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Russell T. Vought
Acting Director
Office of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

Comments Submitted Electronically

RE: Draft Memorandum to the Heads of Executive Departments and Agencies, "Guidance for Regulation of Artificial Intelligence Applications"

Dear Acting Director Vought,

Introduction

The American College of Cardiology (ACC) appreciates the opportunity to provide input on the Office of Management and Budget (OMB) Draft Memorandum to the Heads of Executive Departments and Agencies, "Guidance for Regulation of Artificial Intelligence Applications."

The ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.
As technology rapidly integrates into health care and the practice of medicine fuses traditional and digital solutions, it is important that the federal government, in conjunction with patients, health care clinicians, and industry, work together to foster an ecosystem that provides sufficient regulatory clarity to promote the responsible generation of digital health solutions while not stifling innovation.

The ACC believes it is essential that robust clinical evaluation is at the core of the development and implementation processes for the use of

AI-enabled health solutions to improve outcomes, drive down costs, and improve professional satisfaction for clinicians.

Successful AI-enabled technologies will require early engagement from clinicians and organizations like the ACC that stand at the nexus of this innovation. The College is engaging with both regulatory agencies and industry to ensure the clinician's voice is incorporated into the development of these AI systems.

The OMB's policy considerations to guide the development of oversight in artificial intelligence (AI) applications are a step in the right direction. In the guidance document, OMB rightly acknowledges "the pace of AI development and application will challenge agencies to develop regulatory and non-regulatory approaches that are adaptable." The ACC agrees with this, encourages all federal regulatory agencies to develop consistent policies that provide sufficient regulatory guidance while remaining flexible enough to allow for necessary innovation, and promote a patient and clinician focused approach to AI in health care.

Principles for Stewardship of AI Applications

The ACC thanks the White House, OMB, and other agencies for considering regulatory and non-regulatory approaches to the design, development, deployment, and operation of AI applications which encourage innovation while still allowing for case-specific approaches to the regulation of AI systems. **The ACC believes any regulations, including but not limited to those from the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS) and others, should specifically promote high-quality, clinically-validated AI systems.** While the ACC understands OMB's concern that "agencies must avoid a precautionary approach that holds AI systems to such an impossibly high standard that society cannot enjoy their benefits," it is essential that regulatory agencies establish a standard that requires sufficient scientific scrutiny of AI systems to ensure they are safe and can be trusted.

Public Trust In AI

Regulatory agencies should promote policies that encourage AI system developers to integrate clinicians' perspectives into the development, design, validation and implementation of health care AI. The integration of clinician's perspectives will increase the likelihood user-centered design and clinician workflow are sufficiently built into deployed AI systems. In turn, this will not only make systems less burdensome and improve safety, this will work to promote reliability and trustworthiness which are paramount to the successful integration of AI systems into health care. AI-enabled systems have developed a reputation for being "black boxes" where algorithms make decisions with little transparency. While this perception may not always be reality, the utilization of rigorous, scientific validation tools and clinician perspectives can help combat this perception and encourage trust that the systems will work as designed.

Scientific Integrity and Information Quality

The ACC thanks OMB for working to ensure agencies "hold information, whether produced by the government or acquired by the government from third parties, that is likely to have a clear and substantial influence on important public policy or private sector decisions (including those made by consumers) to a high standard of quality, transparency, and compliance." **The College strongly believes that reliability, repeatability, and scientific integrity in both the pre-and post-market settings are essential to the successful deployment of health care AI systems.** As previously mentioned, clinical validation throughout the development and implementation process will only help to increase public trust and utilization of AI-enabled health care systems. Federal agencies should encourage the development and public availability of these validation tools and ensure reported information meets the highest scientific requirements.

Benefits and Costs

Regulatory agencies review drugs, medical devices, and other health care tools and services to weigh the risk posed compared the benefits offered. A risk-based approach to clinical questions and answers is the proper method for evaluating the efficacy of a given drug or device. The same is true for AI systems. However, when evaluating these benefits and risks, it is important that agencies not only factor in traditional benefits and costs, but ensure developers are factoring in the full societal costs, benefits, and risks. The deployment of AI systems in health care can drastically affect outcomes, access, and costs for vulnerable populations, especially those that have been historically underrepresented. Additionally, the deployment of AI-enabled systems that assist in the medical decision-making process add an additional layer of liability that regulatory agencies, clinicians, and patients must understand and weigh. Clarity and appropriate layers of protection are necessary to ensure the successful deployment of these systems. It is important to ensure these costs are properly weighed when evaluating AI systems and t**he ACC encourages agencies to work with AI developers to ensure all risks and benefits are properly considered.**

Flexibility

It is important that regulatory agencies draft policies that are flexible enough to distinguish between AI-enabled health care applications that actively participate in the practice of medicine, either defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the 21st Century Cures Act, and more broadly designed AI systems that assist with practice of medicine through administrative simplification or other essential tasks. Future AI systems may blur the line between regulated and non-regulated activities. OMB should allow agencies sufficient regulatory flexibility to provide clear guidance. **Regulatory ambiguity will hamper innovation, promote distrust in systems, and result in the development of fewer applications of this promising technology.** Federal agencies should ensure that guidance is constantly reassessed to account for iterative changes in technologies and provide the clearest regulatory picture possible.

