

## Medicine 2.0: Have We Gone Too Far?

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# MEDICINE 2.0: HAVE WE GONE TOO FAR?

ALEXANDRIA K. MONTANIO\*

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## I. INTRODUCTION: #SAVEJOSH

Aimee Hardy, a mother from a small town in Virginia, probably never intended to become the symbol of a new era of medical decision making or the center of a bioethical debate.<sup>1</sup> Her seven-year-old son, Josh, who had battled cancer since he was only a few months old, was dying.<sup>2</sup> Conventional methods to save him had been unsuccessful and it seemed that the only chance for Josh rested in an experimental drug known as Brincidofovir that was in early stages of testing.<sup>3</sup> Josh had not been eligible for those early tests and letters from Josh's medical team to Chimerix, the company that made the drug, had not convinced Chimerix to provide Brincidofovir through a process known as "compassionate use."<sup>4</sup> Compassionate use, also known as expanded access, allows patients who have been approved by the Food and Drug Administration ("FDA") to request that companies provide them with an investigational pharmaceutical product that has not yet been approved for general distribution.<sup>5</sup> On March 6, 2014 Aimee Hardy turned to Facebook and wrote a post seeking anyone who could influence Chimerix to change their mind.<sup>6</sup> In the Internet age, where everything is transmitted almost instantly, movements are often

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1. See Ariana Eunjung Cha, *Crowdsourcing Medical Decisions: Ethicists Worry Josh Hardy Case May Set Bad Precedent*, WASH. POST, Mar. 23, 2014 (reporting on some of the ethical concerns raised by this particular instance of compassionate use). See also Arthur Caplan & Kenneth Moch, *Rescue Me: The Challenge of Compassionate Use in the Social Media Era*, HEALTH AFFAIRS, Aug. 27, 2014 (providing an overview of the specific events surrounding the campaign to get the necessary drug for Josh).

2. See Caplan & Moch, *supra* note 1 (noting that Josh had a deadly infection because of a bone marrow stem cell transplant, which was required because of the various types of cancer he had been battling since he was nine months old, that left his immune system compromised).

3. See David Kroll, *Rescuing Compassionate Use From Social Media and Death Threats*, FORBES, Aug. 27, 2014 (detailing how doctors had already tried the usual "drug of choice," cidofovir, to fight Josh's infection, but repeated use had not improved his condition and was damaging his kidneys).

4. See Caplan & Moch, *supra* note 1 (recounting how St. Jude Children Hospital sent two letters, including one from the Vice President of Clinical Trials Administration, yet both requests were denied).

5. See Alexander Gaffney, *Regulatory Explainer: FDA's Expanded Access (Compassionate Use) Program*, REG. AFFAIRS PROF. SOC'Y (Feb. 4, 2014) (providing a concise overview of the compassionate use program). See also Vicki Brower, *Food and Drug Administration Responds to Pressure for Expanded Drug Access*, 106 J. NAT'L CANCER INST. 1 (2014) (noting that the FDA officially refers to this process as expanded access, and that compassionate use is a colloquial term). For the purposes of this paper, I will use the terms interchangeably.

6. See Caplan & Moch, *supra* note 1.

distilled down to a succinct phrase encapsulated in a hashtag. This was the humble beginning of #SaveJosh.<sup>7</sup>

Over a few days, what started as a plea to friends evolved into a massive campaign with media coverage on every major outlet.<sup>8</sup> Pictures of Josh, first showing him appearing healthy and smiling, often standing outside wearing his favorite baseball hat, were juxtaposed against pictures of him in a hospital bed, connected to tubes, clearly sick.<sup>9</sup> The headlines were damning for the company.<sup>10</sup> CNN reported “Company denies drug to dying child” and included footage of Josh in the hospital.<sup>11</sup> Huffington Post published a blog titled: “A Cancer Drug Could Save This 7-Year-Old, But the Company Behind it Won’t Give Him Access.”<sup>12</sup> It was a situation that resonated with thousands of people who signed online petitions, called the company, and sent letters and emails.<sup>13</sup> On March 12, 120 hours after the initial post, Chimerix announced that they had worked with the FDA to create a new clinical trial for Brincidofovir that would include Josh.<sup>14</sup> Soon after Josh received the medicine, he started to recover.<sup>15</sup> A year later his mom still updates the “SaveJosh” Facebook page, with its nearly 30,000 followers, with pictures of the little boy, not fully healthy, but alive with his loving family.<sup>16</sup>

This is the type of story seemingly everyone can get behind: a compassionless company brought back in line with humanity at the urging

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7. *See id.* (mentioning that Josh’s uncle was the first to use the #SaveJosh tag by creating both a Facebook and a Twitter page the same day that Aimee Hardy posted her request to Facebook).

8. *See* Elizabeth Cohen, *Company Denies Drug to Dying Child*, CNN, Mar. 11, 2014; *see also* Jay Scott, *A Cancer Drug Could Save This 7-Year Old, But the Company Behind It Won’t Give Him Access*, HUFFINGTON POST, Mar. 12, 2014.

9. Cohen, *supra* note 8.

10. *Social Media Shakes FDA’s Power: A Case Study of Compassionate Use*, NAT’L CTR. FOR POL’Y ANAL. (Sept. 2, 2014), <http://healthblog.ncca.org/social-media-shakes-fdas-power-a-case-study-of-compassionate-use/> (stating that Chimerix received “such vilification” that the company was motivated to find a solution to get the drug to Josh).

11. Cohen, *supra* note 8.

12. *See* Scott, *supra* note 8.

13. *See* Cha, *supra* note 1 (detailing how, among the various forms of support people provided for Josh, 20,000 people signed a petition in support of him and even celebrities retweeted the #SaveJosh hashtag). *See also* Caplan & Moch, *supra* note 1 (noting that #SaveJosh twitter feed was amongst the top five national stories on that platform and over one million people had viewed the Facebook page in just four days).

14. *See* Caplan & Moch, *supra* note 1.

15. *See* Marc Dresner, *Social Media “Compassionate Use” Crusade Sets Unsettling Precedent*, P’SHIPS IN CLINICAL TRIALS (Jan. 15, 2015), <http://www.clinicaltrialpartnershipblog.com/2015/01/compassionate-use-social-media-crusade.html> (asserting that the drug saved Josh’s life and that his condition “dramatically improved”).

16. Aimee Hardy, *SaveJosh* (Mar. 12, 2015), <https://www.facebook.com/SaveJoshHardy>.

of thousands of kind strangers motivated only by a sense of justice and desire to help out a family, who in this case, got their happy ending. In fact, after the announcement, Chimerix stock increased nearly fifty percent.<sup>17</sup> As the story faded from the headlines, the casual reader might think that this was a win for all the parties involved.<sup>18</sup> But was it? And even if it was, did this spark a revolution with the potential for serious and unintended consequences?

In this paper, I argue that the story of Josh Hardy and other instances where medicine and new technology collide are emblematic of a revolution in medical decision-making driven by crowdsourcing, direct-to-consumer (“DTC”) products, and apomediation.<sup>19</sup> However, as with most revolutions, these changes come with a cost. Despite the allure of medical breakthroughs and life-saving technology, there are serious risks that have yet to be fully addressed by all of the stakeholders in the medical community.<sup>20</sup> First, research and observation indicates that not every population can access these new technologies, and the breakdown often occurs along traditional divides, such as race and socioeconomic status.<sup>21</sup> The medical, ethical, and legal community must consider issues of social justice in order to ensure that minority groups have the opportunity to participate in and benefit from these changes. Second, the limited availability and high expense of the medical products involved mean that the medical community must deal with the difficulties of allocating finite resources.<sup>22</sup> Third, technology is dramatically altering the nature of doctor-patient relationships, which could impact the quality of care.<sup>23</sup> Finally, researchers and consumers should question the validity and quality of the products that result from new technologies.<sup>24</sup>

Technological advances in medicine, even those with risks associated with them, are unavoidable. I will propose several ways that society can embrace some of the benefits of new technology while addressing the variety of ethical issues raised.<sup>25</sup> In some cases, medicine should be able to harness new technology, like DTC products, to advance research, and ultimately improve the quality of care. In other instances, like crowdsourcing decisions about the allocation of limited resources, the

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17. See Caplan & Moch, *supra* note 1.

18. See Cha, *supra* note 1 (recounting that in the week following the announcement, Chimerix stock was up 29 percent).

19. *Infra* Part II.

20. *Infra* Part III

21. *Infra* Part III.A.

22. *Infra* Part III.B.

23. *Infra* Part III.C.

24. *Infra* Part III.D.

25. *Infra* Part IV.

medical community needs to work together to reject some iterations of new technology that cannot be used in an ethical manner.

## II. THE MODALITIES OF MEDICINE 2.0

To understand Josh Hardy's story and probe its ethical complexities, it is important to understand the technological landscape against which it unfolded. The Internet has existed for decades, but many commentators characterize its current iteration as Web 2.0. Web 2.0 is described as "the new uses of the Internet as a social networking tool as well as a way to create value through mass access and participation."<sup>26</sup> A 2008 study revealed that 53 percent of people surveyed used at least two social media accounts, while another 37 percent used at least one.<sup>27</sup> This can include giant social media platforms like Facebook and Twitter as well as blogs, photo sharing accounts, and many others. A 2013 study by the Pew Research Center determined that 72 percent of American Internet users found general health information online, and that number is expected to continue to grow.<sup>28</sup>

Social media sites have enabled people to harness the power of their networks in a process known as crowdsourcing. Crowdsourcing can take a variety of different shapes but broadly occurs when someone tries to "utilize the power of a distributed group of people to achieve a given result."<sup>29</sup> Companies can utilize this process on a large scale.<sup>30</sup> For example, General Mills has created a variety of ways for customers to provide feedback on its new products, marketing, ingredients, and customer service.<sup>31</sup> Crowdsourcing can also happen on a micro level when friends consult with one another on topics ranging from which restaurant in town is

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26. Terra Stump et al., *The Emergence and Potential Impact of Medicine 2.0 in the Healthcare Industry*, 90 HOSPITAL TOPICS 33 (2012) (recalling how Web 1.0 was designed for information gathering, not interacting with the material).

27. *Id.* at 35.

28. Susannah Fox & Maeve Duggan, *Health Online 2013*, PEW RES. CENTER'S INTERNET & AM. LIFE PROJECT (Jan. 15, 2013), <http://www.pewinternet.org/2013/01/15/health-online-2013/> (sharing that people searched everything from serious medical conditions to minor health ailments).

29. See Jonathan J. Darrow, *Crowdsourcing Clinical Trials*, 98 MINN. L. REV. 805, 824–25 (2014) (describing the ways in which large organizations, such as businesses and governments, have utilized different crowdsourcing techniques).

30. See *id.* at 824 (recalling situations in which prizes have been offered to whoever can find the best solution to a problem or asking for more feedback from any number of parties in the "nebulous" crowd).

31. Jartese, *5 Examples of Companies Innovating With Crowdsourcing*, INNOCENTIVE (Oct. 18, 2013), <http://www.innocentive.com/blog/2013/10/18/5-examples-of-companies-innovating-with-crowdsourcing/> (recounting the General Mills World Innovation Network (G-WIN) where anyone can submit a new idea to the company via the website).

the best to who knows someone with influence at a pharmaceutical company.<sup>32</sup> Social media makes it possible for a user to request feedback on a given topic, parse through the responses, and decide which answers are most helpful, relevant or credible.

Another popular site that runs on crowdsourcing is Change.org.<sup>33</sup> On this website, anyone can start a petition to advocate for a cause they care about and encourage people they know to virtually sign the document.<sup>34</sup> These petitions often get circulated via other social media platforms and have been used to affect change at a variety of organizations, including large companies, government agencies, and small businesses.<sup>35</sup> Several such petitions were started on the behalf of Josh, and the largest of these had nearly 20,000 supporters in less than a week.<sup>36</sup>

Web 2.0 led to Medicine 2.0 and Health 2.0<sup>37</sup>: interchangeable terms coined in 2008 that refer to “web-based services for healthcare consumers, caregivers, patients, health professionals, and biomedical researchers which use the Web 2.0 technologies to enable things such as participation and collaboration among user groups as related to healthcare.”<sup>38</sup> Proponents of Health 2.0 claim that social networking can improve the quality of care by increasing interactions between doctors and patients, while simultaneously reducing health care costs.<sup>39</sup> At its core, Health 2.0 is about active patient participation, which correlates with people discussing and sharing ideas on social media.<sup>40</sup>

Health 2.0 differs from the traditional vision of medicine, which was more paternalistic. In the classic model, people with formal medical training and degrees, including doctors and nurses, were generally the only

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32. See Krissy Brady, *11 Incredible Ways to Crowdfund Your Life*, ECOSALON (Dec. 22, 2014), <http://ecosalon.com/11-incredible-ways-to-crowdfund-your-life/> (listing ways that individuals can utilize crowdsourcing to decrease their commute, find potential dates, decide where to eat, and even diagnosis a personal medical problem).

33. *About*, CHANGE.ORG, <https://www.change.org/about> (last visited Sept. 16, 2015).

