

FALSE PROMISES OF HOPE: A LOOK AT HOW THE STATE “RIGHT TO TRY” LAWS WILL PROVE DETRIMENTAL TO THE DRUG APPROVAL PROCESS AND PUBLIC HEALTH

By: Katelyn Mineo¹

Introduction

On March 4, 2014, seven-year-old Josh Hardy was fighting for his life in the intensive care unit at St. Jude Children’s Hospital in Tennessee.² He was suffering from a life-threatening adenovirus infection and was unable to control the infection because of a weakened immune system due to complications from a previous cancer treatment.³ His physicians tried to treat the infection with the then-current standard of therapy, but were unsuccessful, ultimately causing dialysis-dependent renal failure.⁴ There was, however, another anti-viral product, brincidofovir, in Phase III clinical trials at that time that had demonstrated the potential for enhanced antiviral potency and a more favorable safety profile.⁵

The drug manufacturer of brincidofovir, Chimerix, began the Phase III clinical trial for the prevention of reactivation of infections in adult hematopoietic stem cell transplant recipients in April 2013 and anticipated results to support FDA approval in 2015.⁶ Doctors at St. Jude Children’s Hospital twice requested that Chimerix provide brincidofovir for Josh outside of the clinical trial, since he was ineligible to participate. Both times the doctors’ requests were denied.⁷ In March 2014, Josh’s family posted their story on social media seeking to identify anyone who could influence Chimerix to change its decision regarding expanded access for Josh.⁸

State and national politicians, news channels, TV networks, and private parties called Chimerix within days to set up interviews about Josh’s story and urged the company to change its stance.⁹ Social media criticized Chimerix and its board members so extensively that security needed to be hired for them because of numerous death threats.¹⁰ On March 9, CNN

aired a segment on Josh's story.¹¹ The next day Josh's Twitter page trended in the top five national stories.¹² On March 11, Chimerix announced it would make brincidofovir available to Josh as part of a 20-patient open-label pilot trial.¹³ Josh received the experimental drug the next day and responded well to it.¹⁴ He left the hospital by the end of the month nearly virus-free.¹⁵

The Josh Hardy case study illustrates the pressing concerns that advocates for expanded access have with the U.S. Food and Drug Administration (FDA) and manufacturers that block terminally ill patients from accessing potentially life-saving treatments. Proponents of expanded use stress that terminally ill patients are prevented from receiving potentially beneficial treatments because they do not have the luxury of time to wait for ultimate drug approval or the ability to undergo the lengthy process to obtain expanded access under current FDA compassionate use options.¹⁶ The Goldwater Institute, a conservative nonprofit organization, has joined other proponents to advocate for expanded access through state "right to try" initiatives.¹⁷

Right to Try Laws

This past year, a few states moved to adopt so called "right to try" laws – laws that permit terminally ill persons, who have exhausted all treatment options, to use investigational drugs, biological products, or devices without seeking permission from the FDA.¹⁸ As of March 2015, Michigan, Colorado, Louisiana, Missouri, Arizona, Arkansas, and Wyoming have passed such laws, and over twenty other states may follow.¹⁹ The Goldwater Institute has driven the "right to try" measures state-by-state to allow "terminal patients access to investigational drugs that have completed basic safety testing through Phase I clinical trials, thereby dramatically reducing paperwork, wait times and bureaucracy, and, most importantly, potentially saving lives."²⁰

States that have passed the "right to try" laws have declared that terminally ill patients have a fundamental right to access available potentially life-saving investigational products

given the length of the FDA drug approval process and that such patients do not have the luxury of waiting for a drug during that period.²¹ The laws provide that the patient, with consultation of his or her physician, should make the decision for expanded access while taking into account the potential risks, benefits, and consequences of such use.²²

An “eligible patient” for expanded access under these laws is one who has: (1) a terminal illness, attested by the patient’s physician; (2) considered all other currently approved treatment options; (3) been unable to participate in a clinical trial within 100 miles of the patient’s home or has not been accepted to the clinical trial within one week of completion of the clinical trial application process; (4) received a recommendation from his or her physician for expanded access; (5) given written, informed consent; and (6) obtained documentation from his or her physician that he or she is an eligible patient.²³ A “terminal illness” is defined as a disease that, without life-sustaining procedures, will soon result in death or a state of permanent unconsciousness from which recovery is unlikely.²⁴ An “investigational drug, biological product or device” is defined as one that has successfully completed Phase I of a clinical trial but has not yet been FDA approved and remains under investigation in an approved clinical trial.²⁵