Non-Regulatory Approaches to AI

The development and updating of regulations can be a slow, tedious process, which may not always serve as the most effective method for agencies to communicate guidance and other important information to AI system developers and utilizers. The ACC understands and appreciates non-regulatory approaches may serve as the best mechanism for AI evaluation and deployment while still fostering innovation. As mentioned in the OMB guidance, existing frameworks, pilot programs, and voluntary-consensus standards spur the development of new, innovative systems while ensuring sufficient safety, transparency, and validity. **The College encourages agencies to take advantage of input from stakeholders like the ACC when considering these non-regulatory approaches.** By seeking and incorporating feedback early in the process, agencies can work to develop promote trust in deployed systems.

Agencies should make use of bulletins, sub-regulatory guidance, in-person presentations at highly attended conferences, and other mechanisms to not only allow for effective communication, but non-traditional methods for input from stakeholders. However, these non-regulatory approaches should not supersede and replace communication to stakeholders through traditional rulemaking mechanisms. The rulemaking process allows the public to closely examine proposed regulations, gather information, and provide valuable feedback to regulatory agencies. The ACC encourages all regulatory agencies to continue to make appropriate use of both non-regulatory approaches and traditional rule-making processes.

Access to Federal Data and Models for AI R&D

As the guidance document states, "Executive Order 13859 requires OMB to issue a memorandum to agencies that shall "consider ways to reduce barriers to the use of AI technologies to promote their innovative application while protecting civil liberties, privacy, American values, and United States economic and national security."" **The ACC appreciates the Administration's dedication to reducing barriers to innovation and believes agencies can achieve this mission by providing additional access to health care data such as administrative claims and outcomes data for use in the development of AI systems.**

Executive Order 13859 calls on agencies to increase public access to government data and models where appropriate. As the largest purchaser of health care in the United States, the government has access to health care data that could be used by researchers and developers to fine tune AI systems that improve outcomes, reduce costs, mitigate administrative burdens, and promote equality. Agencies should evaluate what data sources, specifically claims and outcomes data, may be made more widely available to help train systems, mitigate risks, and foster public trust. Additionally, agencies should consider methods for improving transparency for data and models used to train AI systems, especially public data sets, while respecting necessary trade secrets and proprietary methods.

Communication to the Public

Transparency and clear communication is vital to maintaining the public trust in AI systems. As previously stated, the ACC appreciates that traditional regulatory mechanisms may not always serve as the most appropriate method for communicating with the public and updating guidance in an environment with rapid innovation and iteration. Agencies should regularly and clearly communicate with stakeholders through numerous mechanisms, including utilizing traditional rulemaking processes. The rulemaking process affords the public the ability to clearly see comments submitted by other stakeholders and affords regulatory agencies the ability to respond to insights and concerns in writing. These responses often provide the clearest understanding of regulatory agencies decision making processes and helps the public comprehend why a decision was made. **The ACC calls on agencies to remain transparent, clearly promote any guidance and rulemaking documents, and regularly communicate with the public to ensure trust is maintained.**

Conclusion

The ACC believes in the promise of AI. The ability for AI-enabled systems to quickly analyze more data than ever before and produce solutions that can impact the health care system by lowering costs, improving outcomes, streamlining administrative activities, and help patients is the reason continued investment and innovation in AI systems is necessary. Both the federal government and private health care stakeholders must continue to work in tandem to develop an environment that fosters innovation. At the same time, it is important that regulatory agencies promote a climate that not only encourages, but requires robust clinical validation. Public trust in health care is rooted in science and the promise of AI must not override the importance and deployment of safe and trustworthy systems.

The ACC thanks the White House and OMB for beginning to develop a comprehensive, government-wide policy governing the regulation of AI through regulatory and non-regulatory approaches. The proper balance between regulation and innovation will ensure that safe and responsible AI systems can harness the power of big data and work to transform health care delivery. The College looks forward to continuing to work with OMB and all federal agencies as further guidance and regulation are developed. If you have any questions or would like additional information regarding any recommendations in this letter, please contact Joseph Cody, Associate Director, Research and Innovation Policy, at (202) 375-6251 or jcody@acc.org.

Sincerely,

Richard J. Kovacs, MD, FACC
President