34. *Id.*

35. See *Change.org Year in Review: What You Changed in 2014*, CHANGE.ORG (Jan. 13, 2015), <https://www.change.org/year-in-review/2014> (stating that over 5,000 petitions were considered victories, thus achieving the site’s intended effect).

36. Regina Breedlove, *Release Brincidofovir for Compassionate Use to Treat the Adenovirus Plaguing 7-Year Old Josh Hardy Right Now*, CHANGE.ORG, <https://www.change.org/p/chimerix-release-brincidofovir-for-compassionate-use-to-treat-the-adenovirus-plaguing-7-year-old-josh-hardy-right-now> (last visited Sept. 25, 2015).

37. Marjolijn L. Antheunis et al., *Patients’ and Health Professionals’ Use of Social Media in Health Care: Motives, Barriers and Expectations*, 92 PATIENT EDUC. & COUNSELING 426, 427 (2013) (utilizing the terms Medicine 2.0, Health 2.0, and eHealth interchangeably).

38. Stump, *supra* note 26, at 33.

39. See *id.*

40. See *id.* at 34 (observing that social networking has evolved beyond email and chat rooms to “sophisticated virtual networks”).

available sources of medical information.<sup>41</sup> Health 2.0, by contrast, frequently removes the formally trained health care provider from the equation and allows people to gain medical knowledge through direct peer-to-peer connections.<sup>42</sup> With the Internet, not only can people look up almost any medical study, they can also write reviews about their healthcare providers, consult with patients across the globe about their experience with similar symptoms, and read about breakthrough biopharmaceutical and biomedical devices that are improving the quality of life for patients.<sup>43</sup> For example, a recent survey suggests that 35% of adults living in the United States have used the Internet to figure out if they or someone they knew had a specific medical condition.<sup>44</sup> Of those people, just under half then went to a medical provider, armed with medical information from the Internet, and had their diagnosis confirmed.<sup>45</sup> This trend will likely continue to increase in the future.<sup>46</sup>

Some of the social media platforms used in Health 2.0, such as Facebook or Twitter, are familiar to almost anyone with Internet access.<sup>47</sup> These were the first tools used by Josh Hardy's family to raise awareness about his dire circumstances. Healthcare companies, such as hospitals, have made a greater effort in recent years to engage with their current and potential patients using social media.<sup>48</sup> As of 2011, approximately one in six hospitals in the United States used some sort of social media, most

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41. See Sue Hollander & Don Lanier, *The Physician-Patient Relationship in an Electronic Environment: A Regional Snapshot*, 89 BULLETIN MED. LIBRARY ASS'N 397 (2001) (describing how the internet has made medical information available to patients that was previously only accessible by physicians).

42. See Stump, *supra* note 26, at 34–35 (noting that many people learned information about healthcare from the Internet, but only half of those people ever shared that information with their medical provider).

43. See Antheunis, *supra* note 37, at 428 (reporting that the main reasons patients turn to social media for health-related purposes are to increase their knowledge about a health issue, exchange advice, and seek social support). See also Stump, *supra* note 26, at 35–36 (describing the various platforms available for patients and the proliferation of websites tailored to health care practitioners).

44. See Fox & Duggan, *supra* note 28, at 2 (noting that certain groups are more likely to use the Internet this way, including women, young people, white adults, those with advanced degrees, and those living in households earning at least \$75,000 annually).

45. See *id.* (recounting that 41 percent of people had a medical provider confirm their diagnosis while another 2 percent said the doctor partially confirmed the diagnosis).

46. See Antheunis, *supra* note 37, at 430 (recounting how several studies have predicted that the Internet will increasingly impact the healthcare sector).

47. See *id.* at 428 (noting that Twitter and Facebook were the most popular social media platforms for patients to use in a healthcare context, while YouTube and LinkedIn were used far less frequently).

48. See Stump, *supra* note 26, at 35 (reporting that 965 hospitals used social networking as a communication tool in 2011).



commonly Facebook and Twitter, but also YouTube channels and blogs.<sup>49</sup> There are even conferences, such as the annual Social Media in the Pharmaceutical Industry conference held in London, dedicated to how the pharmaceutical industry can better use social media to market their products and engage with customers to promote their business.<sup>50</sup> Other social media platforms are designed entirely for a healthcare purpose.<sup>51</sup> Some social media platforms are geared towards the healthcare industry.<sup>52</sup> For example, Sermo and Doc2Doc are modeled after traditional social media programs but designed specifically for physicians to network with each other, including exchanging information about novel cases or crowdsourcing advice on a challenging patient.<sup>53</sup> Still other platforms are for patients to connect with people with similar conditions, such as PatientsLikeMe, which claims to “make healthcare better for everyone through sharing, support, and research.”<sup>54</sup> Medicine 2.0 can take a variety of forms and the following sections will describe a few of them in greater detail.

#### A. Crowdsourcing and Compassionate Use

Josh Hardy’s story involves the intersection of crowdsourcing and social media in the context of compassionate use. The introduction to this paper demonstrated how Hardy’s family used crowdsourcing to facilitate access to a particular drug and this section will explain the traditional infrastructure of compassionate use. Pharmaceutical companies develop drugs, and the FDA, via the Center for Drug Evaluation and Research, ensures that new drugs are safe and effective before approving them for sale to the public.<sup>55</sup> The approval process requires the company to submit an

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49. *Id.* (noting that 777 hospitals used Facebook, 486 had a YouTube channel, 714 had a Twitter handle, and 120 maintained some kind of blog).

50. *See* Social Media in the Pharmaceutical Industry, SMI GROUP, <https://www.smi-online.co.uk/pharmaceuticals/uk/social-media-in-the-pharmaceutical-industry> (last visited Sept. 18, 2015).

51. *See* Stump, *supra* note 26, at 35 (illustrating how the website PatientsLikeMe.com allows for social networking with a specific health care focus).

52. *See* Antheunis, *supra* note 37, at 430 (revealing how their study data showed that patients and providers use social media for different reasons and gravitate towards different platforms).

53. Matthew O’Donnell, *Top 5 Social Media Sites for Physicians*, HEALTHCAREERS.COM (Feb. 10, 2012), <http://www.healthcareers.com/article/top-5-social-media-sites-for-physicians/168490>.

54. About Us, PATIENTSLIKEME, <https://www.patientslikeme.com/about> (last visited September 23, 2015).

55. *The FDA’s Drug Review Process: Ensuring Drugs Are Safe and Effective*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2014), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm>. *See also* CDER: *The Consumer Watchdog for Safe and Effective Drugs*, U.S. FOOD & DRUG ADMIN. (Aug. 12, 2011), <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143462.htm> (describing how the

Investigational New Drug Application, which the FDA and an Institutional Review Board must review and approve before clinical trials with human subjects can begin.<sup>56</sup> Before the FDA approves the drug, the product will go through three phases of clinical study.<sup>57</sup> The first phase involves studying how the product impacts healthy patients.<sup>58</sup> If no unacceptable dangers are found, the product proceeds to phase two, in which the effectiveness of the drug is tested on patients who actually have the targeted illness.<sup>59</sup> The third phase is an expanded trial with more subjects, ranging from hundreds to several thousand before a final New Drug Application is submitted.<sup>60</sup> Thus, typically, if a patient wants to receive a specific drug that has yet be approved, the only way to do so would be by being selected for a clinical trial.

The compassionate use program was developed in response to a demand from patients who were dealing with terminal or serious illnesses and, often lacking any alternative, wanted access to a particular drug still in a trial phase.<sup>61</sup> Many of these patients were not eligible for ongoing clinical trials for various reasons. For example, a drug may be tested in a clinical trial for one particular type of cancer, and a patient, in conjunction with his physician, may feel that the drug may help treat a different type of cancer not currently being tested.<sup>62</sup> In other instances, a patient may be excluded from a clinical trial because he or she has a variety of medical conditions, and the study needs to isolate the effect of the study drug on a particular illness.<sup>63</sup>

If the patient decides to seek a compassionate use exemption, his or her doctor fills out paperwork that is submitted to the FDA for approval.<sup>64</sup> In recent years, the FDA has received an increasing number of requests,

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center's evaluation process "prevents quackery, but also provides doctors and patients the information they need to use medications wisely").

56. See *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 55.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. See Jonathan J. Darrow et al., *Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs*, 372 N. ENG. J. MED. 279 (2015) (describing the history of the program that arose out of the AIDS epidemic).

62. See Gaffney, *supra* note 5.

63. See Martin Fortin et al., *Randomized Controlled Trials: Do They Have External Validity for Patients with Multiple Comorbidities?* 4 ANNALS FAMILY MED. 104 (2006) (noting that many randomized controlled trials exclude patients with multiple comorbid conditions to increase the internal validity of their findings).

64. See Gaffney, *supra* note 5 (outlining steps taken by the FDA to increase access to the compassionate use program, including a drastic reduction in the amount of paperwork doctors are required to submit).

from 1,000 in 2010 to 1,200 in 2011.<sup>65</sup> The FDA has approved 98% of the individual applications submitted to the agency as of late May 2014.<sup>66</sup> After the FDA approves the expanded access, the company providing the drug can decide if it wants to participate.<sup>67</sup> More broadly, there are four types of expanded access, ranging from single patient to a large patient population, and the company providing the drug chooses which type it is willing to pursue.<sup>68</sup> A company can either create a new clinical trial for a compassionate use patient or amend an ongoing trial to accommodate the new patient.<sup>69</sup> Recent FDA guidance allows companies, in some circumstances, to charge a “reasonable” amount to the patient (or their insurance, though most insurances will not pay for experimental treatment) to cover only the direct cost of manufacturing, shipping, and monitoring of the drug.<sup>70</sup>

The FDA has no legal authority to compel a company to provide a drug even after compassionate use status is granted.<sup>71</sup> The court system has, thus far, decided that patients do not have a constitutional right to experimental treatment.<sup>72</sup> Unless this changes, the final decision to grant or not grant a drug for compassionate use will rest with the pharmaceutical

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65. See Brower, *supra* note 5 (quoting Richard Klein, director of the patient liaison program at FDA’s Office of Special Health Issues).

66. Kroll, *supra* note 3.

67. See Gaffney, *supra* note 5 (noting that although the FDA frequently works with manufacturers to facilitate increased access, the company ultimately has the sole discretion to provide the drug).

68. See *id.* (describing the four types of expanded access which include: (1) Single Patient (Emergency Access), for patients that do not have time to obtain written permission from FDA, (2) Single Patient (Regular Access), which allows one patient to pursue compassionate use, (3) Intermediate Size, which allows for multiple patients to pursue compassionate use, and (4) Treatment, which would allow for widespread use).

69. See *id.*

70. See *id.* (qualifying this compensation scheme by saying that in order to charge, companies must meet a four part test: (1) the drug must exhibit evidence of a clinical benefit; (2) data from the trial is essential to obtaining future approval for it; (3) The trial could no be conducted without charging; (4) The amount being charged is reasonable). See also *Expanded Access: Information for Patients*, U.S. FOOD & DRUG ADMIN. (July 31, 2015), <http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>.

71. See Gaffney, *supra* note 5 (noting that this creates a system where more applicants are approved for compassionate use than are actually receiving the drugs from the companies that own them).

72. See *Abigail Alliance for Better Access to Dev. Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (holding that a college student diagnosed with head and neck cancer did not have a constitutionally protected right to an experimental medication before the FDA had approved the drug for sale). See also Andrea Beth Ott, *At the Altar of Autonomy: The Dangerous Territory of Abigail Alliance v. von Eschenbach*, 56 BUFF. L. REV. 821, 822–23 (2008) (noting that if a constitutional right had been found, there would be a profound impact on science and drug development).

company, resulting in an unpredictable and unfair system of resource allocation.

The story of #SaveJosh that appeared in the media made it difficult to understand why anyone with the power to potentially save a life would withhold a drug from a dying child. The media fueled an image of Chimerix as another giant, unimaginably wealthy pharmaceutical company, like other drug companies that people might be more familiar with, such as Merck or Pfizer.<sup>73</sup> However, Chimerix is a small biopharmaceutical start-up; about fifty-five people worked there at the time that Josh Hardy's family made their plea.<sup>74</sup> Brincidofovir, the drug Josh received, which is still in clinical testing phases today, is not only Chimerix's primary product, but their only product.<sup>75</sup>

Drug development and the accompanying clinical trials are expensive. Some companies may be in a position to provide a drug for free to patients accepted through compassionate use, while others may not.<sup>76</sup> Since companies are only allowed to charge for the cost of manufacturing the drug, many companies may have to bear the costs associated with monitoring the patient after the study concludes, particularly if, as in Josh Hardy's case, the patient is put in a new clinical trial.<sup>77</sup> In addition, the majority of insurance plans do not cover experimental treatment and clinical trials.<sup>78</sup> In denying the initial requests to provide this drug to Josh, Chimerix, which had engaged in compassionate use programs in the past, stated that they had decided to stop granting that type of access so they could focus their limited financial resources on the clinical trials needed to get the drug approved and on the market.<sup>79</sup>

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73. See *Company Denies Drug to 7-Year-Old Boy Struggling Against Curable Virus*, FOX NEWS (Mar. 10, 2014, 9:34 AM), <http://insider.foxnews.com/2014/03/10/drug-maker-chimerix-refuses-release-drug-7-year-old-josh-hardy-struggles-against-curable> (reporting that Chimerix had received \$72 million dollars in federal funds, though neglecting to report other information, financial or otherwise, that would have demonstrated to readers that Chimerix was a small company). See also Kroll, *supra* note 3 (reporting how the issue was framed for the public as "battling an evil pharmaceutical company concerned only about profits").

