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## The Use of Race in Medical Artificial Intelligence

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# The Use of Race in Medical Artificial Intelligence

Priya Desai\*

## I. INTRODUCTION

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Recently, the use of medical algorithms and machine learning (ML) in health care has flourished as the collection of mass health data has become more normalized. Also called “black-box medicine,” the use of artificial intelligence (AI) in medicine has led to medical innovation and efficiency. The goal of this technology is to improve the health care system and people’s health overall by helping to identify risk and allocate resources. But at what cost? A critical issue hidden behind medical AI is the use of race in these algorithms. While society’s understanding of race has advanced significantly over time, such understanding has not led to coherent guidance on the use of race in medicine.<sup>1</sup> One of several ways in which race is becoming embedded into medical AI involves diagnostic algorithms that “correct” their outputs based on a patient’s race or ethnicity.<sup>2</sup> Additionally, inserting race into the data that trains these algorithms promotes race-based medicine.<sup>3</sup>

In this Note, I will first examine the process by which medical algorithms and AI are created and how they work. Next, I will explain the use of race in medical algorithms. I will focus primarily on the problems that arise when using race in medical AI. Furthermore, I will advocate for policy considerations deterring the use of race as a proxy for other social determinants of health in medical algorithms. Alternative factors such as socioeconomic status, geographic area, education, and other social determinants of health should be taken into consideration when training medical AI. Lastly, I will describe the current regulatory landscape for medical AI and conclude by advocating for legislation and regulations that may help to alleviate racial bias in medical AI.

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<sup>1</sup> Darshali A. Vyas et al., *Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms*, 383 NEW ENG. J. OF MED. 874, 874 (2020).

<sup>2</sup> *Id.*

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

## II. BACKGROUND

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### A. *What is Medical AI?*

While AI has been defined in several ways, broadly, AI is the “science and engineering of making intelligent machines, especially intelligent computer programs.”<sup>4</sup> Within the field of AI, ML encompasses the creation of algorithms to learn, recognize patterns, and follow data.<sup>5</sup> With respect to their design, algorithms can be “locked” or can continuously learn and adjust with the addition of new data in order to optimize their real-time effectiveness.<sup>6</sup>

Medical AI is one example of evidence-based medicine, which involves the use of past data to support clinical decision-making.<sup>7</sup> Traditionally, statistical methods have accomplished this feat by describing patterns within data as mathematical equations like a line of best fit; however, ML enables us to bring light to complex associations that cannot be represented as equations.<sup>8</sup> For instance, neural networks, a form of ML, portray data through an abundance of interconnected neurons, similar to the human brain.<sup>9</sup> Thus, ML systems can approach problem-solving and decision-making in the same way that a clinician would—by attentively considering evidence to reach informed decisions.<sup>10</sup> However, in contrast to an individual clinician, neural networks can simultaneously examine and quickly process an almost infinite amount of inputs.<sup>11</sup> In addition, these machines can learn from each additional case in a cumulative manner. Thus, they can come in contact with more cases than a clinician could see in their lifetime, in a matter of minutes.<sup>12</sup> It is worth noting that medical algorithms, as a decision support tool, existed before they incorporated AI. Medical algorithms are much more powerful and can incorporate more data and ML with the addition of AI.

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<sup>4</sup> Timo Minssen et al., *Regulatory Responses to Medical Machine Learning*, 7 J.L. & BIOSCIENCES 1, 2 (2020).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> Varun H. Buch et al., *Artificial Intelligence in Medicine: Current Trends and Future Possibilities*, 68 BRIT. J. GEN. PRAC. 143, 143 (2018).

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

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

<sup>12</sup> *Id.*

### **B. How Does Medical AI Work?**

First, programmers feed structured data to computer systems.<sup>13</sup> Data is structured when each data point is labeled or annotated in a way that makes the information recognizable to the algorithm.<sup>14</sup> Once the algorithm is exposed to a sufficient amount of data points and their labeling conventions, the performance of the algorithm is evaluated to make sure it is reaching accurate conclusions, in the same way that tests are given to students.<sup>15</sup> These algorithm evaluations typically comprise of inputting test data that programmers have the answers to, so that they can observe the algorithm's ability to ascertain the right answer.<sup>16</sup> Based on results from the evaluation process, the algorithm can be adapted, fed additional data, or put to use in the real world.<sup>17</sup> AI algorithms are capable of doing tasks that require human intelligence, such as pattern and speech recognition, image analysis, and decision making.<sup>18</sup>

