

# The Shifting Landscape of Medicine: Patents of Personalized Biologic Treatments and Their Potential Conflicts with Right-to-Try Laws

Johnson T. Laney

*University of Georgia School of Law*

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# THE SHIFTING LANDSCAPE OF MEDICINE: PATENTS OF PERSONALIZED BIOLOGIC TREATMENTS AND THEIR POTENTIAL CONFLICTS WITH RIGHT-TO-TRY LAWS

*Johnson T. Laney\**

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## I. INTRODUCTION

The United States has gone back and forth over whether its citizens have a moral right to access potentially life sustaining or lifesaving treatment when they are terminally ill.<sup>1</sup> Currently, forty-one states and the US Senate have passed “right to try” laws that permit terminally ill patients to have access to experimental treatments that have not yet received FDA approval.<sup>2</sup> The United States has had a difficult time determining whether a patient has the right to refuse life-sustaining or lifesaving treatment because of fear that the patient is

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\*J.D. Candidate 2019, University of Georgia School of Law

<sup>1</sup> See, e.g., Pavlos Eleftheriadis, *A Right to Health Care*, J.L. MED. & ETHICS, 268 (2012) (describing the dichotomy between the moral theories of right to try versus right to die).

<sup>2</sup> RIGHTTOTRY.ORG, <http://righttotry.org/ttt-faq/>. (Last visited Nov. 18, 2018). S. Res. 204, 115th Cong. (2017) (enacted).

suicidal.<sup>3</sup> The Supreme Court has addressed this problem and determined that the State does have an interest in preserving the healthy lives of its citizens.<sup>4</sup>

This dilemma is complicated further by the prospect of personalized medicine, i.e. the use of medicine specifically created for one particular individual. With this narrow application, there would likely be no commercial viability for the treatments elsewhere. Further, due to the complicated nature of these medications, the Supreme Court has allowed “biosimilar” patents, which allow non-exact copies of a drug to be made.<sup>5</sup> This is unlike, and potentially less rigorous than, the standard FDA approval requirements.<sup>6</sup>

This Note addresses the problems that arise when the patent protectors of the personalized product interfere with the patient’s right to receive treatment and the state’s interest in protecting its citizens by making medical treatment available. If the patient cannot afford the personalized medication, and it is the only treatment, is there a right to the treatment? If the patient consented to the creation of the personalized and lifesaving treatment (not just experimental), is there a right to refuse the treatment at a later date?

*First*, this Note will explain what personalized medicine is, and give an overview of how treatment can be so precisely designed for each individual’s genomic makeup. *Second*, this Note will examine the property rights of one’s genetic information, especially when that information is obtained without the patient’s consent. *Third*, this note will summarize the process for patenting these biologic products. *Fourth*, this Note will provide a description of the *Abigail Alliance* case and the idea of medical self-defense. *Finally*, this Note will argue why patents of this nature will interfere with the idea of the moral “right to try” and how that interference will require incentive structuring for medical innovation to change.

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<sup>3</sup> Claire Andre & Manuel Velasquez, *Assisted Suicide: A Right or Wrong?*, Markkula Center for Applied Ethics (Nov. 2015), <https://www.scu.edu/ethics/focus-areas-bioethics/resources/assisted-suicide-a-right-or-a-wrong/>.

<sup>4</sup> *Cruzan ex rel Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 280 (1990).

<sup>5</sup> Patient Protection and Affordable Care Act; Title VII – Improving Access to Innovative Medical Therapies, 42 U.S.C. §262(e) (2011).

<sup>6</sup> *Compare id. with* FDA Approval of Generic Drugs, (updated Aug 1, 2017), <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm506040.htm>.

