March 11, 2022

The Honorable Brad Wenstrup
United States House of Representatives
Washington, D.C. 20515

The Honorable John Joyce
United States House of Representatives
Washington, D.C. 20515

The Honorable Bruce Westerman
United States House of Representatives
Washington, D.C. 20515

Dear Representatives Wenstrup, Joyce and Westerman:

The American College of Radiology (ACR)[1] and Society for Pediatric Radiology (SPR)[2] appreciate the opportunity to respond to the Healthy Future Task Force Treatments Subcommittee's Request for Information (RFI) as the Task Force considers legislation to increase access to medical innovation.

The private sector has invested substantially in radiology artificial intelligence (AI) development; however, with rare exception, innovations currently on the market have been intended for use only on adult patients. Out of the hundreds of AI-enabled software devices cleared by the Food and Drug Administration (FDA), only one has been developed specifically for use on children. Furthermore, there is limited publicly accessible information about whether currently available AI products were trained and/or tested using pediatric data. This is important because AI developed for adults may not always perform effectively, and could pose additional safety concerns, when used on pediatric patients.

The ACR and SPR believe there is a need to promote the development of safe and effective AI-enabled software intended for use by radiologists in the care of pediatric patients. We recommend the following policy approaches:

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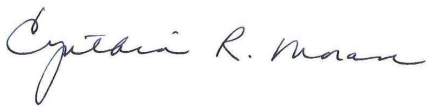
[1] The **American College of Radiology** is a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists,

[2] The **Society for Pediatric Radiology** is dedicated to fostering excellence in pediatric health care through imaging and image-guided care.

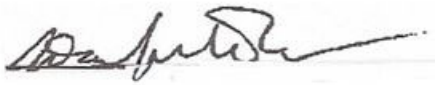
- Designation as a "breakthrough device" within the FDA Center for Devices and Radiological Health (CDRH) Breakthrough Devices Program any submission of an AI-enabled software device that is intended for use on pediatric patients. This would promote future development of pediatric radiology AI solutions via the promise of enhanced agency resources and expedited review.
- Enhanced public access to information about FDA-regulated AI products to enable healthcare providers to assess whether the safety and effectiveness profile is applicable to their respective infrastructure and patient populations. This should include mandatory pediatric use and suitability information, "nutrition label" style presentation of information about the patient population data used in AI training and testing, and more.
- Establishing research programs within the National Institutes of Health, the conceptual Advanced Research Projects Agency for Health (ARPA-H), and/or other public health service agencies prioritizing the development of innovations in pediatric radiology AI.
- Mandating a report to Congress from the Secretary of Health and Human Services on a national strategy to advance safe and effective AI innovations for pediatric patients. In doing so, the Secretary should solicit public comments on ideas for research funding initiatives, AI oversight enhancements, and public transparency requirements.

In closing, the ACR and SPR strongly urge the Subcommittee to draft healthcare policies that encourage innovation in safe and effective pediatric radiology AI. If the Subcommittee would like to discuss this issue further, please do not hesitate to contact the ACR's executive vice president for government relations and economics health policy, Cynthia Moran, at cmoran@acr.org.

Sincerely,



Cynthia Moran
Executive Vice President
Government Relations and Economics Health Policy
American College of Radiology



J. Damien Grattan-Smith, MBBS
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