74. Kroll, *supra* note 3.

75. See *Investor Relations*, CHIMERIX, <http://ir.chimerix.com/> (last visited Feb. 15, 2016) (stating that Brincidofovir is still in phase 3 of clinical trials).

76. See Gaffney, *supra* note 5 (noting that small start-up pharmaceutical companies, like Chimerix, may be particularly concerned with the cost of administering a compassionate use program since they do not have incoming revenue until their product is available for sale).

77. *Id.* (stating that FDA allows companies to charge for compassionate use treatments if they meet the following four criteria: the drug must exhibit evidence of a clinical benefit, data from the trial is essential for future approval, the trial could not be conducted without charging, and the amount being charged is reasonable).

78. See *Expanded Access: Information for Patients*, *supra* note 70.

79. See Caplan, *supra* note 1 (describing how in 2011, Chimerix had received funding from the Health and Human Service's Biomedical Advanced Research and Development Authority and

Of course, as for-profit enterprises, pharmaceutical companies have other economic considerations. There seems to be general industry concern that granting many compassionate use requests, even if done at cost, would hurt future negotiations with insurance providers regarding the cost of the drug when released to the public.<sup>80</sup> CEOs and other pharmaceutical executives are held responsible for profit margins by the shareholders, boards, and other entities they work for.<sup>81</sup> Even from a more practical standpoint, drug companies have to make money on their products because it is incredibly expensive to develop a drug from concept to market.<sup>82</sup> A recent study estimated that the average out-of-pocket cost for a drug that successfully makes it to market is 1.4 billion dollars and rising.<sup>83</sup> That does not even take into account the fact that nearly nine out of ten drugs that start the development process never make it to market, often because they simply do not work or clinical testing uncovers unacceptable safety hazards.<sup>84</sup> Additionally, drug development takes years.<sup>85</sup> Even if a company is not just focused on their bottom line, but truly believes in a mission of improving healthcare for people, it is easy to see under these terms why companies might be hesitant to divert time and financial resources to compassionate use programs that could be put towards getting the product out to a broader market.

There are also the safety concerns related to dispensing a drug at the test phase. Some candidates, particularly those facing eminent death from a

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used that money to provide 215 patients with Brincidofovir for a small pox study; after funding ended in 2012, Chimerix terminated its compassionate use program).

80. See Gaffney, *supra* note 5 (recalling how an FDA official stated that companies feared the “reasonable” price requirement of compassionate use would prevent them from negotiating significantly higher prices with insurance providers once the drug was approved for market).

81. See Cha, *supra* note 1 (noting that as a publicly traded company, Chimerix was particularly vulnerable because their stock fluctuated with the news). See also *Corporations 101: The Role of Corporations and Corporate Governance in Maintaining U.S. Competitiveness*, BUSINESS ROUNDTABLE (July 2008), [http://businessroundtable.org/sites/default/files/Corporations\\_101\\_The\\_Role\\_of\\_Corporations\\_and\\_Corporate\\_Governance.pdf](http://businessroundtable.org/sites/default/files/Corporations_101_The_Role_of_Corporations_and_Corporate_Governance.pdf) (illustrating the intertwined fiduciary relationship between a company’s management, including the CEO, the Board of Directors, and shareholders).

82. See Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds \$2.5B*, SCIENTIFIC AMERICAN (Nov. 24, 2014), <http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/> (calculating the average out-of-pocket cost to develop a new drug at \$1.4 billion dollars and then adding additional costs to represent the returns that investors lose out on during the extensive approval process).

83. See *id.* (estimating the cost at over two billion dollars because they also accounted for the “\$1.2 billion in returns that investors forego on that money during the 10-plus years a drug candidate spends in development”).

84. Michael Hay et al., *Clinical Development Success Rates for Investigational Drugs*, 32 NATURE BIOTECH. 40, 40–51, (2014).

85. *Biopharmaceutical Research & Development: The Process Behind New Medicines*, PHARMA (May 2015), [http://www.phrma.org/sites/default/files/pdf/rd\\_brochure\\_022307.pdf](http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf) (stating that from the earliest stages to market, drug development can take up to ten years).

terminal illness, are willing to risk negative side effects or serious adverse reactions, including the possibility of death, from taking a still unproven drug.<sup>86</sup> While patients may be willing to take the risk, the company is in the position of applying to the FDA for approval of their product, which requires demonstrating that their drug is both effective and safe.<sup>87</sup> Participants in clinical trials are carefully selected and many potential participants are often excluded due to coexisting conditions that could cause the drug to react differently.<sup>88</sup> Companies can also exert a lot of control over how their clinical trials are designed and run; however, when a drug is approved for compassionate use, the company loses some of that control and can be penalized by the FDA if the patient experiences adverse effects, even if that patient was already dying.<sup>89</sup> This concern was recently substantiated when the FDA ordered a drug company to stop enrolling patients in a clinical trial because of an adverse reaction experienced by someone receiving the drug through a compassionate use situation.<sup>90</sup>

Ken Moch was the CEO of Chimerix during the Hardy social media campaign.<sup>91</sup> Very few news outlets reported that in addition to receiving hundreds of letters advocating for Josh, Moch and his employees received death threats.<sup>92</sup> Further, supporters of the campaign posted the personal contact information of Moch and the entire Chimerix Board of Directors online.<sup>93</sup> Moch required a security guard to get to and from work.<sup>94</sup> Officers were placed at the entrances to the office building so that employees could feel safe being at the company, despite the threats.<sup>95</sup> After the Hardy family received Brincidofovir through the clinical trial, they

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86. See Brower, *supra* note 5, at 1 (discussing how the FDA has to balance their job of protecting the safety of patients with the desire of those same patients to take any means necessary to save their lives).

87. See *How Drugs are Developed and Approved*, U.S. FOOD & DRUG ADMIN. (Aug. 18, 2015), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/>.

88. See Alexander Gaffney, *Legislation Seeks to Overhaul FDA's Compassionate Use Program*, REG. AFFAIRS PROF. SOC'Y (Dec. 2014), <http://www.raps.org/Regulatory-Focus/News/2014/12/09/20946/Legislation-Seeks-to-Overhaul-FDA's-Compassionate-Use-Program/>.

89. See *id.* (noting that the FDA can put a trial on a "partial clinical hold," meaning that companies can no longer enroll new patients, or a "clinical hold," which halts all on-going trials completely).

90. See *id.* (describing how CytRx Corporation had a clinical trial placed on partial clinical hold by the FDA after a patient with advanced-stage cancer who was not eligible for any existing clinical trials died after receiving one of their products through compassionate use).

91. See Caplan & Moch, *supra* note 1.

92. Kroll, *supra* note 3.

93. See Caplan & Moch, *supra* note 1.

94. *Id.*

95. David Kroll, *Chimerix CEO Out in Wake of Josh Hardy Compassionate Use Media Frenzy*, FORBES (Apr. 10, 2014, 9:33 AM), <http://onforb.es/Q9ceFB>.

praised Moch for his efforts and collaboration with the FDA.<sup>96</sup> Yet a month later, Moch was fired from Chimerix.<sup>97</sup> Since then, Moch has spoken at conferences and co-authored articles about the issues with compassionate use that often go ignored by the media.<sup>98</sup>

Chimerix had stated that they had stopped allowing compassionate use in 2012 to focus on getting the drug to market, two years prior to receiving the request from Josh Hardy.<sup>99</sup> Moch later shared that Chimerix also lost a major stream of funding at that time, which had supported the company's earlier forays into compassionate use.<sup>100</sup> Moch, a father himself, was not unsympathetic to the struggles of Josh and his family.<sup>101</sup> However, Josh was not the only candidate for compassionate use—in fact, hundreds of patients requested the same expanded access.<sup>102</sup> After funding was unavailable, Moch constantly found himself in the difficult position of having to deny requests, knowing that each denial could lead to someone's death.<sup>103</sup> But if the company were to grant every request, or even some of the requests, it would be difficult to allocate the financial or personnel resources available to proceed with the actual clinical trial.<sup>104</sup> Moch stated he was thinking about the “many Joshes,” which represented everyone who could be helped if the drug was brought to market as fast as possible.<sup>105</sup>

It seems unlikely that the people who simply clicked a button to sign an electronic petition were thinking about the “many Joshes” when they

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96. See Aimee Hardy, *Chimerix Released the Medicine for Josh!*, CARINGBRIDGE (Mar. 13, 2014), <https://www.caringbridge.org/visit/joshuahardy/journal/view/id/5321be78f0ac1f0417d130e7> (updating followers of the #SaveJosh Movement after Josh received Brincidofovir and thanking the Chimerix and FDA for finding a way to help him).

97. *Id.*

98. See Caplan & Moch, *supra* note 1, the most widely circulated article that Moch co-authored.

99. See *id.* (noting that after BARDA funding ended, the company decided to discontinue granting compassionate use requests. It is unclear if the policy was communicated publicly at that time, but all compassionate use requests were denied from that point forward).

100. *Id.*

101. Kroll, *supra* note 95.

102. See Caplan & Moch, *supra* note 1. See also Kroll *supra* note 3 (recounting how Chimerix had provided the drug to 430 patients before funding was canceled and Chimerix stopped granting compassionate use requests).

103. See Cha, *supra* note 1 (noting that after Chimerix stopped granting compassionate use requests, the company received 200 requests that were all rejected, including eighty people who had adenovirus infections like Josh).

104. See Cohen, *supra* note 8 (reporting that Chimerix would have to spend \$50,000 per compassionate use patient in addition to diverting staff to handle the paperwork and other technical aspects required by the FDA for the compassionate use program).

105. See Kroll, *supra* note 95 (“If you make an experimental medicine available to a particular child, how do you not make it available to other children in that developmental process? This was not just about Josh Hardy; it was about the many ‘Joshes.’”).

implored Chimerix to provide the drug.<sup>106</sup> With lopsided media coverage, many did not consider the variety of financial and ethical factors that a company would have to evaluate with each request.<sup>107</sup> Turning down a request from a person with a name, family, and smiling photographs—knowing they will more than likely die—is a brutally difficult ethical dilemma, particularly when the benefit to other potential, unknown patients seems distant.<sup>108</sup> Yet that is exactly the kind of choice Ken Moch faced, and was fired for, at Chimerix. Crowdsourcing is not designed to consider the complexities of compassionate use because it works by making an emotional appeal rather than a balanced consideration of the issues. Yet this ill-suited technology was what ultimately forced the decision to provide the drug to Hardy.<sup>109</sup>

### B. Direct-to-Consumer Research Products

Apple, the highest valued company in American history, recently started releasing health-related products, demonstrating that large companies are willing to invest in DTC medical products.<sup>110</sup> In September of 2014, Apple released a new mobile software application (“app”) called Health on the iOS 8 mobile operating system.<sup>111</sup> Health is an app that aggregates personal biometric data from other healthcare and fitness apps in one easily accessible place.<sup>112</sup> This data might include, for example, information about one’s medications, caloric output during a workout, or blood sugar levels.<sup>113</sup> In 2015, Apple introduced a product called ResearchKit, which is an open source software framework that enables developers and researchers to create apps for medical research, allowing third parties to build on the Health concept.<sup>114</sup> Apple users are able to download these apps, enroll in research studies, and grant researchers

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106. Kroll, *supra* note 3.

107. See *id.* (describing the media’s desire to sensationalize a story like a shark attack, stating that they “smell and taste blood in the water and swarm for the kill”).

108. See *id.* (noting our desire to save a particular child when there is additional, sympathetic identifying information included). See also Caplan, *supra* note 1 (describing a societal bias to save children over elderly people and to help “identified persons over statistical lives”).

109. Caplan, *supra* note 1.

110. Verne Kopytoff, *Apple: The First \$700 Billion Company*, FORTUNE, Feb. 10, 2015. See also Dan Diamond, *Apple’s HealthKit is Finally Here— After Bugs, Botches, and Boatloads of Apple Hype*, FORBES, Sept. 26, 2014 (showing that within the last year and a half Apple has started releasing highly anticipated healthcare related products).

111. *Health*, APPLE, <https://www.apple.com/ios/whats-new/health/> (last visited Apr. 1, 2016). See also Diamond, *supra* note 96.