The patient must have given written, informed consent in order to have access under the “right to try” law.²⁶ “Written, informed consent” means a written document signed by the patient and attested to by the physician that at a minimum: (1) explains the currently approved treatments for the disease; (2) attests that the patient concurs with his or her physician that all approved treatments are unlikely to prolong the patient’s life; (3) identifies the specific proposed investigational product the patient is seeking access to; (4) describes the best and worst outcomes of using the investigational product, including the most likely outcome and that worse symptoms might result; (5) makes clear that the patient’s health insurer and provider are not obliged to pay

for any investigational treatment; (6) makes clear that in-home health care may be denied if treatment begins; and (7) states that the patient understands that he or she is liable for all expenses that result from the use of the investigational product and this liability extends to the patient's estate unless a contract with the manufacturer states otherwise.²⁷

A manufacturer of the investigational product may make the product available, but is not required to, under the "right to try" laws.²⁸ The manufacturer may either give the product away at no cost to the patient or require an eligible patient to pay the manufacturing costs associated with the investigational product.²⁹ A health insurance carrier may, but is not required to, provide coverage for the cost of this expanded access.³⁰ The "right to try" laws prohibit a licensing board from taking any action against a healthcare provider's license or Medicare certification solely because of his or her recommendation to an eligible patient regarding expanded access so long as the recommendation is consistent with medical standards of care.³¹ Similarly, no cause of action against a manufacturer or any other entity involved in the care of a patient using the experimental drug is created by some of these laws as long as the manufacturer exercises reasonable care and acts in good faith.³² Some of the laws further prohibit any employee or agent of the state from attempting to block an eligible patient's access to investigational drugs.³³

Ineffectiveness of Right to Try Laws

The Goldwater Institute and other advocates argue that the FDA is the "arbiter of life and death" for terminally ill patients by standing between the patient and potential for a curative treatment.³⁴ These advocates strongly believe that patients should be able to exercise their freedom and personal liberty in attempting to preserve their own lives through available treatments.³⁵ Ultimately, though, the state "right to try" laws will prove ineffective in making

expanded access more readily available and could have a detrimental effect on the public health at large in undercutting the integrity of the drug approval process.

The “right to try” laws will only foster false hope in patients and their families. These laws do not require a manufacturer to provide an investigational product to a terminally ill patient, but instead the manufacturer retains discretion. As such, it is hard to imagine the manufacturer who would provide a patient an investigational drug under these state laws while the FDA still prohibits such use and possesses the authority to approve or reject the manufacturer’s application prior to marketing to the public at large. Although one manufacturer, Neuralstem, has expressed its support for the state “right to try” laws, it would be surprising to see other companies follow in its footsteps.³⁶

The solution for how to make such use available outside the clinical trial context is complex as most people can sympathize with the devastation that occurs when potentially life-changing drugs are not available for terminally ill patients. Nevertheless, there are concerns in granting early access to unapproved treatments. There are apprehensions unique to the manufacturers of the investigational products, FDA, physicians, and individual patients regarding expanded access. The “right to try” laws may do more harm than good given these concerns by taking away the FDA’s authority to regulate expanded access of drugs used by those most vulnerable.

Currently, a manufacturer must go through the FDA approval process and prove the safety and efficacy of its product through clinical trials before marketing a drug in the United States. Expanded access under these laws does away with this oversight, and raises concerns for drug sponsors. Adverse reactions to the investigational drug may eventually provide the FDA with reasons to withhold approval of the drug.³⁷ This raises an issue when the adverse event

results from expanded use where the patient receiving the investigational product is not the intended patient population to be treated. Safety issues that arise and threaten patient safety could cause drug sponsors to end clinical trials before they are completed.³⁸

Manufacturers are also concerned that expanded access will seriously dilute the potential patients for clinical trials.³⁹ Many patients will have little incentive to enroll in clinical trials and incur the cost and inconvenience of leaving home to participate in trials if they are able to obtain experimental drugs on their own through the “right to try” laws.⁴⁰ Expanded access under these laws may cause clinical trials to be cost ineffective and could end human clinical studies altogether. All of these potential consequences would have a negative impact on public health at large because there is a strong interest in having new drugs developed and tested initially through randomized and controlled trials rather than in the marketplace where money and lives could be wasted.⁴¹ Furthermore, experience has shown that uncontrolled and un-blinded studies raise issues of experimenter bias and make it impossible to distinguish the effects of active ingredients from placebo effects, thereby making it extremely difficult to have an objective analysis of the efficacy of the drug.⁴²