### **C. How is Medical AI Being Used?**

Medical AI has a wide array of uses throughout the health care system, including in administrative, custodial, caregiving, research, imaging, and diagnosis settings. Hospitals and physician offices will soon rely on AI that automates routine office tasks like making appointments, billing patients, and requesting reimbursement.<sup>19</sup> Language processing technology should improve note-taking and reduce the need for scribes.<sup>20</sup> Additionally, health care facilities will make use of service robots such as laundry-pulling driverless vehicles, food service robots, and room-cleaning machines.<sup>21</sup> Finally, caregiving AI includes robotic cribs devised to help babies sleep better, voice companions that will converse and play games with

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<sup>13</sup> Daniel Greenfield, *Artificial Intelligence in Medicine: Applications, Implications, and Limitations*, HARV. U. GRADUATE SCH. ARTS & SCI.: SCI. IN THE NEWS (June 19, 2019), <http://sitn.hms.harvard.edu/flash/2019/artificial-intelligence-in-medicine-applications-implications-and-limitations/>.

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

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

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

<sup>17</sup> *Id.*

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

<sup>19</sup> Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J.L. & TECH. 133, 142 (2019).

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

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

seniors, robot companions for the elderly, and robots that can pick up and move people.<sup>22</sup>

In terms of research, pharmaceutical companies are relying on AI to speed up drug development and have tasked such AI with finding patterns in clinical data.<sup>23</sup> When it comes to imaging, pathology, and radiology, AI is extremely skilled at recognizing patterns, thus making it a good tool for reading screenings for conditions like skin cancer, colon cancer, evidence of stroke, and pneumonia.<sup>24</sup> Lastly, a significant application of AI involves its ability to improve diagnosis by using predictive diagnosis methods.<sup>25</sup> For example, predictive diagnosis is found in the use of *streams*, an algorithm that uses Google's DeepMind and has been trained on over a million patient records.<sup>26</sup> This technology signals clinicians about acute kidney disease in patients.<sup>27</sup>

#### ***D. Benefits of Medical AI***

The benefits to using AI are almost limitless. One of the most significant benefits to using medical AI involves the idea of democratizing expertise.<sup>28</sup> There are overwhelming differences in the quality and degree of care patients receive depending on the context in which they get care.<sup>29</sup> Medical AI aims to decrease this variation by evening out the playing field, meaning it will enable an abundance of low-resource providers to provide care equivalent to the that of an expert or specialist in the field.<sup>30</sup> In regards to patient care, medical AI allows for the use of complex relationships to recommend various treatment options and to improve existing diagnosis and treatment options.<sup>31</sup> Medical AI is the next step towards personalized medicine, as it can give diagnoses or preventive recommendations based on

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<sup>22</sup> *Id.* at 144.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.* at 145.

<sup>25</sup> *Id.* at 146.

<sup>26</sup> *Id.* at 147.

<sup>27</sup> *Id.*

<sup>28</sup> W. Nicholson Price II, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 66, 73 (2019) [hereinafter Price II, *Medical AI and Contextual Bias*].

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

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

<sup>31</sup> W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 420, 435 (2015) [hereinafter Price II, *Black-Box Medicine*].

individual patient data.<sup>32</sup> These machines can detect unseen patterns and relationships.<sup>33</sup> For example, “a black-box medicine prediction might be that patients who have a set of linked variations in a dozen different genes, smoke, and have middling-high blood pressure might predictably respond better to one medication than another—even if those factors could not be explained or even explicitly identified.”<sup>34</sup>

In terms of drug discovery and development, medical AI can help determine when already-approved drugs can be prescribed or used for a new purpose.<sup>35</sup> Another benefit of medical AI includes the automation of routine tasks.<sup>36</sup> This type of medical AI is least likely to be riddled with bias and will be extremely helpful in underserved areas where health care facilities lack sufficient resources to keep up with routine tasks.<sup>37</sup> Finally, unpublished investigations have analyzed algorithms used in “public health, criminal justice and education to human decision-making and found that the [ML] systems were biased—but less so than people.”<sup>38</sup>

### *E. Consequences of Medical AI*

While the benefits of medical AI seem extremely promising, it is crucial to note that there are some negative consequences that may come with its use as well. Medical AI is usually trained in high-resource settings such as university medical centers or extremely sophisticated hospital systems.<sup>39</sup> These facilities tend to have both reliable data and knowledgeable specialists that are experts in their fields.<sup>40</sup> Critically, many high-resource hospitals show patient populations heavily skewed towards upper-class, white communities.<sup>41</sup> Patient population differences such as ancestral origin, genetic variation, socioeconomic status, etc. can guide treatment in various ways.<sup>42</sup> Therefore, if high-resource hospitals have distinctly different patient

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<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.* at 430.