112. *Id.*

113. *Id.*

114. *Research Kit*, APPLE, <https://www.apple.com/researchkit/> (last visited Apr. 20, 2015).



access to personal data collected through surveys and iPhone sensors.<sup>115</sup> On their website, Apple claims that ResearchKit allows “everybody” to “do their part to advance medical research . . . potentially transforming medicine forever.”<sup>116</sup> This perfectly summarizes the attitude surrounding Medicine 2.0. While people have touted the benefits of creating this kind of access for patients, from Apple’s viewpoint, this is what patients and researchers are morally obligated to do.<sup>117</sup>

Apple is arguably the most well-known company in the DTC market, but there are other companies with products that go beyond mere data entry.<sup>118</sup> Personal genetic testing (“PGT”), allows consumers to purchase test kits, collect DNA samples at home, and send the samples back to the company for genetic sequencing.<sup>119</sup> There are several companies that offer this service for different purposes.<sup>120</sup> Theoretically, these products could be marketed to appeal to people seeking genealogical information about their family or to predict the presence of diseases or traits with genetic components.<sup>121</sup> The services also vary because some offer complete genome-wide scans while others are looking for specific genetic markers associated with specific conditions.<sup>122</sup>

In addition to providing information to the individual consumer, many of these companies also store and use the genetic information that consumers provide for research.<sup>123</sup> Just as there is significant variation in the services offered, the focus and execution of research activities vary. Knome offers complete genomic sequencing but also has an arm of their company that is entirely focused on selling that information to external research companies.<sup>124</sup> Other companies, such as deCODE Genetics, contact users and ask them to participate in internal research the company is

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115. *Id.*

116. *Id.*

117. *Id.*

118. Valerie Gutmann Koch, *PGTandMe: Social Networking-Based Genetic Testing and the Evolving Research Model*, 22 HEALTH MATRIX 33, 34–35 (2012).

119. *Id.* at 35.

120. See *List of Personal Genomics Companies*, INT’L SOC’Y OF GENETIC GENEALOGY, [http://isogg.org/wiki/List\\_of\\_personal\\_genomics\\_companies](http://isogg.org/wiki/List_of_personal_genomics_companies) (last accessed on Apr. 28, 2016) (compiling a list of companies that sell PGT products that provide information on health conditions, genetic traits, or pharmacogenetics).

121. See Koch, *supra* note 118, at 36 (noting that deCODE Genetics offers genealogical services and others such as Navigenics, Pathway Genomics, and Interleukin Genetics focus on detecting specific traits. Some companies, such as 23andMe, offer both.).

122. See *id.* (describing a product called Knome that does a full genome scan).

123. *Id.*

124. *Id.* at 37 (describing KnomeDiscovery, a service that helps external researchers design and execute research projects centered on genetic data).

conducting on specific diseases.<sup>125</sup> There is also a social media aspect to some of the services, where users can choose to share the results of their testing with other people on sites created by the companies and form communities based on their genetic make-up.<sup>126</sup>

PGT companies describe their investigative actions as the “democratization of research,” which foreshadows the next section’s discussion of apomediation and is reminiscent of the discussion of crowdsourcing in the previous section.<sup>127</sup> These sites allow users to join together to advocate for certain diseases to be studied over others, allowing the companies to crowdsource their research agendas by surveying the potential pool of research participants.<sup>128</sup> Users can also share their genetic information, and often do so without the oversight of the traditional medical infrastructure of doctors and clinical researchers.

Several sites have already reported success with early PGT-based studies, suggesting the potential to advance medical research and direct the course of the medical field overall.<sup>129</sup> In 2010, 23andMe researchers published the first report using genome-wide association studies (“GWAS”) in the reputable publication *Genetics*.<sup>130</sup> GWAS use genetic information collected through the company’s test kits coupled with the users’ self-report of the presence of observable traits.<sup>131</sup>

One issue that PGT companies can meaningfully address is the perpetual difficulty of finding participants to enroll in research studies. By allowing users to select the area of study that they would like to see investigated, researchers are more likely to have subjects who are eager to participate, eliminating delays in research that frequently occur because of under-enrollment.<sup>132</sup> Alternatively, if PGT companies collect and sell data, they have a large database of genetic information that can immediately be mined for particular research projects, eliminating the need to find new

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125. *See id.* at 38 (reporting that deCODE Genetics has already been able to conduct studies that involve more than 10,000 people with the same disease through its website).

126. *See id.* at 40 (highlighting 23andME which has a password protected website allowing users to participate in groups with people that share similar genetic traits, for the purpose of either fostering new genealogical connections or providing support for people who are at a higher risk of particular negative health outcomes).

127. Koch, *supra* note 118, at 35.

128. *See id.* at 42 (describing how 23andMe markets a product called Research Revolution, where everyone who buys a testing kit gets to vote on which common diseases the company should study).

129. *Id.* at 43.

130. *Id.*

131. *Id.* at 43–44 (noting that publication of the article was delayed as the editors considered the new ethical issues this type of research presents).

132. *Id.* at 35.

subjects for each new study.<sup>133</sup> This may also facilitate the replication of study findings, as the data set could be made available to multiple researchers. Services that send kits to patients' homes may also expand the potential data pool and increase the diversity of study participants.<sup>134</sup> PGT companies may also benefit from long-term cost-savings in two ways. First, the participants are already paying the company for the kit used to generate information for potential research use, thus negating the expense typically shouldered by researchers to pay for participant recruitment.<sup>135</sup> Second, money would be saved by reducing the time and cost associated with recruiting participants.<sup>136</sup>

### C. Apomediation

Another variation of social media technology intersecting with medicine is the concept of apomediation.<sup>137</sup> Earlier iterations of medicine were about hierarchal relationships between providers and patients, with the traditional medical establishment controlling and dispensing information to a passive recipient.<sup>138</sup> These vertical relationships might take the form of doctors conveying information to patients who do not have the knowledge base to challenge or participate in the process, or researchers designing trials where the subjects participate without input into the overall design.<sup>139</sup> Apomediation is when the middleman, often the FDA or a doctor, is either removed completely from the health care decision-making process, or given a diminished role.<sup>140</sup> In contrast to traditional medicine, "apomediation is

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133. Koch, *supra* note 118.

134. *Id.* at 35. See also Press Release, *Apple Introduces ResearchKit, Giving Medical Researchers the Tools to Revolutionize Medical Studies*, APPLE (Mar. 9, 2015), <http://www.apple.com/pr/library/2015/03/09Apple-Introduces-ResearchKit-Giving-Medical-Researchers-the-Tools-to-Revolutionize-Medical-Studies.html> (noting that the participant pool can be greatly expanded by allowing people to contribute data collected on their phone rather than requiring people to travel to a research institution).

135. *But see* Koch, *supra* note 118, at 41 (noting that to encourage users to provide information for specific studies already in progress, 23andMe provided all of their services for free). See also *id.* at 43 (noting that 23andMe's Research Revolution line was ultimately discontinued because it failed to make a profit but that the company's research efforts continue by allowing people to purchase the test kit and opt to allow their information to be used for research).

136. See *Recruit*, BIONEWS SERVICES, <http://bionewsservices.com/2015/02/13/recruit/> (last accessed on Apr. 28, 2016) (acknowledging that 32 percent of total clinical trial costs are incurred during participant recruitment and that on average, clinical trials run 25 percent over their deadline because of recruitment issues).

137. Dan O'Connor, *The Apomediated World: Regulating Research When Social Media Has Changed Research*, 41 J. LAW MED. & ETHICS 470, 471 (2013).

138. See *id.* at 471 (discussing how the hierarchical system created an unequal balance of power between patients and providers).

139. *Id.* (defining the traditional doctor patient relationship as "intermediation," noting that the patient and doctor are on different levels in the hierarchical framework).

140. *Id.*

envisioned as a more horizontal, peer-to-peer style of information exchange in which no single apomediary is essential to the process.”<sup>141</sup> Apomediation is what social media platforms and crowdsourcing allow patients to do together and has allowed patients to have more leverage in their relationships with medical professionals and researchers, if they rely on those relationships at all.<sup>142</sup>

In the medical context, apomediation primarily occurs in the research sector, when patients have the opportunity to organize their own studies.<sup>143</sup> This can range from collaborations between patient representatives and researchers to almost completely patient-driven projects. For example, when Emory University School of Medicine planned a trial studying different epilepsy drugs, the patient representative, Brandy Parker-McFadden, who has epilepsy, made some key suggestions that altered the design of the study to better reflect patient needs.<sup>144</sup> Patient representatives, who work with traditional researchers to develop goals and protocols for studies, are becoming an increasingly common part of research teams.<sup>145</sup> This increase has been driven in large part by a non-profit called the Patient-Centered Outcomes Research Institute (“PCORI”), which Congress created as part of the Affordable Health Care Act.<sup>146</sup> While the researchers still bring medical and scientific expertise to the process, the patient representative embodies the horizontal role central to the concept of apomediation.<sup>147</sup> PCORI funds a variety of medical research projects, contingent upon keeping patients involved in the design of the projects.<sup>148</sup> Susan Sheriden, Director of Patient Engagement at PCORI, stated that the

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141. *Id.* at 471 (noting that the term *apomediaries* comes from the Latin word *apo*, meaning “to stand by” or “next to”).

142. *See id.* at 472 (highlighting the direct relationship between the growth of online social networking and crowdsourcing in healthcare).

143. This is true because patients can research medical conditions without the assistance of doctor, but cannot completely remove the “middle-man” from the process because they still rely on doctors to prescribe most medications. *See* Gary Stern, *Self-Diagnosing: On the Proper Role of Sites Like WebMD*, THE ATLANTIC, Oct. 5, 2012 (describing how patients have used websites like WebMD to better prepare for interactions with a physician).

144. *See* Amy Dockser Marcus, *Design Power: Patients Play Researchers in Drug Trials*, THE WALL STREET JOURNAL, Sept. 29, 2014 (describing Parker-McFadden’s initial concerns that she was not viewed as an equal on the committee designing the epilepsy study, but eventually played a significant role in the development of the research).

145. *See id.* (acknowledging that some researchers are hesitant to include patients in the trial design process, then providing several examples of studies that involved patients at this stage).

146. *See id.* (explaining that all trials that receive funds from PCORI must include patients in the design process); *See also About Us*, THE PATIENT-CENTERED OUTCOMES RES. INSTIT. (Oct. 6, 2014), <http://www.pcori.org/about-us>.

147. *See* O’Connor, *supra* note 137 (defining apomediation as centered on peer-to-peer horizontal relationships, or in this case patient-to-patient).

148. *What We Do*, THE PATIENT-CENTERED OUTCOMES RES. INSTIT. (Sept. 10, 2014), <http://www.pcori.org/content/what-we-do>.

purpose of fostering such participation is primarily to make sure that medical research is grounded in reality by being relevant to the applicable patient community.<sup>149</sup> The drawback to this approach is that by having more people critique and develop trial protocols, the process may take longer.<sup>150</sup> However, by creating PCORI, the U.S. government has made a strong statement that this type of participation is favorable despite potentially slowing down the research process.

The FDA has also gotten involved by collecting patient-reported outcomes (“PRO”); instead of collecting information observed by researchers, the agency gathers information directly from patients about their experiences, symptoms, or characteristics.<sup>151</sup> The PRO Task Force at PCORI has defined a broader category of patient-generated data as “health-related data—including health history, symptoms, biometric data, treatment history, lifestyle choices and other information—created, recorded, gathered or inferred by or from patients or their designs (i.e., care partners or those who assist them) to help address a health concern.”<sup>152</sup> This definition incorporates the idea that the type of data generated by patients may vary widely, from concrete numbers to open-response type prose.<sup>153</sup> This type of research still requires professionals to determine how to incorporate this information into their work and is further limited by the lack of consistency and quality of this type of data.<sup>154</sup> The whole purpose of emphasizing this type of data collection is to have patients participate more in the research process and to have their needs shape the course of research.

Finally, there have been recent incidents where medical research has radically departed from traditional methodology to pursue a completely apomediated approach. In 2011, *Nature Biotechnology* published a study about the effects of using lithium on patients with ALS based on PRO data.<sup>155</sup> What makes this study particularly novel is that it was conceptualized, run, and supported entirely by the ALS patients themselves; professional researchers were only brought in during the final stage to

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149. Marcus, *supra* note 144.

150. See Lynn Howie et al., *Assessing the Value of Patient-Generated Data to Comparative Effectiveness Research*, 33 HEALTH AFFAIRS 1220 (2014) (reiterating that research, particularly regarding treatments, can take over a decade to conduct).

151. See *id.* at 1221 (noting that often the data provided are not truly outcomes but rather descriptions of experiences).

152. *Id.* at 1222.

153. *Id.*

154. See *id.* at 1225 (describing the subjectivity of patients that can be difficult to account for, such as the variation of patients describing their pain on a scale of one to ten).

155. See Paul Wicks et al., *Accelerated Clinical Discovery Using Self-Reported Patient Data Collected Online and a Patient-Matching Algorithm*, 29 NATURE BIOTECH. 411 (2011) (describing the instrumentality of PatientsLikeMe to the study).

analyze the results.<sup>156</sup> One patient with ALS suggested on a website, PatientsLikeMe, that other patients with ALS should track their experiences taking lithium to treat their condition.<sup>157</sup> Other users participated, added their own suggestions, and recruited other people with ALS to participate as well.<sup>158</sup> This is true apomediation, in the sense that the people suggesting, designing, and conducting the study were all also participants; thus, the middle-man has been almost entirely removed. This was heralded by the media as a new era of medical research, particularly because, like DTC research products, this could address the lack of enrollment in studies.<sup>159</sup> If patients rely on each other to design the most relevant studies and encourage each other to participate in them via their social networks, they could advance research faster than traditional modalities.