Additionally, pharmaceutical companies could face liability in a variety of areas where serious and unforeseen side effects arise in expanded access contexts under the “right to try” laws.⁴³ Manufacturers could face legal liability in areas like product liability, failure to warn, fraud, and negligence given the uncertainty surrounding the investigational drug’s safety and a larger population with access to the drug.⁴⁴ Liability issues may also arise in the informed consent context. Advocates for greater regulation claim that it is unlikely that terminally ill patients, perhaps incapacitated and desperate for their lives, can provide meaningful consent for access to an experimental drug when the drug has not been adequately tested and adverse

consequences are not well known.⁴⁵ Moreover, data from Phase I trials only pertain to twenty to eighty subjects and reflect likely short-term side effects and maximum dosages.⁴⁶ This may not be enough information to comprehend the consequences of taking a drug this early in the testing period.⁴⁷ This raises concerns about whether patients with terminal illnesses will be able to fully comprehend the potential consequences of using an unapproved, experimental treatment.

The “right to try” laws do not consist of statutory preclusion of liability for manufacturers. The laws preclude liability from physicians who exercise reasonable care in prescribing the investigational drug. The legal liabilities, then, are on the manufacturer regarding the unknown risks of the investigational product. Manufacturers are wary to put themselves at risk with little to no assurance of any form of indemnity for products that have not undergone rigorous testing for safety and efficacy.⁴⁸ These “right to try” laws do little to ease these worries. Manufacturers and entities involved in the distribution process would be violating FDA regulations that prohibit the sale or marketing of experimental drugs by introducing the unapproved drugs into interstate commerce for patients under the “right to try” laws.⁴⁹

Another issue for manufacturers surrounding the availability of investigational products is cost. Investigational drugs are costly.⁵⁰ Smaller companies may lack the ability to meet demand.⁵¹ Moreover, a sponsor may recover, at most, only the direct costs of making its investigational drug available.⁵² These factors may eventually cause companies to lack the financial capacities – if they do not already lack the finances – for increased production to make investigational products available to an increased population under the “right to try” laws.

Both the manufacturers and the FDA have an ethical obligation to ensure that the highest quality, safest, and most effective products are on the market for the betterment of public health. Together, they strive to act with compassion towards the dying by not providing patients with

false hope of a drug that could have adverse side effects. Opponents of expanded access have argued that allowing expanded access to experimental drugs that have not been tested for their safety and efficacy is unethical because it offers false hope to a vulnerable group of patients.⁵³

There are many additional concerns from the FDA's perspective, which may be why the "right to try" laws circumvent FDA expanded access programs to avoid these issues. The failure rate of new drug candidates in clinical trials exceeds ninety percent.⁵⁴ Even drugs that are approved for market use can cause serious harm to human health. For instance, more people die annually from legal use of prescription medications than from automobile and workplace accidents.⁵⁵ It is evident why the FDA would have concerns regarding expanded access when even FDA-approved drugs only truly benefit a fraction of the patients who receive them.

Further concerns arise between the distinctions of terminally ill patients versus the general public at large. What is stopping any person from taking non-FDA approved drugs if terminally ill patients have a right to experimental drugs under the "right to try" laws? Case law has found that the FDA's authority to regulate drug safety is no different with respect to dying patients than it is with nonterminal patients.⁵⁶ The "right to try" laws raise the possibility that in the future expanded access may be granted to someone who has a serious but not terminal illness and eventually the public at large. Concerns arise that if manufacturers do not have to meet the same standards of the FDA's current approval process they may not conduct as extensive research testing the drug's safety and effectiveness as the FDA had required.⁵⁷ Instead they may be tempted to get the drug on the market as fast as they can and risk marketing drugs with unknown side effects to the public.⁵⁸ There is the potential for the illness to be worsened to the point of death if patients have access to new drugs before testing is complete.⁵⁹ Allowing patients to try experimental drugs outside of clinical trials risks both the validity of the scientific

method of the trials and the health of future patients that might benefit from the deliberate, careful and meticulous process of new drug approval required under FDA regulations.⁶⁰