<sup>35</sup> *Id.* at 435.

<sup>36</sup> Price II, *Medical AI and Contextual Bias*, *supra* note 28, at 73.

<sup>37</sup> *Id.* at 72.

<sup>38</sup> Heidi Ledford, *Millions of Black People Affected by Racial Bias in Health-Care Algorithms*, NATURE (Oct. 24, 2019), <https://www.nature.com/articles/d41586-019-03228-6>.

<sup>39</sup> Price II, *Medical AI and Contextual Bias*, *supra* note 28, at 66.

<sup>40</sup> *Id.* at 67.

<sup>41</sup> *Id.* at 93.

<sup>42</sup> *Id.* at 91.

populations, then medical AI that learns from data representative of high-resource populations and then distributed for use in diverse settings may run into issues due to those patient population differences.<sup>43</sup> This phenomenon is known as contextual bias.<sup>44</sup>

Some treatments are successful when executed by practitioners with expertise and strong support staff but fail if carried out without those resources.<sup>45</sup> ML trained in high-resource settings may learn to select treatments that are only successful due to the fact that they were performed in those high-resource settings.<sup>46</sup> Thus, when those algorithms are utilized in low-resource settings, quality of care may diminish.<sup>47</sup> In addition, training medical AI in high-resource facilities could lead the algorithm to prefer more costly procedures, leading to increased health care expenditures and financial burden on patients.<sup>48</sup>

### III. THE USE OF RACE IN MEDICAL AI

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An algorithm used by hospitals nationwide has been “systematically discriminating against black people.”<sup>49</sup> The algorithm was designed to allocate health care to patients and has been put to use by hospitals and insurers in order to manage care for an estimated 200 million people throughout the country every year.<sup>50</sup> The purpose of the AI was to pinpoint a subset of patients who needed supplementary care for complex health needs before the condition became urgent and expensive.<sup>51</sup>

A study published in *Science* found that the algorithm was “less likely to refer black people than white people who were equally sick to programs that aim to improve care for patients with complex medical needs.”<sup>52</sup> Essentially, the algorithm was assigning risk scores to patients based on total health care costs accrued in one

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<sup>43</sup> *Id.* at 92–93.

<sup>44</sup> *Id.* at 68.

<sup>45</sup> *Id.* at 95.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 97.

<sup>49</sup> Ledford, *supra* note 38.

<sup>50</sup> *Id.*

<sup>51</sup> Ruha Benjamin, *Assessing Risk, Automating Racism*, 366 *SCIENCE* 421, 421 (2019).

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

year.<sup>53</sup> Researchers explain that this assignment appears reasonable at first glance because higher health-care costs are typically associated with more health needs.<sup>54</sup> However, while the average black person in the data set had comparable health care expenses to the average white person, the data actually uncovered that the average black person was considerably more sick than the average white person.<sup>55</sup> Therefore, people who self-identified as black were assigned lower risk scores than equally sick white people since their health care costs were lower.<sup>56</sup> Consequently, black people had to be sicker than white people in order to be recommended additional care.<sup>57</sup> The study also concluded that while 17.7% of patients that the algorithm assigned to receive extra care were black, that number should have been 46.5% if the algorithm was not biased against black people.<sup>58</sup>

The racial differences apparent in sets of data most likely emulates the effects of racism, meaning “the experience of being black in America rather than being black itself.”<sup>59</sup> These effects can manifest in the form of toxic stress and physiological impacts on the body.<sup>60</sup> In these situations, relying on data without recognizing that the data was racially skewed or adjusting risk scores based on race ends up deterring clinicians from providing necessary care to minority patients, and thus reinforces inequity into the health care system.<sup>61</sup>

If foundational data that train medical AI embody racism that is built into social structures, then the use of these technologies for diagnostic and treatment purposes can ingrain racism into both practice and policy.<sup>62</sup> When tools like AI influence serious determinations, whether medically or in other contexts, they exacerbate systemic inequity.<sup>63</sup> The issues arising from biased data and inadequate testing of the data can become more extensive as models become more convoluted and as biases

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

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

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

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

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

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

<sup>59</sup> Vyas et al., *supra* note 1, at 879.

