MANAGING THE MEDICAL MATRIX: A "DAIS" FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE (AND BEYOND)

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AI offers "huge and wide-reaching potential" in health; the futures of health care and AI are deeply interconnected. Use of AI provides the field with never-before-imagined opportunities to streamline and delve more deeply into medical care, including disease identification, diagnosing conditions, and a simpler way to crowdsource and develop treatment plans. Its broad inclusion in the field has created a pressing need for more, and better, regulation. Improved regulation is especially critical because of the possibility that mismanaged AI will allow for incorrect diagnosis of patients or biased predictions and outcomes. In fact, numerous examples of such bias – and attempts to manage bias – already exist, which raises major ethical questions surrounding the use of AI and presents the issue of how to avoid health disparities in AI.

In this Note, I argue that AI is not being adequately managed at the federal level. I further argue that the lack of management is largely due to a general failure to mandate standards for data sourcing, cleaning, and testing. The health care field is rife with examples of the effects of poor management, some of which have immediate and devastating impacts on patients; however, mismanagement of AI is not limited to health care alone. The potential problems that arise from lack of oversight span across industry lines. Thus, no single industry or existing federal agency can claim full ownership of, or expertise in, AI as a tool. I therefore propose that the best possible solution would be to form an entirely new top-level federal agency. This new agency would be tasked with creating federally mandated standards for ethical AI data sourcing, cleaning, and testing across industries. It would provide comprehensive management of AI datasets that do not fall under the umbrella of an existing agency such as the Food & Drug Administration (FDA). I further propose that the new regulatory body be named the "Department of Artificial Intelligence Standardization," or DAIS.

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I.   Introduction

In February 2011, the world watched in entertained awe as the 74-time *Jeopardy!* winner Ken Jennings was unseated not by a human, but a machine. The triumphant contestant was named, simply, "Watson." Watson was a "question answering machine"[1] developed by IBM in 2010.[2] In front of thousands of viewers, Watson showcased its ability to process natural language and quickly provide accurate responses[3]—in the form of a question, of course.[4] Watson runs over 100 algorithms after receiving a query.[5] It uses those algorithms to analyze questions, then finds evidence that may support or refute potential answers to the initial query.[6] In the *Jeopardy!* setting, Watson considered what degree of confidence it had in its answer before choosing whether to "buzz in" and risk losing money, further illustrating its quick-thinking capabilities.[7] Watson was a stunning display of the potential of language processing and automated decision -making. On the heels of the *Jeopardy!* success, IBM quickly announced Watson's next step: applications of its algorithms to medical analysis.[8]

In 2014, IBM made a "moonshot" display of Watson's ability to provide potential patient diagnoses from a "bizarre collection" of patient symptoms.[9] Hopes were high for the automated system.[10] Disappointingly, subsequent Watson projects have fallen short of creating a true "AI doctor."[11] For example, in 2018, Watson stumbled significantly by recommending "unsafe and incorrect"

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[1] John Markoff, *Computer Wins on 'Jeopardy!': Trivial, It's Not*, N.Y. TIMES (Feb. 16, 2011), https://www.nytimes.com/2011/02/17/science/17jeopardy-watson.html.

[2] IBM, *A Computer Called Watson*, IBM, https://www.ibm.com/ibm/history/ibm100/us/en/icons/watson/ (last visited Apr. 19, 2022).

[3] Markoff, *supra* note 1.

[4] *See* Raman Chandrasekar, *Elementary? Question Answering, IBM's Watson, and the Jeopardy! Challenge*, 19 RESONANCE 222, 237–40 (2014) (discussing the rules of the *Jeopardy!* game show that requires contestants to respond to prompts with questions. Watson was programmed to respond in this manner for its appearances on the show.).

[5] IBM, *supra* note 2.

[6] Chandrasekar, *supra* note 4, at 236.

[7] *Id.* at 234.

[8] Markoff, *supra* note 1.

[9] Eliza Strickland, *How IBM Watson Overpromised and Underdelivered on AI Health Care*, IEEE SPECTRUM (Apr. 2, 2019), https://spectrum.ieee.org/biomedical/diagnostics/how-ibm-watson-overpromised-and-underdelivered-on-ai-health-care.

[10] *See generally* Adam Miller, *The future of healthcare could be elementary with Watson*, 185 CMAJ E367, E367–68 (2013) (discussing the advantage for oncologists of staying up to date on research through Watson).

[11] *Id.*

treatments for cancer patients.[12] Both IBM's engineers and Watson's initial adopters, Memorial Sloan Kettering Cancer Center, were blamed for this stumble;[13] together they trained Watson on a limited set of hypothetical cancer cases instead of real patient data and relied on limited treatment recommendations, rather than evidence, in selecting treatment options.[14]

Despite its missteps and although it did not replace traditional diagnosis methods,[15] Watson is still a participant in medical artificial intelligence ("AI").[16] Watson is currently being used for research into the usability of electronic health records ("EHR") and support of "precision medicine," which is "an emerging approach for disease treatment and prevention that takes into account variability in genes, environment, and lifestyle for each person."[17] Watson's early successes and experiments also paved the way for future developments in AI and natural language processing ("NLP") in health care.[18]

AI has gained significant attention in the context of improving health and well-being.[19] AI is exciting and trendy: news media is laden with stories about noteworthy uses of algorithms, including health-related applications ranging from

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[12] Julie Spitzer, *IBM's Watson recommended 'unsafe and incorrect' cancer treatments, STAT report finds*, BECKER'S HEALTH IT (July 25, 2018), https://www.beckershospitalreview.com/artificial-intelligence/ibm-s-watson-recommended-unsafe-and-incorrect-cancer-treatments-stat-report-finds.html [https://perma.cc/T7ND-NTNF].

[13] *Id.*

[14] *Id.*

[15] Strickland, *supra* note 9.

[16] Although Watson is still operational in health care, IBM reportedly began exploring sale of IBM Watson Health and its associated brands in February of 2021 due to its not currently being profitable. *See* Laura Cooper & Cara Lombardo, *IBM Explores Sale of IBM Watson Health*, WALL ST. J. (Feb. 18, 2021), https://www.wsj.com/articles/ibm-explores-sale-of-ibm-watson-health-11613696770 [https://perma.cc/M4KM-PEDN]. As of the date of this writing, Watson Health has not yet been sold. *See id.*

[17] Jennifer Bresnick, *IBM Watson Health Teams Up with Hospitals for AI, EHR Research*, HEALTH IT ANALYTICS (Feb. 20, 2019), https://healthitanalytics.com/news/ibm-watson-health-teams-up-with-hospitals-for-ai-ehr-research; *What is precision medicine?*, NAT. INST. HEALTH: MEDLINEPLUS GENETICS, https://medlineplus.gov/genetics/understanding/precisionmedicine/definition/ (last visited Jan. 26, 2021).

[18] Ashish Kachru, *Why Artificial Intelligence Hype In Health Care Isn't A Bad Thing*, FORBES (Oct. 2, 2019), https://www.forbes.com/sites/forbestechcouncil/2019/10/02/why-artificial-intelligence-hype-in-health-care-isnt-a-bad-thing/ (discussing how, after IBM made its "moonshot" with AI in health care, researchers have begun making incremental developments in health care AI including prediction of risk for hospital admissions and identification of vulnerabilities in home-based "medically fragile" patients).

[19] *Id.* at 5.

virtual fitness to COVID-19 vaccinations.[20] This should be no surprise, as pop culture has been preparing us for machine-based intelligence for most of our lives; to see pop culture's promises begin to come to fruition is inspiring.[21] In the *Jeopardy!* program from 2011, Ken Jennings himself referenced pop culture in his final answer when he realized that Watson had won handily: he wrote "I, for one, welcome our new computer overlords."[22] Early chatter about Watson naturally compared it to the responsive computer system in the *Star Trek* universe.[23] Needless to say, we are not yet at *Star Trek* levels of omnipresent AI, but we are making vast strides towards more effective use of AI in health technology. The industry is ready: the term "AI" is all the buzz in health care.[24]

Because AI offers "huge and wide-reaching potential"[25] in health, the futures of health care and AI are deeply interconnected.[26] Use of AI provides the field with never-before-imagined opportunities to streamline and delve more deeply into medical care, including disease identification, diagnosing conditions,

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[20] *See, e.g.*, *CES 2021 Uniigym combines AI and cloud algorithms to change virtual fitness apps*, PR NEWSWIRE: CISION (Jan. 14, 2021), https://www.prnewswire.com/news-releases/ces-2021-uniigym-combines-ai-and-cloud-algorithms-to-change-virtual-fitness-apps-301208290.html; Siddharth Venkataramakrishnan, *Algorithms and the coronavirus pandemic*, FIN. TIMES (Jan. 10, 2021), https://www.ft.com/content/16f4ded0-e86b-4f77-8b05-67d555838941; Drew Harwell, *Algorithms are deciding who gets the first vaccines. Should we let them?*, WASH. POST (Dec. 23, 2020), https://www.washingtonpost.com/technology/2020/12/23/covid-vaccine-algorithm-failure/.

[21] *See* Frank Landman, *Pop Culture and AI: How Media Is Reshaping Public Perceptions*, READWRITE (July 20, 2018), https://readwrite.com/2018/07/20/pop-culture-and-ai-how-media-is-reshaping-public-perceptions/ ("[Depictions of AI have] inspired thousands, if not millions of curious minds to push the boundaries of what AI can accomplish [and even take efforts to improve our safety].").

[22] The phrase "I, for one, welcome our new computer overlords" paraphrases a quote from a 1994 episode of *The Simpsons* where fictional reporter Kent Brockman states "I, for one, welcome our new insect overlords." Mr. Jennings' paraphrase has been used to describe our communal fear of "robots" taking over the world. *See* Kevin Gannon, *I, For One, Welcome Our New Robot Overlords*, GRAND VIEW UNIV.: CTR. EXCELLENCE TEACHING & LEARNING (Sept. 11, 2015), http://www.grandviewcetl.org/i-for-one-welcome-our-new-robot-overlords/; Gary Booch, *I, for One, Welcome Our New Computer Overlords*, IEEE 8 (Nov. 2015), https://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=7310991.

[23] Markoff, *supra* note 1; *see also* Timothy McGettigan, *Star Trek for a Better Tomorrow: Inventing the Future One Fantasy at a Time*, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3669959.

[24] Tory Waldron, *3 Surprising Ways Healthcare is Using AI*, DEFINITIVE HEALTHCARE (Oct. 10, 2019), https://blog.definitivehc.com/ways-healthcare-using-ai.

[25] Codrin Arsene, *Artificial Intelligence in Healthcare: the future is amazing*, HEALTHCARE WKLY. (Sept. 8, 2020), https://healthcareweekly.com/artificial-intelligence-in-healthcare/.

[26] *Id.*

and a simpler way to crowdsource and develop treatment plans.[27] Its broad inclusion in the field has created a pressing need for more, and better, regulation.[28] Improved regulation is especially critical because of the possibility that mismanaged AI will allow for incorrect diagnosis of patients or biased predictions and outcomes.[29] In fact, numerous examples of such bias—and attempts to manage bias—already exist,[30] which raises major ethical questions surrounding the use of AI[31] and presents the issue of how to avoid health disparities in AI.[32]

In this Note, I argue that AI is not being adequately managed at the federal level. I further argue that the lack of management is largely due to a general failure to mandate standards for data sourcing, cleaning, and testing. The health care field is rife with examples of the effects of poor management, some of which have immediate and devastating impacts on patients;[33] however, mismanagement

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[27] Bernard Marr, *The 9 Biggest Technology Trends That Will Transform Medicine and Healthcare in 2020*, FORBES (Nov. 1, 2019), https://www.forbes.com/sites/bernardmarr/2019/11/01/the-9-biggest-technology-trends-that-will-transform-medicine-and-healthcare-in-2020/#78f74b2e72cd.

[28] Kathleen Walch, *AI Laws are Coming*, FORBES (Feb. 20, 2020), https://www.forbes.com/sites/cognitiveworld/2020/02/20/ai-laws-are-coming/.

[29] Alvin Rajkomar et al., *Ensuring Fairness in Machine Learning to Advance Health Equity*, 169(12) HHS ANN. INTERN. MED. 866 (Dec. 2018) (discussing case studies and clinical applications where machine learning harms protected groups through inaccuracy, diversion of resources, or worsening outcomes).

[30] Algorithmic bias has become a prevalent topic of debate and targeted solutions, which is evident from the fact that there have been legislative attempts surrounding bias and that examples of AI bias are easily located through a quick internet search. *See, e.g.*, Terence Shin, *Real-life Examples of Discriminating Artificial Intelligence*, TOWARDS DATA SCI. (June 4, 2020), https://towardsdatascience.com/real-life-examples-of-discriminating-artificial-intelligence-cae395a90070; Craig S. Smith, *Dealing With Bias in Artificial Intelligence*, N.Y. TIMES (Nov. 19, 2019 [updated Jan. 2, 2020]), https://www.nytimes.com/2019/11/19/technology/artificial-intelligence-bias.html; Bernard Marr, *Artificial Intelligence Has A Problem With Bias, Here's How To Tackle It*, FORBES (Jan. 29, 2019), https://www.forbes.com/sites/bernardmarr/2019/01/29/3-steps-to-tackle-the-problem-of-bias-in-artificial-intelligence/?sh=674a580b7a12.