## II. BACKGROUND

### A. PERSONALIZED MEDICINE

Personalized medicine is the “tailoring of medical treatment to the individual characteristics of each patient.”<sup>7</sup> This new approach to healthcare will analyze the patient’s genetic code, life style, and other environmental factors to provide specifically tailored treatments and therapies.<sup>8</sup> In general, patients will be identified by particular “biomarkers.”<sup>9</sup> These biomarkers will let medical providers know what type of drug and what dose would be most effective, while producing the least amount of side effects.<sup>10</sup> This level of precision will allow patients with certain cancers to be offered a “molecular diagnosis,” which allows their physician to select specific treatments that will respond best to the disease and the patient.<sup>11</sup> For instance, a cancer, such as melanoma can be broken down into subcategories of conditions that will give the physicians a better idea of the behavior of the cancer and how best to treat it.<sup>12</sup>

The landscape of this healthcare model is changing dramatically due to the innovations in the genetic mapping of humans, specifically the genotyping of drug-metabolizing enzymes.<sup>13</sup> Today, the cost and labor to map one’s genome is a fraction of what it was just ten years ago.<sup>14</sup> Because of this reduction in cost, there have been thousands of human genomes sequenced.<sup>15</sup> This mapping has allowed researchers to create over one hundred different genomic medications.<sup>16</sup>

Furthermore, there have been new advancements in medical research that will allow providers to test treatments and medications on the individual without risking harm to that individual.<sup>17</sup> Researchers at the Wyss Institute have created

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<sup>7</sup> U.S. FOOD & DRUG ADMIN., *Paving the Way for Personalized Medicine: FDA’s Role in a New Era of Medical Product Development* 7 (2013) (last visited Aug. 25, 2018) (quoting the President’s Council of Advisors on Science and Technology), <http://www.fdanews.com/ext/resources/files/10/10-28-13-Personalized-Medicine.pdf>.

<sup>8</sup> *See id.*

<sup>9</sup> *See generally*, *Personalized Medicine: Identifying the Appropriate Patient Through Biomarkers in Oncology*, PHARMACY AND THERAPEUTICS, Vol 36 (Jul. 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3171807/>.

<sup>10</sup> *See* Personalized Medicine Coalition, *The Case for Personalized Medicine*, 4 (4th ed. last visited Aug. 25, 2018), [http://www.personalizedmedicincoalition.org/userfiles/PMC-Corporate/file/pmc\\_the\\_case\\_for\\_personalized\\_medicine.pdf](http://www.personalizedmedicincoalition.org/userfiles/PMC-Corporate/file/pmc_the_case_for_personalized_medicine.pdf).

<sup>11</sup> *Id.*

<sup>12</sup> *See id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> Laura Levis, *Mimicking Organs*, HARV. MAG., Jan. 12 – Feb. 14, 2016.

“human-organs-on-chips” that are able to mimic an individual’s physiology.<sup>18</sup> These microchips “recapitulate the microarchitecture and functions of living human organs, including the lung, intestine, kidney, skin, bone marrow and blood brain barrier.”<sup>19</sup> These chips can mimic the microenvironment of the organs, which allows researchers to test different treatments directly on one’s organs as well as enable researchers to test how environmental factors may affect tissue, such as smoking’s effect on one’s lungs.<sup>20</sup>

This work will drastically increase the number of biomarkers identified as well as increase the specificity to which these treatments will be tailored to a particular individual.<sup>21</sup> With more biomarkers identified, pharmaceutical companies will be able to more easily produce these “pharmacogenomic drugs,” or drugs that use the specific map of the patient’s genes to design and control specific aspects of the medication.<sup>22</sup> With a line of more particularized pharmaceuticals, these manufacturers will have a strong interest in maintaining control of these drugs through the use of patents.

#### B. PATIENT’S RIGHTS TO GENETIC INFORMATION:

To understand the right of patients to own their genetic material, one must first understand the reach and purpose of patent law. Patents allow creators to have individual monopolies over certain items or methods, which excludes others from making, using, or selling the patented subject.<sup>23</sup> The idea is that allowing inventors and designers to have control over their product will encourage others to create and develop new technologies that will benefit humanity.<sup>24</sup> The government protects this right and states that “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore.”<sup>25</sup> One limit to that definition is that objects that naturally occur in nature are not patentable.<sup>26</sup>

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Drug-Gene Testing (Pharmacogenomics)*, MAYO CLINIC, <http://mayoresearch.mayo.edu/center-for-individualized-medicine/drug-gene-testing.asp> (last visited Oct. 16, 2018).

<sup>23</sup> *Herman v. Youngstown Car Mfg. Co.*, 191 F. 579–84 (6th Cir. 1911).

<sup>24</sup> *See generally*, David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181 (2009).

