COLLEGE of AMERICAN PATHOLOGISTS

March 13, 2020

Russ Vought
Acting Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Draft Memorandum to the Heads of Executive Departments and Agencies, Guidance for Regulation of Artificial Intelligence Applications [Docket No. OMB_FRDOC_0001-0261]

Submitted via Electronic Submission to www.regulations.gov

Dear Mr. Vought:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Office of Management and Budget (OMB) draft memorandum to the Heads of Executive Departments and Agencies, Guidance for Regulation of Artificial Intelligence (AI) Applications. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. As physicians specializing in the diagnosis of disease through laboratory methods, pathologists have a long track record of delivering high quality diagnostic services to patients and other physicians. The CAP is concerned the OMB's guiding principles in promoting AI adoption and advancements in healthcare does not adequately address the practical difficulties of controlling actions of autonomous machines, the potential unforeseeability of AI actions, and the potential for proprietary or diffuse development of AI.

Artificial intelligence (AI)- and machine learning (ML)-based technologies have the potential to transform healthcare. They are anticipated to become integral adjuncts to all of medicine, including pathology and laboratory medicine. Given the impact AI/ML will have on pathology and laboratory medicine, the CAP urges the OMB to balance the advancement in technology and innovation with patient safety and regulatory oversight. Regulations for AI will need to ensure the appropriate levels of safety can be reliably determined.[1] The CAP has advocated for a risk-based approach to the Food and Drug Administration (FDA) in ensuring safe and effective devices of any AI/ML technologies because of the myriad of uses in pathology and laboratory medicine from digital pathology to next generation sequencing. Moreover, the robustness of the framework's requirements should depend on the risk classification of the AI/ML thus allowing for

[1] Regulating Artificial Intelligence for a Successful Pathology Future Timothy Craig Allen
Archives of Pathology & Laboratory Medicine Oct 2019, Vol. 143, No. 10 (October 2019) pp. 1175-1179

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innovation in a myriad of settings especially the laboratory where initial development of these technologies may occur. Post-marketing (real world) quality control and performance monitoring requirements are needed to prove efficacy of modifications while differentiating local verification and data capture responsibilities between the developers and end-users (eg, laboratories and pathologists). In addition to the above-mentioned criteria for a regulatory structure, AI regulatory approaches need in addition to consider novel aspects of AI as an autonomous system.

The OMB guiding principles should include in any regulatory approach strategies for measuring and verifying performance and calibration like the Clinical Laboratory Improvement Act of 1988 (CLIA). CLIA requires laboratories to verify and substantiate performance of any clinical laboratory test prior to being used for patient testing. Such a strategy allows for methods to catch bias and other performance problems during the pretesting process. The FDA's process to monitor real-world data is not designed to address these types of problems, while the agency's monitoring may capture issues during post-market surveillance as risk remains for patient harm. Implementing standard verification methods would mitigate risk. To do this, the OMB principles should mandate that any AI regulatory approach is:

- **Validated prior to use with documentation kept of such validation with each new and updated implementation of AI.**
- **Checked for potential or actual continuation or exacerbations of bias, prejudice, inequality, risk.**
- **Verified that it performs as intended.**
- **Checked for spurious illogical associations that could increase risk, bias, prejudice, inequality, etc.**

Lastly, the OMB guiding principles should address transparency; however, it is unclear from the OMB proposed principles whether the intent is meant to address transparency of data versus transparency of the AI system functionality. Developers should be required to implement an open system describing updates and modifications to patients and clinicians as they occur. **Transparency considerations for the public and end-users should include:**

- **AI as it is determining and executing decision-making.**
- **Potential risks and benefits of AI as it executes decision-making with continued updates of those autonomous systems' risks and benefits.**
- **Consent options for use of AI algorithms after such risks and benefits are presented to the public.**
- **Awareness when their individual data is being used in AI programming regardless of who is developing the AI (public vs. private entities).**
- **Ability for end-users to override uncertain decisions for wrong or suspected wrong AI system decision-making.**

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AI holds promise to improve effectiveness and efficiency of healthcare system but needs the appropriate controls to benefit human life, health and safety. The CAP welcomes the opportunity to work OMB on implementing balance regulations.

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with the OMB. Please direct questions on these comments to Helena Duncan at (202) 354-7131 or hduncan@cap.org.

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