[31] *See Artificial Intelligence (AI) in healthcare and research*, NUFFIELD COUNCIL ON BIOETHICS (May 2018), https://www.nuffieldbioethics.org/assets/pdfs/Artificial-Intelligence-AI-in-healthcare-and-research.pdf (providing examples of some of the many ethical questions raised by use of AI in health care).

[32] *See, e.g.*, W. Nicholson Price II, *Risks and remedies for artificial intelligence in health care*, BROOKINGS (Nov. 14, 2019), https://www.brookings.edu/research/risks-and-remedies-for-artificial-intelligence-in-health-care/; Sara Gerke et al., *Ethical and legal challenges of artificial intelligence-driven health care*, in ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295 (2020) ("It is [] vital that AI makers are aware of [the] risk and minimize potential biases at every stage in the process of product development.").

[33] *See infra* Part II(B).

of AI is not limited to health care alone. The potential problems that arise from lack of oversight span across industry lines. Thus, no single industry or existing federal agency can claim full ownership of, or expertise in, AI as a tool. I therefore propose that the best possible solution would be to form an entirely new top-level federal agency. This new agency would be tasked with creating federally mandated standards for ethical AI data sourcing, cleaning, and testing across industries. It would provide comprehensive management of AI datasets that do not fall under the umbrella of an existing agency such as the Food & Drug Administration (FDA). I further propose that the new regulatory body be named the "Department of Artificial Intelligence Standardization," or DAIS.

DAIS would be responsible for devising and distributing a baseline set of rules across agencies. It would provide consistency of standards, much like the "guideline" AI standards proposed by the National Institute of Standards and Technologies (NIST),[34] but will bear the weight of federal regulatory authority rather than policy guidelines. DAIS would alleviate some of the mounting pressure within other agencies[35] to create new rules for AI. DAIS would also provide space for tailored oversight of industry-specific AI by employing specialists who are tasked with collaboration between DAIS and other agencies like the FDA.

Part II of this Note will provide a background on what AI and machine learning ("ML") are and how they are used in health care. Part III will speak to the issues that are most important in creation of fair and unbiased AI. Part IV will discuss existing attempts to regulate use of AI both in health care and more broadly. Finally, Part V will delve into the proposed DAIS solution and explain possibilities for rulemaking.

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[34] NIST has outlined a draft plan for developing technical standards for AI and appropriate federal involvement. *See* NATIONAL INST. STANDARDS & TECH., U.S. LEADERSHIP IN AI: A PLAN FOR FEDERAL ENGAGEMENT IN DEVELOPING TECHNICAL STANDARDS AND RELATED TOOLS (submitted Aug. 2019), https://www.nist.gov/system/files/documents/2019/08/10/ai_standards_fedengagement_plan_9aug 2019.pdf [hereinafter NIST AI STANDARDS].

[35] *See, e.g.*, DAVID FREEMAN ENGSTROM ET AL., GOVERNMENT BY ALGORITHM: ARTIFICIAL INTELLIGENCE IN FED. ADMIN. AGENCIES, REP. TO THE ADMIN. CONFERENCE OF THE U.S. (2020).

II.   Algorithms and AI: Magic Words in Health Technology

a.   Defining Algorithms and AI

Algorithms are mathematical models intended to solve a finite set of problems.[36] They are procedures that can generate, or become a part of a "predictive model," which is the program itself.[37] In other words, algorithms use training data to create a model—the "thing" we use to process new data.[38] When a user or system inputs a new set of data to a predictive model, the model produces output based on how it was trained by the initial algorithm; it uses data mining/input and probability to forecast specific outcomes.[39] AI is something more than a predictive model. AI uses models to perform frequent, high-volume, computerized tasks,[40] and it comes in several forms.[41] ML is one form of AI, where a machine using an algorithm "can improve at its programmed, routine, automated tasks"[42]—in other words, ML becomes smarter as it processes more data. ML generally refers to a model based on algorithms that are intended to optimize and automate learning processes.[43] It is what we typically think of when we talk about AI as being "smart." When we envision future androids, like "Data" of *Star Trek: The Next Generation*[44] or "David" from the film *A.I. Artificial*

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[36] Sebastian Sigloch, *What are Algorithms and does it matter?*, TOWARDS DATA SCI. (Dec. 17, 2019), https://towardsdatascience.com/what-are-algorithms-really-and-does-it-matter-75d129d61ed0.

[37] Jason Brownlee, *Difference Between Algorithm and Model in Machine Learning*, MACHINE LEARNING MASTERY (Apr. 29, 2020), https://machinelearningmastery.com/difference-between-algorithm-and-model-in-machine-learning/ [https://perma.cc/2RMP-D8VF].

[38] *Id.*

[39] Stacia Damron, *AI Academy: What's the difference between forecasting and predictive modeling?*, ONEMODEL.CO, https://www.onemodel.co/blog/ai-academy-forecasting-vs-predictive-modeling (last visited Mar. 13, 2021) [https://perma.cc/YAT9-WVN7].

[40] *Artificial Intelligence: What it is and why it matters*, SAS, https://www.sas.com/en_us/insights/analytics/what-is-artificial-intelligence.html (last visited Apr. 19, 2022).

[41] Yulia Gavrilova, *Artificial Intelligence vs. Machine Learning vs. Deep Learning: Essentials*, SEROKELL (Apr. 8, 2020), https://serokell.io/blog/ai-ml-dl-difference.

[42] *Id.*

[43] *See generally* Ravindra Parmar, *Demystifying Optimizations for machine learning*, TOWARDS DATA SCI. (Sept. 5, 2018), https://towardsdatascience.com/demystifying-optimizations-for-machine-learning-c6c6405d3eea.

[44] The android "Data," played by Brent Spiner, was renowned as an "ethical" artificial life form in the *Star Trek: The Next Generation* series. Data struggled regularly with his desire to become more human. The show considered issues of consciousness and intentionality, and suggested that the ability to adapt—thus, the core of machine learning—was central to Data's development in becoming closer to humanity. *See* Victor Grech, Mariella Scerri, & David Zammit, *Evil Doctor, Ethical Android:* Star Trek*'s Instantiation of Consciousness in Subroutines*, 1 J. SCI. FICTION 9, 11 (2017).

Intelligence,[45] who learn as they gain real-world experience, we are imagining future advanced applications of ML.

For purposes of this Note, the terms "algorithm," "AI," and "ML" will normally be collaboratively referred to as "AI," though in some instances, this Note will specifically refer to ML for the sake of clarity. Another important distinction is the difference between "locked AI" and "dynamic AI" as defined by the FDA. A locked algorithm provides the same result each time the same input is applied, whereas dynamic or adaptive algorithms change over time while continuously learning.[46] Presently the FDA only regulates locked AI, although dynamic AI does exist in health care.[47] It does so via the authority to regulate devices granted by the federal Food, Drug, and Cosmetic Act.[48] The FDA has acknowledged that this limitation is problematic, but has also stated that it does not wish to impede development of learning algorithms.[49]

> **b.** **Current Use of and Future Potential for AI in Health Care**

Abundant examples of the growing use of AI in health care can be found anywhere you turn, as AI is already proving valuable in a wide variety of applications. Applications range from low-level decisions like staffing considerations based on hourly availability[50] to highly impactful areas such as

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[45] "David," a humanoid "mecha" in Spielberg's *A.I.*, exhibits an evolving emotional connection to the human who unboxes him; throughout the film, he undergoes an existential crisis over whether he can become a real boy. The film is fraught with examples of living, learning androids, and David is the first of his kind that can experience true emotional connection. *See* Idioa Sanazar, *Robots and Artificial Intelligence: New challenges of journalism*, 27 DOXA COMMUNICACIÓN 295, 297 (2018).

[46] U.S. FOOD & DRUG ADMIN., EXEC. SUMMARY FOR THE PATIENT ENGAGEMENT ADVISORY COMM. MTG.: ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING (ML) IN MEDICAL DEVICES (Oct. 22, 2020) [hereinafter FDA EXECUTIVE SUMMARY]; Stan Benjamens et al., *The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database*, 3 NPJ DIGITAL MEDICINE 118 (2020).

[47] Benjamens, *supra* note 46.

[48] Food, Drug, & Cosmetic Act, 21 U.S.C. ch. 9 § 301 et seq.

[49] *See infra* Part III(A)(1).

[50] *AI-Assisted Decision Making: Health care's Next Frontier,* HEALTH CATALYST (Jan. 30, 2020), https://www.healthcatalyst.com/insights/ai-assisted-decision-making-health cares-next-frontier.

drug development,[51] clinical research,[52] and diagnosing and treating patients.[53] Oncology is one of the most promising areas for the use of predictive models. AI can assist in detecting breast cancer,[54] predicting lung cancer,[55] and classifying types of cancer.[56] Several oncological research institutions have begun investigating use of AI in precision medicine, which attempts to analyze large genomic and molecular datasets.[57] Furthermore, there is a call for increased use of AI in cancer immunotherapy.[58]

In hospital and primary care settings, AI is optimizing physicians' "care pathways,"[59] which are processes designed to aid in decision-making for specific groups of patients.[60] AI has also been utilized to help predict the care needs of trauma patients based on those patients' symptoms and histories.[61] Algorithms are

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[51] *See generally* U.S. GOV'T ACCOUNTABILITY OFF., ARTIFICIAL INTELLIGENCE IN HEALTH CARE: BENEFITS AND CHALLENGES OF MACHINE LEARNING IN DRUG DEVELOPMENT (Dec. 2019) [hereinafter GAO AI REPORT].

[52] *Id*.; Anmol Arora, *Conceptualising Artificial Intelligence as a Digital Health care Innovation: An Introductory Review*, 13 MED. DEVICES (AUCKLAND) 223 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7455610/.

[53] *See* Alexis S. Gilroy et al., *Artificial Intelligence and Health Care—Key Regulatory Considerations for U.S. Operations*, JONES DAY (Jan. 2018), https://www.jonesday.com/en/insights/2018/01/artificial-intelligence-and-health-carekey-regulat.

[54] Alejando Rodriguez-Ruiz et al., *Stand-Alone Artificial Intelligence for Breast Cancer Detection in Mammography: Comparison With 101 Radiologists*, 9 J. NAT. CANCER INST. 111 (2019).

[55] Diego Ardila et al., *End-to-end lung cancer screening with three-dimensional deep learning on low-dose chest computed tomography*, 25 NATURE MEDICINE 954 (2019).

[56] *See generally* Vadim Zhernovoy, *Applying Deep Learning to Classify Skin Cancer Types*, APRIORIT, https://www.apriorit.com/dev-blog/647-ai-applying-deep-learning-to-classify-skin-cancer-types (last visited Apr. 19, 2022) (discussing specific steps that can be taken to screen for and classify skin cancers using deep learning).

[57] Institutions such as DeepThink Health, the American Association for Cancer Research, and the American Society of Clinical Oncology are using precision medicine to investigate treatment options for cancer. *See* mkatip, Big Data and Clinical Genomics, DEEPTHINK HEALTH NEWS, https://www.deepthinkhealth.com/2019/03/27/big-data-and-clinical-genomics/ (last visited Apr. 19, 2020).

[58] Mike Scott, *Powerful push to use AI for cancer immunotherapy*, CASE W. RES. UNIV.: THE DAILY, https://thedaily.case.edu/powerful-push-for-ai-for-cancer-immunotherapy/ (last visited Apr. 19, 2020).

[59] Michael Sanders, *How using artificial intelligence enabled Flagler Hospital to reduce clinical variation*, HEALTHCARE FINANCIAL MGMT. ASSN. (Jan. 17, 2020), https://www.hfma.org/topics/financial-sustainability/article/using-artificial-intelligence-enabled-flagler-hospital-reduce-clinical-variation.html.

[60] Guus Schrjivers et al., *The care pathway: concepts and theories: an introduction*, 12 (Special Ed.) INT'L J. INTEGRATED CARE e192 (2012).

[61] Nehmiah T. Liu et al., *Development and Validation of a Machine Learning Algorithm and Hybrid System to Predict the Need for Life-Saving Interventions in Trauma Patients*, 52 MED. & BIOLOGICAL ENGINEERING & COMPUTING 193 (2014).

prevalent in other areas of health care including cardiology,[62] where use of data sensors, remote monitoring, and connected data from multiple wearable sources aids in the study of heart failure.[63] AI is also increasingly present in wellness products.[64] For example, "smart" home-based sensors can monitor homebound patients and, when coupled with predictive algorithms, can forecast those patients' care needs.[65] The increased prevalence of wellness technologies that can manage and predict health care needs based on personal health data[66] should be of concern to regulators, as the FDA only oversees medical devices at this time.[67]

AI will inevitably continue to be of paramount importance in health technologies. As recently as 2020, several of the "latest" tools in health technology included virtual assistants, early identification of melanoma, "robotic assisted therapy," and software to aid in the capture of echocardiographic images for diagnosis.[68] With the rapid pace of software development,[69] the possibilities are seemingly endless. The health care industry and society in general are facing a "paradigm shift in the level of AI technology and its adoption."[70] This is a

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[62] *See* Arora, *supra* note 52 (discussing use of AI in cardiology and radiology).