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

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

<sup>62</sup> *Id.* at 880.

<sup>63</sup> *Id.*

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can get harder to foresee or recognize.<sup>64</sup> An even greater challenge in trying to prevent biased results grounded in social inequity is when sensitive information like ethnicity is correlated with variables that appear to be neutral, like home address or area code to a phone number.<sup>65</sup> In these situations, eliminating the sensitive information will not stop the machine from reaching biased conclusions.<sup>66</sup>

In order for AI technology to adequately take into account effects of racism and the experience of being black in America, adjustments should be made based on social determinants of health, rather than race itself. Social determinants of health include healthcare access and quality, education access and quality, social and community contexts, economic stability, and neighborhood and built environment.<sup>67</sup> Algorithms must not confuse patients' races with their socioeconomic status or access to health care.<sup>68</sup> These are the factors that should be taken into consideration when medical AI is both being trained and being implemented in the real world. If social determinants of health were factored into medical AI explicitly, they would allow for diagnosis and treatment decisions based on actual elements that contribute to health outcomes, rather than basing them on race, which is a social construct and cannot be directly linked to health outcomes.

Contextual bias that is propagated by the use of medical AI also leads to health care disparities. Instead of bias originating from issues in the fundamental data or bias that arises from health algorithms reflecting racial or gender biases that already exist in health care, contextual bias stems from the process of transferring algorithms from one context to another.<sup>69</sup> For example, voice recognition AI tends to be unsuccessful when interpreting accented voices. Similarly, data sets representative of skin lesions used to teach dermatological AI to identify melanomas lack images from patients with darker skin.<sup>70</sup> Thus, shifting the use of the AI from a high-resource area to an underserved population will not produce adequate or effective results.

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<sup>64</sup> Miriam C. Buiten, *Towards Intelligent Regulation of Artificial Intelligence*, 10 EUR. J. RISK REG. 41, 53 (2019).

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

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

<sup>67</sup> *Social Determinants of Health: Know What Affects Health*, CTR. FOR DISEASE CONTROL & PREVENTION (Mar. 10, 2021), <https://www.cdc.gov/socialdeterminants/about.html>.

<sup>68</sup> Nicoletta Lanese, *Racial Bias is Baked Into Algorithms Doctors Use to Guide Treatment*, LIVESCIENCE (June 29, 2020), <https://www.livescience.com/racial-bis-health-care-algorithms.html>.

<sup>69</sup> Price II, *Medical AI and Contextual Bias*, *supra* note 28, at 67–68.

<sup>70</sup> *Id.* at 94.

A critical issue with translating algorithms developed in high-resource facilities to lower-resource settings is that those algorithms are likely to make decisions that are flawed in those lower-resource settings.<sup>71</sup> This problem can manifest in two forms. First, discrepancies in diagnoses and treatment suggestions can arise due to the contrasting patient populations.<sup>72</sup> Second, differences in suggested treatments can arise due to treatment rankings whose effectiveness changes with available medical resources.<sup>73</sup> Unfortunately, conditions where medical AI has a high probability to face issues are exactly the same conditions where programmers are missing data necessary to enhance the quality of care—low resource communities.<sup>74</sup>

In low-resource settings, we cannot presume that health care professionals will have sufficient knowledge and resources to identify and correct the flawed suggestions medical AI may make when its decision-making skills translate inadequately to the low-resource setting.<sup>75</sup> Additionally, it is doubtful that low-resource facilities possess adequate resources to address legal compliance issues like Health Insurance Portability and Accountability Act (HIPAA) regulations, in the same way that it is doubtful for these facilities to spare resources to comply with technological requirements for data infrastructure in order to partake in representative research.<sup>76</sup>

#### IV. CURRENT REGULATIONS FOR MEDICAL AI

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The Federal Food, Drug, and Cosmetics Act (“FD&C Act”) gives the Food and Drug Administration (FDA) authority to regulate “medical devices.”<sup>77</sup> The definition of a “medical device” is relatively broad and thus includes several forms of medical AI.<sup>78</sup> In addition, the FDA has issued proposed regulatory guidance for Software as a Medical Device (SaMD) and regulatory direction with respect to clinical decision support software under the 21st Century Cures Act (“Cures Act”).<sup>79</sup> The FDA has

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<sup>71</sup> *Id.* at 91.

