusion and exclusion criteria are “important principle[s] of medical research that help to produce reliable results”). Inclusion and exclusion criteria are “based on such factors as age, gender, the type and stage of the disease, previous treatment history, and other medical conditions.” Id. For an example of patient being denied access to clinical trial, see Experimental Drugs for the Terminally Ill: Capitol Hill Hearing Testimony before the H. Comm. on Gov’t Reform, 107th Cong. (2001) (statement of Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs), available at http://abigail-alliance.org/testimony.htm (discussing Doug Baxter, sixteen year old, who was too young to qualify for clinical trials of Imclone drug being tested on older patients with his type of cancer). Additionally, many patients are never even made aware that there are clinical trials for cancer drugs. See National Cancer
Institute, Doctors, Patients Face Different Barriers to Clinical Trials, April 11, 2001, http://www.cancer.gov/clinicaltrials/developments/doctors-barriers0401 (noting one survey found eight out of ten cancer patients are unaware clinical trials could be option). Approximately “only three to five percent of cancer patients are enrolled in clinical trials.” Stanley P.L. Leong, Preface to Cancer Clinical Trials: Proactive Strategies (Stanley P.L. Leong ed., 2007).


9 See Judy Foreman, Patients Fight for Experimental Drugs, September 24, 2003, http://www.myhealthsense.com/F20030923_expermiimentalDrugs.html (noting that Abigail tried to gain access to Erbitux and Iressa by directly contacting drug manufactures; however, ImClone did not have compassionate use program and AstraZeneca was giving Iressa free to people with lung cancer, but refused to give it to Abigail because she had different kind of cancer); see generally American Cancer Society, Compassionate Drug Use, http://www.cancer.org/docroot/ETO/content/ETO_1_2x_Compassionate_Drug_U se.asp (last visited October 12, 2009) (describing various hurdles that patients must go through in order to get access to experimental drugs outside of clinical trial process).
10 See Abigail Alliance, http://abigail-alliance.org (last visited October 12, 2009) (noting Alliance “is promoting creative ways of increasing expanded access and compassionate use programs”).


12 See Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 699 (D.C. Cir. 2007) (discussing Alliance’s filing of
citizen’s petition with FDA). A citizen’s petition was brought pursuant to 21
C.F.R. § 10.25. See id. (discussing procedural history of lawsuit).

13 495 F.3d 695 (D.C. Cir. 2007).

14 Id. at 700. An investigational drug is “substance that has been tested in a
laboratory and has gotten approval from the U.S. Food and Drug Administration.”
National Cancer Institute, Dictionary of Cancer Drugs,
1&version=Patient&language=English (last visited on October 12, 2009).

15 Abigail, 495 F.3d at 700. The Fifth Amendment states “No person shall be . . .
nor be deprived of life, liberty, or property, without due process of law.” U.S.
Const. amend. V.

16 See e.g., Gonzales v. Raich, 545 U.S. 1 (2005) (involving marijuana use for
medicinal purposes); Cruzan ex rel. Cruzan v. Dir., Mo. Dept. of Health, 497 U.S.
261 (1990) (involving right to refuse life-sustaining hydration and nutrition);
United States v. Rutherford, 443 U.S. 544 (1979) (challenging FDA’s ban on
cancer drug Laetrile for terminally ill); Cowan v. United States, 5 F. Supp.2d
1235 (N.D. Okla. 1998) (involving terminally ill patient challenging FDA’s
clinical hold on human testing of pre-Phase I drug to treat HIV).
Substantive due process analysis initially requires careful description of purported right at issue. See id. (discussing various descriptions of right given in lower courts).

See Abigail, 495 F.3d at 712 (noting “[b]ecause the Alliance’s claimed right is not fundamental, the claim . . . is subject only to rational basis scrutiny”).

See id. at 713 (stating “Alliance’s arguments . . . are certainly ones that can be aired in the democratic branches”). The Court encouraging plaintiffs to seek out legislative reform, rather than judicial remedy is an echo from earlier due process cases. See Gonzales v. Raich, 535 U.S. 1, 32 (2005) (emphasizing that “even more important that these legal avenues is the democratic process, in which the voices of the voters allied with the respondents may one day be heard in the halls of Congress”). Abigail’s Alliance did introduce similar arguments within the legislature, and in 2005, Senator Sam Brownbeck introduced legislation entitled the Access, Compassion, Care, and Ethics for Seriously Ill Patients Act (ACCESS Act). See S. 1956, 109th Cong. (2005); H.R. 6303, 109th Cong. (2006) (creating new framework to allow terminally ill patients earlier access to drugs).
20 See U.S. Food and Drug Administration, Significant Dates in U.S. Food and Drug Law, http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm (last visited October 12, 2009) (stating inception of FDA began with passage of 1906 Food and Drugs Act, which prohibited interstate commerce of misbranded and adulterated food, drinks, and drugs). The FDA was initially known as Food, Drug, and Insecticide Administration; the name was shortened to its present form under an agricultural appropriations act in 1930. See id. (discussing historical development of FDA).

21 For an overview of the FDA drug-approval process, see Schacter, infra note 45, at 94-180.

22 For a discussion of early access programs, see supra note 8 and accompanying text.

23 For a discussion of these cases, see infra notes 65-85 and accompanying text.

24 See infra notes 88-108 and accompanying text (discussing majority and dissenting opinions).

25 See infra notes 115-124 and accompanying text (noting Glucksberg fails to consider recent history).

27 See id. at 570-72 (focusing on recent history of regulation of homosexual conduct in order to assess if homosexuals had constitutional right to engage in sexual relations with members of same sex).


29 See Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 713-14 (D.C. Cir. 2007) (emphasizing Alliance can pursue earlier access to drugs via legislative lobbying).

30 U.S. Food and Drug Administration, Milestones in U.S. Food and Drug Law History, http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/default.htm (last visited October 12, 2009). The colonists were concerned about unsafe dosages of drugs, reflected in passage of a 1736 Act that addressed concerns over dispensing more drugs than necessary as this was viewed as “dangerous and intolerable.”

See Edward Kremers & Glenn Sonnedecker, Kremers and Urdang’s History


32 See U.S. Food and Drug Administration, Milestones in U.S. Food and Drug Law History, http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/default.htm (last visited October 12, 2009) (noting Bureau of Chemistry was predecessor to present-day FDA).


