American College *of* Radiology™

September 22, 2023

The Honorable Bill Cassidy
Ranking Member
Health, Education, Labor, and Pensions Committee
United States Senate
455 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Exploring Congress' Framework for the Future of AI: The Oversight and Legislative Role of Congress Over the Integration of Artificial Intelligence in Health, Education, Labor; Comments of the American College of Radiology

Dear Senator Cassidy,

The American College of Radiology (ACR)—a professional association representing over 41,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide comments to the Senate Health, Education, Labor, and Pensions (HELP) Committee regarding the white paper, "*Exploring Congress' Framework for the Future of AI: The Oversight and Legislative Role of Congress Over the Integration of Artificial Intelligence in Health, Education, Labor*."[1]

The ACR is a leader in artificial intelligence (AI) research and regulatory policy through the programs and initiatives of its Center for Research and Innovation (CRI)[2] and Data Science Institute (DSI).[3] The ACR CRI conducts clinical trials and serves as a partner and a resource for members, academia and industry on clinical trial design and management, and on precision diagnostics and treatment. The ACR DSI empowers the advancement, validation, and implementation of AI in medical imaging via programs to define radiology AI use cases, evaluate and monitor AI algorithms prior to and after deployment in clinical practice, educate the physician community, and provide helpful information about AI to end-users to empower radiologists to identify the right AI tools for their patients and practices.

The ACR is enthusiastic about advancing safe and effective AI innovations used by radiologists to better serve their patients. Most AI tools authorized by the Food and Drug Administration (FDA) for the U.S. market have been radiology devices under 21 CFR Part 892. We believe the FDA has served the public well in its key oversight role and we welcome additional progress by the U.S. government to support AI innovations and to ensure that these technologies continue to perform safely and effectively in real-world settings.

Supporting Medical Innovation

The FDA has worked to meet AI oversight challenges through the agency's Software Precertification Pilot, guidance updates for Software as a Medical Device (SaMD), new device types established in 21 CFR via

[1] https://www.help.senate.gov/imo/media/doc/help_committee_gop_final_ai_white_paper1.pdf
[2] https://www.acr.org/Research/Clinical-Research
[3] https://www.acrdsi.org/

De Novo requests, regulatory framework documents, and establishment of the Digital Health Center of Excellence, among other activities. The ACR recommends the following policy goals to complement FDA's existing policy portfolio, some of which may benefit from expanded agency authorities:

- ***Improved AI transparency –*** Hundreds of exciting radiology AI innovations have been authorized by FDA to date. Yet, it is generally infeasible for radiologists to determine which algorithms have been vetted for use with patient populations, clinical settings, and input/image acquisition devices that represent how they themselves would use those devices. AI transparency challenges can lead to safety and effectiveness concerns via unwitting off-label use of devices by clinicians in ways for which they were not intended by the manufacturer nor reviewed by FDA.[4] The lack of centralized information about AI development, testing, and performance can serve as a barrier to adoption and commercial success, as the best AI tool for a given clinical use case, patient population, and/or practice setting may not be easily discoverable. It can also lead to unintentional bias in decisions informed by the algorithm's outputs, as physician end-users do not typically have the product information needed to avoid or mitigate algorithmic bias.

  The ACR recommends enhanced accessibility of performance testing dataset characteristics and other device information to guide purchasing decisions, implementation in the clinical setting, and safe/effective patient care decisions.[5] Progress could include an in-depth database/registry with relevant dataset characteristics and "nutrition label" style information at a glance on the intended uses of AI algorithms, intended end-user qualifications, and development/testing dataset characteristics (patient populations, input/acquisition devices, etc.).

  Publicly accessible information should also include easy-to-find statements on whether the algorithm has been developed and tested for use with pediatric patient populations to ensure that AI trained and tested with exclusively adult-aged patient datasets are not used unintentionally off-label on children absent assurance of safety and effectiveness. A particular challenge in this regard is the heterogenous nature of the pediatric patient population which ranges from newborns to near adults, is constantly developing, and requires very specific labeling of the software with an applicable age range the AI was trained and tested for.

- ***Post-Market Surveillance –*** AI performance variability can be caused by differences between the development/testing and real-world use environments, such as differing patient population characteristics, input data acquisition devices (e.g., imaging scanner models and versions), the qualifications and expertise of the clinical end-user, how future software modifications are implemented, and other variables. It is therefore critical for FDA and industry to implement post-market surveillance approaches that are appropriate for the risk/effectiveness profile of the AI type in question.