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

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

<sup>74</sup> *Id.* at 100.

<sup>75</sup> *Id.* at 104.

<sup>76</sup> *Id.* at 83.

<sup>77</sup> *Id.* at 84.

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

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

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not published any official requirements or regulations regarding the quality and source of data used to develop medical AI.<sup>80</sup>

Under the FD&C Act, FDA regulates medical devices using a risk-based classification system.<sup>81</sup> All devices must follow registration, listing, and adverse-event-reporting obligations.<sup>82</sup> Class I devices are low-risk and therefore are subject only to those obligations.<sup>83</sup> Class III devices are considered high-risk, so they must follow the premarket-approval pathway (PMA).<sup>84</sup> This pathway requires developers to perform clinical trials and demonstrate safety and efficiency to the FDA.<sup>85</sup> Finally, Class II devices are moderate-risk and can be approved by following the PMA pathway mentioned above or by following the 510(k) guidelines and establishing that the device is comparable to an already-approved device using.<sup>86</sup> A challenge with the current classification system and regulating medical AI is that it is difficult to identify and quantify the risk associated with medical AI, thus making it a bad fit for the FDA's existing regulatory scheme.

To qualify as a medical device that must be regulated, a product must be “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.”<sup>87</sup> Most medical AI technologies are intentionally designed “. . . for use in the diagnosis, cure, treatment, or mitigation of disease or other conditions in humans . . .” and therefore meet the intent element of the definition.<sup>88</sup> Regardless of whether the FDA can regulate medical AI as devices under existing law, it can generally regulate medical AI as accessories to medical devices, “. . . such as monitors, special-purpose medical computers, or wearable medical devices . . .,” which unquestionably meet the FDA's definition of a device.<sup>89</sup> Nevertheless, whether FDA truly has the authority to regulate complex medical AI is still unsettled.<sup>90</sup> For many years, the

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<sup>80</sup> *Id.* at 85.

<sup>81</sup> W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 438 (2017) [hereinafter Price II, *Regulating Black-Box Medicine*].

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

<sup>83</sup> *Id.*

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

<sup>85</sup> *Id.*

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

<sup>87</sup> *Id.* at 439.

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

<sup>89</sup> *Id.* at 440.

<sup>90</sup> *Id.* at 441.

FDA has asserted that it does not regulate the practice of medicine, and it made this position explicit when the FD&C Act was passed.<sup>91</sup> Therefore, insofar as the use of medical AI to make diagnoses and treatment recommendations is considered the practice of medicine, the FDA's distinction between devices and the practice of medicine may not be so clear-cut.<sup>92</sup>

It is worth noting that under-regulation of medical AI may become a prominent issue under the existing FDA regulatory system, because algorithm developers are the only people with the requisite knowledge regarding how the algorithm was trained.<sup>93</sup> Consequently, creators of the technology may be incentivized to understate possible problems with the model in order to receive FDA approval without difficulty.<sup>94</sup> This means that any biases or errors that existed during the development of the model may not be picked up by the current FDA regulatory processes.<sup>95</sup>

In terms of the future for AI regulation, the FDA is in the process of creating the National Evaluation System for Health Technology (NEST).<sup>96</sup> The goal of NEST is “to generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence, and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.”<sup>97</sup> This development may play a role in an attempt to design a more flexible approach to regulating AI. Moreover, the FDA has acknowledged the utility of digital health products and AI by issuing a Digital Health Innovation Action Plan that “proposed new guidance, increased in-house expertise through hiring, and a more flexible approach to approving software products.”<sup>98</sup>

It is evident from the patchwork of regulatory guidance and proposals that the FDA's work to create uniform standards for regulating AI, and medical AI specifically, is far from over. The procedure currently in place is not ideal for algorithms and models due to its static nature, and the system does nothing to prevent racial biases from becoming entrenched in medical AI systems. Furthermore, the “medical devices” versus “practice of medicine” distinction is becoming less clear

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<sup>91</sup> *Id.*

<sup>92</sup> *Id.* at 441–42.