See Ceccoli, supra note 31, at 66-67 (noting that PFDA maintained “relatively weak control over impure drugs” and left Bureau of Chemistry with “little enforcement power”); Philip J. Hilts, Protecting America’s Health: The FDA, Business, and One Hundred Years of Regulation 68 (2003) (stating PFDA “was built on the idea that false claims must be prosecuted, rather than addressing the real issues of whether food additives and drugs put on the market were safe and worked as they claimed”). One serious flaw of the PFDA was that government’s sole enforcement tool was the court system. See Fran Hawthorne,
Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat 41 (2005) (emphasizing PFDA gave administrative agency no power to enforce its rules, thus dangerous drug could be out on market for years while lengthy court battles occurred).

36 See Hilts, supra note 35, at 88-92 (discussing distribution of Elixir Sulfanilamide in various states and post-distribution discovery that chemists did not test safety of drug).

37 See Ceccoli, supra note 31, at 70-71 (discussing Sulfanilamide tragedy and resulting deaths); Miller, supra note 34, at 12-13 (same).

39 See Ceccoli, supra note 31, at 13 (noting that if drug sponsor submitted New Drug Application and FDA took no action, then drug was passively approved for marketing).

40 See Wyeth v. Levine, 129 S. Ct. 1187, 1195 (2009) (noting that 1962 amendments shifted burden of proof from FDA to manufacturer forcing manufacture to prove drug was safe prior to allowing FDA approval); see also Ceccoli, supra note 31, at 15 (discussing impact of 1962 Amendments). The 1962 Amendments to FDCA were spurred by news of tragic release of drug Thalidomide in Germany, which resulted in birth defects. See id. at 76-78 (discussing impact of Thalidomide tragedy on food and drug reform in America). Thalidomide had been in clinical testing in United States during 1950s, but was not yet marketed to general public; however, it is estimated that seventeen Thalidomide babies with severe birth defects were born in the U.S. as a result of Thalidomide drug trials. See Hawthorne, supra note 35, at 44 (discussing devastating impact of Thalidomide clinical trials within United States).

41 Ceccoli, supra note 31, at 79.

42 See 21 U.S.C. § 355(a) (stating that FDA approval is required before introduction of new drug into interstate commerce).
U.S. Food and Drug Administration, The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective, http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm (last visited October 12, 2009). This phase in drug development is often referred to as the preclinical phase. See Strongin et al., supra note 11, at 301 (discussing animal testing protocols).


U.S. National Institute of Health, Understanding Clinical Trials, http://clinicaltrials.gov/ct2/info/understand (last visited October 12, 2009); see Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 473 (discussing Phase I testing); Schacter, supra note 45, at 93-99 (same); see also 21 C.F.R. § 312.21 (noting that Phase I studies also “gain early
evidence on effectiveness if possible” and typically involve between twenty to eighty patients).

47 See 21 C.F.R. § 312.21(b) (noting that Phase II studies determine “effectiveness of the drug” and “short-term side effects and risks associated with the drug”); Schacter, supra note 45, at 10 (stating “Phase II trials essentially establish that . . . agent has potential as . . . useful drug”); Strongin et al., supra note 11, at 302 (noting “Phase II trials are controlled efficacy studies”).

48 See 21 C.F.R. 312.21(c) (stating Phase III trials evaluate “overall risk-benefit analysis” and “usually involve from several hundred to several thousand people”); see also U.S. National Institute of Health, Understanding Clinical Trials, http://clinicaltrials.gov/ct2/info/understand (last visited October 12, 2009) (describing Phase III of clinical trial process).


50 See Schacter, supra note 45, at 10 (discussing that FDA physicians and scientists carefully examine results of Phase I-III clinical trials in order to determine safety and efficacy of drugs). Often outside experts also review
applications and make independent judgments about the safety and efficacy of drugs. See id. (stating outside reviews ensure fairness in approval process).

51 Strongin et al., supra note 11, at 303 (emphasis in original). The FDA does not regulate off-label drug use; off-label use is common with cancer drugs. See American Cancer Society, Off Label Drug Use, http://www.cancer.org/docroot/ETO/content/ETO_1_2x_Off-Label_Drug_Use.asp (last visited October 12, 2009) (discussing some of potential benefits and dangers in off-label drug use).

52 See U.S. National Institute of Health, Understanding Clinical Trials, http://clinicaltrials.gov/ct2/info/understand. (last visited October 12, 2009) (describing post-marketing studies as Phase IV trials); Strongin et al., supra note 11, at 303 (noting main objective is to “examine long term safety and effectiveness” including to monitor adverse drug reactions). An example of Phase IV trials and importance of post-marketing governance surfaced in 2004, when, after gaining FDA-approval, Merck voluntarily withdrew the drug Vioxx from the market after it was shown to increase risk of heart attack and stroke. See Jennifer Wolsing, The Vioxx Litigation: Disincentivizing Patient Safety Through Misdirected Tort Rules, 75 Def. Couns. J. 209, 210-11 (2008) (discussing post-marketing studies that led to decision to take Vioxx off market).
53 See Zettler, supra note 8 at 45-50 (discussing early access programs). Prior to the 1962 Amendments to the FDCA, the FDA had no programs in place to allow patients early access to drugs outside the clinical trial process; however, during 1970s and 1980s patients were able to obtain early access to some drugs. See Benjamin R. Rossen, FDA’s Proposed Regulations to Expand Access to Investigational Drugs for Treatment Use: The Status Quo in the Guise of Reform, 64 Food & Drug L. J. 183, 193-94 (2009) (discussing patients obtaining drugs prior to NDA application approval).

54 See Michael D. Greenberg, AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process, 3 N.Y.U. J. Legis. & Pub. Pol’y 295, 309-10 (2000) (noting FDA recognized that AIDS patients were dying while waiting to gain access to non-FDA approved drugs that were undergoing testing).

55 For a comprehensive discussion of early access programs see Anthony W. Fox, Emergency and Compassionate-Use INDs and Accelerate NDA or ANDA Approvals – Procedures, Benefits, and Pitfalls in Principles and Practice of Pharmaceutical Medicine 301 (Andre J. Fletcher, Lionel D. Edwards, Anthony W. Fox & Peter Stonier eds., 2002).

56 See e.g., supra note 5 and accompanying text discussing how Abigail Burroughs was denied access to clinical trials.
See generally Ashley Ochs, *A Study in Futility: Abigail Alliance for Better Access to Developmental Drugs Will Not Expand Access to Experimental Drugs for the Terminally Ill*, 39 *Seton Hall L. Rev.* 559, 580-93 (2008) (noting numerous barriers terminally ill patients would face even if there was constitutional right to access experimental drugs). Drug manufacturers have little incentive to make experimental drugs available to terminally ill patients. See Benjamin P. Falit & Cary P. Gross, *Access to Experimental Drugs for Terminally Ill Patients*, 300 *J. Am. Med. Assoc.* 2793, 2794 (2008) (stating manufacturers have concerns over “litigation, production barriers for complex agents, and inability to profit from investigational drugs”).