### III. THE ETHICAL ISSUES OF MEDICINE 2.0

Crowdsourcing compassionate use, DTC research products, and apomediation all deliver potential new means for the advancement of medicine by making medicine more accessible to the average patient, speeding up cumbersome processes, and allowing patients to have a greater stake in setting the field's priorities. However, there are a multitude of ethical issues that have yet to be sufficiently addressed. Despite society's unyielding demand for innovation, it is imperative that ethicists and other stakeholders consider the drawbacks of these new modalities before fully committing to regularly employing them.

#### A. Social Justice

The most glaring problem with crowdsourcing compassionate use is that there are obvious social justice issues. Josh and his family were not the first, and will not be the last, to use social media to gain this type of access. Before them, other individuals like Nick Auden, Darlene Grant, Andrea Sloan, and Jack Fowler's family all used social media, with varying success, to compel companies to provide their products for compassionate use.<sup>160</sup> Since Josh Hardy, others including Mikaela Knapp, have

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156. See O'Connor, *supra* note 137, at 472 (detailing how the patients collected their information in an online spreadsheet that was then shared with researchers).

157. See Wicks et al., *supra* note 155 (noting the medical community's skepticism regarding the anecdotal reports that drove the patients to create their own study).

158. See O'Connor *supra* note 137, at 472.

159. See *id.*

160. See Claire Martin, *Nick Auden, Who Lobbied to Use Experimental Skin Cancer Drug, Has Died*, THE DENVER POST (Nov. 29, 2013), [http://www.denverpost.com/breakingnews/ci\\_24625182/nick-auden-who-lobbied-use-experimental-skin-cancer](http://www.denverpost.com/breakingnews/ci_24625182/nick-auden-who-lobbied-use-experimental-skin-cancer) (reporting on the death of Auden, who did not receive a drug via

followed.<sup>161</sup> These are all cases that have garnered mainstream media attention, and the individuals (or their families) have attempted to capitalize on crowdsourcing to put pressure on pharmaceutical companies of various sizes. Remember that hundreds of people request compassionate use exemptions from the FDA each year, but only some garner significant attention on social media.<sup>162</sup> Looking at these cases in the aggregate, some interesting trends appear.

The most apparent trait is that every person in these social media campaigns appears to be white.<sup>163</sup> There do not appear to be any statistics available relating to the race of people who have requested compassionate use through the FDA or actually received drugs in this method. From the social media aspect, Facebook is also unable to provide concrete data on the ethnic breakdown of their users because that is not information that is included in a user's online profile.<sup>164</sup> However, data engineers at Facebook have been able to provide estimates based on a statistical analysis of

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compassionate use, despite getting half a million people to sign his Change.org petition); *See also Darlene Grant, Mom Dying of Cancer, Inspires Drug Maker to Release Trial Drug Pertuzumab Via YouTube Video*, THE HUFFINGTON POST (May 1, 2012), [http://www.huffingtonpost.com/2012/05/01/darlene-grant-mom-dying-cancer-video-genentech\\_n\\_1465938.html](http://www.huffingtonpost.com/2012/05/01/darlene-grant-mom-dying-cancer-video-genentech_n_1465938.html) (recounting how a mother posted her plea for a drug via compassionate use to the website YouTube); *See also Darlene Grant, My Cancer Story*, CANCER AVENUE, <http://www.canceravenues.com/darlenes-corner/my-cancer-story> (recalling a patient's first person account of using social media to gain access to a drug via compassionate use). *See also Tracy Jan, Hopes of Family, Firm Collide on Unproven Drug*, THE BOSTON GLOBE (Jan. 31, 2014), <http://www.bostonglobe.com/news/nation/2014/01/31/family-quest-for-experimental-drug-underscores-dilemmas-for-patients-drug-companies/2BFtW16dPf6RHOSphehcgL/story.html> (explaining the ethical tensions that underscored a meeting between a family seeking compassionate use and the pharmaceutical company that was not willing to provide the drug); *See also William Hudson, In Cancer Drug Battle, Both Sides Appeal to Ethics*, CNN (Sept. 28, 2013) (describing the case of Andrew Sloan who was using social media to try to compel a company to provide a drug to help her survive ovarian cancer).

161. *See* David Kroll, *Husband Seeks Compassionate Use of Anti-PD-1 Drug For Young Wife With Rare Kidney Cancer*, FORBES (Mar. 26, 2014) (acknowledging that the couple seeking the drug contacted him specifically to gain exposure to their need because he had previously reported on the Josh Hardy case).

162. *See* Kroll, *supra* note 3 (cautioning his readers to remember that "in hospitals around the country- or at home for those without intensive care access- thousands of faceless and nameless people suffer from similar infections sometimes without computers or Internet access, most without the PR savvy to mount a similar campaign." *See also* Gaffney, *supra* note 5 (stating that in 2012 over 1,200 patients participated in the FDA's compassionate use campaign. Less than a dozen people have had large scale compassionate use campaigns on social media judging by media coverage of the topic, *supra* note 140).

163. *See* Kroll, *supra* note 161 (reporting on various people who have lunched public campaigns for compassionate use, all of whom appear to be white).

164. Mary Ellen Slayter, *Facebook Finds a Way to Predict Your Ethnicity*, SMARTBLOG (Aug. 2, 2010), <http://smartblogs.com/social-media/2010/08/02/facebook-finds-a-way-to-predict-your-ethnicity/>.

people's names.<sup>165</sup> Their report suggests that Caucasian and Asian/Pacific Islanders originally dominated Facebook, though the site has become increasingly diverse in recent years.<sup>166</sup> The study also notes that Facebook users are more likely to communicate and interact with people of their own race.<sup>167</sup> Thus, if Facebook users are sharing stories or circulating online petitions, they may be more likely to see and engage with the story if the user is someone of their own race.

Additionally, the mainstream media plays a significant part in which stories go “viral” by reporting on them and thus increasing their popularity. However the media also struggles with social justice issues.<sup>168</sup> This has been written about in other contexts, but not applied to the compassionate use issue. For example, there has been discussion in academia about how the race of a missing child impacts the amount of media coverage the story receives.<sup>169</sup> Critics have called this phenomenon “Missing White Girl Syndrome,” observing that the media portrays missing white children as innocent victims and missing children of color, if they even cover the story at all, as culpable quasi-victims.<sup>170</sup> There are many possible explanations for why this disparity in coverage exists. Washington Post columnist Eugene Robinson called the ideal character for this type of story a “damsel in distress” and described the archetype this way:

A damsel must be white. This requirement is nonnegotiable. It helps if her frame is of dimensions that breathless cable television reporters can credibly describe as “petite,” and it also helps if she's the kind of woman who wouldn't really mind being called “petite,” a woman with a good deal of princess in her personality. She must be attractive — also nonnegotiable. Her economic status should be middle class or higher, but an exception can be

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165. *Id.*

166. *Id.* (qualifying that the researchers only analyzed the social media activity of the four largest ethnic groups in the U.S., Caucasians, African-Americans, Asian/Pacific Islanders, and Hispanics).

167. *Id.*

168. See Lisa Wade, *Racial Bias and How the Media Perpetuates It With Coverage of Violent Crime*, PACIFIC STANDARD (Apr. 17, 2015), <http://www.psmag.com/books-and-culture/racial-bias-and-how-the-media-perpetuates-it-with-coverage-of-violent-crime> (noting that 51 percent of people arrested for violent crimes occurring in NYC are black but that 75 percent of the media reports that cover violent crime in the same area report on black perpetrators).

169. See *Missing White Girl Syndrome*, JOURNALISM CTR. ON CHILDREN & FAMILIES, <http://journalismcenter.org/when-a-child-dies/missing-white-girl.html> (last visited Apr. 20, 2016) (noting that 42 percent of missing children are black, but the media coverage is so inadequate that there is a separate alert system for missing children of color).

170. *Id.*



made in the case of wartime . . . Put all this together, and you get 24-7 coverage.<sup>171</sup>

Both commentators and journalists admit that there is a racial hierarchy in the way that crimes and other news stories are reported.<sup>172</sup> It is often attributed to the fact that media viewers and the people creating the news find people of the same race more relatable.<sup>173</sup> Racial minorities are underrepresented in journalism jobs; 32 percent of the population is non-white or Hispanic, while only 22 percent of television reporters and 13 percent of newspaper journalists identify as non-white or Hispanic.<sup>174</sup> Collectively, this helps explain why popular social media stories about compassionate use, propelled by the traditional media, portray exclusively white people. Instead of being a case of “Missing White Girl Syndrome,” compassionate use stories are subject to “Dying White Person Syndrome.”

While gender seems to be less of a factor in which stories gain traction in the public consciousness, family status is critical. In almost every news story about compassionate use, the person who needed the drug could be sorted into one of two categories: either the child of a loving family or a parent of a loving family.<sup>175</sup> Though it has not been discussed in a compassionate use context, these stories may be appealing because these candidates seem more deserving of aid.<sup>176</sup> The news stories emphasize this angle, almost always including pictures of the patient surrounded by his or her family.<sup>177</sup> The patients themselves, at least the adult ones, use this angle

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171. Eugene Robinson, Op-Ed., *(White) Women We Love*, WASH. POST, June 10, 2005, <http://www.washingtonpost.com/wp-dyn/content/article/2005/06/09/AR2005060901729.html> (responding to the intense media coverage of the disappearance of Natalie Holloway in Aruba).

172. See Tara McKelvey, *Cleveland Abductions: Do White Victims Get More Attention?*, BBC NEWS (May 9, 2013), <http://www.bbc.com/news/magazine-22441124> (noting that 80 percent of the coverage of missing children is devoted to non-African American children).

173. *Id.*

174. *Missing White Girl Syndrome*, *supra* note 169 (quoting Maynard as saying that journalists have a “tendency to consciously or unconsciously cover communities that remind them of their own”).

175. See Kroll, *supra* note 161 (recounting various news stories that often lead with the family angle of the story).

176. See Govind Persad et al., *Principles for Allocation of Scarce Medical Interventions*, 373 THE LANCET 423, 425–26 (detailing the variety of ethical considerations that could be used to allocate finite medical resources like vaccines or organs). The article says one method could be allocating based on “social value,” which prioritizes “specific individuals to enable them to promote other important values, or rewards them for having promoted these values.” The article cautions that actually implementing a social values based method of allocation is not ethically advisable because of the variety of legitimate views on what is socially valuable. However, the article notes that at one point in time Seattle had a dialysis policy that, among other categories, favored parents. While the article demonstrates that this is a policy that should be rejected, it shows that this type of bias for parents and families is common. *Id.*

177. See e.g. Jan, *supra* note 160 (showing then-six-year-old Jack Fowler surrounded by his family in the midst of his battle to gain compassionate use access).

to attract sympathy in their outreach efforts on social media. Nick Auden garnered 500,000 signatures on a Change.org petition for his compassionate use request and started a website called “Save Locky’s Dad.”<sup>178</sup> On the website, seven-year-old Lachlan “Locky” Auden, the eldest of Nick’s three children, was featured in a linked YouTube video explaining how much he loved his father and asking people to support their social media campaign to get a medication via compassionate use.<sup>179</sup> Similarly, many media stories about Darlene Gant, a woman dying of breast cancer, conspicuously included the fact that she was also a mother either in the headline or in the first paragraph of the report.<sup>180</sup>

Out of all the adults mentioned above, only Mikaela Knapp was not a mother or a child; nonetheless, the media coverage in her case emphasized her potential to be a mother.<sup>181</sup> The headline about her in Forbes highlighted that her husband led the compassionate use campaign for his “young wife.”<sup>182</sup> By emphasizing her age (twenty-five) and marital status (she married her high school sweetheart), there was an unspoken assumption that had she not been stricken by this disease, Knapp would have been a mother one day. The reader actually has no knowledge of the Knapp’s plans for children, but the story seems deliberately written to stir up those ideas. Young children like Jack Fowler and Josh Hardy fall in a separate, tragic-yet-engrossing category of patients saddled with the burden of deadly diseases at heartbreaking and unfairly young ages.<sup>183</sup>

The final factor that unites many of these individuals is affluence. There are two types of affluence at work here: the traditional monetary type and the social capital type.<sup>184</sup> Social capital is the “collective value of all ‘social networks’ [who people know] and the inclinations that arise from these networks to do things for each other [‘norms of reciprocity’].”<sup>185</sup>

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178. See Merck & Bristol-Myers Squibb: *Save Locky’s Dad: Provide Nick Auden access to the PD1 drug on a compassionate basis*, CHANGE.ORG, <https://www.change.org/p/merck-bristol-myers-squibb-save-locky-s-dad-provide-nick-auden-access-to-the-pd1-drug-on-a-compassionate-basis> (last accessed on Apr. 28, 2016) (collecting 525,739 signatures in support of Auden’s cause). See also SAVE LOCKY’S DAD, <http://www.savelockysdad.com/> (last accessed on Apr. 28, 2016).

179. *Save Locky’s Dad*, YOUTUBE, (Aug. 28, 2013), <https://youtu.be/3teA62o5eLY>.