[63] Patrik Bachtiger et al., *Artificial Intelligence, Data Sensors, and Interconnectivity: Future Opportunities for Heart Failure*, 6 CARDIAC FAILURE REV. 11 (2020), https://www.ncbi.nih.gov/pmc/articles/PMC7265101.

[64] *See generally* Lydia Kostopoulos, *The Emerging Artificial Intelligence Wellness Landscape: Opportunities and Areas of Ethical Debate*, TRANSFORMATIVE TECH (Feb. 25, 2019), https://www.transformativetech.org/blog-single?id=3103 (providing examples of types of AI in wellness products including Fitbit, Apple Watch, virtual therapists, smart journaling, and smart sleep devices).

[65] For an example of a proposed use of IoT in home monitoring and care predictions, *see* Olutosin Taiwo & Absalom E. Ezugwu, *Smart health care support for remote patient monitoring during COVID-19 quarantine*, 20 INFORMATICS MED. UNLOCKED (2020). One company attempting to leverage this technology is VINYA Intelligence, a startup offering patient monitoring via a sensor system that detects daily activities and offers "identification of early warning signs." *See What is the VINYA app?*, VINYA, https://www.vinya.com/vinya-app (last visited Apr. 19, 2022).

[66] *AI-Assisted Decision Making: Healthcare's Next Frontier*, HEALTH CATALYST (Jan. 30, 2020), https://www.healthcatalyst.com/insights/ai-assisted-decision-making-healthcares-next-frontier.

[67] *See generally* FDA EXECUTIVE SUMMARY, *supra* note 46.

[68] Micah Castelo, *The Future of Artificial Intelligence in Healthcare*, HEALTHTECH (Feb. 26, 2020), https://healthtechmagazine.net/article/2020/02/future-artificial-intelligence-healthcare. Castelo implies that this is just the beginning of an "explosion in innovation."

[69] Adam Bohr & Kaveh Memarzadeh, *The rise of artificial intelligence in healthcare applications*, 1 A.I. HEALTHCARE 25, 26 (2020) ("Although research in AI for various applications has been ongoing for several decades, the current wave of AI hype is different from the previous ones. A perfect combination of increased computer processing speed, larger data collection data libraries, and a large AI talent pool has enabled rapid development of AI tools and technology, also within healthcare.").

[70] *Id*. ("[Rapid development of AI] is set to make a paradigm shift in the level of AI technology and its adoption and impact on society.").

thrilling and dangerous path: medical algorithms may require "special policies and guidelines" for oversight due to concerns about their safety and efficacy.[71]

III.   The Wild West: Untamed Data and Unregulated Practice

The present state of AI and digital health research in health care has been likened to the "wild west,"[72] in terms of both the data itself[73] and the practice of using AI in health care. The lack of sufficient regulation tailored for AI is also of concern.[74] At the development end, which is arguably the most important aspect to consider in future regulation, AI developers face persistent issues in data collection (*i.e.*, poor quality data or lack of uniformity of training data).[75] "Training data" is the initial set of data that acts as a baseline or foundation for teaching a model how to evaluate live datasets.[76] These quality issues are

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[71] Sandeep Reddy et al., *A governance model for the application of AI in health care*, 27 J. AM. MED. INFORMATICS ASS'N 491, 492 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7647243/pdf/ocz192.pdf ("Algorithms that are unexplainable in their decision making, change continuously with use, and autoupdate, perhaps with features that go beyond the initial approved clinical trials, may require special policies and guidelines. Concerns also emerge about the safety and efficacy of AI medical software that does not necessarily align with current models of care delivery. Regulatory standards to assess AI algorithmic safety and impact are yet to be formalized in many countries. This can both present barriers to entry of AI in health care and enable unsafe practices in which AI is already being used in health care.").

[72] *See, e.g.*, Camille Nebeker et al., *Building the case for actionable ethics in digital health research supported by artificial intelligence*, 17 BMC MEDICINE 137 (2019) ("As the 'Wild West' of digital health research unfolds, it is important to recognize who is involved, and identify how each party can and should take responsibility to advance the ethical practices of this work."); WILLIAMS & NICKL, ARTIFICIAL INTELLIGENCE & MEDICINE IN ILLINOIS (July 13, 2020), https://www.williamsnickl.com/illinois-license-defense-law-idfpr/artificial-intelligence-medicine-in-illinois ("Over the next few years, decisions on how and when to use the new advancements [in AI] may look like the Wild West.").

[73] *See* Gilroy et al., *supra* note 53 ("As the use of AI in the clinical space increases and evolves, legal and regulatory risk can escalate, particularly with the growing attention and unique application of traditional regulatory principles not yet attuned to AI.").

[74] *See* NAT'L ACAD. MED., ARTIFICIAL INTELLIGENCE IN HEALTH CARE: THE HOPE, THE HYPE, THE PROMISE, THE PERIL (Michael Matheny et al., eds. 2019) ("AI tools are being implemented in an environment of inadequate regulation and legislation.").

[75] Hayden Field, *A Lack of Diverse Data Is Hurting Healthcare AI. Here's How*, MORNING BREW: EMERGING TECH (Nov. 9, 2020), https://www.morningbrew.com/emerging-tech/stories/2020/11/09/lack-diverse-data-hurting-healthcare-ai-heres ("An ML model is only as good as the data it's trained on. And issues with that data—like narrow scope and existing biases—can easily compound over time. For example: A model trained mostly on medical data from a predominantly white area could have trouble diagnosing black women. Accounting for these types of discrepancies is key, especially before an AI healthcare product goes to market.").

[76] *What is Training Data?*, APPEN (Apr. 14, 2020), https://appen.com/blog/training-data/; Alexandre Gonfalonieri, *How to Build a Data Set For Your Machine Learning Project*, TOWARDS

primarily due to inconsistencies in data collection, data definitions, and the absence of widespread shared standards for training data.[77] The lack of shared standards in turn leads to inaccurate output and unintended disparities, as non-diverse datasets will lead to biased output.[78] Because the quality issue stems directly from the data input, sourcing, and testing phases, any solution must speak to standardization.

a. Taming the Beast: Clean Data, Interoperability, and Data Standardization

The greatest need in creating a functioning AI is well-curated data,[79] yet health data is rife with errors.[80] Without mandated standards for clean data, data sourcing and collection are major stumbling blocks in the development of accurate predictive models.[81] Although there are examples of data standardization in health,[82] existing standardization practices are nothing more than unenforceable guidelines. The health industry is faced with three questions: 1) how to address the data entry issues prevalent in EHR systems; 2) how to ensure clean data; and 3) how to enforceably standardize its data, which may be a task best suited to AI developers.

DATA SCI. (Feb. 13, 2019), https://towardsdatascience.com/how-to-build-a-data-set-for-your-machine-learning-project-5b3b871881ac.

[77] *See, e.g.*, Pam Arlotto, *Artificial intelligence: 5 realities for financial leaders*, HEALTHCARE FIN. MGMT. ASSN. (Feb. 4, 2020), https://www.hfma.org/topics/hfm/2020/february/artificial-intelligence--5-realities-for-financial-leaders.html ("Problems in data collection accuracy, variable data definitions and limited interoperability across disparate systems create data quality issues.").

[78] Bibb Allen et al., *The Role of an Artificial Intelligence Ecosystem*, ARTIFICIAL INTELLIGENCE IN MEDICAL IMAGING RADIOLOGY 300 (Erik Ranschaert et al., eds., 2019) ("Both developers and consumers of AI applications in health care . . . must be cognizant of the broad diversity in patient populations so that there will be similar diversity in training data so that algorithms will be free of unintended bias.").

[79] *See* Divya Singh (@divyasingh456), *The Role of Data Curation in Big Data*, DATA SCI. CENT.: BLOG (Apr. 28, 2019, 4:00 PM), https://www.datasciencecentral.com/the-role-of-data-curation-in-big-data/.

[80] A 2019 study found that 21.1% of survey participants found errors in their health reports, and 42.3% of those described "serious" or very serious mistakes. Sigall K. Bell et al., *Frequency and Types of Patient-Reported Errors in Electronic Health Record Ambulatory Care Notes*, 3 JAMA NETWORK OPEN 1, 4 (2020).

[81] *See* Jessica Kent, *Data Quality, Equity Essential for Artificial Intelligence Use*, HEALTH IT ANALYTICS (Dec. 19, 2019), https://healthitanalytics.com/news/data-quality-equity-essential-for-artificial-intelligence-use ("Methods to assess data quality are often not standardized or nonexistent.").

[82] *See, e.g.*, *Introduction to HL7 Standards*, HL7 INT'L, https://www.hl7.org/implement/standards/index.cfm (last visited Jan. 30, 2021) (listing health care standards frameworks for electronic health information).

1. Electronic Records Data: "Garbage In/Garbage Out"

EHRs, which focus on a "total health" picture of a patient, and electronic medical records ("EMR"), which are the digital equivalent of paper patient charts,[83] are substantial sources of datasets for health care AI. Developers who create applications for hospital systems or medical research facilities frequently obtain datasets from EHRs and EMRs.[84] EHRs contain rich data[85] including clinical history, laboratory tests, treatments, and prognoses,[86] and databases sourced from their contents are extremely valuable potential sources for clinical research.[87] Yet because of a lack of standardization, records sourced from one institution or research facility may have completely different characteristics than those from another.[88] Some hospital systems even employ multiple types of EHRs and EMRs internally that do not speak to each other—for example, an EMR from a hospital's emergency department may have no connection to another from its primary care offices.[89] In 2018, Healthcare IT News reported that the average

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[83] An electronic medical record (EMR) is a digital version of a paper patient chart, while an EHR focuses on the "total health" of the patient and are designed to "reach out beyond" the organization that compiles the record. Peter Garrett & Joshua Seidman, *EMR vs EHR: What is the Difference?*, HEALTHIT (Jan. 4, 2011), https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference.

[84] Ayaka Shinozaki, *Electronic Medical Records and Machine Learning in Approaches to Drug Development,* ARTIFICIAL INTELLIGENCE IN ONCOLOGY DRUG DISCOVERY AND DEVELOPMENT (John W. Cassidy & Belle Taylor, eds.) (2020).

[85] Effy Vayena & Lawren Madoff, *Navigating the Ethics of Big Data in Public Health, in* THE OXFORD HANDBOOK OF PUBLIC HEALTH ETHICS 354, 355 (Anna C. Mastroianni et al. eds., 2019).

[86] Young Juhn & Hongfang Liu, *Artificial intelligence approaches using natural language processing to advance EHR-based clinical research*, 145 J. ALLERGY & CLINICAL IMMUNOLOGY 463 (2020).

[87] *Id*.

[88] *See* Grant Barrick, *4 Reasons Why EHR Interoperability is a Mess (and How to Fix It)*, DATICA BLOG (June 17, 2019), https://datica.com/blog/reasons-ehr-interoperability-is-a-mess-and-how-to-fix-it ("Hospital consolidation is accelerating, which means that the resulting multi-hospital health systems and health networks are using EHR systems from different vendors. These EHR vendors are often creating proprietary communication and language protocols that make them unable to communicate with other EHRs. Providers of all types and sizes throughout the health care continuum must then find ways to integrate the different EHRs both inside and outside of their own facilities.").

[89] *See* Jeff Lagasse, *How disparate EHR systems, lack of interoperability contribute to physician stress, burnout*, HEALTHCARE FIN. (June 29, 2018), https://www.healthcarefinancenews.com/news/how-disparate-ehr-systems-lack-interoperability-contribute-physician-stress-burnout ("What a physician might have in their physician care practice might be Athena, or an EMR customized to their workflow, or a public-type vendor. When they go in to do rounding, it's usually an Epic or a Cerner, a large system. They have to deal with three

hospital had 16 disparate EMR vendors in use at its affiliated practices.[90] Even those systems that create records with similar characteristics may provide incomplete data due to inconsistencies in input.[91] These discrepancies lead directly to issues in creation of training datasets and algorithmic testing;[92] sourcing patient data from different systems or in different formats "makes ML more difficult and complex" and can create poor output.[93] The lack of interoperability of existing data systems results in the use of necessarily incomplete datasets in testing.[94] This can tangibly impact patients: a gap in critical information may lead to adverse events at the direct care level,[95] and that same gap may cause incorrect algorithmic predictions for care needs.[96]

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or more EMR systems depending on how they're caring for their patients. If there is no standardization . . . then imagine the challenge of only having a few minutes for the patients and having to provide a full realm of care for them.").

[90] Tom Sullivan, *Why EHR data interoperability is such a mess in 3 charts*, HEALTHCARE IT NEWS (May 16, 2018), https://www.healthcareitnews.com/news/why-ehr-data-interoperability-such-mess-3-charts.

[91] *See* Cassandra Willyard, *Can AI Fix Electronic Medical Records?*, SCI. AM. (Feb. 1, 2020), https://www.scientificamerican.com/article/can-ai-fix-electronic-medical-records ("EHRs include a wide variety of unstructured data . . . For example, a strawberry allergy might end up documented in the clinical notes rather than being listed in the allergies box. In such cases, a model that looks for allergies only in the allergy section of the EHR 'is built off of inaccurate data.'").

