United States Senate

WASHINGTON, DC 20510

December 19, 2023

The Honorable Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

Left unregulated, digital health technologies (DHT) — including artificial intelligence, telehealth, and wearable devices — carry significant risks of exacerbating existing health disparities in the United States. The development, regulation, and implementation of these technologies must be guided by principles that prioritize the health and safety of all individuals. The U.S. Food and Drug Administration's (FDA) recently announced Digital Health Advisory Committee (the Committee) is a good start,[1] but to ensure that the Committee considers the cutting-edge legal, moral, and labor implications these devices present, I/we write to urge the FDA to include on the Committee at least one voting member with a background in civil rights, one voting member with a background in medical ethics, and one voting member from a disability rights organization. We also urge the Committee to consult with diverse health care workers and/or labor unions representing health care workers when making recommendations.

DHTs have rapidly proliferated in our health care system. They include artificial intelligence and machine learning technologies/algorithms, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, and software. Although they promise to improve patient outcomes, reduce cost, and improve health provider recruitment and retention, DHTs have also shown a dangerous capacity to worsen existing problems in our health care system. For example, the New York City Coalition to End Racism in Clinical Algorithms found that clinical algorithms over-recommended cesarean sections for Black and Hispanic pregnant patients, relied on debunked medical science regarding muscle mass of Black patients, and used incorrect information about Black and Asian patient lung capacity that could contribute to underdiagnosing COVID-19 and other pulmonary diseases.[2]

Other studies have found that clinical algorithms perpetuate biases. These include a tool that routinely reviewed chest X-rays but underdiagnosed disease in under-served patient populations,[3]

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[1] Digital Health Advisory Committee Charter, U.S. Food and Drug Administration (accessed Nov. 7, 2023), https://www.fda.gov/media/172939/download?attachment.

[2] New York City Coalition to End Racism in Clinical Algorithms (CERCA), Inaugural Report: Fall 2021 to Summer 2022, NYC Health (accessed Nov. 7, 2023), https://www.nyc.gov/assets/doh/downloads/pdf/cmo/cercareport.pdf.

[3] Laleh Seyyed-Kalantari et al., Underdiagnosis bias of artificial intelligence algorithms applied to chest radiographs in under-served patient populations, 27 Nature 2176-2182 (2021), https://www.nature.com/articles/s41591-021-01595-0.

a statistical model that failed to accurately predict suicide risk in Black patients,[4] and an algorithm that incorrectly assumed that Black patients would need less health care than white patients.[5] Routine underrepresentation of marginalized groups, like marginalized racial and ethnic groups, the elderly, people with disabilities,[6] and non-native English speakers, within datasets can result in algorithms that underperform with these groups or perpetuate biases.[7] Consequently, as the *New York Times* reported, the number of algorithms that have been found to perpetuate biases and worsen patient outcomes have eroded both health care provider and patient trust in these tools.[8] Buy-in from health care workers is crucial to the effective and safe deployment of these tools.

The FDA rightly established the Digital Health Advisory Committee in recognition of the need to "support safe and effective regulation."[9] The members of the Digital Health Advisory Committee will be responsible for advising the FDA Commissioner on issues related to DHTs, including FDA policies and regulations. The Committee members will also "provid[e] relevant expertise and perspective to improve the FDA's understanding of the benefits, risks, and clinical outcomes associated with the use of DHTs, as well as identifying risks, barriers, or unintended consequences that could result from proposed or established FDA policy or regulation for topics related to DHTs."[10]

The civil rights and medical ethics implications of DHTs are manifest. It is essential that voices with a background in civil rights, in medical ethics, and from a disability rights organization are part of the Digital Health Advisory Committee, in order to assist the FDA as it develops regulatory guidelines that will determine the safety and efficacy of these products. It is also crucial that the voices of those who will be using these tools are consulted when developing these regulations. In fact, the inclusion of the recommended individuals would align the Digital Health Advisory Committee with President Biden's executive orders making clear that all branches of the federal government, including the Department of Health and Human Services,

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[4] R. Yates Coley et al., Racial/Ethnic Disparities in the Performance of Prediction Models for Death by Suicide After Mental Health Visits, 78 JAMA Psych. 1-9 (2021), https://pubmed.ncbi.nlm.nih.gov/33909019/.

[5] Ziad Obermeyer et al., Dissecting racial bias in an algorithm used to manage the health of populations, 366 Science 447-453 (2019), https://www.science.org/doi/10.1126/science.aax2342.

[6] Mary Fetzer, *Trained AI models exhibit learned disability bias, IST researchers say,* Pennsylvania State University (Nov. 30, 2023), https://www.psu.edu/news/information-sciences-and-technology/story/trained-ai-models-exhibit-learned-disability-bias-ist/#:~:text=Sciences%20and%20Technology-,Trained%20AI%20models%20exhibit%20learned%20disability%20bias%2C%20IST%20researchers%20say,biases%20against%20people%20with%20disabilities.

[7] Natalia Norori et al., *Addressing bias in big data and AI for health care: A call for open science*, 2 Patterns (2021), https://doi.org/10.1016/j.patter.2021.100347.

[8] Christina Jewett, Doctors Wrestle With A.I. in Patient Care, Citing Lax Oversight, N.Y. Times (Oct. 30, 2023), https://www.nytimes.com/2023/10/30/health/doctors-ai-technology-health-care.html.

[9] FDA Digital Health Advisory Committee, U.S. Food and Drug Administration (accessed Dec. 4, 2023), https://www.fda.gov/medical-devices/digital-health-center-excellence/fda-digital-health-advisory-committee.
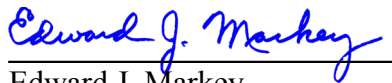
[10] Id.

are responsible for identifying bias and discrimination perpetuated by artificial intelligence and delivering equitable outcomes and should incorporate civil rights expertise in their decision-making.[11]

The risks of DHTs to patients, health care workers, and the health system as a whole are significant, but as the Biden administration noted in the Blueprint for an AI Bill of Rights, "they are not inevitable."[12] Only through robust and clear regulation of these products — including an active and intentional consideration of their ethical implications and the disparities they can propagate — can we hope to ensure public safety. With the Digital Health Advisory Committee, the opportunity exists to incorporate civil and disability rights as well as medical ethics into FDA regulation and oversight, to include health care workers' voices, and to guarantee the development and use of these technologies respects everyone's dignity, rights, and well-being.

Thank you for your time and consideration. We look forward to your prompt response.
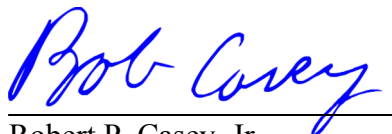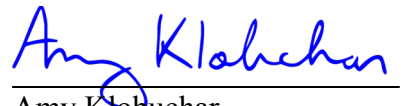
Sincerely,

Edward J. Markey
United States Senator

Bernard Sanders
United States Senator

Robert P. Casey, Jr.
United States Senator

Amy Klobuchar
United States Senator

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[11] Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, The White House (Oct. 30, 2023), https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-orderon-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/; Executive Order on Further Advancing Racial Equity and Support for Underserved Communities Through The Federal Government, The White House (Feb. 16, 2023), https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/16/executive-orderon-further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/

[12] Blueprint for an AI Bill of Rights, The White House (accessed Dec 4, 2023), https://www.whitehouse.gov/ostp/aibill-of-rights/.

Tammy Duckworth
United States Senator

Alex Padilla
United States Senator