A significant concern with the “right to try” laws is that there is no requirement for a private or government health insurance company to pay for expanded access. Drugs are not approved for Medicare or for insurance purposes until after they have completed the FDA approval process.⁶¹ The patient would bear the cost of an experimental drug treatment under the “right to try” laws if the manufacturer decided to forgo the FDA governance and provide expanded access. The manufacturing cost allowed to be recovered under the “right to try” laws can still be extremely costly and prevent many lower-income individuals from being able to afford the investigational drug. This in turn contradicts the initiative for equal access and leaves low-income persons with the opportunity to access investigational drugs solely through clinical trials where they would face the risk of receiving a placebo instead of the desired drug or may not even be eligible to participate.⁶²

Issues also arise regarding the physicians who prescribe the experimental drugs under the “right to try” laws. Action against a healthcare provider who recommends treatment using an investigational product to an eligible patient is prohibited under the “right to try” laws so long as the recommendation is consistent with the standard of care. The question thus becomes: what will the standard of care in prescribing experimental drugs be? A physician who refuses to prescribe such drugs may be liable for medical malpractice if enough physicians prescribe experimental drugs so that it becomes the standard of care. These laws open the door for physicians to exploit terminally ill patients by offering medicines that are expensive but have no realistic benefit.⁶³

There is also the potential for a patient, who becomes aware of experimental treatment, to stress the pain of the potential loss of life and demand that he get access to the drug despite his physician's belief that it would be inappropriate treatment. Physicians already face considerable pressure from patients regarding approved drugs that are heavily marketed through direct-to-consumer advertising. There is an additional burden to the risk-benefit discussion between the physician and patient pertaining to investigational drugs with insufficient data to support the physician's opinion regarding safety and efficacy.⁶⁴

Overall, the "right to try" laws will do little in expanding access to investigational products outside FDA regulations. The FDA and manufacturers have a variety of legitimate concerns that have not been resolved by the "right to try" laws. It would be surprising to find manufacturers that provide expanded access under these laws that so greatly compromise FDA regulatory authority when the manufacturers will need FDA approval for their drugs when it comes time to market to the public at large.

Conclusion

The tension between the urgency for expanded access to provide potentially beneficial treatment to dying patients and the concerns of the FDA and industry in regulating when and what treatments will be safe and effective enough for investigational use has existed for decades. What is evident is that the state "right to try" laws are not the answers to the legitimate apprehensions of the FDA and manufacturers. Those new laws do nothing to require manufacturers to provide the investigational drugs to eligible terminally ill patients. Regulators should continue to seek a balance between supporting the needs of terminally ill patients with the responsibility of the FDA and manufacturers to provide the most safe and effective products for the public at large. Potential improvements to the current expanded access programs must

receive FDA support and involve collaboration with the agency in the interest of encouraging manufacturers to more willingly provide access to the investigational products.

¹ Katelyn Mineo is a third year student at Seton Hall University School of Law where she is pursuing the Health Law concentration, Compliance track. Katelyn graduated from Rutgers University in 2011 with a B.S. in Marine Chemistry and a minor in Mathematics. After graduation, she worked for one year at Merck & Co., Inc. as an associate analytical chemist in late stage drug development. Katelyn spent her first summer in law school interning at Johnson & Johnson as a legal and compliance fellow at world headquarters. She spent her second summer working at Reed Smith LLP as a summer associate in the Life Sciences Transactions and Regulatory Group. This past fall Katelyn did independent research on the state right to try laws and expanded access issues under the guidance of Dean Boozang, which resulted in this volume's abbreviated article. She attended Seton Hall's Healthcare Compliance Certification Program in October 2014. Currently, Katelyn is interning with the Office of Policy at the Food and Drug Administration. She has accepted a position in the Life Sciences group with Reed Smith for after graduation and is excited to continue her career in the health regulatory and compliance sector. In addition to pursuing her passion for health law, Katelyn has actively participated in the Women's Law Forum in Secretary and Vice-Chair roles as well as the Mock Trial team.

² Arthur Caplan & Kenneth Moch, *Rescue Me: The Challenge of Compassionate Use In The Social Media Era* (Aug. 27, 2014), <http://healthaffairs.org/blog/2014/08/27/rescue-me-the-challenge-of-compassionate-use-in-the-social-media-era/>.

³ *Id.*

⁴ *Id.*

⁵ *Id.*

⁶ Caplan, *supra* note 2.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

¹¹ Caplan, *supra* note 2.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ David Kroll, *Josh Hardy Going Home After Getting Chimerix Anti-Viral Drug* (July 17, 2014), <http://www.forbes.com/sites/davidkroll/2014/07/17/josh-hardy-going-home-after-getting-chimerix-anti-viral-drug/>.