<sup>25</sup> 35 U.S.C. §101 (1952).

<sup>26</sup> Leland L. Black, *Patenting and Protecting Personalized Medicine Innovation Post-Mayo*, Myriad, and *Limelight*, 95 N.C. L. REV. 493, 503 (2017).

Although one's genetic information is considered to be naturally occurring, the Supreme Court held in *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*,<sup>27</sup> that the stable, lab-generated complementary DNA (cDNA) of the same gene is patentable.<sup>28</sup> In *Myriad*, medical organizations brought an action against the Patent and Trademark Office (PTO) challenging the validity of patents for DNA sequences associated with a predisposition to breast and ovarian cancers and methods for identifying particular mutations in those sequences.<sup>29</sup> The Court held that "cDNA differs from DNA in that the non-coding regions have been removed."<sup>30</sup> The cDNA's sequence may be dictated by nature, but without the coding regions, the cDNA would not be able to replicate or exist in nature.<sup>31</sup> The Court reasoned that a lab technician creates something new when cDNA is made,<sup>32</sup> even though cDNA is nothing more than a mirror image of the organic gene.<sup>33</sup>

The decision in *Myriad* opens the door for almost any DNA sequence to be patented so long as it is isolated, copied, and the original gene has its own introns.<sup>34</sup> Introns are portions of a DNA sequence that do not code genetic information.<sup>35</sup> The importance of the lack of introns regarding patentability is that, if the gene did not have its own introns, then there would be no difference between the organic gene DNA and the cDNA.<sup>36</sup> And, if the sequence of the cDNA is indistinguishable from that of the organic DNA sequence, then the cDNA sequence cannot be patented.<sup>37</sup> So long as the targeted DNA sequence has its own introns, the cDNA sequence can be patented, which would include a significant number of gene sequences for each individual.<sup>38</sup>

One of the growing concerns about personalized medicine and the use of genetic information for medical research is that the individual no longer has complete control over his or her "body." This is not a new issue and has actually found its way into the courts before.<sup>39</sup> In *Moore v. Regents of Univ. of Cal.*, John Moore was receiving medical treatment for hairy-cell leukemia at the Medical

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<sup>27</sup> 569 U.S. 576 (2013).

<sup>28</sup> *See Id.*

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* at 581.

<sup>31</sup> *Id.*

<sup>32</sup> Olson, *supra* note 25.

<sup>33</sup> *See* Megan Krench, *New Supreme Ct. Decision Rules That cDNA is Patentable: What It Means for Research and Genetic Testing*, SCIENTIFIC AMERICAN (Jul. 9, 2013), <https://blogs.scientificamerican.com/guest-blog/new-supreme-court-decision-rules-that-cdna-is-patentable-what-it-means-for-research-and-genetic-testing/>.

<sup>34</sup> Dan Liu, *Owning The Code*, 36-DEC L.A.L. 20, 25 (2013).

<sup>35</sup> *Id.* at 24.

<sup>36</sup> *Id.* at 25.

<sup>37</sup> *Id.*

<sup>38</sup> *See supra* note 34.

<sup>39</sup> 249 Cal. Rptr. 494, 498 (Ct. of App. 1988), *superseded by* 271 Ca. Rptr. 146 (1990).

Center of the University of California.<sup>40</sup> As a part of his treatment, his physician, Dr. David Golde, removed Moore's spleen.<sup>41</sup> It turned out that the patient's cells were unique and the cell line could produce "pharmaceutical products with enormous therapeutic and commercial value."<sup>42</sup> Without telling the patient, Dr. Golde patented the cell-line and teamed up with a pharmaceutical company that estimated the potential market of these products to be three billion dollars.<sup>43</sup> Moore filed a lawsuit against Dr. Golde and the research facility for conversion and lack of consent.<sup>44</sup> Moore further alleged that his "spleen, blood, and the cell-line derived from his cells 'are his tangible personal property.'" <sup>45</sup> The California Supreme Court, however, held that Moore did not have a cause of action for conversion because he "clearly did not expect to retain possession of his cells following their removal."<sup>46</sup>

