

A.I. HEALTHCARE WORKING GROUP

July 15, 2024

U.S. Department of Justice
Antitrust Division
ATR.2024AIworkshop@usdoj.gov

Re: Workshop on Promoting Competition in Artificial Intelligence

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 on the “Healthcare Spotlight” panel that was to focus on promoting competition in AI. While it was valuable to raise the issue of how data access, especially as it applies to individuals, will be crucial to AI innovation in healthcare, there was scant discussion that related to how current federal policy and policy being adopted in some states are already posing significant threats to innovation –making this issue all the more important.

The panel provided important context for why innovation is desirable and can have transformational impacts on healthcare delivery including better patient outcomes, reduced costs to the system, and allowing providers to provide more engagement and direct care for their patients.

Unfortunately, the vast majority of time was spent on how data access is a bottleneck to innovation with little to no attention paid to the current federal and state policies that pose the greatest threats to innovation and competition. The panelists discussed the challenges of privacy laws and difficulties in de-identifying data, as well as large companies having proprietary datasets that could disadvantage smaller companies. The inability to improve FDA-cleared algorithms in real-time was also discussed briefly.

The Biden Administration’s Executive Order on AI, issued last October, professes to champion innovation in AI, but it burdens the health care industry with compliance costs that only the market giants can likely absorb, squeezing out smaller players.

The order also calls for greater transparency but then imposes reporting requirements that could hinder open-source AI development, a cornerstone of collaborative and rapid innovation in the field.



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The cozy relationship between senior administration officials and a nonprofit group, Coalition for Health AI (CHAI), led by some of the nation's largest data aggregators that would establish assurance labs to test AI products used in healthcare is a major concern for us and multiple Members of Congress. Involvement of Federal officials on this board is a clear conflict of interest, and raises questions previously asked in an Energy and Commerce hearing as to the role of this nonprofit organization in regulating AI. While we welcome the resignation of these officials from the board, they should never have been involved to begin with in light of their official responsibilities. The creation of assurance labs to regulate AI in healthcare should have been a dominant point of discussion at this meeting, but unfortunately, it was omitted.

Government should not be a barrier to prevent powerful AI tools from being developed in a vibrant innovation ecosystem responsive to consumer opportunity. Nor should it engage in actions that would cede authority and control to would-be competitors. The department should scrutinize the structure, governance, and use of proposed assurance labs for evaluating AI in healthcare going forward – and the potential anti-competitive outcomes of such an approach.

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 domestic 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.