180. Mikaela Conley, *After YouTube Plea, Dying Mom Clears Hurdles to Start Trial Drug Pertuzumab Friday*, ABC NEWS (Apr. 26, 2012), <http://abcnews.go.com/Health/youtube-plea-dying-mom-clears-hurdles-start-trial/story?id=16224371>.

181. See Kroll, *supra* note 161.

182. *Id.*

183. See Persad et al., *supra* note 176, at 425 (suggesting that another way to think about allocating medical resources is to give them to younger people, because saving their lives at a young age would create the maximum benefit).

184. *About Social Capital*, HARVARD KENNEDY SCHOOL: THE SAGUARO SEMINAR, <http://www.hks.harvard.edu/programs/saguaro/about-social-capital> (last visited Sept. 23, 2015).

185. *Id.*

Many studies suggest that there is some degree of racial inequity in social capital as well.<sup>186</sup> Some of the aforementioned compassionate use seekers have financial affluence; for example, Nick Auden's website describes him as a successful businessman.<sup>187</sup> Auden also had the resources to design an entire website for his cause, including a well-produced YouTube video.<sup>188</sup> Regardless of their actual socioeconomic status, all of the parties were able to leverage their social capital to help boost their social media presence and traditional media coverage. Josh Hardy had the support of a lawyer to help lobby media outlets to carry his story.<sup>189</sup> Before her cancer diagnosis, Mikaela Knapp had a career in public relations, and many of her former colleagues helped leverage their social capital, including connections to journalists, to spread her story.<sup>190</sup>

Social justice concerns are also raised by DTC medical research products and apomediation because there is less control over who uses the products to contribute to medical research. First, to take advantage of products like applications developed with Apple ResearchKit, users have to be able to afford the compatible Apple equipment, such as an iPhone.<sup>191</sup> Because the types of people that utilize these apps to participate in studies are likely to be more affluent, the resulting research may not be generalizable to more diverse populations.<sup>192</sup> Similarly, this holds true for any company that uses data generated from PGT kits that consumers purchase. These items are not covered by medical insurance and are a luxury item that large segments of the population cannot afford.<sup>193</sup> For

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186. Rodney E. Hero, *Social Capital and Racial Inequality in America*, 1 PERSP. ON POLITICS 113, 113–22 (2003).

187. *Save Locky's Dad*, SAVE LOCKY'S DAD (March 2014), <http://www.savelockysdad.com/>.

188. *Id.*

189. See Richard Plotkin, *Live or Let Die: Who Makes the Hard Decisions*, MAX CURE FOUND., <https://maxcurefoundation.org/liveorletdie/> (last visited Sept. 23, 2015) (detailing retired trial lawyer Richard Plotkin's successful attempt to secure the necessary drug for Josh Hardy). It is interesting to note that after that event, Plotkin has joined with Chimerix supervisor Moch to advocate for a better system to handle this type of resource allocation, in part because Plotkin had to turn down a number of other families requesting his help after his national public success working on behalf of the Hardy family and realized there was no obvious way to choose who to help and who to turn away. *Id.*

190. See Kroll, *supra* note 161.

191. See *Buy iPhone 6*, APPLE, <http://www.apple.com/shop/buy-iphone/iphone6> (last accessed on Apr. 28, 2016) (selling the current version of the iPhone for \$549 or \$649 for the iPhone 6 Plus version, which has a slightly larger screen).

192. See Brandon Bailey, *Software Turns Smartphones Into Tools For Medical Research*, AP (July 27, 2015), <http://bigstory.ap.org/article/1a59a2e8e6e1478697c1fdabeacf7a04/software-turns-smartphones-tools-medical-research> (noting that iPhone users tend to be more affluent, therefore studies conducted via this medium might not "accurately mirror" the larger population).

193. See Jim Edwards, *Still Don't Believe Android Is For the Poor? This Chart Proves It*, BUSINESS INSIDER (Aug. 15, 2014) <http://www.businessinsider.com/android-iphone-market-share-by-price-2014-8> (arguing that Android phones are generally bought by people with lower

example, 23andMe sells their test kit for ninety-nine dollars.<sup>194</sup> This kit is marketed as a product that helps people determine their genetic ancestry and then allows consumers to indicate if they are willing to have their results also used for research purposes.<sup>195</sup>

Similarly, patients who are using apomediation to design research studies run the risk of creating participant pools that lack diversity. By recruiting via word of mouth, patients rely on their social networks to attract patients to their studies. While this could address the problem of chronically slow enrollment in research studies, it also creates problems because the majority of people do not have diverse networks of friends.<sup>196</sup> A 2013 survey of social media habits revealed that 75 percent of white Americans have entirely white social networks.<sup>197</sup> The figures are similar, though not as drastic for people of other racial backgrounds. For example, 65 percent of black Americans report having exclusively black friend groups.<sup>198</sup> With the reality that many Americans have segregated networks, relying so heavily on referring friends could lead to heavily skewed results that do not account for the actual diversity of the patient population.

Even websites such as PatientsLikeMe acknowledge bias in their data sets.<sup>199</sup> They note that their users are slightly younger, more likely to be female, and are better educated than the general population.<sup>200</sup> PatientsLikeMe has taken steps to try to account for these differences by over-sampling patients who self-identify with underrepresented demographics.<sup>201</sup> Still, researchers and scientists should be working to actively recruit and assist patients who are less educated, older, and more racially diverse while employing new technology in the research sphere.

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incomes because of their significantly lower price point and that Apple's iPhone is geared toward the upper end of the market).

194. 23ANDME, [www.23andMe.com](http://www.23andMe.com) (last visited Apr. 1, 2016).

195. *Id.*

196. See Daniel Cox et al., *Analysis: Race and Americans' Social Networks*, PUB. RELIGION RES. INSTITUTE, <http://publicreligion.org/research/2014/08/analysis-social-network> (last visited Sept. 24, 2015) (reporting on the social homogeneity of social networks based on self-report).

197. *Id.*

198. *Id.* (observing also that 46 percent of Hispanic Americans have entirely homogenous social networks).

199. *Isn't Your Data Biased?*, PATIENTSLIKEME HELP CENTER, <https://support.patientslikeme.com/hc/en-us/articles/202224430-Isn-t-your-data-biased> (last visited Sept. 25, 2015).

200. *Id.* (comparing PatientsLikeMe populations to databases such as organ transplant registries, insurance claims data, and specialist centers focused on particular diseases).

201. *Id.*

*B. Resource Allocation and Access Issues*

Ken Moch, the CEO of Chimerix described his concerns with the Josh Hardy situation in terms of resource allocation.<sup>202</sup> As he put it, he was concerned not just about Josh, but the “many Joshes”: all of the patients who were not famous but who suffered from similar conditions and would benefit from his company’s product if it got approval for widespread sale.<sup>203</sup> Difficult decisions about resource allocation are made more challenging by adding an emotional layer to the appeal.<sup>204</sup> It is easier to make a decision about who lives and who dies when just considering figures and data on a sheet of paper, rather than connecting with patients on a personal level. In the realm of soliciting donations to charity, academics have called this the “identifiable victim” phenomenon.<sup>205</sup> When faced with a prospective candidate, people can often be swayed to make irrational choices if given relatable and identifiable information.<sup>206</sup> However, when those irrational choices impact the allocation of a finite resource, this can lead to particularly unfair results, in light of the social justice concerns described above.<sup>207</sup> There is a utilitarian argument in forgoing compassionate use altogether in order to maximize the positive impact of getting the drug to market quickly. Since compassionate use campaigns divert resources from the main study, they can severely slow down the research needed to get the drug to the broadest range of beneficiaries.<sup>208</sup> Yet, over the last few decades, people have demanded a compassionate use option so a balance must be found with addressing the needs of very ill patients who advocate for themselves and the needs of present and future patients who cannot advocate for themselves.

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202. Caplan & Moch, *supra* note 1.

203. *Id.*

204. See *To Increase Charitable Donations, Appeal to the Heart — Not The Head*, WHARTON SCH. OF BUS. AT THE UNIV. OF PA. (June 27, 2007), <http://knowledge.wharton.upenn.edu/article/to-increase-charitable-donations-appeal-to-the-heart-not-the-head/> (reporting that charities often make emotional appeals, particularly by describing in detail one particular recipient to make the problem more relatable to potential donors).

205. See *id.* (detailing the difference between the identifiable victim and what the study called the *statistical victim*: one or a group only known by their numerical or data characteristics).

206. See Deborah A. Small et al., *Sympathy and Callousness: The Impact of Deliberative Thought on Donations to Identifiable and Statistical Victims*, 102 ORGANIZATIONAL BEHAVIOR & HUMAN DECISION PROCESS 143 (2007) (arguing that people do not “value lives consistently” when making charitable donations).

207. See *id.* (suggesting that collectively society would benefit from distributing resources more rationally by donating money to the places it would have the largest impact).

208. *Cf.* Caplan & Moch, *supra* note 1 (arguing that smaller companies are particularly ill-positioned to meet the demands of a compassionate use program and still maintain regular operations).

### C. Deterioration of the Doctor Patient Relationship

Both DTC products and apomediation threaten the doctor-patient relationship. This special relationship is built on trust and has been described as the “keystone of care” because the primary means by which a doctor provides care is through talking to and observing the patient while communicating medical information to them.<sup>209</sup> Patients who are directly engaged with their providers have better care outcomes and are more satisfied with their healthcare experience.<sup>210</sup> Despite all of the well-documented benefits of a strong doctor-patient relationship, apomediation and DTC products do not typically involve doctors, or at most, involve them peripherally.<sup>211</sup> For example, DTC products take traditional medical or genetic testing and allow people to conduct those tests on themselves.<sup>212</sup> While this may give users more autonomy, it essentially denies them the benefit of an expert interpreting all of the resulting data, unless they take the extra step of bringing their purchased data to a medical professional.<sup>213</sup> In particular, supplying genetic tests without the support of a medical professional raises concerns because these tests are rarely entirely conclusive and may not always be accurate.<sup>214</sup> Rather, genetic sequencing can reveal some information about the statistical likelihood of developing a certain condition—subject to interpretation.<sup>215</sup> Many genetic conditions are the result of a variety of genetic factors and that might not be clear to a

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209. See Susan Dorr Goold & Mark Lipkin, Jr., *The Doctor-Patient Relationship: Challenges, Opportunities, and Strategies*, 12 J. GEN INTERN MED. S26 (1999) (listing different responsibilities of the relationship, such as diagnosing the patients, ensuring compliance with treatments, engaging and healing the patient, and providing support).

210. See *id.* (observing that a successful doctor-patient relationship also increases provider satisfaction and prevents burn-out).

211. See Misti Crane, *Dispatch Special Report: Bypassing Doctors*, THE COLUMBUS DISPATCH (Dec. 11, 2012, 6:17 AM), <http://www.dispatch.com/content/stories/local/2012/12/11/bypassing-doctors.html> (recounting that, at the time the article was published, there were twenty companies offering genetic testing without physician involvement).

212. *Id.*

213. See *id.* (suggesting that without experts to interpret the data, people “can be misled, scared or given false reassurances that prompt them to make bad decisions,” though some companies also offer access to genetic counselors).

214. See *id.* (recalling one patient, who saw ultimately saw a doctor after a 23andMe genetic test indicated he was at higher risk for esophageal cancer, found out that risk was based on a study conducted on a small population in China that was not applicable to a Caucasian male living in Ohio). See also Dina F. Maron, *What Rare Disorder Is Hiding In Your DNA?*, SCIENTIFIC AMERICAN (Jan. 1, 2015), <http://www.scientificamerican.com/article/what-rare-disorder-is-hiding-in-your-dna/> (noting that genetic tests are not always conclusive).

215. See Maron, *supra* note 214 (reporting that in 2013, the American College of Medical Genetic and Genomics suggested that results should be returned from fifty-six genes tested by comprehensive tests because there was enough information that particular mutations associated with those genes “met a standard of relatively high likelihood of being disease-causing”).

consumer based on the information they receive from an at-home test kit.<sup>216</sup> Further, many of these results could merit follow-up with a medical provider but users may feel unsure of which doctor to go to with questions, if they choose to seek one out at all.<sup>217</sup> These DTC products could be helpful if patients use them to have a dialogue with the provider, but are potentially dangerous if people rely exclusively on these for-profit tests to glean important medical information about themselves. Doctors are legally and ethically required to always act in consideration of the patient's best interest and well-being. A for-profit company and its executives have a fiduciary duty to investors or shareholders and their primary responsibility is to make money. This is not conducive to helping patients sort through complex medical information or make important health care decisions.