This ruling is significant, but limited to the state of California. It is also significant that, following the ruling, research and treatment facilities have been better about clarifying intentions and obtaining proper consent from their patients.<sup>47</sup> Thus, because the court in *Moore* relied heavily on the intentions of the parties it did not fully answer the question of what happens when the *entire purpose* of creating the treatment is to provide treatment for that individual. Nor does the result guide decisions regarding genetic information being obtained without consent. As a result, the tissues of millions of Americans are used in medical research without their knowledge or consent, leaving the issue of patentability unresolved and relevant.<sup>48</sup>

### C. PATENTING BIOLOGICS AND PHARMACOGENOMICS:

Biologics are any pharmaceutical drug synthesized from a biological source, such as a protein, virus, blood component, or other living cell.<sup>49</sup> A biosimilar product is one that is "highly similar" to, and has no clinically meaningful

<sup>40</sup> *Moore*, 249 Cal. Rptr. 494, 498.

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 503.

<sup>46</sup> *Moore v. Regents of Univ. of Cal.*, 51 Cal. 3d 120, at 154 (1990).

<sup>47</sup> See generally, Robert Klitzman, *How IRBs View and Make Decisions About Consent Forms*, 8 J. EMPIRICAL RES. ON HUM. RES. ETHICS 8 (2013).

<sup>48</sup> Rebecca Skloot, *Your Cells. Their Research. Your Permission?*, N.Y. TIMES, Dec. 30, 2015, <https://www.nytimes.com/2015/12/30/opinion/your-cells-their-research-your-permission.html>.

<sup>49</sup> *What Are "Biologics" Questions and Answers*, FDA Basics, <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/cm133077.htm> (last visited Aug. 27, 2018).

difference from, an existing FDA-approved reference product.<sup>50</sup> Biosimilars are allowed because biologics are much more complicated than normal drugs and are very sensitive to the manufacturing process.<sup>51</sup> After the patent expires, follow-on manufacturers will not have access to the exact ingredients, environment, and processes that the originator used, and therefore, the follow-on manufacturers would not be able to meet the strict standards the FDA has set forth for other generic drugs.<sup>52</sup>

Because no competing manufacturer could create an exact copy of the original drug, the FDA has published broader standards for biologics to be classified as a biosimilar or “follow-on biologic,” which requires that the new biologic satisfy all five criteria set forth in the PHSA §35(E)(k).<sup>53</sup> First, the biologic must be substantially significant to the reference product.<sup>54</sup> Second, the biologic must use the same mechanisms of action.<sup>55</sup> Third, the reference product must be licensed for the use prescribed, recommended, or suggested.<sup>56</sup> Fourth, the biologic and reference product must have the same route of administration, dosage form, and strength.<sup>57</sup> Finally, the facility where the biosimilar product is manufactured must meet standards sufficient to assure the product is safe.<sup>58</sup>

These standards uphold the principles of FDA approval for generic pharmaceuticals in that the drugs must be safe and have the same effects as the original, but the FDA has relaxed its requirement of exact duplication.<sup>59</sup> The FDA clarifies that to be “highly similar,” the drug must be similar in structure and function, including the chemical identity.<sup>60</sup> The differences that the FDA allows for these biosimilar products are merely the inactive components of the product.<sup>61</sup> Examples of these inactive components include the particular stabilizer or buffer the drug may use.<sup>62</sup>

The difference-and-precision standard that a biologic follow-on must meet becomes important as the prevalence of pharmacogenomics increases. Pharmacogenomics is the study of how the genome of an individual affects his

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<sup>50</sup> *Biosimilar and Interchangeable Products*, FDA, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.html> (Last visited Aug. 27, 2018).

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *See id.*

<sup>60</sup> *Id.*

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

or her response to drugs.<sup>63</sup> Pharmacogenomics can look at particular marker genes as well as how the entire genome functions and interacts with the drug.<sup>64</sup> Further, with the extreme improvements in technology and the large number of genomes that have been sequenced, the field of pharmacogenomics has increased dramatically.<sup>65</sup> Two big changes are responsible for this revolution: the first is testing and human research, and the second is new understandings of certain diseases and the different approaches to treat them.<sup>66</sup>