58 U.S. Const. Amend. V.


60 See *Chavez v. Martinez*, 548 U.S. 760, 775 (2003) ("[W]e have expressed our reluctance to expand the substantive due process, in large part because guideposts for responsible decision-making in this unchartered area are scare and open-ended"); see also Brian Hawkins, *The Glucksberg Renaissance: Substantive Due

61 See Abigail Alliance for Better Access to Developmental Drugs v. Von Escenhbach, 445 F.3d 470, 476 (D.C. Cir. 2006), rev’d en banc 496 F.3d 695 (D.C. Cir. 2007) (“[T]he Supreme Court has employed two distinct approached when faced with a claim to a fundamental right.”) This Note argues the Supreme Court has employed three approaches to assess if a fundamental right exists. See infra, notes 87-96 (discussing the fundamental rights test used in Lawrence v. Texas, 539 U.S. 558 (2003)). Other commentators opine that Lawrence created a new standard for assessing fundamental rights under the Due Process Clause. See David O. Conkle, Three Theories of Substantive Due Process, 85 N.C. L. Rev. 63, 117 (2006) (stating Lawrence used “a third theory, that of evolving national values” to assess fundamental right in case); Lawrence H. Tribe, Lawrence v. Texas: The “Fundamental Right” that Dare Not Speak Its Name, 117 Harv. L. Rev. 1893, 1898-99 (2004) (asserting Lawrence recognized new test for due process cases). But see Charles E. Mauney, Jr., Landmark Decision or Limited Precedent: Does Lawrence v. Texas Require Recognition of a Fundamental Right to Same Sex Marriage?, 35 Cumb. L. Rev. 147, 147-48 (2005) (opining “suggestion that Lawrence requires recognition of a federal fundamental right to same-sex marriage is based on an overly broad reading of Lawrence”).

63 Id. at 721. This Glucksberg test requires that asserted right initially be described in detail. See id. (requiring “careful description of the asserted right”).

64 Planned Parenthood v. Casey, 505 U.S. 833, 851 (1992). The idea that all rights associated with autonomy are protected rights under the Due Process Clause was rejected in Glucksberg. See 521 U.S. at 727-28 (“That many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decision are so protected . . . and Casey did not suggest otherwise”). The autonomy logic was also rejected by other courts. See Blouin ex rel. Estate of Pouliot v. Spitzer, 356 F.3d 348, 360 (2d Cir. 2004) (“[T]he personal autonomy rationale employed here does not create new substantive rights entitled to protection under the Due Process Clause.”) One commentator opines that Lawrence rejected the autonomy-based due process rights as well. See Robert C. Post, Foreword: Fashioning the Legal Constitution: Culture, Courts, and Law, 117 Harv. L. Rev. 4, 98 (2003) (noting that Lawrence “marks a point of departure from the autonomy approach to due process”).

65 See Abigail, 445 F.3d at 477 (noting Glucksberg analysis is “seemingly more restrictive”).
66 See Glucksberg, 521 U.S. at 720-21 (discussing that right must be rooted within traditions and history of America).

67 See id. at 707 (noting plaintiffs who initially brought lawsuit passed away; appeal was carried out by the plaintiff’s physicians who stated they would have assisted the patients in hastening death if it were not for statute that barred this conduct as illegal).

68 See id. at 728 (opining that “assistance in committing suicide is not a fundamental liberty interest protected by the Due Process Clause”).

69 See id. at 720-21 (stating “established method of substantive-due-process analysis has two primary features”).

70 See id. at 721 (noting that courts should show restraint when recognizing liberty interests as fundamental). Courts have been stringent on the requirement that the right is narrowly defined and not too broad of a concept. See Giordano v. Connecticut Valley Hosp., 588 F. Supp. 2d 306, 315-22 (rejecting plaintiff’s assertion that after hospital instituted ban prohibiting smoking by patients, that right at issue was ”right to refuse forced medical treatment” and redefining right as either “right to refuse a smoking ban” or “right to smoke”); Doe v. Moore, 410 F.3d 1337, 1343 (11th Cir. 2005) (concluding that defendants’ claims that Sex
Offender Act infringes on rights to privacy, housing, employment, and religious practices are too broad and that right at issue must be more narrowly defined as “right of a person, convicted of ‘sexual offenses’, to refuse subsequent registration of his or her personal information with Florida law enforcement . . . and prevent publication of this information on Florida’s Sexual Offender/Predator website”). The Court in Glucksberg placed stringent limits on the connection between broad ideals such as autonomy and fundamental rights. See 521 U.S. at 725 (noting that whether asserted right is fundamental for due process purposes cannot “simply [be] deduced from abstract concepts of personal autonomy”). The court seemed to reject broad language used in earlier cases involving recognition of constitutional rights. See e.g., Planned Parenthood v. Casey, 505 U.S. 833, 851 (1992) (“The heart of liberty is the right to define one’s own concept of existence of meaning, of the universe, and of the mystery of human life,” and thus government is not permitted to infringe upon individual’s right to make “choices central to personal dignity and autonomy”).

71 Glucksberg, 521 U.S. at 721. In order to show a right is “deeply rooted” a party can show the right is “so rooted in the traditions and conscience of our people as to be ranked fundamental.” Snyder v. Massachusetts, 291 U.S. 97, 105 (1934). For a discussion of the origins of this “traditions” test for a fundamental right see Robert C. Farrell, An Excess of Methods: Identifying Implied Fundamental Rights in the Supreme Court, 26 St. Louis U. Pub. L. Rev. 203, 225-233 (2007).
72 See Glucksberg, 521 U.S. at 728 (discussing society’s rejection of person’s right to commit suicide).

73 497 U.S. 261 (1990). This case arose out of a hospital’s refusal to stop life-sustaining nutrition and hydration of Nancy Cruzan, a twenty-five year old girl who was in a vegetative state after having a car accident. See id. at 266 (describing accident and medical state giving rise to this lawsuit).

74 See id. at 280 (holding that U.S. Constitution does not forbid state to allow surrogate to refuse life-sustaining treatment on behalf of incompetent person).

75 See id. at 269-79 (discussing how unwanted life sustaining treatment falls within realm of touching that patient has not consented to, invoking battery doctrine, and noting informed consent requires that person be aware of all options, including option to refuse medical treatment).


