January 3, 2024

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

Dear Dr. Califf:

Artificial intelligence in health care is growing rapidly, having reached a market value of roughly $11 billion in 2021 and estimated to skyrocket at a compounded annual growth rate of 37% to $188 billion in 2030.[1] Additionally, the technology could eliminate up to $360 billion in health care spending in the United States alone.[2] Such savings could be realized from administrative cost reductions, rooting out inappropriate medical care, and increasing labor productivity. For example, when considering prior authorization denials, implementing innovative technologies "could lead decision makers to evaluate the underlying root causes of denials and identify ways to use improved stakeholder collaboration and advanced technology tools on the horizon to avoid them."[3] With such extraordinary incentives to improve the efficiency and cost-effectiveness of care delivery, a revolution in the field of medicine is at our doorstep.

AI will undoubtedly transform patient care in ways that we never thought possible. From diagnostics and personalized medicine to administrative functions and augmentation of clinical practice, the opportunities to increase efficiency and the standard of care are boundless. Further, it will enable medical practices to scale their service capacity, empower physicians, and potentially mitigate the impact of a variety of clinical workforce shortages.

Recently, the European Parliament and European Council came to a provisional agreement on the Artificial Intelligence (AI) Act.[4] Negotiators established a framework to achieve the broad goal of preserving fundamental rights and democratic principles while cultivating a robust economic environment. Additionally, the framework details certain banned applications of AI, law enforcement exemptions, obligations for high-risk systems, consumer rights, innovation, and safety measures.

In the coming weeks, further negotiations will provide substantive details on how the AI Act will influence the burgeoning field of artificial intelligence across sectors in the European Union. Although several proposals to establish artificial intelligence regulatory frameworks have been introduced in both chambers of Congress, no serious effort has been made by either body to pass comprehensive legislation. Such proposals should be narrow in scope and strike a delicate balance between

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[1] Stewart, C. (2023, September 28). *AI in Healthcare Market Size Worldwide 2030*. Statista. https://www.statista.com/statistics/1334826/ai-in-healthcare-market-size-worldwide/#:~:text=In%202021%2C%20the%20artificial%20intelligence,11%20billion%20U.S.%20dollars%20worldwide.

[2] Baxi, S., Parikh, S., Peterson, M., & Ray, A. (2023, July 25). *Setting the revenue cycle up for success in automation and ai*. McKinsey & Company. https://www.mckinsey.com/industries/healthcare/our-insights/setting-the-revenue-cycle-up-for-success-in-automation-and-ai

[3] Ibid

[4] *Artificial Intelligence Act: Deal on comprehensive rules for trustworthy AI: News: European parliament*. Artificial Intelligence Act: deal on comprehensive rules for trustworthy AI | News | European Parliament. (2023, December 9). https://www.europarl.europa.eu/news/en/press-room/20231206IPR15699/artificial-intelligence-act-deal-on-comprehensive-rules-for-trustworthy-ai

encouraging continued investments in AI/ML-enabled devices while ensuring federal agencies can utilize their respective technical expertise and adapt regulatory frameworks, if necessary, to accommodate AI as a regulated product. Inflexible constraints and one-size-fits-all policy will entrench this industry in bureaucracy and hinder innovation.

The Food and Drug Administration (FDA) has a unique responsibility to balance consumer safety and industry stability as it considers regulatory guardrails and the processes of machine learning and AI-enabled device approval. To date, the FDA has already cleared over 500 such devices utilizing current 510(k) clearance/premarket approval (PMA) frameworks.[5] However, unclear liability guidance and overlapping regulatory governance responsibility is undermining product manufacturers and will hinder patients' access to emerging therapeutic technologies.

As a urologic surgeon of over 30 years, Co-Chair of the Doctors Caucus, and the only practicing physician in Congress, the expansion of artificial intelligence in the field of health care is of great importance to me. I am committed to ensuring the FDA has the authority and tools it needs to cultivate an environment that advances innovation in the development and use of artificial intelligence in health care to fortify the doctor-patient relationship and improve care outcomes through lower costs, increased patient convenience, and personalization. Considering the broad and rapid debate of AI regulatory policy in the European Union, please respond to the follow questions by January 31, 2024:

1) What actions is the FDA taking to prepare for a rapid increase in 510(k) and PMA requests for ML and AI devices?

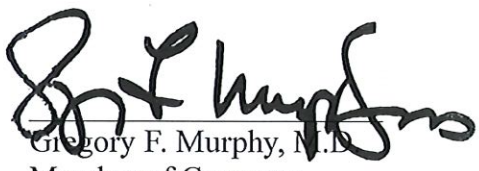
2) Does the FDA plan to strengthen its 510(k) Third Party Review program in order to offload less complex products and free up human capital?

3) Do you support voluntary alternative pathways for approval of AI products and integrated devices?[6]

4) Do you support a liability safe harbor for AI-enabled devices and physicians using such devices in the context of continued compliance with post-market surveillance programs?

5) What role should market actors, such as medical licensing bodies, hospital credentialing boards and medical societies play in establishing standards of use?

Sincerely,



Gregory F. Murphy, M.D.
Member of Congress

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[5] Center for Devices and Radiological Health. (2023, March 30). *CDRH Draft Guidance on change control plans for AI/ML-enabled devices*. U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-draft-guidance-predetermined-change-control-plans-artificial-intelligencemachine

[6] Cho T, Gowda V, Schulzrinne, Miller BJ. "Integrated Devices: A New Regulatory Pathway to Promote Regulation Innovation." June 2023. *SSRN working paper* available from: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4486757