First, regarding human research, with the breakthrough of “gut-on-a-chip” technology, the individual does not have to be the direct subject of the test.<sup>67</sup> Further, the patient does not even have to be present in the laboratory or even the same state.<sup>68</sup> As stated earlier, the lab will have a micro-simulation of the patient’s organs and will be able to run various tests that will show how the individual’s organs react to particular drugs.<sup>69</sup> This would in effect allow the medical providers to tell beforehand whether the standard version of the drug will produce severe adverse effects or react poorly with other medications that the individual is taking before the patient actually receives the treatment.<sup>70</sup>

The second breakthrough is the molecular-targeted therapy in oncology.<sup>71</sup> This therapy looks at molecular alterations that may serve as predictors in one’s genome, which “can be simple DNA sequence variants or complex chromosomal rearrangements.”<sup>72</sup> Doctors will be able to look at an individual’s genome and determine, based on the markers that exist or altered, that the individual will be predisposed to certain types of cancers.<sup>73</sup> The best example of this is the BRCA1 and BRCA2 genes that were identified in the *Myriad* case.<sup>74</sup> Further, this new technology is not limited to cancers and can be used in a wide variety of treatments, from hormonal therapies to understanding how a patient will interact with anesthesia.<sup>75</sup>

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<sup>63</sup> Roberta Ferraldeschi and William Newman, *Pharmacogenetics and Pharmacogenomics: A Clinical Reality*, 48 J. OF L., MED., & ETHICS Sept. 2011, at 410.

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

<sup>67</sup> Levis, *supra* note 18, at 12.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> Ferraldeschi, *supra* note 63, at 412.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *See generally id.* (describing the effects of molecular targeting on hormone therapies); and Gordon Bush, *Pharmacogenomics and Anesthesia*, 61 PROC. SOC. R. MED.(1968) (identifying the importance of understanding that genes are what determine the differences in ways people react to anesthesia).

## D. MEDICAL SELF-DEFENSE

Self-defense is a long recognized and widely accepted right.<sup>76</sup> It is accepted to the point that almost no courts have put restrictions on self-defense, and other courts have directly considered whether it is a constitutional right.<sup>77</sup> In a plurality opinion in *Montana v. Egelhoff*, Justice Scalia suggested that the right to self-defense is protected by the Constitution.<sup>78</sup> Self-defense is so broad, that the Supreme Court has recognized the right of self-defense in the medical field.<sup>79</sup> In *Roe* and *Casey*, the Supreme Court recognized that a woman has the right to an abortion when it is necessary “to preserve the life or health of the mother.”<sup>80</sup> This reasoning can also be described as “a right to defend oneself using medical care.”<sup>81</sup> Although this right has not been applied in any other medical setting, it seems logical that the right must extend beyond just post-viability abortions.<sup>82</sup> It seems obvious that in certain circumstances, if there is a medical treatment that would be necessary to save someone’s life, the doctrine of self-defense should apply.

One example of the prevalence of the idea of medical self-defense is that bishops and other Catholic leaders are supporting doctors in Catholic hospitals to perform abortions if it is medically necessary to save the life of the mother.<sup>83</sup> It is a rare and unique circumstance but, nonetheless, real.<sup>84</sup> In fact, the ACLU filed a suit against Trinity Health Corporation due to a systematic failure to provide women with appropriate emergency abortions as required by federal law.<sup>85</sup> Trinity Health Corporation (“Trinity”) is a Catholic health system, which owns and operates more than 80 hospitals in the United States.<sup>86</sup> Further, Trinity requires that all of its hospitals abide by the Ethical and Religious Directives for Catholic Health Care Services.<sup>87</sup> One of these directives includes the prohibition of Catholic hospitals from performing emergency abortions if there is a pregnancy complication, even though the abortion may be the only way to save

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<sup>76</sup> Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1818 (2007).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> *Id.* at 1824

<sup>80</sup> *Id.* (citing *Roe v. Wade*, 410 U.S. 113, 163-64 (1973) and *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992)).

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> See generally, Matthew Newsome, *Abortion and Double Effect*, CATHOLIC ANSWERS (Sept. 1, 2006) (<https://www.catholic.com/magazine/print-edition-abortion-and-double-effect>).