77 See id. at 572 (2003) (stating “history and tradition are the starting point but not in all cases the ending point of the substantive due process inquiry”) (citations omitted); see also Hawkins, supra, note 71 at 420-21 (discussing how Lawrence approach to due process inquiry was departure from Glucksberg test).
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78 See Lawrence, 539 U.S. at 578 (stating homosexuals’ “right to liberty under the Due Process Clause gives them the full right to engage in [consensual sexual conduct with members of the same sex] without intervention of the government”).

79 See id. at 572 (emphasizing that although prior to 1961 all fifty states outlawed sodomy, “these prohibitions often were ignored”).

80 See id. at 571-72 (noting that many states have repealed laws that made homosexual conduct criminal).

81 See id. (analogizing autonomy of homosexuals with autonomy rights protected and recognized by Supreme Court in Planned Parenthood of Southeastern PA v. Casey, 505 U.S. 833 (1992)).

of its core requirements: that a fundamental right be carefully described and that there be objective evidence that the right is deeply rooted in our nation’s history and tradition”).


84 See Abigail, 445 F.3d at 472 (noting Alliance “contends the FDA’s policy violates . . . substantive due process rights to privacy, liberty, and life”).

See Abigail 445 F.3d at 470, 473; see also 21 C.F.R. § 10.30(e)(2) (2008) ("The Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition.")

Id. at 472 (evaluating if court properly granted dismissal of claim); see Fed. R. Civ. P. 12(b)(6) (identifying "failure to state a claim upon which relief can be granted" as defense that can be asserted via motion).

See Abigail, 445 F.3d at 472 (stating that plaintiffs were proposing novel interpretation of Due Process Clause because there was no precedent ensuring that patients had right to receive medical treatment).

Id. at 486. In this case, the court relied on the common law ideas of self preservation and self defense to give rise to the patients’ rights to make medical decisions without government interference. See id. at 480 (noting "right of control over one’s body has deep roots in the common law").

See Abigail, 445 F.3d at 491 (Griffith, J., dissenting) (opining that majority’s opinion was flawed in that “[f]undamental right may ‘not be [be] simply deduced from abstract concepts of personal autonomy”) (citation omitted).

See id. at 714 (noting opinion leaves Abigail Alliance free to pursue arguments in democratic branches of government). The panel was divided eight to two in reaching this decision. See id. at 714 (stating Chief Justice Ginsberg and Justice Roberts dissented). This verdict resulted in the Alliance filing a petition for certiorari to the U.S. Supreme Court, but the Supreme Court declined to hear the case. See Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach, 128 S. Ct. 1069 (2008) (denying petition for certiorari without opinion).

Abigail, 495 F.3d at 700.

See supra notes 74-77 and accompanying text (discussing Glucksberg test).

See Abigail, 495 F.3d at 703 n.6 (noting that assuming Alliance’s description of asserted right met careful description requirement, court had “serious doubts” if this was actually true).

See id. at 703 (noting that America “has long expressed interest in drug regulation, calibrating its response in terms of capabilities to determine risks associated with both drug safety and efficacy”).

See id. at 703 (observing that later phases test for safety and efficacy); see also Strongin, supra note 11, at 302 (noting that Phase III trials analyze “long-term
safety”); 21 C.F.R. § 312.21(B)(2008) (noting that Phase II studies examine short
term side effects and risks).

98 See Abigail, 495 F.3d at 707 n.13 (stating FDA argued that this reference to
common law rights was attempt to base fundamental right off “abstract concepts
of personal autonomy”).

99 See Abigail, 495 F.3d at 707-8 (discussing United States v. Oakland Cannabis
Buyer’s Cooperative, 532 U.S. 483 (2001), case in which court rejected finding
constitutional right for patients to smoke marijuana)).

100 See id. at 709 n.15 (citing statistics stating five percent of all cancer drugs that
begin clinical trials are ultimately approved).

101 See id. at 709-10 (observing that Alliance’s self defense argument was
premised on abortion cases). Ultimately, the court rejected this abortion analogy
on the basis that abortions had been proven effective at preserving health of
woman, whereas non-FDA approved drugs had not. See id. at 710 (“[T]his case
involves risk from drugs with no proven therapeutic effect, which at a minimum
separates this [case] from the abortion ‘life of the mother’ exception.”)

102 See id. at 712 (“The rational basis test requires that the Alliance prove the
government’s restrictions bear no rational relationship to a legitimate state
interest.”)
103 See id. at 713 (noting that “this conclusion was compelled by the Supreme Court’s decision in United States v. Rutherford, 442 U.S. 544 (1979”).

Rutherford was a case in which the Supreme Court rejected terminally ill patients’ argument that the safety requirement of FDA approval did not apply to them. See 442 U.S. at 559 (noting FDCA does not contain exception for terminally ill patients). For a discussion of Rutherford and the Court’s deference to the FDA, see Edward M. Basile & Melanie Gross, The First Amendment and Federal Court Deference to the Food and Drug Administration: The Times They Are a Changin’, 59 Food & Drug L.J. 31, 34-35 (2004).

104 Abigail, 495 F.3d at 713 (“Our Nation’s history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology. . . .”)

105 Id. at 713.

106 See id. at 716 (Rogers, J., dissenting) (noting majority “fundamentally misunderstands the right claimed by the Alliance and trivially casts it as a function of the regulatory scheme”). In framing right at issue as right to life, dissent relies on past due process cases that inferred narrower right from broader concept. See e.g., Loving v. Virginia, 388 U.S. 1, 12 (1967) (inferring right to
chose who one marries from broader right to orderly pursue happiness); Griswold v. Connecticut, 381 U.S. 479, 484-86 (1965) (extrapolating right to use contraception from broader right to be free from intrusion into “sacred precincts of martial bedrooms”). The Alliance made the argument that Roe v. Wade, 410 U.S. 113 (1973) and subsequent abortion cases were decided not based on a privacy right, but rather on basis of right to medical self defense. See Abigail, 495 F.3d at 709 (rejecting idea of medical self defense and noting it “fails because this case is not about using reasonable force to defend one’s self”).

107 See Abigail, 495 F.3d at 716 (Rogers, J., dissenting) (noting that our Nation has recognized individual’s right to make personal medical decisions).

108 See id. at 717 (relying on idea that self defense was “an inherent right of man at common law” and extended to fighting off one’s attackers and protecting one’s own property against trespassers). In rejecting majority’s argument that non-FDA approved drug are not proven effective, thus are not necessary, the dissent argued that drugs are necessary since terminally ill patients are going to die anyways. See id. at 719 (noting “[b]y the court’s reasoning, it is not ‘necessary’ for the driver of a car that is hurtling toward a cliff to press the brake because [one] ‘cannot know until after’ he has done so whether the car will stop in time”).