[92] For a discussion of some of the types of issues that can be raised by missing or inconsistent EHR data, *see* Nariman Noorbakhsh-Sabet et al., *Artificial Intelligence Transforms the Future of Health Care*, 132 AM. J. MED. 795, 799 (2019).

[93] Any datasets that are sourced from multiple systems using different EHRs will themselves be divergent, since independent EHR systems employ proprietary coding and data standards. *See* Dan Soule, *The Biggest Barriers to Healthcare Interoperability*, HEALTH CATALYST (Apr. 22, 2020), https://www.healthcatalyst.com/insights/healthcare-interoperability-barriers-solutions.

[94] *The Future of Clinical Interoperability in Healthcare*, FORESEE MED. (Aug. 24, 2020), https://www.foreseemed.com/blog/clinical-interoperability-in-healthcare ("As you would expect, the lack of interoperability in healthcare also hinders development, which may be the biggest missed opportunity for the health interoperability ecosystem. Innovators in healthcare face challenges accessing data, integrating into highly-customized environments, and scaling semantic interoperability across a variety of data landscapes.").

[95] *See* Jason Walonoski et al., *Validation and Testing of Fast Healthcare Interoperability Resources Standards Compliance: Data Analysis*, 6(4) J. MED. INFORMATICS (2018) ("The lack of interoperability leads to gaps in critical information at the point of care . . . An inpatient study found that 18% of medical errors leading to adverse drug events could be traced back to missing data in the patient's medical record.").

[96] *See* Moritz Lehne et al., *Why digital medicine depends on interoperability*, 2 NPJ DIGITAL MED. 79 (2019). Lehne et al. discuss the need for interoperability and multiple data sources for precision medicine in particular, but note that data processing is difficult due to the current infrastructure. ("Unfortunately, today's digital health infrastructure makes large-scale data processing across IT systems still unnecessarily difficult . . . [R]unning algorithms on unstructured, non-standardized

Because EHRs contain text entry fields, abundant sources of patient information and potential training data can be gained via NLP.[97] NLP provides incredible and valuable opportunities to glean far more information from EHRs than that which can be obtained by pulling pre-sorted data from labeled fields.[98] However, NLP is not always available or accurate, so precious data can be left unused in text fields.[99] Those text fields may also be the sole sources of socioeconomic, behavioral, or other non-medical information obtained about a patient during their visit.[100] That untapped data can be crucial in creating a full, connected picture of a patient's health,[101] and may be invaluable in creating a predictive model.[102]

A common problem in text entry is "garbage in/garbage out" ("GI/GO") where poorly created, poorly curated datasets create poor output.[103] Consistency

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data can introduce errors that distort analysis results. An AI algorithm programmed to identify, for example, diabetes patients from unstructured text could erroneously select patients with a family history of diabetes, not actual diabetes (not to mention the different types and subgroups of diabetes that could easily be confused) . . . This can introduce systematic biases, which compromise the validity of analysis results and which will eventually undermine trust in digital health technologies . . . [M]odern AI algorithms could do more harm than good—not because their calculations are wrong but because they rely on questionable input.").

[97] *See* "Healthcare NLP: The Secret to Unstructured Data's Full Potential," HEALTH CATALYST (Apr. 2, 2019), https://www.healthcatalyst.com/insights/how-healthcare-nlp-taps-unstructured-datas-potential.

[98] *Id.*

[99] *See* VERA EHRENSTEIN ET AL., TOOLS AND TECHNOLOGIES FOR REGISTRY INTEROPERABILITY, REGISTRIES FOR EVALUATION PATIENT OUTCOMES: A USER'S GUIDE (3rd Edition, Addendum 2 [Internet]) (R. Gilcrich et al. eds., 2019) ("[E]xisting text mining tools and natural language processing applications have limited accuracy in extracting information from free text . . . [This] increases the likelihood of low data quality (e.g., missing data) when data are extracted from structured EHR data only.").

[100] *See* Elham Hatef et al., *Assessing the Availability of Data on Social and Behavioral Developments in Structured and Unstructured Electronic Health Records*, 7 JMIR MED. INFORMATICS (2019) ("Health care systems seeking access to SBDH [social and behavioral determinants of health] data through their electronic health records (EHRs) face various challenges in searching and summarizing structured and unstructured data (clinical free-text notes).").

[101] *Id.*

[102] One recent study discusses the use of free-text processing to improve accuracy of predictions, indicating that examination of "socioeconomic, demographic and clinical factors" during emergency visits and inclusion of unstructured textual data "provided significant improvement in accuracy." Xingyu Zhang et al., *Use of natural language processing to improve predictive models for imaging utilization in children presenting to the emergency department*, 19 BMC MED. INFORMATICS & DECISION MAKING 287 (2019).

[103] Monique F. Kilkenny & Kerin M. Robinson, *Data Quality: "Garbage in—Garbage out"*, 47 HEALTH INFO. MGMT. J. 103, 103 (2018).

of input—that is, using standard input methods and standard language—should be considered by everyone involved at the data entry level, otherwise data analytics, applications or business processes will be unreliable.[104] Established procedures are needed to ensure that good quality data are collected in the health information management and care systems in order to avoid the GI/GO pitfall.[105] However, many doctors have claimed to experience EHR-related stress or burnout because of the need to use EHRs to record patient encounters,[106] which leads to inaccurate text entry and information errors.[107] This presents a genuine need for standardization of NLP and input methods and, perhaps, use of automated systems to ease input fatigue.[108] One potential method of easing fatigue is automated voice recognition and voice typing, which is use of NLP at the input rather than retrieval stage.[109]

2. *Taking Out the Trash: Clean Predictions*

Tied to the GI/GO concern is a lack of mandated "clean data" requirements.[110] "Clean data" is attained by correcting and deleting inaccurate records from a dataset,[111] and this process is of utmost importance when creating predictive models.[112] Data entry errors and duplicate records[113] abound in EHR datasets. At least half of EHRs may contain an error which is "nontrivial,"[114] and

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[104] *Id.*

[105] *Id.*

[106] Christopher Curley, *Doctors Tell Us Why Electronic Health Records Are Causing Burnout*, HEALTHLINE (Feb. 6, 2019), https://www.healthline.com/health-news/why-electronic-health-records-are-burning-out-doctors#1.

[107] *Id.*

[108] Thomas H. Davenport et al., *Using AI to Improve Electronic Health Records*, HARV. BUS. REV. (Dec. 13, 2018), https://hbr.org/2018/12/using-ai-to-improve-electronic-health-records.

[109] *Id.*

[110] Bill Siwicki, *Clean data, AI advances and provider/payer collaboration will be key in 2020*, HEALTHCARE IT NEWS (Jan. 27, 2020), https://www.healthcareitnews.com/news/clean-data-ai-advances-and-providerpayer-collaboration-will-be-key-2020 ("There is no machine learning without clean data—meaning the data needs to be aggregated, normalized and deduplicated.").

[111] *See* Cem Dilmegani, *Data Cleaning in 2021:What it is, Steps to Clean Data & Tools*, AI MULTIPLE: RESEARCH (Jan. 6, 2021), https://research.aimultiple.com/data-cleaning/.

[112] *Id.*

[113] *See* Jackie Drees, *Survey: Providers identify data entry errors as biggest contributor to duplicate medical records*, BECKER'S HEALTH IT (Feb. 12, 2020), https://www.beckershospitalreview.com/ehrs/survey-providers-identify-data-entry-errors-as-biggest-contributor-to-duplicate-medical-records.html.

[114] Data entry errors are a common source of inaccuracies: at least half of EHRs may contain an error related to medication lists, erroneous examination findings, or a lack of critical information. Bell et al., *supra* note 80, at 2.

poor data quality "inevitably leads" to poor algorithmic performance.[115] The absence of clean data is creating challenges in health analytics[116] as well as predictive modeling. Since doctors and health care professionals are already overburdened with data input fatigue, the solution must be to require data cleaning by internal technical departments and further require secondary verification of cleaning by the companies intending to use the data in their development processes. Cleaning tasks should include exporting raw data, checking for completion and accuracy, clearing duplicates, and verifying consistency of field information.[117]

3. *Standardization: Knowing What to Expect When You're Extracting*

A sister issue to clean data is standardization of dataset curation and collection practices. Collection of training data is itself "like the wild west,"[118] as many software companies do not have systems in place to ensure "collection and curation of balanced or representative datasets."[119] This renders them unable to hazard a guess as to whether their work will lead to biased results, which is problematic: bias is one of the core issues facing AI developers,[120] and bias is visibly impactful in the health context.[121] Standardization could help to eliminate some or even a majority of implicit bias at the development stage.

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[115] Sharona Hoffman & Andy Podgurski, *Artificial Intelligence and Discrimination in Health Care*, 19 YALE J. HEALTH POL'Y, L., & ETHICS 1, 13 (2020).

[116] *See* Chris Nerney, *Poor data can sabotage AI initiatives in healthcare*, DXC TECHNOLOGY: BLOG (Mar. 3, 2020), https://blogs.dxc.technology/2020/03/03/poor-data-can-sabotage-ai-initiatives-in-healthcare/ (discussing a 2019 survey of health care providers which indicated that 66% of respondents cited data entry errors in EHRs and 38% said a "lack of data governance" was a barrier to their research).

[117] For a general discussion of data cleaning principles and tasks, *see* Dlmegani, *supra* note 111.

[118] Kenneth Holstein et al., *Improving Fairness in Machine Learning Systems: What Do Industry Practitioners Need?* CHI '19: PROCEEDINGS OF THE 2019 CHI CONFERENCE ON HUMAN FACTORS IN COMPUTING SYSTEMS 1 (May 2019), https://dl.acm.org/doi/pdf/10.1145/3290605.3300830.

[119] *Id.*

[120] *See, e.g.*, Richmond Alake, *Algorithm Bias In Artificial Intelligence Needs To Be Discussed (And Addressed)*, TOWARDS DATA SCI. (Apr. 27, 2020), https://towardsdatascience.com/algorithm-bias-in-artificial-intelligence-needs-to-be-discussed-and-addressed-8d369d675a70; James Manyika et al., *What Do We Do About the Biases in AI?*, HARV. BUS. REV. (Oct. 25, 2019), https://hbr.org/2019/10/what-do-we-do-about-the-biases-in-ai.

[121] Professors Hoffman and Podgurski recently authored a paper that speaks directly to the bias issue in health-related AI, in which they discuss discriminatory effects of AI in health and disadvantages experienced by specific groups of patients as a result of the use of AI. Hoffman & Podgurski, *supra* note 115, at 12–15.

While some standards do exist for health data, they are not well-developed and not consistent. The health industry is striving to implement and develop sets of standards across practice areas, but recent articles and studies have indicated that those standards are not consistently adopted or used effectively.[122] Rather than attempting to adhere to generalized policy, health organizations would be better served by federal requirements ensuring that data specifications are prioritized and "well documented through a repeatable process."[123]

The lack of standardization of data curation methods can lead directly to bias in algorithmic output.[124] In other words, "wild west" data at the input and testing phases of AI development can lead directly, and inadvertently, to an algorithm's unfairly biasing against members of the groups it was designed to serve. As recently as October 2020, the FDA's "Patient Engagement Advisory Committee" spoke of the need to focus upon datasets in the effort to prevent bias.[125] The chief medical officer stated: "In many instances, AI and ML devices may be learning a worldview that is narrow in focus, particularly in the available training data, if the available training data do not represent a diverse set of patients."[126] A lack of diverse, clean input data can cause algorithms to misdiagnose patients who did not fit the mold created by that input data.[127] The

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[122] *See, e.g.*, Christopher Jason, *Identifying Data Standards for Home Healthcare Data Exchange*, EHR INTEL. (Sept. 14, 2020), https://ehrintelligence.com/news/identifying-data-standards-for-home-healthcare-data-exchange; Jessica Kent, *Lack of Data Standards Hinders Patient Matching Improvements*, HEALTH IT ANALYTICS (May 15, 2019), https://healthitanalytics.com/news/lack-of-data-standards-hinder-patient-matching-improvements; AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, PROSPECTS FOR CARE COORDINATION MEASUREMENT USING ELECTRONIC DATA SOURCES: KEY CHALLENGE AREA 2: LACK OF DATA STANDARDIZATION AND LIMITED HEALTH IT SYSTEM INTEROPERABILITY, https://www.ahrq.gov/research/findings/final-reports/prospectscare/prospects1.html (last visited Apr. 19, 2022).

[123] OFC. NAT'L COORD. HEALTH INFO. TECH., PATIENT DEMOGRAPHIC DATA QUALITY FRAMEWORK: INTRODUCTION, https://www.healthit.gov/playbook/pddq-framework/introduction/ (last visited Apr. 19, 2022).

[124] *See* Cristina Goldfain, *Sources of unintended bias in training data,* TOWARDS DATA SCI. (Aug. 19, 2020), https://towardsdatascience.com/sources-of-unintended-bias-in-training-data-be5b7f3347d0 (discussing common sources of bias in training data, including proxies, limited features, skewed samples, tainted examples, and sample size disparities).

[125] Kat Jercich, *FDA highlights the need to address bias in AI*, HEALTHCARE IT NEWS (Oct. 22, 2020), https://www.healthcareitnews.com/news/fda-highlights-need-address-bias-ai.