<sup>84</sup> *Id.*

<sup>85</sup> Amended Complaint at 2, *ACLU v. Trinity Health Corp.*, No. 15-cv-12611 (E.D. Mich. Oct. 1, 2015).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

the woman's life.<sup>88</sup> The ACLU brought this claim under EMTALA, the Emergency Medical Treatment and Active Labor Act.<sup>89</sup> However, the court dismissed this case due to lack of standing, and no conclusions were reached as to whether the right existed under the Act.<sup>90</sup>

Although the ACLU's complaint failed, the argument of medical self-defense was also raised in *Abigail Alliance v. Escobenbach*.<sup>91</sup> There, the court held that terminally ill patients did not have a fundamental right of access to medical treatment under the common law doctrine of self-defense.<sup>92</sup> The Abigail Alliance for Better Access to Developmental Drugs (the "Alliance") was an organization that wanted to expand access to experimental medications that had not been FDA certified for terminally ill patients.<sup>93</sup> However, the court found that the Due Process Clause of the Fifth Amendment, which provides that no person shall be deprived of "life, liberty, or property, without due process of law,"<sup>94</sup> did not protect a terminally ill adult's access to investigational drugs.<sup>95</sup> Further, the common law doctrine of necessity was not enough to recognize it as a fundamental right.<sup>96</sup> The common law doctrine of self-defense does not weigh in favor of recognizing access to treatment as a fundamental right because the patients were not using "reasonable force" to defend themselves when they took unproven and possibly unsafe drugs.<sup>97</sup> However, all of this reasoning changes with the federal government passing a bill stating that patients do have a right to try.<sup>98</sup>

### III. ANALYSIS

Even with *Moore* and *Abigail Alliance* on the books, other states are taking a different approach to the issue of property rights over genetic information and the right to access. Thirty-seven states have adopted "right to try" laws stating that a terminally ill patient does have the right to access experimental drugs that have not received FDA approval if there is a chance that the medication could

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<sup>88</sup> *Id.* at 3.

<sup>89</sup> *Id.* at 1.

<sup>90</sup> *ACLU v. Trinity Health Corporation*, No. 15-cv-12611 (E.D. Mich. Apr. 11, 2016).

<sup>91</sup> 495 F.3d 695 (D.C. Cir. 2007).

<sup>92</sup> *Id.* at 710.

<sup>93</sup> *Id.* at 697.

<sup>94</sup> U.S. CONST. amend. V.

<sup>95</sup> Volokh, *supra* note 76, at 1827.

<sup>96</sup> *Abigail Alliance*, 495 F.3d at 696.

<sup>97</sup> *Id.* at 723.

<sup>98</sup> S. Res. 204, 115th Cong. (2017) (enacted).

save their lives.<sup>99</sup> The overwhelming support for passing these laws shows that our country has a moral interest in providing people with the best possible options to survive.<sup>100</sup> Further, one of the basic principles of law is that it is the responsibility of the legal institution to reflect the moral inclinations of society, which in this case means the law should not limit the rights of terminal patients to use untested, experimental drugs.

Despite state legislatures' best intentions, the way in which the pharmacogenomic drugs are patented will have an effect on whether a patient would have access to potentially lifesaving treatment, even with the right-to-try laws. On one hand, if the patent of the patient's particular medicine is novel, then the medication will be subject to the standard FDA approval process but may also fit within the exceptions of the right-to-try laws. Alternatively, if the new medication is similar enough in nature to other biologics, then it will not need to be put through the same laborious process of FDA approval.<sup>101</sup> Avoiding the standard FDA process may also eliminate the new medication's eligibility for general access under the right-to-try laws, even though the typical ethical issues surrounding the right-to-try laws would not apply, such as, "using humans as guinea pigs" and "the giving of false hope." Additionally, if the treatment is certified to be similar, then that would be even more evidence of the drug's effectiveness. This will give the patient a stronger argument that the new pharmacogenomic drug will actually be lifesaving, and under medical self-defense, the patient should have a right to access the treatment.