109 See id. at 719 (discussing Roe, 410 U.S. at 164-65 and Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 846 (1992)). The idea that terminally ill
patient’s potential right to obtain non-FDA approved drugs can be derived from abortion cases is a hotly debated issue. Compare Eugene Volokh, Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs, 120 Harv. L. Rev. 1813, 1824 (2007) (supporting idea that right to medical self defense can be rooted in woman’s right to choose) with Comment, Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs, 127 U. Pa. L. Rev. 233, 259-60 (1978) (criticizing this self defense connection to abortion rights).

110 See Abigail, 495 F.3d at 721-22 (Rogers, J., dissenting) (noting that common law roots of necessity and self defense refute FDA’s claim that right to save one’s life with medical advances cannot be deeply rooted).

111 See id. at 726 (noting that “[g]overnment regulation of . . . drugs premised on concern over a new drug’s efficacy, as opposed to its safety, is of very recent origin). Arguably, the dissent is internally contradictory in emphasizing recent regulation of drug efficacy to illustrate that terminally ill patients have a constitutional right to access non-effective drugs because earlier in the opinion, the dissent emphasized that not all fundamental rights need to show legislative contemplation. See id. at 722 (noting “it is doubtful that many courts or legislatures have discussed whether the government can determine whether we are allowed to breathe air, but this does not make our right to oxygen any less grounded in history”).
112 See Riach v. Gonzales, 500 F.3d 850, 865 (9th Cir. 2007) (refusing to find constitutional right to medical usage of marijuana, and noting that although past ten years have “been characterized by an emerging awareness of marijuana’s medical value” there is still not enough evidence to show such right is fundamental). Although the focus of this article is on scientific developments, the Glucksberg framework is also not viable when applied to emerging social and culture values issues. See Lisa K. Parshall, Redefining Due Process Analysis: Justice Anthony M. Kennedy and the Concept of Emergent Rights, 69 Alb. L. Rev. 237, 241-42 (2005) (discussing how Justice Kennedy went outside strict confines of Glucksberg framework to infer fundamental right to grandparent visitation rights from evolving concept of family life).

113 See generally infra note 125 (noting that if Glucksberg test is applied to emerging technologies then there will be no constitutional right due to lack of history of technologies). If other constitutional rights were based on historical evidence, then some of the most basic rights Americans enjoy today would not exist. See e.g., Brown v. Board of Education, 347 U.S. 483 (1954) (rejecting “separate but equal” doctrine under Fourteenth Amendment and de-segregating schools). Brown did not address if “such segregation also violat[ed] the Due Process Clause of the Fourteenth Amendment.” See id. at 495 (noting discussion of due process challenge was unnecessary as case had already been decided on other grounds). If Brown was decided under the Glucksberg test, the right of
different races to attend school together would not have been fundamentally
rooted in our Nation’s history. See generally Brown v. Board of Education: A
Brief History with Documents 1-19 (Waldo E. Martin, Jr. ed., 1996) (providing
overview of turbulent history leading up to Brown decision).

114 See e.g., Steven Galson, FDA Initiatives to Improve Safety: Perspectives on
Drug Benefits and Risks, in Perspectives on Risk and Regulation: The FDA at
One Hundred 19 (Arthur Dammrich and Joanna Radin, eds., 2007) (noting that
FDA was not created until 1906); U.S. Consumer Product Safety Commission,
visited October 3, 2009) (stating that Consumer Product Safety Commission was
not created until 1972); U.S. Nuclear Regulatory Commission, Our Governing
October 12, 2009) (stating U.S. Nuclear Regulatory Commission was established

115 See Note, Assessing the Viability of a Substantive Due Process Right to
Invitro Fertilization, 118 Harv. L. Rev. 2792, 2803-4 (2005) (emphasizing that if
court were to engage in Glucksberg analysis of constitutional right to invitro
fertilization, it is “highly unlikely that such a novel right would be” found based
on lack of history of invitro fertilization); Cass R. Sustein, Is There A
“right to clone is not something that Anglo-American law traditionally protects,”
therefore, under Glucksberg, there would not constitutional right to clone); Note,
Human Cloning and Substantive Due Process, 111 Harv. L. Rev 2348, 2359 (1998) (noting that “courts might be reluctant to extend substantive due process protection to a new reproductive technique” based on lack of scientific evidence and history of use of such technique). Commentators opining that there could be fundamental right to clone or genetically engineer one’s self rely on privacy cases, including Roe v. Wade, 410 U.S. 113 (1973). See e.g., Russell Korobkin and Stephen R. Munzer, Stem Cell Century: Law and Policy for a Breakthrough Technology, 80-85 (2007) (noting that regulations banning human cloning might be found as violation of Fifth Amendment Due Process Clause under the logic of Roe); Robert A. Burt, Constitutional Constraints on the Regulation of Cloning, 9 Yale J. Health Pol'y L. & Ethics 495, 499 (2009) (stating arguments supporting constitutional right to therapeutic and reproductive cloning could rely on Roe reasoning).

116 See CareToLive v. Von Escenbach, 525 F. Supp.2d 952, 965 (S. D. Ohio 2007) (questioning how constitutional right could be “defined by an administrative regulation that is subject to change”); Powerblogs.com, [Volokh] Jonathan Adler: Roger Pilon on Abigail Alliance, (August 10, 2007) http://lists.powerblogs.com/pipermail/volokh/2007-August/010309.html (emphasizing right to “experimental and unproven drugs implies a regime like the FDA” which makes it impossible to conclude such right is deeply rooted). One commentator opines that FDA standards for defining Phase I clinical trials are outdated because Phase I trials for oncology drugs emphasize both safety and
efficacy. See Jamie L. Aldes, The FDA Clinical Trial Process: Effectuating Change in the Regulatory Framework Governing Clinical Trials to Account for the Historical Shift from “Traditional” to “New” Phase I Trials, 18 Health Matrix 463, 473-77 (2008) (discussing how “new” Phase I clinical trials are actually similar to the traditional Phase II trials as they establish evidence of drug’s safety and efficacy in humans).

117 See Abigail, 495 F.3d at 703 (discussing concerns with basing fundamental right on administrative agency’s judgment). The court stated:

[t]he Alliance's claimed right depends on a regulatory determination that the drug is safe for testing, prompting an obvious question: How can a constitutional right be defined by an administrative regulation that is subject to change? Would an FDA decision requiring increased testing for safety and efficacy before the commencement of human clinical trials affect the Alliance's constitutional right?

Id. at 703 n.6.