<sup>93</sup> *Id.* at 457.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* at 464.

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

<sup>98</sup> Minssen et al., *supra* note 4, at 3.

as the days go by, thus clouding developers' abilities and incentives to create groundbreaking technology. Overall, there is more that can be done to prevent systemic racism from being exacerbated by medical algorithms, while still retaining incentives for developers to create AI.

## V. PROPOSED LEGISLATION AND REGULATIONS

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Typically, developers of devices use clinical trials and comparative effectiveness trials to decide when to start implementing new medical technologies into the real world; however, these methods do not perform adequately to assess the quality of many sophisticated medical algorithms.<sup>99</sup> Information about how medical algorithms are created is materially different from clinical-trial data that providers and insurers are used to.<sup>100</sup> Plus, developers of medical AI tend to hide information about their algorithms in order to maintain competitive advantage over other developers.<sup>101</sup> Even when facilities learn how the AI functions from their own personal experiences, providers are usually barred from publicizing their knowledge through nondisclosure agreements levied by the developers.<sup>102</sup> In order to address these obstacles, along with the issues of contextual and racial bias in medical AI, the government should invest in public data infrastructure, which can force developers to rely on representative data when training medical AI.<sup>103</sup>

In terms of infrastructure for data, the government should provide “computer servers, personnel, standards and procedures that enable data be collected, controlled for quality, and made available at lower resource settings.”<sup>104</sup> Grants aimed at assisting low-resource facilities to purchase adequate computer systems and hire data personnel could completely alleviate the data-procurement obstacle that low-resource settings face.<sup>105</sup> Additionally, the government should set uniform specifications for electronic health records so that they would not be in a variety of different formats like they are currently.<sup>106</sup> Also, the government can add a research

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<sup>99</sup> Price II, *Regulating Black-Box Medicine*, *supra* note 81, at 434.

<sup>100</sup> *Id.* at 436.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> Price II, *Medical AI and Contextual Bias*, *supra* note 28, at 100–01.

<sup>104</sup> *Id.* at 107–08.

<sup>105</sup> *Id.* at 108.

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

exemption to HIPAA to simplify the legal compliance process for low-resource facilities to collect and obtain data.<sup>107</sup>

The value of data collected through a public infrastructure is that it can better reflect the quality and type of care that patients actually encounter.<sup>108</sup> If high-quality data are gathered from an array of patient populations, the apprehension regarding the translation of medical AI to diverse patient populations diminishes.<sup>109</sup> Plus, if data are gathered from a variety of care settings, such as community hospitals, that data can be more representative of resources accessible in that setting, the kinds of practices adopted, treatments that are commonly administered, and the health outcomes that arise.<sup>110</sup> NIH's "All of Us" initiative is an illustration of this type of proposal. Through the program, NIH intends to collect comprehensive health information that consists of genetic sequences, treatments, and outcomes from a million Americans. Imperatively, the sample population is expected to be representative of the U.S. population.<sup>111</sup>

Despite this push for publicly funded data infrastructure, representative datasets do not necessarily have to be funded by the government. One idea is to combine "private spending on infrastructure for data with private acquisition of data."<sup>112</sup> Thus, developers could supply low-resource medical facilities with infrastructure to collect representative data and, in return, these developers would utilize the data that is collected to train their medical AI.<sup>113</sup>

Another approach to reducing contextual and racial bias in medical AI involves revamping the way in which the FDA provides approval for these technologies. The FDA should require evidence of the degree of agreement between performance of the AI where it was first developed versus performance in a setting different from the initial environment. A requirement to demonstrate cross-context effectiveness can prevent developers from hiding potential biases embedded within the AI and discourage them from solely creating these models in high-resource settings.<sup>114</sup> Plus, the FDA should establish requirements that force developers to disclose the data that

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

<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.* at 109.

<sup>112</sup> *Id.* at 110.

<sup>113</sup> *Id.*

<sup>114</sup> *Id.* at 101.