[126] *Id.*

[127] *See, e.g.,* Dave Gershgorn, *If AI Is Going to be the World's Doctor, It Needs Better Textbooks*, QUARTZ (Sept. 6, 2018), https://qz.com/1367177/if-ai-is-going-to-be-the-worlds-doctor-it-needs-better-textbooks (discussing an instance where AI had been trained on the voices of English speakers of a "particular Canadian dialect" and misconstrued non-native speakers' speech as indicative of Alzheimer's disease).

standardization task is one that should be managed and regulated at the development level.

b.   The Significant Issue of Disparity

The health care industry is rife with bias, both algorithmic and in standard practice.[128] For algorithms, preventing bias requires oversight aimed at the initial data sourcing and testing phases. The increasingly prevalent use of algorithms without such oversight leads to situations where specific demographic groups are excluded from beneficial treatments and therapies,[129] which may be a violation of those groups' civil rights.[130] It can also lead to altogether incorrect predictions about the types of treatments that may be effective for specific patients.[131]

Biased output from a health-focused algorithm is a serious, possibly life-threatening issue.[132] That issue becomes even more important during a pandemic.[133] The introduction of automated decision-making systems to aid in health care is potentially disastrous for low-income patients, minorities, and women, as AI may "create self-fulfilling prophesies that confirm our pre-existing

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[128] *See* Alvin Rajkomar et al., *supra* note 29; *see also* Muhammad Aurangzeb Ahmad et al., *Fairness in Machine Learning for Healthcare*, KDD '20: PROCEEDINGS OF THE 26TH ACM SIGKDD INTERNATIONAL CONFERENCE ON KNOWLEDGE DISCOVERY & DATA MINING 3259 (August 2020) ("Even outside of AI/ML, healthcare and medicine have a long history of implicit or explicit bias which has been well documented: There is a large body of research showing that minority patients receive poorer quality of care despite similar disease severity, clinical presentation and medical insurance. Healthcare has been rife with examples of algorithmic discrimination.").

[129] *See, e.g.*, Natasha Lomas, *DeepMind touts predictive healthcare AI 'breakthrough' trained on heavily skewed data*, TECHCRUNCH (July 31, 2019), https://techcrunch.com/2019/07/31/deepmind-touts-predictive-healthcare-ai-breakthrough-trained-on-heavily-skewed-data/ (discussing how Google's AI model predicting likelihood of kidney injury produced heavily flawed results which excluded specific demographic groups); Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 SCIENCE 447 (2019) (evaluating a specific health care algorithm which disproportionately favored distributing limited resources to white patients because their average cost of care was higher than a black patient's).

[130] Hoffman & Podgurski, *supra* note 115, at 6 (noting that algorithmic discrimination may violate sections of both the Civil Rights Act and the Affordable Care Act).

[131] *See, e.g.*, Spitzer, *supra* note 12 (discussing Watson's mistaken recommendation of inappropriate treatments for cancer patients).

[132] *See* Ben Dickson, *Healthcare Algorithms Are Biased, and the Results can be Deadly*, PC MAG (Jan. 23, 2020), https://www.pcmag.com/opinions/healthcare-algorithms-are-biased-and-the-results-can-be-deadly.

[133] *See* Eliane Röösli et al., *Bias at warp speed: how AI may contribute to the disparities gap in the time of COVID-19*, 28 J. AM. MED. INFORMATICS ASSOC. 190, 191 (2020) (arguing that AI models used in allocation of limited-availability ICU beds for COVID-19 patients may improperly allocate those beds based on biased data about comorbidity).

biases."[134] Biased algorithms exist everywhere: two notable examples of visibly biased output from algorithms are 1) Amazon's employment algorithm, which unfairly disqualified women as candidates for high-ranking positions at the company;[135] and 2) Google DeepMind's predictor of kidney injury,[136] which despite its claim of high success, had not been trained on adequate data for women or minorities.[137]

While not a health-related example, the Amazon situation was noteworthy due to the glaring employment discrimination that resulted from its use of biased AI. Amazon had been running algorithms for the purpose of recruiting "top talent."[138] The algorithms gave job candidates a ranking of one to five stars, much like Amazon's virtual catalog of goods.[139] The ranking was based on the similarities between candidates' résumés and patterns observed in résumés submitted over the course of ten years.[140] The patterns were predominantly learned from men's résumés, since men held most of the positions in the company; thus, the system taught itself that résumés with the word "women's" were less desirable than others.[141] The technology also favored descriptive words more commonly found on male engineers' résumés, such as "executed" or "captured."[142]

The second example, Google DeepMind, came as a surprise after the company had touted its ability to correctly predict "90 percent of acute kidney injuries that would end up requiring dialysis."[143] What Google failed to announce was that its breakthrough was built on data that skewed 93.6% male;[144] additionally, only 18.9% of patients were Black, and no other ethnicities were

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[134] *See* Dhruv Khullar, *A.I. Could Worsen Health Disparities*, N.Y. TIMES (Jan. 31, 2019), https://www.nytimes.com/2019/01/31/opinion/ai-bias-healthcare.html.

[135] Jeffrey Dastin, *Amazon Scraps Secret AI Recruiting Tool that Showed Bias Against Women*, REUTERS (Oct. 10, 2018), https://www.reuters.com/article/us-amazon-com-jobs-automation-insight/amazon-scraps-secret-ai-recruiting-tool-that-showed-bias-against-women-idUSKCN1MK08G.

[136] Lomas, *supra* note 129.

[137] *Id.*

[138] Dastin, *supra* note 135.

[139] *Id.*

[140] *Id.*

[141] *Id.*

[142] *Id.*

[143] Christina Farr, *Google's DeepMind says its A.I. tech can spot acute kidney disease 48 hours before doctors spot it*, CNBC (Jul. 31, 2019), https://www.cnbc.com/2019/07/31/googles-deepmind-says-its-ai-sees-acute-kidney-disease-48-hours-early.html.

[144] Lomas, *supra* note 129. Lomas notes that DeepMind's AI was trained using patient data from the U.S. Department of Veteran Affairs, which skews heavily male and white.

designated in the results data.[145] The predictive capability may be valuable, but it remains untested on a more representative population.

One area of major concern is in clinical trial data: most clinical trials take place in Europe and the United States,[146] and middle-class white males are overrepresented in those trials.[147] This is problematic in that new treatments and therapies are often not tested on a representative group of would-be patients, and thus the un- or underrepresented groups have no data indicating whether a proposed treatment would be effective (or cause harm).[148] Datasets compiled from clinical trials in general require significant curation and correction to avoid inaccuracies leading to biased algorithmic output.[149]

A recent and ongoing concern is that AI bias may have worsened or will continue to worsen inequalities for people of color in terms of response to COVID-19.[150] Use of unrepresentative data samples to predict the effect and severity of COVID-19,[151] where the data has been independently collected by separate entities and does not include representative data for minority groups, may lead to non-optimal allocation of vital resources to those groups.[152] People of color may thus be less likely to receive life-saving treatment when presenting with COVID symptoms. The reason for these disparities is simple, but difficult to remedy without acknowledging and correcting disparities in healthcare treatment: available training data is mostly "white and male."[153]

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[145] *Id.*

[146] NIALL MCALISTER & ROLAND WIRING, AI IN LIFE SCIENCES & HEALTHCARE: LEGAL PERSPECTIVES ON THE OPPORTUNITIES AND CHALLENGES OF AI FOR LIFE SCIENCES COMPANIES 30 (2021).

[147] *Id.*

[148] *Id.*

[149] *Id.*

[150] Kat Jercich, *AI bias may worsen COVID-19 health disparities for people of color*, HEALTHCARE IT NEWS (Aug. 18, 2020), https://www.healthcareitnews.com/news/ai-bias-may-worsen-covid-19-health-disparities-people-color; Röösli et al., *supra* note 133.

[151] Jercich, *supra* note 150 (arguing that models built on biased data or that improperly exclude race and gender, for example those that include comorbidities without allocating for socioeconomic reasons for those comorbidities, "could reinforce the structural biases that lead to some groups experiencing those comorbidities.").

[152] *Id.* (listing resources such as ventilators and intensive care unit beds).

[153] *A.I. Bias in Healthcare: Human Pride, Machine Prejudice*, MED. FUTURIST (Sept. 19, 2019), https://medicalfuturist.com/a-i-bias-in-healthcare/ (discussing the disparities in source, quality, diversity, historical social practices, and social structures involved in health care datasets).

c. The Question of Transparency and Explainability

Previous administrations, and Congress itself, have noted the bias and disparity issues inherent in AI, and one common aspect of their proposed responses is a requirement for increased transparency into algorithmic processes.[154] However, there is a sizable gap between traditional notions of transparency and what is realistic or feasible for insight into AI. Software transparency refers to visibility of the actual code being used when a program is running. ML processes learn from data and solve problems dynamically.[155] After an ML algorithm has been developed, tested, and pushed to market in any form, it is normally "black boxed"[156]—that is, it is programmed such that its input and output is visible without giving the user any knowledge of the internal workings of the algorithm.[157] An end user (a hospital, doctor's office, patient, or research facility) would therefore have no visibility into that algorithm's operation.

This lack of transparency has understandably been a pivotal concern for lawmakers.[158] However, the solution to black boxing is not simple. "White-boxing" code[159] very likely infringes on the intellectual property rights of the company that wrote the algorithm.[160] In addition, white-boxing code may be an inadequate method of governing algorithmic solutions.[161] Because ML algorithms are constantly learning, an engineer who designed an ML system may not be able

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[154] This was referenced in the most comprehensive piece of attempted legislation, the Algorithmic Accountability Act of 2019. In the case of the Act, the "transparency" requirement included a reportability requirement. For a deeper discussion of the Act, s*ee infra* Part III(C).

[155] *See* Yavar Bathaee, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, 31 HARV. J. L. & TECH. 889, 899 (2018).

[156] *See* Vanessa Burhmeister et al., *Analysis of Explainers of Black Box Deep Neural Networks for Computer Vision: a Survey*, ARXIV (Nov. 27, 2019) https://arxiv.org/pdf/1911.12116.pdf (discussing black box setups for deep learning).

[157] Bennie Mols, *In Black Box Algorithms We Trust (or Do We?)*, COMM. ACM (Mar. 16, 2017), https://cacm.acm.org/news/214618-in-black-box-algorithms-we-trust-or-do-we/fulltext.

[158] *See, e.g.*, Baobao Zhang, *Public opinion lessons for AI regulation*, BROOKINGS (Dec. 10, 2019), https://www.brookings.edu/research/public-opinion-lessons-for-ai-regulation/.

[159] *White Box Testing*, IMPERVA, https://www.imperva.com/learn/application-security/white-box-testing/ ("White box testing is an approach that allows testers to inspect and verify the inner workings of a software system—its code, infrastructure, and integrations with external systems.") (last visited Nov. 1, 2020).

[160] *See* Frank A. DeCosta, III & Aliza G. Carrano, *Intellectual Property Protection for Artificial Intelligence*, FINNEGAN (Aug. 30, 2017) https://www.finnegan.com/en/insights/articles/intellectual-property-protection-for-artificial-intelligence.html (discussing patent, trade secrets and copyright protection as it relates to programmed code).

[161] Mike Ananny & Kate Crawford, *Seeing Without Knowing: Limitations of the Transparency Ideal and Its Application to Algorithmic Accountability*, 20 NEW MEDIA & SOC'Y 973, 978 (2018).

to precisely say where a problem is occurring even with total visibility.[162] Some aspects of algorithmic calculations "never take durable, observable forms."[163] This has been referred to as the "transparency paradox": more data does not mean more information.[164]

The lack of comprehensibility would strongly favor an "explainability" model. In this model, a developer or company would provide an explanation of a code's process– in plain language– to an end user rather than opening the code for viewing.[165] The explainability model is favored by NIST,[166] which states that "explainable AI is a key element of trustworthy AI."[167] Explainability should be contextual: some audiences will require "global" (entire) explanations while others will need "local" explanations (specific to one algorithmic decision).[168] This approach is preferable to traditional white-boxing in most contexts. The Harvard Data Science Review has promulgated an alternative, but similar, approach: "interpretable" models using simpler, more intelligible algorithms.[169] Wider-spread development of interpretable AI would provide an alternative to both black-boxing and the need to have developers, or companies, fully explain an algorithm.

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[162] *Id*. at 978, 981.

[163] *Id.* at 981.

[164] Alexander Buhmann et al., *Managing Algorithmic Accountability: Balancing Reputational Concerns, Engagement Strategies, and the Potential of Rational Discourse*, 20 J. BUS. ETHICS 265, 267 (2019); *but c.f.* Gerke et al., *supra* note 32, at 303 (Adam Bohr & Kaven Memarzadeh eds., 2020) (arguing that "in an ideal world all data and algorithms would be open for the public to examine," while acknowledging that the AI might have "sophisticated transformations beyond the skills of clinicians (and especially patients) to understand.").

[165] For a discussion of the "explainability" method, *see* Seng W. Loke, *Achieving Ethical Algorithmic Behaviour in the Internet of Things: A Review*, 2 IOT 401 (2021).