The right to access life-sustaining or lifesaving treatments further depends on the method by which the biotech or pharmaceutical company obtained the patient's genetic information. If the patient contracted with the company to develop a specialized treatment for their disease, they would likely have waived certain claims of necessity in their consent form.<sup>102</sup> However, as stated earlier, there are millions of Americans that have their tissue samples being experimented on without their knowledge and/or consent.<sup>103</sup> Further, contained in everyone's tissues are their DNA and gene sequences, which means that these labs have access to millions of people's genes, but the people have not consented to research or waived any particular rights.<sup>104</sup>

Additionally, with the organizations like "23andME," "deCODEME," and "Knome," the number of people who have unwittingly given their genetic

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<sup>99</sup> Goldwater, *U.S. Senate Approves Right to Try Law*, RIGHTTOTRY.ORG (Aug. 4, 2017), <http://righttotry.org/u-s-senate-approves-right-to-try-law/>.

<sup>100</sup> *Id.*

<sup>101</sup> Biosimilar and Interchangeable Products, *supra* note 50.

<sup>102</sup> See generally Amy McGuire & Laura Beskow, *Informed Consent in Genomics and Genetic Research*, 11 ANN. REV. GENOMICS HUM. GENETICS 361–68 (2010).

<sup>103</sup> Skloot, *supra* note 48.

<sup>104</sup> *Id.*

information away to corporations is even higher.<sup>105</sup> 23andMe does not make a large profit from its \$100 genetic test kits; instead, it makes its profits from the genetic information that it sells to third parties.<sup>106</sup> Although the companies claim they de-identify the data before they sell it, they still keep the genetic profiles of their participants on their private records.<sup>107</sup> Additionally, there are currently no regulations preventing them from divulging that personal and identified information to third party companies that have the intention of developing new pharmacogenomics.<sup>108</sup>

Because the field of these genetic tests and genomic profiles lack proper oversight, and the public is substantially uneducated on these topics, it is necessary to have substantive laws in place that will protect individuals from pharmaceutical companies effectively having monopoly over potentially lifesaving treatment.

In one notable example, a man interested in knowing whether his family was more Irish or Welsh purchased a home genetic kit from 23andMe. As it turns out, the test told him not only that he was over 60% Irish, but also that he had genetic markers indicating predisposal to heart disease, just like his father and grandfather. What the information pack he *did not* tell him was that the company would continue to use his genetic information for further testing. This testing showed that there was a different, less common combination of markers that identified a strong likelihood of developing kidney disease. Instead of informing all of the people with these markers, the company sold that information to a third-party pharmaceutical company that was developing new kidney medications. During the development of these new medications, the pharmaceutical company discovered that those uncommon genetic markers also had an extremely adverse effect to the more common treatments for heart disease. Armed with this discovery, the pharmaceutical company developed a new type of treatment for this rare form of kidney disease.

After a few years, the man developed kidney disease and went to his doctor. The pharmaceutical company reached out to his doctor, notifying him of the patient's unique form of the disease, and claimed to have the only appropriate treatment. The company informed the physician that the standard treatment would be ineffective and may even have adverse effects on the patient. If the

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<sup>105</sup> Kristen Brown, *23andMe Is Selling Your Data, But Not How You Think*, GIZMODO (April 14, 2017), <https://gizmodo.com/23andme-is-selling-your-data-but-not-how-you-think-1794340474>.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> Jane Kaye, *The Regulation of Direct-to-Consumer Genetic Tests*, 17 HUM. MOLECULAR GENETICS R180, Kay Davies & Anthony Wynshaw-Boris eds., R2 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2672785>.

patient did not receive this particularized treatment, he would most likely die within six months.

The doctor, wanting to adhere to best practices and do good for the patient, prescribed the unique treatment. However, the cost was 400 times the price of the standard treatment. Unsurprisingly, the man could not afford it. So, the question becomes, does he get to be treated anyways? And if so, through what channel should he be provided this treatment? Should he have a right to the treatment if he cannot afford it?

The argument for his right to the treatment is that it was discovered and based on his own genetic information, and it is likely the only treatment that will save him from a terminal condition. A man in this position would be able to claim a property interest in the genetic information that was derived from his tissue sample. Further, the particular sample that was used for the research was arguably obtained without his consent for that specific use, and therefore he did not waive any rights he had in that genetic information.