#### *D. Jeopardizing the Quality of Science*

Concerns abound regarding the quality of the medical research produced by these new products and procedures. Crowdsourcing compassionate use decisions can impact the quality of science because recipients may not fit into the strict criteria of studies approved by the FDA, yet the FDA will still consider how the drug impacts these patients when deciding to approve additional or continuing research.<sup>218</sup> Based on the urgency of the compassionate use patients that need a particular drug, pharmaceutical companies are forced to temporarily suspend many of the hallmarks of reputable scientific process.<sup>219</sup> These patients are not a part of double-blind studies with placebos and control groups, nor are they carefully selected based on the narrow criteria that allow scientists to accurately evaluate the drug's efficacy.<sup>220</sup> Recipients of compassionate use are typically already dying, so if they receive the drug and die anyway, it is nearly impossible to determine what role the drug played in that event.<sup>221</sup>

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216. See Rachael Rettner, *23andMe: What's Really Wrong with Personal Genetic Tests*, LIVESCIENCE (Nov. 26, 2013, 1:55 PM), <http://www.livescience.com/41534-23andme-direct-to-consumer-genetic-test-shortcomings.html> (observing that many factors, including genetic markers not tested by kits like 23andMe, contribute to the development of any single disease).

217. See *id.* (noting that companies like 23andMe offer to connect patients to genetic counselors, but it unclear how many follow-up on that offer).

218. See Gaffney, *supra* note 5 (noting that an incident that occurs with a patient in a compassionate use program could cause the FDA to prevent the product from reaching the market).

219. See *id.* (suggesting that companies might not want to participate in compassionate use because it would mean "letting products out of tightly controlled and heavily monitored environments, potentially subjecting the product to incorrect use and previously unknown adverse events").

220. *Id.*

221. See *id.* (noting that to be eligible for the program, patients must have serious or immediately life-threatening diseases).

Compassionate use cases are not quality research, yet the FDA considers the outcomes in these cases when determining if trials should continue.<sup>222</sup> Even if they do not ultimately impact the quality of research performed, they slow down the process significantly and prevent promising new drugs from reaching the market sooner.<sup>223</sup>

In the last few years, the FDA has increasingly scrutinized PGT companies over concerns that the products that they sell do not produce accurate scientific results.<sup>224</sup> The increased pressure has caused many companies to stop marketing their DNA sequencing tests to the public.<sup>225</sup> While these types of companies may have a legitimate interest in attempting to further medical innovation, they are still at their core for-profit businesses and are vulnerable to similar financial pressures as pharmaceutical companies. Financial concerns often create a conflict with the pursuit of quality scientific work and may lead companies to make false claims about the capabilities of their products in order to sell a few more units.<sup>226</sup>

23andMe is one of these direct-to-consumer PGT businesses that has a long history of struggling with the FDA.<sup>227</sup> The company started negotiating with the agency in 2009 and continued for years before the talks deteriorated in 2013.<sup>228</sup> 23andMe stopped participating in the talks while simultaneously launching a national ad campaign with the goal of having one million users purchase their ninety-nine dollar test kit.<sup>229</sup> 23andMe produced a commercial that heralded the tests supposed ability to tell users hundreds of things about their health, but the FDA intervened and issued a warning letter demanding that 23andMe stop airing the ad until their genetic testing had been proven to actually provide accurate information regarding consumers health.<sup>230</sup> The FDA also expressed concerns that the test could

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222. *Id.*

223. *Id.*

224. See Andrew Pollack, *FDA Orders Genetic Testing Firm to Stop Selling DNA Analysis Service*, N.Y. TIMES, Nov. 25, 2013 (reporting on a letter the FDA sent to one company ordering them to halt public sales of their genetic testing kit).

225. *Id.*

226. See Kira Lerner, *23andMe Faces Suit Over Recently Banned DNA Tests*, LAW360 (Jan. 22, 2014), <http://www.law360.com/articles/502855/23andme-faces-suit-over-recently-banned-dna-tests> (describing a lawsuit alleging that 23andMe embellished their product's capabilities to increase sales).

227. George J. Annas & Sherman Elias, *23andMe and the FDA*, 370 NEW ENG. J. MED. 985, 985–88 (2014).

228. *Id.* at 985.

229. *Id.*

230. See Warning Letter from Alberto Gutierrez, Director of the Office of In Vitro Diagnostics and Radiological Health at the Center for Devices and Radiological Health, U.S. Food & Drug Admin., to Ann Wojcicki, CEO of 23andMe, Inc. (Nov. 22, 2013),



lead users to take drastic action regarding potential health concerns, which, given that the test kit was not validated, could be particularly dangerous to patients.<sup>231</sup> As a result of the warning letter, 23andMe stopped marketing their test kit as a health product, and marketed the product only on its ability to provide users information about their genealogy and their raw genetic data.<sup>232</sup> 23andMe was no longer able to provide customers with interpretive information about their genetic data, including health risks, drug responses, and inherited conditions.<sup>233</sup>

Apomediation may also compromise the quality of science by failing to utilize all of the safeguards developed over time to protect patients. The ALS study run by users on PatientsLikeMe was not subject to any of the usual research requirements such as submitting plans to an Institutional Review Board to ensure that subjects are not at risk.<sup>234</sup> IRB requirements have developed out of necessity because in the past doctors have taken advantage of these special relationships and performed inappropriate tests on unknowing patients.<sup>235</sup> Though this could still occur today, it would be more difficult for a doctor to escape notice because of the amount of requirements that must be adhered to before conducting research, particularly on human subjects.<sup>236</sup>

Especially since the 1970s, when the Belmont Report was published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the medical and ethical communities have attempted to hold their members to certain standards of practice and provide avenues to hold them legally accountable when those principles are

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<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm376296.htm> (exuding obvious frustration with the company for not fully responding to FDA requests).

231. *See id.* (noting that the risk of a false positive is that patients will begin to pursue a variety of potentially invasive screening and prevention methods for a particular disease that are “morbidly-inducing actions” and that a false negative could provide users with a false sense of security that would prevent them from seeking potentially life-saving early intervention measures).

232. *See FDA Update: December 5th, 23ANDME* (Dec. 5, 2013), <https://customercare.23andme.com/hc/en-us/articles/202908030-FDA-Update-December-5th> (offering customers who purchased the kit in the time between the FDA’s letter and this announcement a full refund as they could no longer provide the services that had been advertised).

233. *Id.*

234. *See O’Connor, supra* note 137, at 473 (stating that an IRB was not required because it was conducted without receiving any federal funding).

235. *See* Margaret R. Moon & Felic Khin-Maung-Gyi, *The History and Role of Institutional Review Boards*, 11 *VIRTUAL MENTOR*, 311 (2009) (recalling historical horrors such as the Tuskegee Syphilis Study or the Willowbrook study of hepatitis in intellectually disabled children, both examples of studies conducted without the patients’ knowledge or consent which ultimately prompted regulation on research in the United States).

236. *See Ethical Guidelines & Regulations, NAT’L INSTS. OF HEALTH, RESEARCH INVOLVING HUMAN SUBJECTS* (Feb. 5, 2016), <https://humansubjects.nih.gov/ethical-guidelines-regulations>, (noting that in addition to ethical guidelines, both the Department of Health and Human Services and the FDA have regulations designed to protect human research subjects).

violated.<sup>237</sup> Patient groups are not required to submit their research designs to anyone.<sup>238</sup> If someone in the PatientsLikeMe ALS research had gotten hurt because of the study, they would have no clearly identifiable avenue of recourse.<sup>239</sup> Individual people operating without oversight do not have to provide informed consent agreements, or to explain how they intend to use the collected data.<sup>240</sup> They could also, intentionally or unintentionally, mislead patients into participating in something that is either dangerous or promises benefits that cannot be substantiated.<sup>241</sup> Good science protects the consumer, and supporters of apomediation have not satisfactorily addressed the lack of oversight inherent in a process without traditional medical infrastructure. Supporters have suggested that patients who participate in apomediated studies are more willing to undergo greater risk because they are more likely to personally gain from the results.<sup>242</sup> However, there still might be people who are willing to take advantage of that willingness and convince others to engage in a harmful study or practice, under the guise of advancing science.<sup>243</sup> Dangerous research without certain procedures to minimize risk should be viewed critically.

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237. See NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RES., THE BELMONT REPORT 1-7 (1979) (articulating the guiding principles for human subjects research, which include respect for persons, beneficence, and justice).

238. O'Connor, *supra* note 137.

239. See Lauren Solbert, *Regulating Human Subjects Research in the Information Age: Data Mining on Social Networking Sites*, 39 N. KY. L. REV. 327, 354 (noting that it is unclear how federal law covers entities like PatientsLikeMe where users have very different expectations than those engaging in traditional research and accept more risk when they join the site).

240. See O'Connor, *supra* note 137 (stating that studies formed by individual patients, with no connection to federal funding sources, operate outside of the boundaries Common Rule, which requires informed consent). See also *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (Mar. 18, 2016), <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> (explaining that the Common Rule outlines provisions for IRBs and informed consent).

241. See Jef Akst, *Do-It-Yourself-Medicine*, THE SCIENTIST (Mar. 1, 2013), <http://www.the-scientist.com/?articles.view/articleNo/34433/title/Do-It-Yourself-Medicine/> (noting that many ALS patients joined the PatientsLikeMe study because of promising results from a study using lithium in Italy, but even though lithium is approved for other uses in the U.S., the drug could interact in different, unforeseen ways with this patient population and actually harm them).

242. See *id.* (quoting Richard Bedlack, director of the Duke University ALS Clinic, who while discussing this new form of what he calls DIY research programs, stated "I don't think anybody has more to gain or lose from all than patients").

243. See Colleen C. Denny & Christine Grady, *Clinical Research With Economically Disadvantaged Populations*, 33 J. MED. ETHICS 382, 383 (2007) (recounting how economically disadvantaged patients may be so desperate for the potential benefits of a study, such as access to medical treatments or free healthcare, that they will ignore risks and participate in the study no matter what, leading to questions about the ethics of that research).

## IV. ADDRESSING THE PROBLEMS

## A. Crowdsourcing

There is no fair and ethical way that crowdsourcing can be used in the compassionate use context. Crowdsourcing the decision about which musical artist should get a record deal and other lighthearted popular culture decisions may work, but the same technique should not be applied to an ethically complex and technical medical decision. While giving power to the people is generally a commendable action, at some points the general population is not in the best position to determine who gets a valuable, finite resource. Since the news coverage of Joshua Hardy's request for compassionate use was so skewed, it is reasonable to suggest that the average person who signed an online petition or sent an email did not know all of the factors Chimerix had to balance. If many members of the general population do not take the time to become informed voters in a presidential election campaign held once every four years, it is both unreasonable and unrealistic to think the same population could ever be informed about the small, yet critical, details that are associated with the hundreds of people that request compassionate use.<sup>244</sup> The FDA should prohibit companies from considering such campaigns when making decisions and provide an alternative structure.

The FDA cannot simply instruct pharmaceutical companies to ignore crowdsourced compassionate use campaigns because the companies could still be influenced by their shareholders and stock prices; therefore, a new structure needs to be established. One solution is to create a new organization, be it a government agency or a private entity, to review and allocate compassionate use resources.<sup>245</sup> This entity should be funded by each pharmaceutical company, which would contribute money based on the size of their business and the number of their clinical trials under review by the FDA.<sup>246</sup> For example, Merck and other behemoths of the pharmaceutical industry should contribute a greater amount of funds than a small start-up like Chimerix. Companies should factor this into the cost of bringing a drug to market. The money would be used to not only staff this entity but to support the cost of actually providing a drug for compassionate

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244. See Steve Chapman, *Mixing Ignorance and Democracy: Can Our System Work with Uninformed Voters?*, CHICAGO TRIBUNE, Apr. 19, 2012 (lamenting the fact that most voters will not make the effort to learn even the most basic facts of most candidates running for election).

245. See Caplan & Moch, *supra* note 1 (suggesting that an organization independent of pharmaceutical companies needs to be created, but not suggesting whether such an entity should be a government undertaking something unaffiliated with the federal government).

246. *But see id.* (suggesting that the public, presumably through government taxes, might fund compassionate use since the people are demanding such a program).

use, thus eliminating the need for companies to divert additional resources from clinical trials. The entity would then have the responsibility for reviewing all compassionate use requests and not just approving them, like the FDA currently does, but also allocating the resources. The entity—and not the pharmaceutical company—would then be in the position of making the difficult decision of denying a requested drug. This entity and pharmaceutical companies would work together to determine how many patients could feasibly receive a given drug at any stage of development. This model would share some similarities with the way organ donations, another finite medical resource, are allocated.<sup>247</sup> There are only two ethically appropriate ways for the general population to be more broadly involved in the compassionate use context. First, crowdsourcing could be translated into crowdfunding to help bolster the compassionate use program.<sup>248</sup> Second, crowdsourcing could be used to help find the necessary patients to fill studies quickly and get the drugs to mass market faster.<sup>249</sup>

### B. Direct-to-Consumer

In February 2015, the FDA announced that they would authorize 23andMe to market a product that would inform healthy adults if they possessed a genetic variant that would increase their odds of their children having Bloom Syndrome.<sup>250</sup> More broadly, the FDA also stated their intent to exempt all carrier screening test devices from premarket review by the

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247. See *Organ Allocation*, UNITED NETWORK FOR ORGAN SHARING, [http://www.unos.org/donation/index.php?topic=organ\\_allocation](http://www.unos.org/donation/index.php?topic=organ_allocation) (last visited Sept. 25, 2015) (describing how UNOS prioritizes patients for organ donations by considering a variety of factors including match and recipient urgency, geography, and how long a recipient had been waiting. UNOS does not factor in “celebrity status.”).