[166] *See* Chad Boutin, *NIST Asks A.I. to Explain Itself*, NIST (Aug. 18, 2020), https://www.nist.gov/news-events/news/2020/08/nist-asks-ai-explain-itself; NIST, *AI Fundamental Research—Explainability,* https://www.nist.gov/artificial-intelligence/ai-foundational-research-explainability (last visited Jan. 30, 2021) [hereinafter *NIST AI Research*].

[167] *NIST AI Research*, *supra* note 166.

[168] Yukti Sharma et al., *'Reasonable Explainability' for Regulating AI in Health*, 401 OBSERVER RES. FOUND. ISSUE BRIEF 1, 5 (Sept. 2020).

[169] Cynthia Rudin & Joanna Radin, *Why Are We Using Black Box Models in AI When We Don't Need To? A Lesson From an Explainable AI Competition*, HDSR (Nov. 22, 2019), https://hdsr.mitpress.mit.edu/pub/f9kuryi8/release/7. Interpretable AI has already been explored in the health care context, as well. *See* Rich Caruana et al., *Intelligible Models for HealthCare: Predicting Pneumonia Risk and Hospital 30-Day Readmission*, KDD '15: PROC. 21TH ACM SIGKDD INT'L CONF. ON KNOWLEDGE DISCOVERY & DATA MINING 1721 (2015) (discussing two examples of highly accurate intelligible models in health care studies).

IV.   Current Attempts to Manage the Medical Matrix

> **a.   Navigating the Regulatory Landscape: the FDA, the FCC, and the FTC**

AI models are woefully under-regulated at every stage of development and use.[170] Some health-related AI is currently subject to regulation by the FDA, and other AI may fall under a general purview of the Federal Trade Commission (FTC) or Federal Communications Commission (FCC). Yet more must be done: the evolution of AI is swift and dynamic while legislation and rulemaking are not.[171]

> *1.   The Self-Limited Role of the FDA*

The FDA currently governs medical devices and "Software as a Medical Device" ("SaMD").[172] The agency is aware that something must change. It has stated that its "traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies."[173]

The obvious answer for regulation of all health-focused AI would be FDA oversight, but the obvious answer is not always the correct one. Although some AI is subject to FDA oversight, the broader regulatory framework "is yet to be developed."[174] The U.S. Government Accountability Office's report on AI in health care dated December 2019 summarizes stakeholders' concerns that there is

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[170] *See* Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 133 (2019).

[171] *Id.* at 150 ("[A] real question arises as to whether the FDA can keep up with the rapid innovations in digital health and, particularly, in healthcare AI").

[172] Examples of SaMD include: software that allows a smartphone to view MRI imaging, software intended for diagnosis of a specific medical condition; and computer-aided detection software that performs image post-processing to help detect breast cancer. *See What are examples of Software as a Medical Device?*, FDA (Dec. 6, 2017), https://www.fda.gov/medical-devices/software-medical-device-samd/what-are-examples-software-medical-device.

[173] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, FDA (Sept. 22, 2021), https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device#regulation [hereinafter *FDA AI/ML*].

[174] *See* Kavita Sharma and Padmavati Manchikanti, *Regulation of Artificial Intelligence in Drug Discovery and Health Care*, 39 BIOTECHNOLOGY L. REP. 371 (2020) ("While there are a good number of AI-based applications being developed, some being approved for commercialization and use by United States Food and Drug Administration (FDA) in the health care sector, the regulatory framework is yet to be developed.").

"not enough guidance about what information or data FDA will require for approval of machine learning uses."[175]

Indeed, the FDA has been grappling with regulation of health technology for years. It was given authority to regulate medical devices as far back as 1976,[176] which later expanded to SaMD.[177] In 2016, the definition of "medical device" was altered under the 21st Century Cures Act.[178] Under the new definition, the FDA "will not regulate software that uses 'big data' to provide clinical decision support,"[179] with an exception for situations where it "would be reasonably likely to have serious adverse health consequences."[180] On top of the changes made by the 21st Century Cures Act, as of 2020, the FDA had only approved device-based, higher-risk, health-focused AI with "locked" algorithms.[181] The agency does not intend to regulate lower-risk software, out of a desire not to hinder development.[182]

In 2019, the FDA proposed an "innovative framework" for AI which considered a "total product lifecycle."[183] The total product lifecycle would involve an approach in which the FDA "would expect a commitment from manufacturers on transparency and real-world performance monitoring . . . as well as periodic updates to the FDA on what changes were implemented."[184] Still, this does little in terms of regulatory action—it is more of a notice requirement, and it includes the arguably flawed obligation of transparency. In January of 2021, the agency published an action plan to update its policies on AI/ML devices and

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[175] GAO AI REPORT, *supra* note 51.

[176] *See A History of Medical Device Regulation and Oversight in the United States*, FDA (June 24, 2019), https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states.

[177] *Id*.

[178] U.S. FOOD & DRUG ADMIN., FDA-2017-D-6294, CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21ST CENTURY CURES ACT (2019), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act.

[179] Sarah Faulkner, *How the 21st Century Cures Act will affect medical devices*, MASS DEVICE (Dec. 8, 2016), https://www.massdevice.com/21st-century-cures-act-will-affect-medical-devices.

[180] *Id.* (quoting 21st Century Cures Act, Pub. L. No. 114–255, § 3060, 130 Stat. 1033, 1132 (2016)).

[181] U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE (AI) AND MACHINE LEARNING (ML) IN MEDICAL DEVICES (Oct. 22, 2020), https://www.fda.gov/media/142998/download.

[182] *See* H. Benjamin Harvey & Vrushab Gowda, *How the FDA Regulates AI*, 27 ACAD. RADIOLOGY 58, 60 (2020) (discussing the FDA's proposed "total product lifecycle approach," by which "the Agency attempts to strike a balance between reducing the overall regulatory burden incumbent on AI SaMD developers while achieving its regulatory objectives").

[183] *Id.* at 59; *see also FDA AI/ML, supra* note 173.

[184] *FDA AI/ML, supra* note 173.

SaMD.[185] The plan outlines five components that the agency plans to implement, including: 1) a tailored regulatory framework; 2) good machine learning practice ("GMLP"); 3) a patient-centered approach incorporating transparency; 4) use of regulatory science methods related to bias and robustness; and 5) "real-world performance" metrics.[186]

Although the 2021 plan specifically mentions the need to improve methodologies for identifying bias in ML, it does not address the larger issue of poorly-sourced and poorly-tested datasets in health-focused AI outside of SaMD.[187] It also does not speak to the rapidly-changing nature of AI devices or models in health technology.[188] Further, it echoes the "transparency" language found in other government proposals, language which would be better stated as "explainability," or even, following the Harvard Data Science Review's argument, "interpretability."[189] The plan does, however, speak to standardization via the GMLP step.[190]

2. *Traversing the Health/Wellness Terrain: the FCC and FTC*

A remaining issue lies in the narrowing gap between health and wellness devices. Commonly used "wellness" physical technologies include wearable fitness trackers and at-home "Internet of Things" tools such as smart scales, technologies which are subject to a variety of regulatory schemes and agencies.[191]

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[185] U.S. FOOD & DRUG ADMINISTRATION, ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN, FDA.GOV (Jan. 2021), https://www.fda.gov/media/145022/download [hereinafter FDA ACTION PLAN JAN. 2021].

[186] *Id.*

[187] *Id.* at § 4.

[188] *See* Andrej Kovacevic, *AI Moving into Healthcare, Regulatory Challenges Await*, READWRITE (Mar. 13, 2020), https://readwrite.com/2020/03/13/ai-moving-into-healthcare-regulatory-challenges-await/ ("[T]he capabilities, safety, and efficacy of some of the newest medical AI solutions can't be assessed [quickly enough] for regulators to grant approvals. Unlike medications and standard medical devices, applied AI in medicine is a moving target. Whereas a non-AI device can undergo thorough testing and gain approval, an AI's performance may be different the day after its undergone testing. What's more, there's no telling if the performance differences will make it work better or worse. That's why regulators like the US's Food and Drug Administration (FDA) have thus far only started to approve locked-algorithm solutions.").

[189] Rudin & Radin, *supra* note 169.

[190] FDA ACTION PLAN JAN. 2021, *supra* note 185.

[191] *See* Gicel Tomimbang, *Wearables: Where do they fall within the regulatory landscape?*, IAPP (Jan. 22, 2018), https://iapp.org/news/a/wearables-where-do-they-fall-within-the-regulatory-landscape/; Charlotte A. Tscheider, *Regulating the Internet of Things: Discrimination, Privacy, and Cybersecurity in the Artificial Intelligence Age*, 96 DENV. L. REV. 87 (2018) (explaining the efforts made by the FTC, FCC, and NTIA to regulate IoT devices).

Many wellness-based physical home devices fall under separate regulatory structures outside the scope of the FDA.[192] Thus, a significant question in oversight is which agency, if any, has authority over a specific type of health-related AI. The answer is not always clear. Companies that produce devices walk a line—one that is blurring[193]—between creating health devices (which are regulated by the FDA via the Food, Drug, & Cosmetic Act)[194] and wellness technologies (which are not).[195] This gap in oversight largely exists because current regulatory agencies only regulate the technologies that fall specifically within their preordained domain. In the case of the FDA, those technologies are medical devices and SaMD.

Wellness devices may be subject to scrutiny and oversight that has nothing to do with health care data, at least not directly. The FCC governs devices that emit a radio or Bluetooth signal,[196] while the FTC oversees truth-in-advertising issues for health-based services or devices.[197] The FTC also acts as the "default regulator" of privacy and security issues.[198] Yet devices that only fall under these limited regulations may still be running predictive algorithms, learning personal health data, and creating valuable databases of (non-medical) information. Of additional concern to the health industry is that if a health-focused software

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[192] *See* Tschider, *supra* note 191, at 123.

[193] *See generally* Lauren Horwitz, *Line Between Consumer Wellness and Traditional Medicine Blurs Further*, IoT WORLD TODAY (Jan. 28, 2020), https://www.iotworldtoday.com/2020/01/28/line-between-consumer-wellness-and-traditional-medicine-blurs-further/.

[194] Food, Drug, & Cosmetic Act, *supra* note 48.

[195] *See* Brian Dolan, *FDA clarifies the line between wellness and regulated medical devices*, MOBI HEALTH NEWS (Jan. 16, 2015), https://www.mobihealthnews.com/39775/fda-clarifies-the-line-between-wellness-and-regulated-medical-devices (explaining the differences in types of wellness devices, the FDA draft guidance on the topic, and claims that a "general wellness device" manufacturer should not make "if they are aiming to remain unregulated.").

[196] *Federal Communications Commission*, USA.GOV, https://www.usa.gov/federal-agencies/federal-communications-commission ("The Federal Communications Commission regulates interstate and international communications through cable, radio, television, satellite and wire. The goal of the Commission is to promote connectivity and ensure a robust and competitive market.") (last visited Apr. 19, 2022); s*ee also* Kristi Wolff & Chip Yorkgitis, *From FitBit to Quitbit: The Role of Federal Agencies and Consumer Electronics*, KELLEY DRYE: AD LAW ACCESS (Jan. 15, 2015), https://www.adlawaccess.com/2015/01/articles/from-fitbit-to-quitbit-the-role-of-federal-agencies-and-consumer-electronics/ (providing an example of a medical device potentially under FCC jurisdiction due to radio connectivity).

[197] FED. TRADE COMM'N, *Health Claims*, https://www.ftc.gov/news-events/media-resources/truth-advertising/health-claims (last visited Apr. 19, 2022).

[198] HEALTH IT POL'Y COMM. PRIV. & SEC. WORKGROUP, HEALTH BIG DATA RECOMMENDATIONS, HEALTHIT.GOV (Aug. 2015), https://www.healthit.gov/sites/default/files/facas/HITPC_Health_Big_Data_Report_FINAL.pdf.

company's work falls outside the scope of the FDA because it uses adaptive, dynamic algorithms,[199] that company's data standards may not currently be regulated.[200]

b.   If Not the FDA, Who?: Former Executive Orders and Policymaking

It is clear to the author that AI requires regulation, and that regulation needs to be "unitary, not fragmented."[201] That unity cannot exist without centralized standardization. Both the Obama administration and the Trump administration acknowledged the importance of AI,[202] and President Trump released two Executive Orders on the subject.[203] The Biden administration will likely start regulating in a manner akin to EU.[204] Several pre-existing initiatives are already in place, including creating a new National AI Initiative Office.[205]

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[199] The FDA currently only regulates locked, device-based algorithms in health care, which can include algorithms that manage a physical medical device or algorithms that perform a specific, non-adaptive health-related function. *See generally* Benjamens et al., *supra* note 46.

[200] *See* Joe Corrigan & Isabel Losantos, *The potential of AI in medicine and how it's changing regulation*, EPM MAG. (Sept. 28, 2020, 11:30 am), https://www.epmmagazine.com/opinion/the-potential-of-ai-in-medicine-and-how-it-s-changing-regula/ ("[B]ecause the risk from an Adaptive system can change as it learns, existing regulation does not effectively manage potential risks and a new approach is required.").

[201] *See* Terry, *supra* note 170.