118 See id. at 703 (stating it is “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”) (internal citations and quotations omitted). One potential solution to the issue of defining right so narrowly as to involve regulations of an administrative
agency is to link the right at issue to a broader right. See *Roe*, 410 U.S. at 118 (linking right to abortion to broader right of privacy). But see *Glucksberg*, 521 U.S. at 723 (refusing to classify right at issue as right to die, and instead more narrowly describing right as “right to commit suicide which itself includes a right in assistance to doing so”); *Cruzan ex rel. Cruzan v. Dir. Mo. Dept. of Health*, 497 U.S. 261, 279 (1990) (classifying right at issue as “right to refuse lifesaving hydration and nutrition” and rejecting broader description of right to die).

119 See *Abigail*, 495 F.3d at 701 (framing issue as whether there was right to “seek access to medications that the [FDA] concedes are safe and promising enough for substantial human testing”). Although the court later discusses the issue in terms of if terminally ill patients have a constitutional right to access drugs which have gone through Phase I testing, this can be read as a narrower question within the broader right at issue. See *Glucksberg*, 521 U.S. at 723 (including right to assisted suicide within the more general right to commit suicide). Framing right at issue as solely based on drugs that have gone through Phase I testing would defeat the constitutionality of such a right at onset because this is a procedural provision within the FDA’s regulatory policy, which could change in the future. See generally, Amanda Brower, *Phase Four Research Grows Despite Lack of FDA Oversight*, *Biotechnology Healthcare*, October 2007, http://www.biotechnologyhealthcare.com/journal/fulltext/4/5/BH0405016.pdf?CFID=45032788&CFTOKEN=88392932 (noting that FDA is likely to increase
levels of post-marketing surveillance, which is considered Phase IV of FDA testing process).

120 See Abigail, 495 F.3d at 701 (noting right at issue deals with FDA’s judgment that certain investigational medications are “promising enough for substantial human testing”). Drugs deemed promising enough for substantial human testing are not necessarily proven completely safe or effective. See supra notes 46-48 (noting various phases of clinical trial process seek to continually monitor safety and efficacy of drugs).

121 See Abigail, 495 F.3d at 703 n.6 (admitting it is difficult to understand how right based on regulatory agency could have been deeply rooted in history prior to existence of agency); CaretoLive v. Von Eschenbach, 525 F. Supp.2d 952 (S.D. Ohio 2007) (finding “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’”).

122 See Lawrence v. Texas, 539 U.S. 558, 570-74 (2003) (emphasizing importance of recent history in conducting due process analysis); State v. Korrell, 690 P.2d 992, 999 (Mont. 1984) (emphasizing that “[a]n examination of the common law in a search for fundamental rights can be misleading”); see generally Poe v. Ullman, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting) (stating that “[d]ue process has not been reduced to any formula; its content cannot be determined by reference to
any code”); Rochin v. California, 342 U.S. 165, 171-72 (1952) (stating “[t]o believe that this judicial exercise of judgment could be avoided by freezing ‘due process of law’ at some fixed stage of time or thought is to suggest that the most important aspect of constitutional adjudication is a function of inanimate machines and not for judges”).

123 See Loving v. Virginia, 388 U.S. 1, 12 (1967) (framing right at issue as right to marry, rather than more specific right of people to marry interracially). For comprehensive discussion of how the Supreme Court has dealt with broadening or narrowing scope of a purported right in order to reach a specific conclusion despite the history of America, see Veronica C. Abreu, The Malleable Use of History in Substantive Due Process Jurisprudence: How the “Deeply Rooted” Test Should Not Be a Barrier To Finding The Defense of Marriage Act Unconstitutional Under the Fifth Amendment’s Due Process Clause, 44 B.C. L. Rev 177 (2002).

124 See Roe v. Wade, 410 U.S. 113, 136-39 (1973) (discussing that there is long history of moral outrage to abortions, yet finding fundamental right to have abortion rooted in privacy rights); Loving, 388 U.S. at 6, 12 (1967) (noting that sixteen states criminalized interracial marriages and that there had been criminal penalties for such marriages since colonial period, yet upholding fundamental right to marry including marrying interracially); Griswold v. Connecticut, 381
U.S. 579, 486 (1965) (finding that fundamental right to privacy includes right to use contraceptives despite history of disapproval of use of contraceptives).

125 See supra note 134 (discussing how there is evidence on both sides in due process cases); Nicole E. Lombard, Paternalism v. Autonomy: Steps Towards Resolving the Conflict Over Experimental Drug Access Between the Food and Drug Administration and the Terminally Ill, 3 J. Health & Biomedical L. 163, 177-185 (2007) (evaluating evidence on both sides of claim of access raised in Abigail). Ultimately, the question of whether a right is fundamentally rooted in our Nation’s history depends upon how “fundamental” is defined. See Ronald J. Krotoszynski, Jr., Dumbo’s Feather: An Examination and Critique of the Supreme Court’s Use, Misuse, and Abuse of Tradition in Protecting Fundamental Rights, 48 Wm. & Mary L. Rev. 923 (2006) (opining there is inherent ambiguity in fundamentally rooted analysis of tradition and discussing various approaches taken by Supreme Court in defining scope of traditions).

126 See County of Sacramento v. Lewis, 523 U.S. 833, 862 (1998) (Scalia, J., dissenting) (pointing out that majority failed to use Glucksberg analysis and stating “[a]dhering to our decision in Glucksberg, rather than whether the police conduct here at issue shocks my conscious, I would ask whether our Nation has traditionally protected the right respondents assert”).

128 See Freddie Ann Hoffman & Peter H. Rheinstein, Health Professionals and the Regulatory Industry: The Laws and Regulations Enforced by the U.S. Food and Drug Administration, in Legal Medicine 113 (American College of Legal Medicine Textbook Committee, ed., 7th ed. 2007) (noting that 1962 amendments to FDCA required drug manufacturers to not only prove safety, but also efficacy of drug).


131 See Lawrence v. Texas, 539 U.S. 558, 570-74 (2003) (focusing on recent history of past fifty years to determine that there was constitutional right of persons to engage in private sexual activities with members of same sex).
Although the FDA urged the court to use the Lawrence analysis, the court did not find this necessary because there was deeply rooted history of drug regulation over centuries, not just past fifty years. See Abigail 495 F.3d at 706 n.10 (“We need not determine today whether recent history is particularly relevant in measuring the scope of rights under the Due Process Clause.”)

