COLLEGE of AMERICAN PATHOLOGISTS

September 4, 2025

The Honorable Morgan Griffith
Chairman
Subcommittee on Health
House Committee on Energy and Commerce
Washington, D.C. 20515

Statement for the Record: Examining Opportunities to Advance American Health Care through the Use of Artificial Intelligence Technologies

Dear Chairman Griffith,

The College of American Pathologists (CAP) appreciates the opportunity to submit a statement for the House Committee on Energy and Commerce Subcommittee on Health's hearing entitled, "Examining Opportunities to Advance American Health Care through the Use of Artificial Intelligence Technologies." As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (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 recognizes that artificial intelligence (AI) health tools can complement and augment the diagnostic capabilities of pathologists. However, patient safety and clinical validity must be prioritized for AI development and responsible implementation. The best performance of AI in pathology accrues when machine capabilities provide physicians (i.e., pathologists) with added information to extend analysis, enhancing rather than replacing human expertise. The medical integration of clinical laboratory or molecular test results, examination of anatomic specimens, patient history, and other clinical data into an interpretation and diagnostic report requires a licensed physician. Artificial intelligence and machine learning systems can be an additional source of information for a physician to integrate into the overall diagnostic report, but these systems cannot provide a medical diagnosis or be responsible for decision-making in patient care. Physician review and approval are necessary.

Current Pathology Use of AI

Many AI pathology tools require high quality digital images of the glass slides pathologists view under their microscopes to function. Digital pathology refers to the process of getting those glass slides scanned into a computer so that digital slide images can be analyzed, rather than directly visualized through a microscope. Digital pathology is thus a necessary precursor to the adoption of those AI tools in pathology.

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The national adoption of digital pathology has been slow, largely due to infrastructural demands, including substantial investments in hardware (scanners), digital storage, powerful servers, and other health information technology (HIT) infrastructure. Standardization and interoperability are necessary precursors for adoption, particularly in terms of anatomic pathology's digital imagery standardization. CAP survey data over the last two years indicate that only about one quarter of pathology practices report utilizing digital slides images (otherwise known as whole slide imaging). Early adoption of this technology has not been evenly distributed. CAP survey data indicates that large academic medical centers and reference laboratories are more readily adopting this technology relative to other practice settings. Given that digital pathology is a necessary precursor to the use of such AI tools in pathology and that national adoption of digital pathology has been slow, the integration of AI technologies into the clinical workflows consequently remains in the early stages.

Nevertheless, there are established uses of AI in pathology. AI systems have been implemented to screen peripheral blood smears in hematology, for assisted screening of Pap smears to identify negative slides for manual review, and to analyze prostate biopsies. Some of these devices have been granted Breakthrough Designation by the Food and Drug Administration (FDA) because of their innovation. Moreover, AI in pathology holds significant promise for cancer care, particularly in risk stratification and predicting treatment response. These tools can detect subtle features in tissue samples or correlations across laboratory results, enabling precise and personalized therapies.

It is important, however, to note the specific role that AI plays in these use cases in pathology. Specifically, AI tools in these cases support pathologists by offering additional insights and are not meant to make decisions on their own. Indeed, commercially available AI tools for pathology are intentionally designed to be cautious, flagging anything that might be relevant to avoid missing critical findings. This can lead to overdiagnosis and inappropriate treatment if the AI's suggestions are accepted without the pathologist's professional judgment. Consequently, the pathologist must assess the outputs and predictions made by the AI tools and integrate the information into a final diagnosis on a case-by-case basis. To summarize, AI tools make predictions. Pathologists make diagnoses. Although AI tools can enhance the diagnostic process, it is ultimately the pathologist that makes the final diagnosis and guides patient care.

Challenges in AI implementation exist and will require implementation of guardrails to ensure identification and mitigation. For example, generative AI models can produce outputs that are not grounded in truth (a phenomenon often termed as hallucinations). Bias in AI models can arise from various sources, such as imbalanced datasets, training data that does not accurately reflect the intended deployment context, and implicit biases in the training processes and algorithms. Finally, overfitting can cause a model to perform exceptionally well on training data but fail to generalize effectively to the unseen data, producing inaccurate output.

The AI Product Lifecycle Must Incorporate the Input and Expertise of Pathologists

Pathologists are responsible for clinical review and approval of the design and operation of HIT, including AI. Consequently, as AI technology is developed, deployed, and configured, it is critical that pathologists are engaged in these processes to ensure the unique knowledge of pathology and laboratory medicine are incorporated into AI systems, including patient safety issues, risks, workflow, and other challenges. Further, FDA review and clearance of AI devices will help ensure transparency in product labeling to enable pathologists to understand the data that was used to train and test the device, thereby making it easier for them to verify device use in the laboratory setting and approve devices, as appropriate, for clinical use.

The CAP maintains that pathologists with responsibility for oversight of clinical and anatomic pathology laboratories must have a 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 is dependent on the characteristics of the local data over which the AI operates, local pathologists are the best-positioned experts to evaluate the performance of AI systems using their laboratories' data at the time of deployment and over time during use.

Additionally, ethical considerations must play a central role in the design, implementation, and maintenance of AI, including patient privacy and autonomy, transparency, accountability, beneficence, and non-malfeasance. Pathologists act as advocates for patients in ensuring AI performance quality, including monitoring for potential biases in AI tools for which they are responsible. Biases that are present in AI systems must be understood and addressed. It is important that the techniques and authority to measure AI performance and respond to performance problems are available to pathologists to ensure ethical application and clinical validity.

Federal Policy Considerations

Should the Committee be interested in pursuing legislation related to AI, the CAP recommends that any federal policies be reasonable and not overly burdensome from a laboratory perspective, prioritizing patient safety, ensuring clinical validity, allowing for innovation, and preserving the role of pathologists as physicians and advocates for patients. The CAP also recommends that any new federal requirements not duplicate existing regulations and not infringe on the practice of medicine.

Further adoption of AI in pathology will also require investment in digital infrastructure and workforce training. Pathologists need additional resources to support these efforts as the current lack of an annual inflationary update for pathologists, especially those that operate small businesses, compounds the wide range of shifting economic factors impacting the practice of pathology, such as increasing administrative burdens, staff salaries, office rent, and purchasing of essential technology when determining their ability to provide care to Medicare patients. The absence of an annual inflationary update, combined with the physician fee schedule's statutory budget neutrality requirements and ongoing Medicare payment cuts, further compounds the difficulties pathologists face in managing resources to continue caring for patients in their communities.

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Finally, payment for AI in pathology and laboratory medicine should appropriately advance its use, promote safety in its clinical application, and recognize the professional role and responsibility of pathologists in its implementation, clinical application, and management.

The CAP appreciates the Committee's efforts in this space. We look forward to working with you on policies that allow AI to complement and augment the diagnostic capabilities of pathologists. Please contact Hannah Burriss at hburris@cap.org, if you have any questions regarding these comments.

Sincerely,

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President

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