  For example, a future fully autonomous AI solution would likely need the most rigorous pre-market review and continuous post-market surveillance to reasonably ensure safety and effectiveness, as there would not be an appropriately qualified end-user overseeing the input and output data who can sufficiently identify and mitigate unexpected performance issues. By contrast, an assistive/augmentative AI tool used to inform a physician-expert who has the

[4] https://www.fda.gov/medical-devices/letters-health-care-providers/intended-use-imaging-software-intracranial-large-vessel-occlusion-letter-health-care-providers

[5] https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr-comments_fda-ai-transparency.pdf

training and experience to independently perform that same service without the tool's assistance (e.g., a board-certified radiologist using an AI-enabled Computer-Assisted Detection Device) would likely not require the same rigor of post-market surveillance due to the risk mitigation of the expert who can readily bypass the AI and flag performance issues. A notable exception would be devices with a quantitative output for which real time radiologist generated ground truth is not feasible to assess accuracy. In those instances, validity checks (e.g., for artifacts in the source data) and comparison with other correlated clinical data points, performed on a reasonable sample of transactions, may indicate whether the output is reliable.

- ***FDA-CMS and Third-Party Collaboration –*** Appropriate payment policy is necessary to support industry innovation, provider adoption and prevent exacerbation of healthcare disparities between patients treated at well-resourced institutions that may be able to implement AI solutions without third-party reimbursement and resource-challenged institutions in rural our underserved areas, where patients may benefit from AI the most. The ACR welcomes collaboration between FDA and the Centers for Medicare and Medicaid Services (CMS) to improve the timeliness and adequacy of appropriate reimbursement for AI tools and uses. Collaborative efforts on payment policy must actively engage physician groups and other public stakeholders.

  Beyond FDA-CMS collaboration, the FDA has partnered well with the National Institutes of Health, the Advanced Research Projects Agency for Health (ARPA-H), ACR, and other third-party organizations on research projects and innovative regulatory science approaches to AI oversight challenges. The ACR recommends continued collaboration between regulators, researchers, and physicians/end-users on issues such as AI use case identification, pre-market evaluation, post-market surveillance, and device information transparency via databases/registries.

- ***AI End-User/Facility Oversight –*** Federal regulatory and research agencies should additionally partner with physician specialty societies such as ACR to oversee the processes, workflows, and infrastructure related to appropriate *clinical implementation* of AI by qualified end-users within their medical specialties. This could include quality registry participation and/or credentialing of provider sites. A real-world example of the benefits would be the FDA's implementation of the Mammography Quality Standards Act (MQSA), which has substantially improved the quality of breast cancer screening through accreditation of mammography facilities.[6]

Medical Ethics and Protecting Patients

The ACR strongly supports the goal of avoiding bias in AI-enabled medical decision-making. To that end, it is important for a clinical end-user of any AI tool to have appropriate training and experience to oversee the AI tool's performance and provide the same care independently without the assistance of that AI tool should there be any unexpected performance that could lead to biased decision-making.

Due to the aforementioned transparency issue, healthcare providers may not always have access to robust AI device information they need to avoid and/or mitigate bias created by AI. Therefore, federal policies meant to penalize or disincentivize bias, such as current rulemaking efforts within the HHS Office

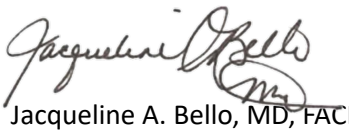
[6] https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program/about-mammography-program

of Civil Rights,[7] should consider the accessibility of product information required by the clinician to anticipate, preempt, and/or mitigate bias.

Importantly, not all AI devices were intended by the manufacturer to be generalizable across all patient populations, input/data acquisition technologies, and clinical settings. Certain AI devices may create unavoidable differences in care or workflows due to intended limitations of the tool's development and testing. Additionally, a radiologist may review imaging studies for multiple sites of service that have differing capabilities and image acquisition devices which do not perform equally effective with a given AI tool, necessitating site/input device-specific changes in AI-enabled decision-making. Therefore, federal policies against AI-enabled bias must also consider any intended limitations by the manufacturer's design that would necessitate end-users to restrict AI to specific patient populations, clinical settings, or input devices for reasons of safety and effectiveness.

The ACR welcomes continued dialog with the Senate HELP Committee on healthcare AI topics. Please contact Gloria Romanelli, JD, Senior Director, Legislative and Regulatory Relations and Legal Counsel, Quality and Safety, at gromanelli@acr.org; or Michael Peters, Senior Government Affairs Director, at mpeters@acr.org, with questions.

Sincerely,



Jacqueline A. Bello, MD, FACR
Chair, Board of Chancellors
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[7] https://www.acr.org/-/media/ACR/Files/Advocacy/Regulatory-Issues/acr_comments_ocr-cms-aca1557_9-28-2022.pdf