

A.I. HEALTHCARE WORKING GROUP

March 27, 2024

National Telecommunications and Information Administration
United States Department of Commerce

Re: Docket No. 240216-0052/NTIA-2023-0009, "Dual Use Foundation Artificial Intelligence Models with Widely Available Model Weights"

Thank you for the opportunity to participate in the Request for Comment. We, Joe Grogan and Naomi Lopez, are co-founders of the AI Healthcare Working Group (aihealthcareworkinggroup.com). Our bios are included below.

We will focus primarily on the following two questions as they generally relate to clinical development:

- 2(b) Could open foundation models reduce equity in rights and safety impacting AI systems?
- 3(c) Could open model weights, and in particular the ability to retrain models, help advance equity in rights and safety impacting AI systems?

The integration of open foundation models and the capability to retrain model weights in clinical drug development hold considerable promise for advancing equity, rights, and safety. As with any new and powerful technology, it comes with risks. These risks range from biases in decision-making to the creation of new, nefarious molecules, and the defensive measures to counteract these risks must be adaptable and forward-looking.

And let's not forget the FDA's recent experiences with medical devices, such as the pulse oximeter, highlight the ongoing challenge of ensuring that countering potential bias is not a new challenge unique to AI. In contrast, AI by democratizing information sharing and analysis can make considerable progress to advance human knowledge and thus equity.

The gap in computer power open to the wealthy and the poor or middle class promises to be narrowed considerably by AI tools. Government cannot be a barrier to prevent powerful AI tools from being developed in a vibrant innovation ecosystem responsive to consumer opportunity. Too often government colludes with large organizations and prevent small players from achieving access. The risks of technology are real, but their promise outweighs those risk and those risks should be viewed and evaluated in the context of marginal risk.



Realizing the enormous potential requires an agile approach focused on opportunity not risk or fear. The field of clinical drug development can harness the benefits of AI to reduce development times and costs and thus advance equity for those needing treatment.

Impact of Open Foundation Models on Equity in Rights and Safety

Customization and Accessibility. Open foundation models can significantly enhance equity and accessibility in clinical drug development in two important ways. First, the ability to seek new treatments for rare-diseases and emerging public health threats allows for the rapid development of treatments that don't have commercialization potential. And, over time, access to advanced computational tools will allow researchers across the globe, including those from low-resource settings, to participate in drug discovery processes. This broadens the diversity of diseases researched and the potential for finding treatments that benefit underserved populations.

Enhancing Equity in Rights and Safety with Open Model Weights and Retraining

Proactive Defense Strategies. The ability to retrain model weights presents an opportunity to proactively defend against risks, ensuring that AI systems in clinical drug development evolve to meet emerging challenges. Adaptive frameworks and continuous learning mechanisms are vital for addressing biases, enhancing data security, and maintaining the relevance of AI applications in drug development.

Continuous Improvement. Transparent safety policies, as well as the combination of rules-based and risk-based approaches, sharing knowledge on vulnerabilities and defensive techniques, and engaging in continuous improvement processes, helps in creating more robust AI systems. Moreover, the adoption of transparent practices and proactive risk assessments can facilitate the early identification and mitigation of potential issues.

The potential for defending against the risks associated with AI open foundation models in healthcare lies in the adoption of dynamic, adaptive, and collaborative approaches that evolve in concert with technological advancements. By fostering an environment of continuous improvement, ethical vigilance, and proactive risk management, the healthcare sector can maximize the benefits of AI while minimizing its risks.

Joe Grogan and Naomi Lopez

Co-founders of the AI Healthcare Working Group

aihealthcareworkinggroup.com



About Joseph Grogan, JD

Joe Grogan is a Nonresident Senior Fellow at the USC Schaeffer Center. Grogan served as Assistant to President Donald J. Trump and Director of the Domestic Policy Council. He was the President's lead advisor on a variety of domestic policy issues relating to health care, regulatory and deregulatory initiatives, economic expansion, commercial space exploration, environment, agriculture, civil rights, and education. He is a health policy thought leader who has played a key role in the health sector's most consequential debates of the last decade.

Grogan was also a member of the White House's COVID-19 Task Force, where he worked with Executive Branch officials to respond to the COVID-19 public health emergency.

During his time as Director of the Domestic Policy Council, Grogan led a White House team that directed the focus and attention of all major policy initiatives, including the development of regulations, Executive Orders, Presidential Decision Memorandums, and major Presidential announcements. In his role, Grogan coordinated with the President's Cabinet, National Economic Council, White House Communications, Office of Management and Budget, and White House Legislative Affairs to drive the President's domestic policy agenda. Notably, Grogan negotiated provisions of the 2020 Omnibus Spending Bill with Congressional leadership and members which eliminated a number of significant health care taxes. He developed a reputation as having an open door across the political spectrum for innovators and private industry seeking to solve complex problems in a highly regulated environment.

Before serving as Director of the Domestic Policy Council, Grogan was Associate Director for Health Programs at the Office of Management and Budget. During his tenure at the Office of Management and Budget, Grogan was responsible for overseeing all domestic health spending, totaling \$1.3 trillion per year. Grogan also supervised the development of the President's annual health budget, worked within the Executive Office of the President to formulate policy, and reviewed regulatory and administrative actions relating to Medicare, Medicaid, and other health programs to ensure they adhered to the President's healthcare policy agenda. Grogan also provided technical assistance to Congress in drafting legislative proposals and managed a staff of 46 civil-service employees.

In the George W. Bush administration, Grogan served as Senior Advisor to the Commissioner at the Food and Drug Administration, advising the Commissioner on a broad spectrum of food and drug regulatory issues. In the private sector, Grogan led the Washington Office for Gilead Sciences; and worked at Amgen and the Marwood Group.

Grogan is the author of numerous opinion pieces on prescription drug pricing, mental health, school choice programs, surprise medical billing, and Medicare spending. His articles have appeared in the *New York Times*, the *Wall Street Journal*, *USA Today*, *Fox News*, and the *Washington Post*.

Grogan holds a Juris Doctor from William and Mary School of Law. He also holds a Bachelor of Arts from the State University of New York at Albany.



About Naomi Lopez

Naomi brings over 30 years of experience and is a nationally recognized healthcare policy expert. Her expertise includes developing innovative policy ideas, crafting legislation and associated legislative strategies, and coordinating stakeholder groups, particularly patient organizations, to influence legislative changes at both federal and state levels.

She is founder and principal of Nexus Policy Consulting and has held positions at the Goldwater Institute, Illinois Policy Institute, Pacific Research Institute, Institute for Socioeconomic Studies, and the Cato Institute.

Recognized as a healthcare thought leader, Naomi is a regular contributor to media discussions and a seasoned public speaker. She has penned hundreds of scholarly articles, studies, and commentaries. Academically, she holds a B.A. in Economics from Trinity University, Texas, and an M.A. in Government from The Johns Hopkins University.