248. See Gaffney, *supra* note 5 (attributing part of pharmaceutical companies’ hesitancy in participating in compassionate use to the financial burdens of fulfilling requests).

249. See *E-Recruiting: Using Digital Platforms, Social Media, and Mobile Technologies to Improve Clinical Trial Enrollment*, INVENTIVE HEALTH (Oct. 14, 2013), [http://www.inventivehealth.com/docs/e-Recruiting\\_Using\\_Digital\\_Platforms\\_Social\\_Media\\_and\\_Mobile\\_Technologies\\_to\\_Improve\\_Clinical\\_Trial\\_Enrollment.pdf](http://www.inventivehealth.com/docs/e-Recruiting_Using_Digital_Platforms_Social_Media_and_Mobile_Technologies_to_Improve_Clinical_Trial_Enrollment.pdf) (advising pharmaceutical companies to identify key opinion leaders, such as bloggers who could support trial participation, or post in patient-led online community groups to boost trial enrollment).

250. *FDA Permits Marketing of First Direct-To-Consumer Genetic Carrier Test for Bloom Syndrome*, U.S. FOOD & DRUG ADMIN. (Feb. 19, 2015), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm435003.htm>; See also *Bloom Syndrome*, U.S. NAT’L LIBR. OF MED.: GENETICS HOME REFERENCE (Apr. 2015), <http://ghr.nlm.nih.gov/condition/bloom-syndrome> (describing Bloom syndrome as a genetic disorder marked by “short stature, sun-sensitive skin changes, an increased risk of cancer, and other health problems”).

agency, pending a thirty-day period for public comment.<sup>251</sup> This represents a compromise between the FDA, which is responsible for ensuring that consumers get accurate information from healthcare products, and companies like 23andMe that advocate for broader, if not total, consumer access to genetic information.<sup>252</sup> To secure this approval, 23andMe went through a rigorous process to ensure the accuracy of this specific test, its replicability across a wide number of laboratories, and the intelligibility of the accompanying literature provided to consumers.<sup>253</sup> 23andMe does not intend to market their test for Bloom Syndrome yet, instead choosing to wait until they have completed the “regulatory process” for additional carrier tests so that they can market a more comprehensive testing package.<sup>254</sup>

Commentators observe that this is a small step that is likely to lead to future acceptance of broader availability of genetic sequencing.<sup>255</sup> 23andMe and the FDA have laid the framework for safely marketing these products in the future. However, there is still a large difference between providing a test that screens for a few specific carrier genes and marketing a product that provides a complete genetic sequence. Ultimately, users should have access to their genetic information if they desire it, just like patients have a right to their medical records and other test results generated by doctors.<sup>256</sup> Attempts to address this issue must take into consideration consumer autonomy.<sup>257</sup> However, we have agencies such as the FDA in order to protect consumers from companies, because consumers are often unable to question the effectiveness of a product or understand all of the

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251. *See id.* (stating that such action created “the least burdensome regulatory path for autosomal recessive carrier screening tests with similar uses to enter the market”).

252. *See* David Kroll, *FDA Approves 23andMe Gene Carrier Test*, FORBES (Feb. 19, 2015), <http://www.forbes.com/sites/davidkroll/2015/02/19/fda-okays-23andmes-direct-to-consumer-gene-carrier-testing-starting-with-bloom-syndrome/>.

253. *23andMe Granted Authorization by FDA to Market First Direct-to-Consumer Genetic Test Under Regulatory Pathway for Novel Devices*, 23ANDME (Feb. 19, 2015), <http://www.pnewswire.com/news-releases/23andme-granted-authorization-by-fda-to-market-first-direct-to-consumer-genetic-test-under-regulatory-pathway-for-novel-devices-300038925.html>.

254. *Id.*

255. *See* Kroll, *supra* note 252 (observing that “choosing autosomal recessive gene traits for exemption from premarketing approval gives the FDA more time to discern how they will manage direct-to-consumer gene testing where the results have short- or long-term impact on the person being tested”).

256. *See* Abena Yeboa, *What Is the Future For Genetic Testing and Personalized Medicine*, PENN PROGRAM ON REG. (Feb. 6, 2014), <http://www.regblog.org/2014/02/06/06-yeboa-personalized-medicine/> (noting that this is an area of considerable debate).

257. *See id.* (noting that consumers want full access to genetic testing services but still wanted some protection in the form of government oversight).

science a device, test, or drug employs.<sup>258</sup> The biggest concern is making sure that users understand the information that they receive, particularly if it indicates that they are at risk for a genetic condition.

There are three possible ways the DTC market could develop. First, companies could be given free rein to sell their products to consumers. While this gives users the most autonomy to access their genetic information, it is also the most likely to lead to the lowest quality science. This approach seems unlikely given that the FDA has already gotten so involved with the issue. The second and more restrictive way would be to retreat from the DTC approach and have these products available through licensed professionals only, such as doctors or genetic counselors.<sup>259</sup> While some tests that are available to consumers at home, such as a pregnancy test, the vast majority of medical screening is still done in the traditional healthcare setting.<sup>260</sup> This theoretically ensures that patients have professional interpretation of their results. However, market demand and regulatory trends indicate that backtracking in this direction is also unrealistic.<sup>261</sup> As the FDA has already started to demonstrate, the ethical approach moving forward should be somewhere in between these two extremes. When the FDA approved 23andMe's at home test for Bloom's Syndrome, they required the labeling to explain what the results of the test might mean for users.<sup>262</sup> Further, if these products were sold over the counter, the FDA would also require the company to inform consumers

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258. See *How Can Consumers Be Sure a Genetic Test is Valid and Useful?*, GENETICS HOME REFERENCE: U.S. NAT'L LIBRARY OF MED. (Apr. 26, 2016), <https://ghr.nlm.nih.gov/primer/testing/validtest> (noting that patients might have a difficult time determining the quality of at home genetic testing, particularly if the company providing the test are not certified under federal laboratory standards).

259. See *About Genetic Counselors*, NAT'L SOC'Y OF GENETIC COUNSELORS, <http://nsgc.org/p/cm/ld/fid=175> (last visited Apr. 24, 2015) (noting that genetic counselors have specialized graduate degrees that they use interpret genetic data both from tests and family histories).

260. See *Home Use Tests*, U.S. FOOD & DRUG ADMIN. (June 5, 2014) <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/HomeUseTests/>, (cataloging the ten types of currently approved home-use diagnostic tests, including tests for pregnancy, ovulation, and HIV). See also Mary K. Caffrey, *FDA Moves to Regulate Thousands of Diagnostic Tests*, AM. J. MANAGED CARE (Aug. 25, 2014), <http://www.ajmc.com/journals/evidence-based-oncology/2014/august-2014/fda-moves-to-regulate-thousands-of-diagnostic-tests> (noting that there are thousands of diagnostic tests).

261. See *Testing for HIV*, U.S. FOOD & DRUG ADMIN. (Aug. 8, 2013), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/HIVHomeTestKits/ucm126460.htm> (describing the availability of FDA approved test-kits that allow users to test for HIV at home, which shows that the direct-to-consumer market is expanding to include diagnostic tests for serious conditions).

262. *FDA Permits Marketing of First Direct-To-Consumer Genetic Carrier Test for Bloom Syndrome*, *supra* note 250 (noting that some people might be better served by tests, but that the agency would not limit who should or should not use the test).

about professionals—in this case, a board-certified clinical molecular geneticist or equivalent—that could provide pre- and post-test counseling.<sup>263</sup> This type of counseling was already suggested by some of the companies that produce PGT products, but had never been prominently advertised.<sup>264</sup> Having this counseling advertised in conjunction with the marketing of the product is critical. Because it seems these companies are driven by collecting profitable banks of genetic data rather than by providing individual patients the data they need to make better health care decisions, counseling has thus far been an afterthought.

The FDA should also be closely monitoring the informed consent documents associated with both using these products for testing and, separately, allowing genetic information to be stored in a data bank and used or sold for future research. One possibility would be to have users provide a general consent for future research studies, but notify them of new uses periodically and allow them to remove their information if they no longer wish to participate.<sup>265</sup> The burden should be on the companies to maintain contact about the latest studies, not forcing consumers to seek out that information. Companies should maintain information on their websites about all of the studies that are currently in progress using data collected from their products. Another idea would be to limit private companies' ability to wholesale databanks of genetic information to third parties. Rather than having a private buyer just buy a database, researchers and other companies should be required to have a specific proposal for how they intend to use the data and a legal obligation to refrain from using the information for other purposes. The selling company should also have to provide information about third party studies to consumers as well, along with the pertinent contact information to the third party if the individual

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263. See *id.* (implying that the burden is on consumers to decide if they want to follow-up on their results with a professional).

264. See *23andMe Carrier Status Tests: What You Should Know*, 23ANDME, <https://www.23andme.com/carrierstatus-fda/> (last accessed on Apr. 29, 2016) (recommending that patients contact the National Society of Genetic Counselors to find a professional near them that can help them decide if certain genetic testing for carrier traits is “right for” the patient). This information is available by clicking a link labeled “Important Info: Carrier Status Reports” on the main purchasing page for the company, though the purchasing page itself does not mention genetic counseling. *Id.*

265. See David R. Karp, et al., *Ethical and Practical Issues Associated with Aggregating Databases*, PLOS MED (Sept. 23, 2008), <http://dx.doi.org/10.1371/journal.pmed.0050190> (offering alternative ways to navigate the ethical concerns of informed consent for research when data is collected and the future uses are unknown, including the possibility of providing future updates regarding findings). The proposals suggested in this paper call for a much greater degree of specificity and a greater burden on the company collecting data to provide information about potential studies on an ongoing basis. Karp acknowledges that one cannot truly give informed consent to unspecified actions that might occur in the future, and since informed consent is a cornerstone of research ethics, this paper argues that more specific steps are necessary.

wishes to withdraw their information because of the nature of a particular study.

Finally, even if they are not legally required to, companies should work harder to increase the diversity of the population using their products. Whether through donations, grants, or other fundraising mechanisms, companies should actively strive to make sure their products are used by people from varied racial, ethnic, and socioeconomic backgrounds. This could mean getting test kits into public health departments, or partnering with local non-profits to create a distribution program for low-cost smartphones preloaded with data collection apps.

### C. Apomediation

Since apomediation is not under the purview of the traditional regulations that oversee research and protect participants, the responsibility falls to the publisher of studies to ensure that the data collected meets the same quality standards that would be required of traditional research. Further, if researchers worked more in conjunction with patients, as envisioned by the Affordable Care Act, the scientific and medical community could gain the benefits of apomediation without the potential for poorly conducted science.<sup>266</sup> Patients should be able to suggest what illnesses and conditions should be researched and researchers should be reaching out to patients groups to develop hypotheses based on the experiences, concerns, and suggestions of the patients. This is where social media and even DTC products could be extremely valuable. Using products like Apple's ResearchKit will give researchers more insight into the daily experiences of people suffering from a variety of conditions and should influence the course of future study.<sup>267</sup> Rather than full apomediation, the goal should not be to remove the traditional intermediary, but rather to include the patient in the conversation in an equal capacity with doctors, researchers, and other professionals. While researchers can certainly learn more from their patients, the professionals contribute a level of technical

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266. 111 P.L. 148, 124 Stat. 119.

267. See, e.g., Ian Paul, *Stanford's ResearchKit App Gained More Users in 24 Hours Than Most Medical Studies Find in a Year*, MACWORLD (Mar. 12, 2015), <http://www.macworld.com/article/2895941/stanfords-researchkit-app-gained-more-users-in-24-hours-than-most-medical-studies-find-in-a-year.html> (recounting how over 11,000 people signed up to participate in a Stanford study about heart health on the first day, a feat that would normally take researchers about a year to accomplish). See also Caitlin McGarry, *ResearchKit at 6 Months: 100,000 People Now Using Medical Apps*, MACWORLD (Oct. 15, 2015), <http://www.macworld.com/article/2993838/ios/researchkit-at-6-months-100-000-people-now-using-medical-apps.html> (demonstrating that patients have been very interested in using the apps, new apps, studying conditions such as autism, melanoma, and epilepsy were recently released, and while still a new product, researchers are optimistic about the products ability to impact science).



expertise and objectivity that patients themselves may lack. Additionally, by including professionals who are subject to a variety of oversight, from licensing boards to federal agencies, there is some avenue of recourse if these professionals do not meet legal and ethical standards. Medical research has an unfortunate history of abuse and apomediated research could be just as dangerous without any of the safeguards that have been developed for traditional medicine.

#### V. CONCLUSION

There has always been tension between pursuing medical innovation and developing laws and policies that ensure breaking developments stay within ethical bounds. In that regard, Medicine 2.0 is no different from its early predecessors. While modern technology has allowed for many important advancements, it also demands further scrutiny to determine if every new product or concept is actually something that improves health outcomes and patient experiences. New technology can be so appealing that it may distract users from unaddressed ethical issues. Rather than just allowing these new technologies to grow unchecked, it is important to question innovation and find ways to incorporate new technologies into our societal norms and ethical expectations.