[202] *See, e.g.*, Ed Felten & Terah Lyons, *The Administration's Report on the Future of Artificial Intelligence*, WHITE HOUSE: BLOG (OBAMA ADMINISTRATION) (Oct. 12, 2016), https://obamawhitehouse.archives.gov/blog/2016/10/12/administrations-report-future-artificial-intelligence; *Artificial Intelligence for the American People*, WHITE HOUSE (TRUMP ADMINISTRATION), https://trumpwhitehouse.archives.gov/ai/ (last visited Apr. 19, 2022).

[203] Note, however, that President Trump's orders were aimed at propelling American AI development more than they were preventing algorithmic bias.
See Exec. Order No. 13,859, 84 Fed. Reg. 3967 (Feb. 11, 2019), https://www.federalregister.gov/do cuments/2019/02/14/2019-02544/maintaining-american-leadership-in-artificial-intelligence [hereinafter Maintaining Leadership]; Exec. Order. No. 13,960, 85 Fed. Reg. 78939 (Dec. 3, 2020), https://www.federalregister.gov/documents/2020/12/08/2020-27065/promoting-the-use-of-trustworthy-artificial-intelligence-in-the-federal-government. For a description of the order of December 2020, *see generally* Campbell Kwan, *Trump signs another executive order on governmental AI development*, ZDNET (Dec. 4, 2020), https://www.zdnet.com/article/trump-signs-another-ai-executive-order/.

[204] Alex Engler, *The EU and U.S. are Starting to Align on AI Regulation*, BROOKINGS (Feb. 1, 2022), https://www.brookings.edu/blog/techtank/2022/02/01/the-eu-and-u-s-are-starting-to-align-on-ai-regulation/.

[205] The National AI Initiative Office was authorized in the 2020 National Defense Authorization Act; it is unclear at the time of writing this Note as to whether the Biden administration will leave AI work to this new office or retain some responsibility for initiatives under the White House Chief Technology Officers. *See* Alex Engler, *6 developments that will define AI governance in*

President Trump's order of 2019, the Executive Order titled "Maintaining American Leadership in Artificial Intelligence,"[206] signaled the growing and thriving role of AI throughout the U.S. economy and worldwide. It called for an interagency approach to the development and regulation of AI.[207] That approach was to be spearheaded by the National Science and Technology Council.[208] It would have involved a staggering number of agencies, including the National Security Foundation, National Institutes of Health, U.S. Department of Energy, and the Intelligence Advanced Research Projects Activity board.[209] This was notable because the Trump White House presented another interagency-themed approach towards the end of his presidency in 2020, signaling the continued prevailing belief that this issue needs to be addressed by experts in multiple fields.[210]

A later document, a memorandum released by the White House Office of Management and Budget (OMB) in November 2020, offered guidance for the regulation of AI.[211] The guidance was based upon the NIST AI standards, which are a work in progress.[212] It provided a broad set of principles for managing AI through interagency regulatory and non-regulatory methods. Those methods would be overseen by the Office of Information and Regulatory Affairs (OIRA).[213] This guidance was meant to be a comprehensive, final statement on how the federal government will be approaching AI.

However, the OMB memorandum misses the mark in several ways. The memorandum strongly favored a hands-off approach: the OMB indicated that federal agencies "must avoid regulatory or non-regulatory actions that needlessly hamper AI innovation and growth."[214] This would continue, if not exacerbate, the existing problem of "wild west" data. The memorandum stressed fairness, non-

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2021, BROOKINGS (Jan. 21, 2021), https://www.brookings.edu/research/6-developments-that-will-define-ai-governance-in-2021/.

[206] Maintaining Leadership, *supra* note 203.

[207] *See* Maintaining Leadership, *supra* note 203.

[208] *Id*.

[209] Felten & Lyons, *supra* note 202.

[210] Memorandum from the Executive Office of the President to the Heads of Executive Departments and Agencies (Nov. 17, 2020), https://www.whitehouse.gov/wpcontent/uploads/2020/11/M-21-06.pdf [hereinafter OMB Memorandum on AI].

[211] *Id*.

[212] *See* NIST AI STANDARDS, *supra* note 34.

[213] OMB Memorandum on AI, *supra* note 210, at 10.

[214] OMB Memorandum on AI, *supra* note 210, at 2.

discrimination, disclosure, and transparency[215] and required agencies to adopt common (NIST) standards,[216] which are admirable guidelines, but challenging if not impossible to enforce. It placed a high hurdle to clear before OIRA would approve any rulemaking,[217] effectively tying the hands of the agencies involved.

The NIST standards are too loose to be adequately implemented, as they are non-specific and intended to be frameworks rather than enforceable regulations.[218] Additionally, OIRA may not have the ability to adequately manage regulatory oversight: OIRA has a relatively small staff and likely lacks the required AI expertise to suggest or approve AI regulations, not to mention that OIRA's role is primarily reactive rather than proactive.[219] Lastly, "transparency," as mentioned in the document, is too broadly defined to be of practical use, a common problem in proposals relating to AI management.[220] The OMB memorandum is wholly insufficient in areas like health care that require stricter, tougher regulation to avoid potentially harmful consequences.[221]

c. The Algorithmic Accountability Act of 2019

Numerous attempts at federal legislation involving AI have been made.[222] In 2018 alone, thirty-nine bills were introduced that included the words "artificial intelligence" in the text.[223] Each attempt, however, has been met with confusion

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[215] *Id*. at ¶¶ 7, 8.

[216] *Id*. at 10.

[217] *Id*.

[218] NIST AI STANDARDS, *supra* note 34; *see also* Nate Lord, *What is NIST Compliance?*, DATAINSIDER: BLOG (Dec. 1, 2020), https://digitalguardian.com/blog/what-nist-compliance ("NIST standards are based on best practices from several security documents, organizations, and publications, and are designed as a framework for federal agencies and programs . . . ").

[219] *Id. But see* Lisa Schulz Bressman, *Flipping the Mission of Regulatory Review*, REGULATORY REV. (Feb. 18, 2021), https://www.theregreview.org/2021/02/18/bressman-flipping-mission-regulatory-review/ (discussing President Biden's suggestion that OIRA be given authority to develop, rather than review, "regulations that advance the Administration's values." It is plausible that AI would become one of those values if this moved forward.)

[220] The OMB Memorandum on AI states: "What constitutes appropriate disclosure and transparency is context-specific, depending on assessments of potential harms." OMB Memorandum on AI, *supra* note 210, at ¶ 8. This language is so broad that it leaves the assessment of harm open to total interpretation.

[221] *Id*.

[222] *AI Legislation Tracker—United States*, CTR. FOR DATA INNOVATION, https://www.datainnovation.org/ai-policy-leadership/ai-legislation-tracker/ (showing ten AI related bills in 2020, eight in 2019, and three in 2018) (last visited Apr. 19, 2022).

[223] James Martin, *United States: Federal Legislation and Regulatory Action*, *in* REGULATION OF ARTIFICIAL INTELLIGENCE IN SELECTED JURISDICTIONS 27, LIBR. OF CONG. (Jan. 2019), https://www.loc.gov/law/help/artificial-intelligence/regulation-artificial-intelligence.pdf.

and questioning at the Congressional level[224] due at least in part to a misunderstanding of the technologies involved.[225] Congress has realized that there is a need for some form of government action given the observable "racist impacts" of AI[226] and has signaled that it is serious about equity and bias. It made its farthest-reaching attempt into regulating AI with the Algorithmic Accountability Act of 2019.[227]

In 2019, Senators Cory Booker and Ron Wyden, along with Representative Yvette Clarke, introduced a bill titled the "Algorithmic Accountability Act" ("the Act").[228] The Act was Congress' first real foray into national governance of AI.[229] It directed the FTC to make rules that would regulate "impact assessments" for "high-risk automated decision-making systems,"[230] and would have applied to companies that had over $50 million a year in average annual gross receipts.[231] An impact assessment would have involved a study evaluating development, design, and training data, but also

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[224] *See* Gopal Ratnam & Kate Ackley, *Artificial intelligence is coming. Will Congress be ready?*, ROLL CALL (June 10, 2019), https://www.rollcall.com/2019/06/10/artificial-intelligence-is-coming-will-congress-be-ready/ (quoting Rep. Lamar Smith, R-TX: "Capitol Hill, Congress, the House and Senate, are just sort of trying to feel their way forward. I think they're really just at the beginning of information gathering and the self-education process.").

[225] *See, e.g.*, Jaclyn Diaz, *Congress Plays Catch-Up on Artificial Intelligence at Work*, BLOOMBERG L. (Aug. 27, 2019), https://news.bloomberglaw.com/daily-labor-report/congress-plays-catch-up-on-artificial-intelligence-at-work; Tony Samp & Steven R. Phillips, *DC policymakers working to stay ahead of—or keep up with— AI innovations*, DLA PIPER: AI OUTLOOK (Nov. 4, 2019), https://www.dlapiper.com/en/us/insights/publications/2019/10/dc-policymakers-working-to-stay-ahead-of/; Mike Snider, *Congress and technology: Do lawmakers understand Google and Facebook enough to regulate them?*, USA TODAY (Aug. 2, 2020), https://www.usatoday.com/story/tech/2020/08/02/google-facebook-and-amazon-too-technical-congress-regulate/5547091002/.

[226] Margot E. Kaminski & Andrew D. Selbst, *The Legislation That Targets the Racist Impacts of Tech*, N.Y. TIMES (May 7, 2019), https://www.nytimes.com/2019/05/07/opinion/tech-racism-algorithms.html

[227] Algorithmic Accountability Act of 2019, S. 1108, 116th Cong. (1st Sess. 2019).

[228] *Id*.

[229] Joshua New, *How to Fix the Algorithmic Accountability Act*, CTR. FOR DATA INNOVATION (Sept. 23, 2019), https://www.datainnovation.org/2019/09/how-to-fix-the-algorithmic-accountability-act/.

[230] *Id.*

[231] Adi Robertson, *A new bill would force companies to check their algorithms for bias*, THE VERGE (Apr. 10, 2019), https://www.theverge.com/2019/4/10/18304960/congress-algorithmic-accountability-act-wyden-clarke-booker-bill-introduced-house-senate; Algorithmic Accountability Act, *supra* note 227.

required that all of the above be made publicly available.[232] The Act was a well-meaning but flawed attempt to force private sector entities to closely examine and audit their AI for bias.[233]

The Act fell short of covering health industry-related needs in that it only applied to major companies with large systems[234]—which may include some larger hospital systems, but not smaller health offices and health-related companies.[235] The Act was also impractical in that it ignored the reality of software development and the iterative process.[236] Due to the nature of software development and testing, it would not be feasible to require impact assessments for every new update that was pushed by the developer or developing company.[237] A better option would be to require standardization of sourced data and data input, as the OMB attempted to do with its memorandum.[238]

Commendably, the Act did set forth requirements for running an impact assessment on an automated decision system's "process," including its design and its training data.[239] The authors of the Act seemed to recognize that bias could be inadvertently introduced at the training stage. However, the Act did not directly provide for the ability to review data sourcing or impose a set of data quality standards on the creators of the algorithms.

The Act "produced more lessons learned and questions than actionable law,"[240] which its proponents recognized. In December of 2019, Senator Booker sent letters to the FTC and the Centers for Medicare and Medicaid Services

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[232] *See* Vaidyanathan Balasubramanian, *Algorithmic Accountability Act of 2019—Challenges & Opportunities*, WIPRO (June 2019), https://www.wipro.com/blogs/vaidyanathan-balasubramanian/algorithmic-accountability-act-of-2019-challenges-and-opportunities/.

[233] *See* Elena Kuenzel et al., *How to Mitigate Bias in Healthcare Algorithms*, BOOZ ALLEN HAMILTON, https://www.boozallen.com/c/insight/blog/how-to-mitigate-bias-in-healthcare-algorithms.html (last visited Apr. 19, 2022).

[234] *See* Robertson, *supra* note 231 ("The Algorithmic Accountability Act is aimed at major companies with access to large amounts of information. It would apply to companies that make over $50 million per year, hold information on at least 1 million people or devices, or primarily act as data brokers that buy and sell consumer data.").

[235] *See* Algorithmic Accountability Act*, supra* note 227.

[236] *See* New, *supra* note 229.

[237] *Id*.

[238] OMB Memorandum on AI, *supra* note 210.

[239] Algorithmic Accountability Act*, supra* note 227.

[240] Justin Chae, *Seeking Transparency in Algorithmic Accountability with the Help of the SEC*, NW. J. TECH. & INTELL. PROP.: JTIP BLOG (June 26, 2020), https://jtip.law.northwestern.edu/2020/06/26/seeking-transparency-in-algorithmic-accountability-with-the-help-of-the-sec/.

requesting that they provide information on how they were addressing biases in health care.[241] This at least implies that Congress is seriously considering how to include health care in future attempts at oversight of AI.