132 See Lawrence, 539 U.S. at 572 (focusing on “emerging awareness” of right of persons of same sex to engage in sexual relationships without fear of criminal penalties). The Lawrence emphasis on “emerging awareness” is in essence a modernization of due process rights. See David A. Strauss, The Modernizing Mission of Judicial Review, 76 U. Chi. L. Rev. 859, 865-66 (2009) (noting Lawrence “shifted the focus from tradition to current understandings”). Although Lawrence analysis has yet to be applied to a scientific-based constitutional right question, it has been cited in cases involving due process challenges in areas that are undergoing social evolution. See e.g., Cook v. Gates, 528 F.3d 42 (1st Cir. 2008) (applying Lawrence framework to assess validity of military’s “don’t ask, don’t tell policy” requiring separate housing for openly homosexual soldiers). Commentators have used Lawrence to support concept of constitutional right to clone. See Kerry Lynn Macintosh, Illegal Beings: Human Clones and the Law, 191-95 (2005) (stating Supreme Court would be unlikely to ban cloning on basis of moral grounds due to Court’s rejection of moral grounds in Lawrence); Steven Goldberg, Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research, 4 Yale J. Health Pol’y L. & Ethics 305, 314-17 (2004) (noting

133 For a discussion of various arguments in support of and against recognition of a fundamental right under the Lawrence calculus, see supra notes 141–42 and accompanying text.

134 See Congressional Research Service, Drug Safety and Effectiveness: Issues and Action Options After FDA Approval (March 8, 2005), http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3279703082005.pdf (noting “[t]here has not been a decade since FDA’s creation without a highly publicized incident involving drug safety that has led to legislation expanding and strengthening FDA’s authority to protect the public”). The FDA was created in response to outcry from the public about adulterated meat products. See Ceccoli, supra note 31, at 62 (discussing concerns about meat-packing industry).


See Carnohan v. United States, 616 F.2d 1120, 1122 (9th Cir. 1980) (declining to find constitutional right to obtain medications “free of the lawful exercise of government’s police powers”); United States v. Cannabis Cultivator’s Club No. C 98-00085 CRB, 1999 WL 111893, at *1 (N.D. Cal. Feb. 25, 1999) (refusing to find “fundamental right ‘to be free from governmental interdiction of [people’s]
personal, self-funded medical choice, in consultation with their personal physician, to alleviate suffering through the only effective treatment available”).

139 See United States v. Rutherford, 442 U.S. 544, 551 (1979) (refusing to recognize that terminally ill patients had special rights to access drugs under Federal Food, Drug, and Cosmetic Act).


141 See supra notes 147–150 and accompanying text (providing evidence of FDA’s failure to monitor off-label drug use).

See American Cancer Society, Off-Label Drug Use, http://www.cancer.org/docroot/ETO/content/ETO_1_2x_Off-Label_Drug_Use.asp (last visited October 12, 2009) (noting “off-label use of FDA-approved drugs is not regulated, but is entirely legal”).
See id. (noting studies done in United States show “up to one-half of all chemotherapy was used for an off-label condition”, and that sixty percent of medical oncologists had prescribed chemotherapy drug off-label). If drugs that Abigail Burroughs was waiting for had been FDA-approved, then she would have been able to access them through an off-label use protocol in conjunction with her physician; however, neither drug was FDA approved for any condition. See supra note 5 (noting that both drugs later gained FDA approval).

See Buckman Co. v. Plaintiff’s Legal Comm., 531 U.S. 341, 350 (2001) (stating “off-label’ usage of medical devices . . . is an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine”); see also Richardson v. Miller, 44 S.W.3d 1, 13, n.11 (Tenn. Ct. App. 2000) (noting “pace of medical discovery runs ahead of the FDA’s regulatory machinery,” and concluding “[i]n some circumstances, an off-label use . . . may even define the standard of care”).

See Stafford, supra note 153, at 1428 (discussing diminishing role of FDA in regulation of drugs by increasing indifference to off-label uses).

through clinical trial testing for safety and effectiveness, but “once the FDA approves a drug for one use doctors can prescribe it for whatever they want”).

148 See Lambert v. Yellowley, 272 U.S. 581 (1926) (rejecting plaintiff’s contention that there is right to proscribe intoxicating liquors even when physician thinks it is necessary for patient’s well-being). Although decided under the prohibition-era of the Eighteenth Amendment, this rejection of medical necessity has been used recently to support rejection of a constitutional right to access medical marijuana. See United States v. Oakland Cannabis Buyers’ Coop., 523 U.S. 438, 486 (2001) (stating there is not “medical necessity exception” to Controlled Substances Act).


150 See Michael D. Christel, Drug Safety Burden a Plus for CROs, R&D Directions, http://www.pharmalive.com/magazines/randd/view.cfm?articleID=8066 (last visited October 12, 2009) (discussing recent FDA focus on safety of drugs). “Since the passage of FDA’s Amendments Act of 2007 and a flurry of high-profile withdrawals in recent years, there has been a heightened focus on drug
safety, with particular emphasis on . . . post-marketing surveillance.” Id. “FDA wants to ensure that drugs are monitored more rigorously for their safety and effectiveness . . . .” Id.

151 See Ukens, supra note 147 (noting public places confidence in FDA and relies on FDA determinations about new drugs).

152 For a discussion of legislative action attempting to secure earlier access to experimental drugs, see infra notes 170-177 and accompanying text.

153 See Nancy Pham, Choice v. Chance: The Constitutional Case for Regulating Human Germline Genetic Modification, 34 Hastings Const. L. Q. 133, 139-40 (2006) (noting first genetically altered human being was born in 2004 and that inheritable genetic modifications were only successful in animals beginning in 1976; thus, this recent history should be considered in assessing constitutional right to genetically modify one’s child).

154 See generally Dwayne D. Kirk & Kim McIntosh, Social Acceptance of Plant-Made Vaccines: Indications from a Public Survey, 8 J. Agrobiotechnology Mgmt. & Econ. 228, 228-234 (2005), available at http://www.agbioforum.missouri.edu/v8n4/v8n4a05-kirk.htm (discussing human acceptance of plant-made vaccines and relation to acceptance of genetically modified agricultural products). Currently, many Americans fear getting the
H1N1 vaccine due to safety concerns regarding unknown side effects; however, as more information is known about the potential side effects, it is likely that society’s views on the H1N1 vaccine will change. See Rob Stein, Vaccine Is On Its Way, But Public Still Wary, Washington Post, October 4, 2009, available at http://www.washingtonpost.com/wp-dyn/content/article/2009/10/03/AR2009100303041.html?hpid=topnews&sid=ST2009100401131 (noting public will be more likely to get H1N1 vaccine if they are educated about need for vaccine and its overall safety).