Does the patient deserve the treatment out of the doctrine of medical necessity? The argument here is that he is terminal without the particularized treatment, and his only mode of survival is to be given this one particular treatment. If drastic measures are used in other circumstances, why not use less these, relatively less drastic, measures to save the patient here? If we require physicians to terminate a pregnancy to save the life of a mother, which is obviously an extremely sensitive and critical issue, then why not require that these particularized medicines be reasonably available to the people for and arguably by whom they were made? It is hard to argue that six months of suffering from a terminal illness is morally different from an emergency abortion.

Further, if people are really concerned with terminal patients' "right to try," then why not expand that right to affordability by limiting exclusion rights instead of granting access to treatment that has not been properly researched? The "right to try" laws currently on the floor of the Senate pertain to medications that have only passed stage one of the FDA approval process.<sup>109</sup> However, only 33% of medications advance from stage 2 to stage 3.<sup>110</sup> This means that the law gives terminal patients access to the 67% of drugs that would have been rejected, and the patients will be vulnerable to extreme risks and potentially painful side effects. Alternatively, by limiting the exclusion rights of the pharmaceutical companies' control of personalized medicine, patients would not only have better access to the pharmacogenomics, but the treatment would have a higher chance of success than those that merely passed phase one of the development process.

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<sup>109</sup> S. Res. 204, 115th Cong. (2017) (enacted).

<sup>110</sup> Bill Berkrot, *Success Rates for Experimental Drugs Falls: Study*, REUTERS (Feb. 14, 2011), [https://www.reuters.com/article/us-pharmaceuticals-success/success-rates-for-experimental-drugs-falls-study-idUSTRE71D2U920110214?feedType=nl&feedName=ush\\_ealth1100](https://www.reuters.com/article/us-pharmaceuticals-success/success-rates-for-experimental-drugs-falls-study-idUSTRE71D2U920110214?feedType=nl&feedName=ush_ealth1100).

Granting the public access to pharmacogenomics would likely cause a shift in the economic structure of pharmaceutical companies because they would not have the exclusive rights that normally allow them to have a monopoly over new medications. This leads some to have the fear that pharmaceutical companies will stop producing potential life-sustaining or lifesaving treatments and researching new ones. However, universities and research labs, not pharmaceutical companies, are the entities doing most of the current research for groundbreaking biologics.<sup>111</sup> Further, pharmaceutical companies are already looking for other sources for income other than their patent rights on drugs.<sup>112</sup> Knockoffs and generics are becoming too easy to make, and these particularized medicines do not have the same type of versatility or broad market like their big moneymakers do.<sup>113</sup> Therefore, it is likely that pharmaceutical companies will be forced to make a market shift for maintaining their profits before particularized medicines are on the market. And, therefore, to reduce their exclusive rights over pharmacogenomics will not be a substantial enough deterrent to reduce their economic incentives from producing any pharmacogenomics.

#### IV. CONCLUSION

What happens to innovation if companies face the possibility of having to “donate” their new drugs to ill patients? Will a “right to try” necessarily deter pharmaceutical companies from continuing to innovate in the field of personalized medicine? Will states need to step in and establish a reimbursement method that encourages innovation but also gives access to the medication that was created specifically for the patient?

The concept of medical self-defense should be expanded beyond emergency abortions. New right-to-try laws show a moral shift in our society that encourages providing terminal patients with all available options. And under our understanding of property rights, if a medication is developed using the genetic information of individuals, then they should have a right to access that medication, even if they would otherwise not be able to afford it.

If society wants to avoid the circumstance that would allow a pharmaceutical company to have a monopoly over a patient’s only chance at survival, it must embrace these alternative reimbursement methods and allow patients, when it is medically necessary, to have access to the treatments that were designed for them.

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<sup>111</sup> Shuai Xu and Aaron S. Kesselheim, *Medical Innovation Then and Now: Perspectives of Innovators Responsible for Transformative Drugs*, 42 J. OF L., MED., & ETHICS 564 (Winter 2014).

<sup>112</sup> Id. at 572.

<sup>113</sup> Alexandra Ossola, *The Fake Drug Industry Is Exploding, and We Can't Do Anything About It*, NEWSWEEK MAGAZINE, (Sept. 17, 2015) <https://www.newsweek.com/2015/09/25/fake-drug-industry-exploding-and-we-cant-do-anything-about-it-373088.html>.