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their AI has learned from.<sup>115</sup> This disclosure should be monitored by relevant third parties, such as providers, hospitals, and insurers, alongside supervision by the FDA.<sup>116</sup> The cooperative strategy could strengthen the FDA's approval process by providing firsthand observations from parties who are active in the field of health care.<sup>117</sup> This type of approach would emphasize the practicability of post-market scrutiny, as opposed to the FDA's current focus on pre-market examination.<sup>118</sup> With this strategy in place, the FDA should play the role of an information hub, where it can share information gained from AI developers in a usable and comprehensible form with the third parties involved, so that they can assess the quality and efficacy of the algorithm, in the same way that these actors evaluate different drug or treatment alternatives.<sup>119</sup>

Similarly, in the E.U., “. . . medical devices are regulated by the Member States who can designate independent accredited ‘notified bodies’ to conduct the required conformity assessments and by national competent authorities appointed by the Member States that are . . . responsible for monitoring notified bod[ies].”<sup>120</sup> This resembles the approach proposed above in that the European Medicines Agency, comparable to the FDA in the U.S., is not the sole regulator of medical devices. It employs designated bodies that conduct the approval process. The E.U. approach differs in that these bodies are not active market players such as hospitals and providers.

However, forcing AI developers to disclose the data and methods on which their medical AI was trained on seemingly eliminates any incentive for producing the AI because disclosure takes away any competitive advantage the developers may have had. Therefore, there must be some kind of protection for developers in order to preserve their incentive to create medical AI.

One proposal is to allow for a delay in disclosure, so that fast-moving companies can acquire first-mover advantages and can build their models before possible adversaries can see the disclosed information.<sup>121</sup> Nevertheless, this approach could cause a delay in the cooperative regulatory strategy proposed above, in that the information would not become available to the involved third parties until much later

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<sup>115</sup> Price II, *Regulating Black-Box Medicine*, *supra* note 81, at 421.

<sup>116</sup> *Id.* at 424.

<sup>117</sup> *Id.* at 458.

<sup>118</sup> *Id.*

<sup>119</sup> *Id.*

<sup>120</sup> Minssen et al., *supra* note 4, at 14.

<sup>121</sup> Price II, *Regulating Black-Box Medicine*, *supra* note 81, at 471.

in the approval process.<sup>122</sup> Another option for disclosure is that data could be examined by the regulatory bodies, but not used as the foundation for competitors' algorithms for a certain period of time, like a patent.<sup>123</sup>

A few miscellaneous suggestions that do not fall within the FDA's authority include designing algorithms that can audit other AI for bias, establishing an independent agency outside of Health and Human Services (HHS) for AI regulations in general, and addressing racial bias in algorithms through anti-discrimination law.<sup>124</sup> The first would involve significant investment, either private or public, in creating a whole new type of algorithm that would be run against all newly developed medical AI in order to evaluate for contextual and racial bias. The second would require an enormous overhaul in the current system and legislation authorizing a new body to take control over AI regulation. While it is a drastic measure, establishing an independent body to regulate AI would clear up the confusion with the FDA's "medical devices" and "practice of medicine distinction," and it would streamline the process of getting AI approved without changing the system for any other product that requires approval from the FDA. The third would call for a private cause of action for disparate impact discrimination.<sup>125</sup>

An article by Hoffman and Podgurski argues that discriminatory medical AI ". . . can violate civil rights laws such as Title VI and Section 1557 of the Affordable Care Act (ACA) when it exacerbates health disparities or perpetuates inequities."<sup>126</sup> If health care providers do not act in good faith or act with deliberate indifference to medical AI's potential discriminatory impacts, they may encounter intentional discrimination suits.<sup>127</sup> Yet medical AI can also give rise to unintentional discrimination when algorithms which seem neutral on their face harm certain communities/populations.<sup>128</sup> Here, the relevant cause of action is disparate impact.<sup>129</sup>

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<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> Terry, *supra* note 19, at 168, 173–74; Sharon Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 1, 1 (2020).

<sup>125</sup> Hoffman & Podgurski, *supra* note 124, at 30.

<sup>126</sup> *Id.* at 1.

<sup>127</sup> *Id.* at 24.