155 See Washington v. Glucksberg, 521 U.S. 702, 767 (Souter, J., concurring) (rejecting examining historical traditions as static approach to due process jurisprudence and emphasizing that often seeing if earlier traditions have been broken should be considered). Although Lawrence did not directly mention the AIDS epidemic in its analysis, commentators have opined that Lawrence’s overturning of laws against homosexuality is illustrative of new knowledge about how HIV is spread. See Ellen Ann Andersen, Out of the Closet and Into the Courts: Legal Opportunity Structure and Gay Rights Litigation, 120 (2006) (discussing emerging knowledge of HIV and impact on gay rights movement).

156 See note 164 supra (noting that genetic modification technology did not even exist until 1976).
157 See Kamisar, supra note 93 at 110-13 (opining that, even under Lawrence analysis, purported right to physician assisted suicide would not gain constitutional recognition); Pham, supra note 164, at 140 (discussing right to genetic modification and noting that this would fail under Lawrence analysis because careful description requirement would prevent recognition of such technology that is so new to our society).


159 See et al., supra note 126 at 245-46 (2007) (noting if treatments are available outside of clinical trials, then “it can be difficult to recruit patients for randomized trials at all”). This is illustrated by treatment of cancers with high-dose chemotherapy and autologous bone marrow transplants, a technique that was widely used by physicians outside of the clinical trial process in the 1980s and 90s. See id. (discussing this treatment plan and how early patient access caused it to take “two decades to recruit enough patients for large-scale clinical trials”). Ultimately, the combination therapy was proven to be ineffective in the fight against cancer. See id. (noting this created false home for many breast cancer patients).

See Korobkin et al., supra note 126 at 246 (noting that with lower numbers of patients enrolling in clinical trials it will take much longer to conduct large-scale clinical trials aimed at assessing effectiveness of drugs); Shira Bender et al., Access for the Terminally Ill to Experimental Medical Innovations: A Three-Pronged Threat, 7 Am. J. Bioethics 3, 4-6 (2007), available at http://bioethics.net/journal/j_articles.php?aid=1365 (same).

See Korobkin et al., supra note 126, at 4 (discussing therapeutic misconception and its impact on researchers and public bias towards encouraging earlier drug approval); Arthur Caplan, Is it Sound Public Policy to Let the Terminally Ill Access Experimental Medical Innovations?, 7 Am. J. Bioethics 1, 2 (2007) (stating “desire to hope for the best - what is sometimes termed the therapeutic misconception - is often present on the part of those facing death”).

(“The main purpose of the FDA is to protect citizens from products that are inherently unsafe or that make claims of effectiveness that cannot be substantiated.”) Thus, if patients can access drugs that are not proven safe or effective this weakens FDA’s authority. See Ukens, supra note 147 and accompanying text (discussing public’s reliance on FDA).


165 See generally supra notes 170-72 and accompanying text (stating that less number of people will engage in clinical trials prolonging drug approval times and resulting in uncertain research methods that may taint results of trials determining efficacy and safety of drugs).

www.fda.gov/oc/ohrt/irbs/irbletr.html (asserting FDA authority over cloning regulations). Commentators have questioned the FDA’s authority to regulate cloning. See e.g., Elizabeth C. Price, Does the FDA Have Authority to Regulate Cloning?, 11 Harv. J. L. & Tech. 619 (1998) (questioning if there is statutory basis for FDA’s purported right to govern cloning).

167 See Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 713 (D.C. Cir. 2007) (“[O]ur holding today ensures that . . . debate among the Alliance, the FDA, and the scientific and medical communities, and the public may continue through the democratic process.”)


169 See ACCESS Act, H.R. 6303, 109th Cong. (2005), http://www.govtrack.us/congress/bill.xpd?bill=h109-6303 (last visited Oct. 12, 2009) (noting bill was reintroduced by Representative Christopher Shays and subsequently was referred to committee). The bill was again reintroduced in June 2008. See ACCESS Act, H.R. 6270, 110th Cong. (2008),
http://www.govtrack.us/congress/bill.xpd?bill=h110-6270 (last visited October 12, 2009) (noting bill was reintroduced by Representative Diane Watson and was subsequently referred to committee).


171 See S. 1956 at § 506 (describing different phases of approval). For the purposes of this discussion the bill introduced in the 109th Congress is used; although this bill was not identical to the bill introduced in the 110th Congress, the bills are similar and have non-substantive differences. See Austin Winniford, Expanding Access to Investigation Drugs for Treatment Use: A Policy Analysis and Legislative Proposal, 19 Health Matrix 205, 238 n.221 (2009) (stating there is relatively little difference between initial and reintroduced bill).

two different versions of bill). The content of the bill remained relatively the same. See id. (noting minor changes were made).

173 See S. 1956 § 506(b)(1)(A)(ii) (stating “preliminary evidence that the product may be effective against a serious or life-threatening condition or disease” should be submitted in order to gain Tier I approval).

174 See S. 1956 § 506(b)(5)(A)(i) (stating patient must have “exhausted all treatment options approved by Secretary for the condition or disease for which the patient is a reasonable candidate”). This was probably included to address concerns that early access to drugs weakens clinical trial participation. See Korobkin et al. supra note 126, at 145-46 (discussing how early access can make people avoid participation in clinical trials).


this relatively new disease”). Additionally, studies show that Americans do not understand complexities behind genetic technologies. See NewsRx, Study Demonstrates that Misconceptions About Genetics Remain Prevalent in U.S. Science Classrooms, April 9, 2008, http://www.newsrx.com/press-releases/4380.html (discussing study of high school students that found “incomplete understanding of the complexity of scientific research, including biotechnology and genetic engineering”). A lack of knowledge or understanding about a new technology leads to rejection by society, thus preventing a deeply rooted history of acceptance of the technology. See National Science Board, Science and Technology: Public Attitudes and Understanding, http://www.nsf.gov/statistics/seind04/c7/c7s2.htm (last visited October 12, 2009) (opining “public’s lack of knowledge about science may have far-reaching consequences”).


178 See e.g., Pham, supra note 164, at 139-40 (stating genetic modification of humans was not even contemplated until recently).

179 See supra notes 45-47(discussing FDA’s emphasis on drug safety and efficacy).
See Wyeth v. Levine, 129 S. Ct. 1187, 1230 (2009) (Alito, J., dissenting) (stating the FDA’s “drug-approval determinations consider the interests of all potential users of a drug, including ‘those who would suffer without new [drugs]’

See Christel, supra note 161, and accompanying text (noting FDA’s recent emphasis on tighter monitoring of safety and efficacy of drugs, especially in post-marketing category).

See Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 712 (D.C. Cir. 2007) (opining Alliance’s claimed right is not fundamental).

See id. at 713 (noting court opinion leaves door open for Alliance to continue debate through legislature).