¹⁷ Christina Corieri, *Everyone Deserves the Right to Try: Empowering the Terminally Ill to Take Control of Their Treatment* (February 11, 2014), <http://goldwaterinstitute.org/article/everyone-deserves-right-try-empowering-terminally-ill-take-control-their-treatment>.

¹⁸ Caplan, *supra* note 2.

¹⁹ Stephanie Baum, *2014 election results: Voters support experimental drugs in AZ, sick days in Mass.*, MEDCITY NEWS (Nov. 5, 2014), <http://medcitynews.com/2014/11/voters-arizona-favor-access-experimental-drugs-support-sick-days-massachusetts/>; Cheryl Wetzstein, *Wyoming passes ‘right to try’ law for desperate patients* (March 11, 2015), <http://www.washingtontimes.com/news/2015/mar/11/wyoming-passes-right-to-try-law-for-desperate-pati/>; *The Right-to-Try Revolt*, THE WALL STREET JOURNAL (Feb. 9, 2015, 7:16 PM), available at <http://www.wsj.com/articles/the-right-to-try-revolt-1423527365>; *“Right to Try” Bill Signed into Law in Arkansas* (March 11, 2015), http://www.ozarksfirst.com/story/d/story/right-to-try-bill-signed-into-law-in-arkansas/35947/zYXAboKECEqW9jz_63HEng.

²⁰ Corieri, *supra* note 7.

²¹ Colo. Rev. Stat. § 25-45-102 (LEXIS 2014).

²² *Id.*

²³ Colo. Rev. Stat. § 25-45-103(1)(a) (2014); Mo. Rev. Stat. § 191.480(I)(1) (2014); La. Rev. Stat. § 1300.383 (2014); S.B. 991 (Mich. June 11, 2014); Ariz. Rev. Stat. § 36-1311 (2014); Ark. Code § 20-15-2003 (2015); Wyo. Stat. § 35-7-1802 (2015).