V. The Final Frontier: Next Steps in Creating Oversight

AI touches every aspect of industry and technological development, and as such, it absolutely requires oversight. There is strong support for AI regulation in big tech.[242] Professional organizations and policy institutes like the American Medical Association[243] and the Department of Health and Human Services' Center for Open Data Enterprise, a nonprofit focused on shared data,[244] should be applauded for their efforts in providing a path to responsible AI implementation. However, several journalists and scholars have expressed disdain for continued "ethical guidelines" for "trustworthy AI" without regulatory action.[245] Even industry megaliths have called for regulation of AI.[246] Google CEO Sundar Pichai

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[241] *See* Robertson, *supra* note 231 ("The Algorithmic Accountability Act is aimed at major companies with access to large amounts of information. It would apply to companies that make over $50 million per year, hold information on at least 1 million people or devices, or primarily act as data brokers that buy and sell consumer data.").

[242] *See, e.g.*, Mark MacCarthy, *AI needs more regulation, not less*, BROOKINGS (Mar. 9, 2020), https://www.brookings.edu/research/ai-needs-more-regulation-not-less/ ("In today's world, the real task for AI regulators is to create a rules structure that both protects the public *and* promotes industry innovation") (emphasis in original); Jamie Condliffe, *Big tech says it wants government to regulate AI. Here's why.*, PROTOCOL (Feb. 12, 2020), https://www.protocol.com/ai-amazon-microsoft-ibm-regulation (discussing big tech's interest in AI regulation). *See also* Mina Hanna, *We Don't Need More Guidelines or Frameworks on Ethical AI Use. It's Time for Regulatory Action*, BRINK (July 25, 2019), https://www.brinknews.com/we-dont-need-more-guidelines-or-frameworks-on-ethical-ai-use-its-time-for-regulatory-action.

[243] *See Policy: Augmented Intelligence in Healthcare*, AM. MED. ASS'N. (2018), https://www.ama-assn.org/system/files/2019-08/ai-2018-board-policy-summary.pdf.

[244] *See Roundtable Report: Sharing and Utilizing Health Data for AI Applications*, U.S. DEP'T HEALTH & HUMAN SERV., CTR. OPEN DATA ENTERPRISE (2019), https://www.hhs.gov/sites/default/files/sharing-and-utilizing-health-data-for-ai-applications.pdf.

[245] *See* Hanna, *supra* note 242; Daphne Leprine-Ringuet, *The trouble with AI: Why we need new laws to stop algorithms ruining our lives*, ZDNET (Dec. 8, 2020), https://www.zdnet.com/article/the-trouble-with-ai-why-we-need-new-laws-to-stop-algorithms-from-ruining-our-lives/ (arguing that "trustworthy AI" is "nothing more than a 'branding exercise' that failed to actually provide accountability"); Brent Mittelstadt, *Principles alone cannot guarantee ethical AI*, 1 NATURE MACHINE INTEL. 501 (2019) ("The . . . weakness of a principled approach to AI Ethics is the absence of proven methods to translate principles into practice. The prevalence of essentially contested concepts in AI Ethics begs a question: How can normative disagreements over the 'correct' specification of such concepts be resolved?").

[246] *See, e.g.,* Sebastian Herrera, *Tech Giants' New Appeal to Governments: Please Regulate Us*, WALL ST. J. (Jan. 27, 2020), https://www.wsj.com/articles/tech-giants-new-appeal-to-governments-please-regulate-us-11580126502.

recognized the need for "proactive, sector-by-sector" regulation.[247] Ryan Hagemann of IBM is calling for "co-regulation" with government entities.[248] Elon Musk of Tesla and SpaceX called for increased regulation as far back as 2017.[249] Furthermore, Jack Clark of OpenAI "supports the idea of governments taking increasing responsibility for monitoring and evaluating AI."[250] The industry is aware of the need, and federal agencies have a basic understanding of the need to regulate. The solution here is standardization, and standardization can be achieved via the creation of a new regulatory body.

a. One Does Not Simply Rewrite the Algorithmic Accountability Act

As tempting an answer as it might be, the Algorithmic Accountability Act cannot simply be rewritten to address its original shortcomings. The heart of the bias problem that the Act intended to address lives in the data itself, far more than in transparency and public access, which were the focus areas of the Act. Thus, a second attempt at an Algorithmic Accountability Act is not advisable. Policy alone is also not the answer: broad policy frameworks can be informative, but are high-level and often contain ill-defined principles.[251] They are not sufficient for comprehensive management of AI.[252] What is required is the creation of a new regulatory body.

The creation of a new regulatory body may seem to be an extreme solution; after all, the most recently created entity was the Department of Homeland Security in 2002 following the terrorist attacks of September 11,

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[247] *See* MacCarthy, *supra* note 242.

[248] Condliffe, *supra* note 242 ("We're not calling for self-regulation. We're calling for co-regulation," says Ryan Hagemann, the co-director of IBM Policy Lab. "We think we have a valuable voice to lend to the conversation.").

[249] Samuel Gibbs, *Elon Musk: regulate AI to combat 'existential threat' before it's too late*, THE GUARDIAN (July 17, 2017), https://www.theguardian.com/technology/2017/jul/17/elon-musk-regulation-ai-combat-existential-threat-tesla-spacex-ceo.

[250] Condliffe, *supra* note 242.

[251] Andrew Burt, *Ethical Frameworks for AI Aren't Enough*, HARV. BUS. REV. (Nov. 9, 2020), https://hbr.org/2020/11/ethical-frameworks-for-ai-arent-enough.

[252] *See* GOOGLE, RECOMMENDATIONS FOR REGULATING AI 1 (2018) ("While self-regulation is vital, it is not enough. Balanced, fact-based guidance from governments, academia, and civil society is also needed to establish boundaries, including in the form of regulation. As our CEO Sundar Pichai has noted, AI is too important not to regulate."); *see also* Sundar Pichai, *Why Google Thinks We Need to Regulate AI*, FIN. TIMES (Jan. 19, 2020), https://www.ft.com/content/3467659a-386d-11ea-ac3c-f68c10993b04.

2001.[253] It can be argued, however, that AI and the need to manage it at the federal level is as important as the need to prevent terrorism (if not more so). AI is present in all Americans' everyday lives in some way, shape, or form.[254] It is potentially seriously damaging to both individuals' and organizations' finances, health, privacy, and safety if not properly managed.[255] Because of this, a new agency may be the only logical way to oversee and manage this exciting, but possibly dangerous, technology.

Any act of Congress would therefore need to detail how to create this new entity and determine the rulemaking authority it ought to have. This is not the first proposal calling for a new digital or data-focused agency,[256] but it is the only one (to the author's knowledge) that is focused solely on AI.

b. Raising the DAIS (Department of Artificial Intelligence Standardization)

Regulation is the best answer to the issues presented by AI, as evidenced by the fact that regulation has already been proposed by Congress and the OMB. However, neither the FTC (as suggested by Congress)[257] nor OIRA (as suggested by the OMB) would provide sufficient oversight. What is needed is a regulatory body comprised of experts in technology and software development which operates at the highest tier and creates rules for data standardization in AI.

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[253] *Creation of the Department of Homeland Security*, U.S. DEPT. HOMELAND SEC. (Jan. 30, 2021), https://www.dhs.gov/creation-department-homeland-security.

[254] Craig S. Smith, *A.I. Here, There, Everywhere*, N.Y. TIMES (Feb. 23, 2021), https://www.nytimes.com/2021/02/23/technology/ai-innovation-privacy-seniors-education.html.

[255] *See* Benjamin Cheatham et al., *Confronting the risks of artificial intelligence*, MCKINSEY Q. (Apr. 26, 2019), https://www.mckinsey.com/business-functions/mckinsey-analytics/our-insights/confronting-the-risks-of-artificial-intelligence#.

[256] *See* STIGLER COMM. ON DIGITAL PLATFORMS, FINAL REP. (Sept. 2019), https://www.chicagobooth.edu/-/media/research/stigler/pdfs/digital-platforms---committee-report---stigler-center.pdf (proposing a "Digital Authority" that would be responsible for developing targeted regulation to engage in monitoring and enforcement of tech). *See also* Daniel R. Stoller, *Facebook, Google Would Get New Data Cop in House Privacy Bid (1)*, BLOOMBERG L. (July 9, 2019), https://news.bloomberglaw.com/privacy-and-data-security/facebook-google-would-get-new-data-cop-in-house-privacy-bid (detailing a proposal made by Reps. Anna Eshoo and Zoe Lofgren of California to create a new "U.S. Data Privacy Agency" responsible for regulations around data handling).

[257] Critiques have been levied against the FTC for its failure to adequately enforce regulations or policies that are aimed at technology companies. *See, e.g.*, Nicholas Confessore & Cecilia Kang, *Facebook Data Scandals Stoke Criticism That a Privacy Watchdog Too Rarely Bites*, N.Y. TIMES (Dec. 30, 2018), https://www.nytimes.com/2018/12/30/technology/facebook-data-privacy-ftc.html (discussing the "systemic failure to police Silicon Valley's giants"); Kaminski & Selbst, *supra* note 226 (stating that the FTC "too rarely enforces its settlements").

The Department of Artificial Intelligence Standardization (DAIS) would provide authoritative expertise in AI and ML across industries. DAIS would be responsible for creating and maintaining a shared, mandatory set of rules for data sourcing and cleaning. Those rules would create a baseline across industries while providing flexibility for other agencies, like the FDA, to integrate their own future (or existing) rules around ethical use of AI. DAIS would also create rules around explainability or intelligibility.[258] DAIS would necessarily include a new White House Cabinet position, since a Presidential advisor would be required in order to apprise the administration of rulemaking decisions or propositions related to this extremely important technology.[259]

DAIS could also be tasked with some of the same goals that the Algorithmic Accountability Act assigned to the FTC: issuing and enforcing regulations that require entities using AI to run internal "impact assessments" for the purpose of identifying bias or security issues.[260] DAIS could require use of clean, cohesive, and representative datasets in training and testing predictive models by creating compliance rules for technology companies around data sourcing and cleaning. In addition, DAIS could work with the FDA in a joint review of EHRs to identify data input needs and regulate use of NLP for data retrieval.[261]

An act of Congress creating DAIS would need to include the following elements. First, Congress must provide that DAIS have overarching authority to create rules that address standardization of data sourcing across industries—for example, it might require that testing datasets meet a specific quality threshold, and that training data be obtained from broad representative sources. Second, Congress must provide that all other agencies overseeing AI, or which have regulatory authority over industries that utilize AI, adhere to the DAIS set of uniform fields when designing AI systems. Third, Congress must provide the ability for DAIS to collaborate with other regulatory agencies as required to

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[258] *See* Sharma et al., *supra* note 168.

[259] The Cabinet's role is "to advise the President on any subject he or she may require relating to the duties of each member's respective office." WHITEHOUSE.GOV: THE CABINET, https://www.whitehouse.gov/administration/cabinet/ (last visited Apr. 19, 2022). AI and its management have been important topics for past administrations and should continue to be integral to the government's interests.

[260] *See* Emily J. Tait et al., *Proposed Algorithmic Accountability Act Targets Bias in Artificial Intelligence*, JONES DAY (June 2019), https://www.jonesday.com/en/insights/2019/06/proposed-algorithmic-accountability-act.

[261] For a discussion of the lack of consistent data input standards in disparate EHRs, *see supra* Part III(A)(1).

create, publish, and review supplementary rules specific to those agencies' served industries; for example, the "joint review" of EHRs suggested above.[262] Fourth, Congress must provide that DAIS periodically—perhaps annually—revisit, refresh, and publish updated standards that integrate any new developments in how AI technologies are built. Fifth, and lastly, Congress must dictate that DAIS create a uniform method for data cleaning and de-identification.[263] DAIS would itself be comprised of data engineers, experienced technology managers, and an advisor (Cabinet member) to the President's office on all matters related to regulation of AI.

VI.   Conclusion

AI is an extraordinary, exciting, and burgeoning field—one that is broadly infiltrating health care and all other technology industries and will continue to do so. Inherent in any rapid and far-reaching developments in technology are inevitable stumbling blocks, all of which are part of the development process. However, the stumbling blocks and hazards of health-related AI are not benign. Real and tangible consequences of poorly sourced training datasets are rooted in a dearth of standardization. Consequences include inappropriate or deficient treatment methods, incorrect predictions of disease, and even refusal of life-saving services. While data standards have been suggested, and although the health care industry is aware of the dangers involved with use of AI, no method of mandating those standards or ensuring clean representative data has been established. The answer does not lie in broad policy frameworks or in oversight by a non-AI-specific authority. It also should not lie in assigning additional, unwanted responsibility to an already overtaxed regulatory authority like the FDA. Instead, a new, AI-specific regulatory body, DAIS, must be established.

Increased regulation may not seem like an ideal solution given the rapid pace of software development. It is for this reason that I suggest that DAIS be comprised of data engineers and technical experts who would be responsible for creating workable data standards that keep pace with the evolving nature of technology. I further suggest that DAIS could and should collaborate with industry-specific agencies on creating rules for their needs. This would provide for deeper, broader oversight of the use of AI in health care while still encouraging development and discovery. Uniform, enforceable standards would

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[262] *Id.*

[263] A potentially workable baseline for de-identification is the HIPAA standard from § 164.514(b)(2) of the HIPAA Privacy Rule, which lists 18 different types of identifiers for removal and the requirement that no residual information can identify the individual. *See* 45 C.F.R. § 164.514(b)(2) (2013).

allow for swifter and more widespread use of high-quality training data, which would in turn lead us towards truly unbiased AI and far better predictive capabilities.