COLLEGE of AMERICAN PATHOLOGISTS

March 15, 2025

Office of Science and Technology Policy (OSTP)
Executive Office of the President
Eisenhower Executive Office Building
1650 Pennsylvania Avenue
Washington, D.C. 20504

Re: Request for Information on the Development of an Artificial Intelligence (AI) Action Plan

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To the Office of Science and Technology Policy (OSTP):

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Office of Science and Technology Policy's (OSTP's) *Request for Information: Development of an Artificial Intelligence Action Plan*. 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 deliver high quality diagnostic services to patients and other physicians. The pathologist's diagnosis and value are recognized throughout the care continuum and many patient encounters. For almost 80 years, the CAP has been the advocate for pathologists, patients, and the public when it comes to improving laboratory quality and assuring that patients receive the right test, at the right time, and with the right result.

The OSTP's Request for Information (RFI) notes that responses can address "any relevant AI policy topic, including but not limited to: hardware and chips, data centers, energy consumption and efficiency, model development, open source development, application and use (either in the private sector or by government), explainability and assurance of AI model outputs, cybersecurity, data privacy and security throughout the lifecycle of AI system development and deployment (to include security against AI model attacks), risks, regulation and governance, technical and safety standards, national security and defense, research and development, education and workforce, innovation and competition, intellectual property, procurement, international collaboration, and export controls." As the CAP noted in its letter to the Trump Presidential Transition Team and 119th Congress,[1] artificial intelligence (AI) is one of the CAP's

[1] https://newsroom.cap.org/latest-news/cap-shares-top-6-priority-issues-with-new-congress-and-administration-for-success-in-2025/s/cee599e6-d9d1-4564-bd91-74019d6299c7.

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top priority policy and regulatory issues impacting the delivery of high-quality diagnostic services to patients. In this response to OSTP's RFI, we will focus on regulation and governance, the application and use of AI in laboratory medicine, and cybersecurity.

In the development of a national AI plan, the CAP notes the following:

Regulation and Governance
The CAP recommends that federal regulations on AI should be reasonable and not overly burdensome from a laboratory perspective, prioritize patient safety, ensure clinical validity, allow innovation, and preserve the role of pathologists as physicians and advocates for patients. The CAP also recommends that any new regulatory requirements should not be duplicative of existing regulations and should not infringe on the practice of medicine. Moreover, payment for AI in pathology and laboratory medicine should appropriately advance its use, promote equity in its clinical application, and recognize the professional role and responsibility of pathologists in its implementation, clinical application, and management.

The Application and Use of AI in Laboratory Medicine
The CAP prioritizes patient safety and clinical validity in development and responsible implementation of AI in pathology. The best performance of AI in pathology accrues from an optimal blend of human and machine capabilities, yielding "augmented intelligence" rather than artificial intelligence (enhancement rather than replacement of human expertise). AI systems should not replace pathologists—for example, they cannot independently sign out a pathology case—but have the potential to enhance some pathology services. A pathologist must be the final decisionmaker regarding all cases. Thus, pathologists must have an essential leadership role in the selection, configuration, deployment, application, and monitoring of AI systems that will be involved in the pre-analytical, analytical and post-analytical phases of laboratory workflow. Because the clinical performance of AI will be dependent on the characteristics of the local data over which the AI operates—local pathologists will be the best-positioned experts to evaluate the performance of AI systems using their laboratories' data during development, at the time of deployment, and over time during use. Moreover, pathologists' engagement in the development, deployment, and configuration of AI technology will ensure that the pathologists' unique knowledge of pathology and laboratory medicine, including patient safety issues, risks, workflow, and other challenges, are incorporated into AI systems.

Consequently, we recommend that federal AI policy ensure that pathologists will be able to effectively fulfill their expanded responsibilities in the laboratory concerning AI. To accomplish these responsibilities, the techniques (including required transparency) and authority to measure AI performance and respond to performance problems should be available to pathologists to ensure the ethical application and clinical validity of the use of AI systems in the laboratory.

Cybersecurity
We believe the Trump Administration should employ a standardized, consistent, and uniform cybersecurity approach across the entire federal government to avoid burdensome, inconsistent or overlapping requirements. As part of this approach, we suggest that federal government

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enforcement of cybersecurity responsibilities and expectations be based on the levels of risk posed by entities. We view risk as defined not only in terms of an entity's size and the number of patients that entity affects, but also the risk they pose to the entire health system. For example, if a small rural private practice gets hacked, the effects of that hack do not impact the entire U.S. health system in a way that could happen if a large corporate entity got hacked. Consequentially, the federal government's cybersecurity enforcement should be measured for a small rural private practice as compared to a large corporate entity because the effect of a successful attack on a large corporate entity is more significant.

As the infrastructure for cybersecurity protection is being built and constantly changing, the federal government's adoption and implementation approach to cybersecurity protection should not be punitive; rather, it should enable providers to demonstrate that they are meeting recommended standards. We recommend that the federal government's approach to cybersecurity protection involve incentivization and education. Specifically, the federal government should incentivize adoption and implementation of cybersecurity protection by health care entities; incentives should include financial assistance from federal agencies (such as grants and increased federal healthcare program payments) for steps taken to improve cyberattack prevention and response. With respect to education, we recommend that federal oversight agencies provide educational resources and guidance to enable entities to demonstrate that they are following optimal approaches to address an evolving landscape of cybersecurity.

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Thank you for the opportunity to submit these comments. We would welcome the opportunity to meet with Trump Administration leadership as a critical next step. We look forward to coordinating this meeting at your earliest convenience. The CAP looks forward to working with the OSTP and always stands willing to collaborate with government agencies, industry, pathologists, and other stakeholders to support high quality laboratory operations and medical care. Please direct questions on these comments to Han Tran at htran@cap.org.

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