- ²⁴ Colo. Rev. Stat. § 25-45-103(3); Mo. Rev. Stat. § 191.480(I)(3); La. Rev. Stat. § 1300.383(3); S.B. 991(I)(2)(a); Ariz. Rev. Stat. § 36-1311; Ark. Code § 20-15-2003; Wyo. Stat. § 35-7-1802.
- ²⁵ Colo. Rev. Stat. § 25-45-103(2); Mo. Rev. Stat. § 191.480(I); La. Rev. Stat. § 1300.383; S.B. 991(I)(2)(c); Ariz. Rev. Stat. § 36-1311; Ark. Code § 20-15-2003; Wyo. Stat. § 35-7-1802.
- ²⁶ Colo. Rev. Stat. § 25-45-103(1)(a); Mo. Rev. Stat. § 191.480(I); La. Rev. Stat. § 1300.383; S.B. 991(I)(2)(d); Ariz. Rev. Stat. § 36-1311; Ark. Code § 20-15-2004; Wyo. Stat. § 35-7-1802.
- ²⁷ Colo. Rev. Stat. § 25-45-103(4); Mo. Rev. Stat. § 191.480(I); La. Rev. Stat. § 1300.383; S.B. 991(I)(2)(d); Ariz. Rev. Stat. § 36-1311.
- ²⁸ Colo. Rev. Stat. § 25-45-104(1) (2014); Mo. Rev. Stat. § 191.480(II); La. Rev. Stat. § 1300.384; S.B. 991(II); Ariz. Rev. Stat. § 36-1312; Ark. Code § 20-15-2005; Wyo. Stat. § 35-7-1803.
- ²⁹ Colo. Rev. Stat. § 25-45-104(2); Mo. Rev. Stat. § 191.480(II); La. Rev. Stat. § 1300.384; S.B. 991(II); Ariz. Rev. Stat. § 36-1312; Ark. Code § 20-15-2006; Wyo. Stat. § 35-7-1803.
- ³⁰ Colo. Rev. Stat. § 25-45-104(3)(b); Mo. Rev. Stat. § 191.480(III); La. Rev. Stat. § 1300.384; S.B. 991(III); Ariz. Rev. Stat. § 36-1312; Ark. Code § 20-15-2007; Wyo. Stat. § 35-7-1803.
- ³¹ Colo. Rev. Stat. § 25-45-105 (2014); Mo. Rev. Stat. § 191.480(V); La. Rev. Stat. § 1300.386; S.B. 991(III); Ariz. Rev. Stat. § 36-1313; Ark. Code § 20-15-2008; Wyo. Stat. § 35-7-1804.
- ³² Colo. Rev. Stat. § 25-45-107 (2014); Mo. Rev. Stat. § 191.480(VII); S.B. 991(VIII); Ark. Code § 20-15-2010; Wyo. Stat. § 35-7-1806.
- ³³ Colo. Rev. Stat. § 25-45-106 (2014); Mo. Rev. Stat. § 191.480(VI); Ariz. Rev. Stat. § 36-1314; Wyo. Stat. § 35-7-1805.
- ³⁴ Corieri, *supra* note 17.
- ³⁵ *Id.*
- ³⁶ Brandy Dennis & Ariana Eunjung Cha, 'Right to Try' laws spur debate over dying patients' access to experimental drugs, THE WASHINGTON POST (May 16, 2014), http://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5c0_story.html.
- ³⁷ Elizabeth Weeks Leonard, *Right to Experimental Treatment: FDA New Drug Approval, Constitutional Rights, and the Public's Health*, 37 J.L. MED. & ETHICS 269, 272 (2009).
- ³⁸ Weeks Leonard, *supra* note 37, at 272.
- ³⁹ Clayton R. Portell, *Live or Let Die: Will the Courts Recognize In Terminally Ill Patients a Fundamental Right to Choose Non-FDA Approved Drugs or Does the FDA's Stringent Approval Process Carry Sufficient Merit?*, 5 IND. HEALTH L. REV. 123, 142 (2008).
- ⁴⁰ *Id.*, at 142. Jerome Groopman, *The Right To a Trial: Should Dying Patients Have Access to Experimental Drugs?*, THE NEW YORKER (Dec. 18, 2006), <http://www.newyorker.com/magazine/2006/12/18/the-right-to-a-trial>.
- ⁴¹ Portell, *supra* note 39, at 142.
- ⁴² Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 308 (2000).
- ⁴³ Priya Brandes, *Regulation of Drugs: A Death Sentence for the Terminally Ill?*, 46 U.S.F. L. REV. 1149, 1166 (2012).
- ⁴⁴ Brandes, *supra* note 43, at 1167.
- ⁴⁵ Linda Katherine Leibfarth, *Giving the Terminally Ill Their Due (Process): A Case for Expanded Access to Experimental Drugs through the Political Process*, 61 VAND. L. REV. 1281, 1303 (2008).
- ⁴⁶ Austin Winniford, *Expanding Access to Investigational Drugs for Treatment Use: A Policy Analysis and Legislative Proposal*, 19 HEALTH MATRIX 205, 215 (2009).
- ⁴⁷ *Id.* at 215.
- ⁴⁸ James M. Beck, *On "Right to Try" Legislation*, DRUG AND DEVICE LAW (October 23, 2014), <http://druganddevicelaw.blogspot.com/>.
- ⁴⁹ 21 U.S.C.S. §355(a) (LEXIS current through 2014).
- ⁵⁰ Weeks Leonard, *supra* note 37, at 272.
- ⁵¹ *Id.*
- ⁵² See 21 C.F.R. § 312.8 (2014) (charging for Investigational drugs).
- ⁵³ 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, 592 (2009).
- ⁵⁴ Michael J. Malinowski, *Throwing Dirt on Doctor Frankenstein's Grave: Access to Experimental Treatments at the End of Life*, 65 HASTINGS L.J. 615, 644 (2014).

⁵⁵ Malinowski, *supra* note 54, at 645.

⁵⁶ *United States v. Rutherford*, 442 U.S. 544, 551 (1979).

⁵⁷ Portell, *supra* note 39, at 143.

⁵⁸ *Id.*, at 126.

⁵⁹ *Id.*

⁶⁰ Weeks Leonard, *supra* note 37, at 270.

⁶¹ Portell, *supra* note 39, at 143.

⁶² Patricia Zettler, *The Implications of Post-Phase I and “Off-Label” Treatment Use of Experimental Drugs: How Expansive Should Expanded Access Be?*, 18 KAN. J. L. & PUB. POL’Y 135, 169 (2009).

⁶³ Caplan, *supra* note 2.

⁶⁴ Peter D. Jacobson & Wendy E. Parmet, *A New Era of Unapproved Drugs: The Case of Abigail Alliance v. Von Eschenbach*, 297 JAMA 205, 207 (2007).