<sup>128</sup> *Id.*

<sup>129</sup> *Id.*

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The disparate impact theory allows plaintiffs to bring claims for discrimination without being required to show an intent to discriminate.<sup>130</sup>

Unfortunately, in *Alexander v. Sandoval*, the Court held that private citizens cannot bring disparate impact claims under Title VI, and only the government can bring forward disparate impact concerns.<sup>131</sup> Additionally, it is unclear whether § 1557 of the ACA allows for disparate impact claims.<sup>132</sup> Courts have come to mixed holdings on this issue. The authors above contend that with the recent proliferation of AI, it is unreasonable to bar private citizens from pursuing disparate impact claims in the health care sphere, especially because government enforcement of disparate impact cases is contingent on political priorities.<sup>133</sup>

While I commend Hoffman and Podgurski's approach of adapting anti-discrimination law to combat racism in medical AI, I do not think it can be practical in the real world. The proposed change in Title VI to accommodate private citizens' disparate impact claims sweeps too broadly, as Title VI applies to any program receiving federal funding. If there was a way to limit allowance of disparate impact claims solely to those involving medical AI, Hoffman and Podgurski's proposal would be an ideal solution. However, it is impractical to broadly permit any and all disparate impact claims under Title VI, especially considering that the Court in *Alexander v. Sandoval* held there is no evidence that Congress intended to create a private cause of action.<sup>134</sup> The Court looks to what party the statute focuses on in its definition of the specific regulation.<sup>135</sup> In § 602, the statute's focus is on neither the individuals protected nor the regulated entity itself.<sup>136</sup> Rather, the focus is on "the agencies that will do the regulating."<sup>137</sup> This focus is so far removed from the private individuals that the statute intends to protect and thus leads the Court to believe that Congress did not intend to establish a private cause of action for disparate impact cases.<sup>138</sup>

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<sup>130</sup> *Id.* at 24–25.

<sup>131</sup> *Id.* at 26.

<sup>132</sup> *Id.* at 27.

<sup>133</sup> *Id.* at 32.

<sup>134</sup> *See Alexander v. Sandoval*, 532 U.S. 275 (2001).

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

As a result, this solution would require Congress to amend the Civil Rights Act significantly—something that is unlikely to happen. Noting that the probability of such a consequential amendment is low, the only other way Hoffman and Podgurski’s proposal would be feasible is if Congress legislates carve-outs in Title VI that would allow disparate impact claims for health care-related AI issues. While this may sound optimal, it will be very difficult to draw the line at which carve-outs should and should not be allowed. This can lead to a slippery slope of allowing too many carve-outs and thus changing Congress’s intent in passing Title VI. Therefore, I find that the approach I propose, which consists of a public data infrastructure and an overhaul of the FDA’s approval system specifically for AI, is preferable to an antidiscrimination approach.

All in all, medical AI can be influenced greatly by factors like access to resources, staffing, skills, training, and workflow.<sup>139</sup> AI also diverges from other medical devices because it can continuously learn, it has the capability to be omnipresent in medical relationships, and the way it makes decisions is likely ambiguous to its users.<sup>140</sup> We also need to consider the technology’s interactions with other aspects of providing care, including “. . . the payment structure, data providers, software components provider, and trainers.”<sup>141</sup> As a result, the whole system must be evaluated as a complex entity, through a systems approach.<sup>142</sup> That is the benefit of regulating these technologies through a cooperative strategy, as it enables relevant market actors, who have hands-on experience with the AI and contribute to the entire system, to play a role in the approval process.

## VI. CONCLUSION

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While medical technology continues to advance at astounding rates, these developments may come at a cost to particular members of our society. Medical AI has proven to be beneficial in administrative, custodial, caregiving, research, imaging, and diagnosis settings; however, these algorithms have also been exacerbating racism in the medical field. Due to data that is not representative of patient populations and racial bias already present in medicine, medical AI has learned to discriminate against minority populations. Current regulatory schemes fail to prevent or reduce this discrimination. Therefore, the FDA must rethink its strategy for regulating medical AI, possibly by investing in data infrastructure to reduce

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<sup>139</sup> Sara Gerke et al., *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPJ DIGITAL MED. 1, 2 (2020), <https://www.nature.com/articles/s41746-020-0262-2.pdf>.

<sup>140</sup> *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> *Id.* at 3.

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inequities in the availability of resources, requiring developers to disclose pertinent data, or implementing various other means to eliminate racial bias in medical AI. In the future, AI may become a universal mechanism in the field of public health in order to recommend how to diminish social determinants of health and promote health equity, but for now, the pressure is on for regulatory bodies to make sure that medical AI is both available and beneficial to each and every member of our community.