Written Statement

Dr. William T. Thorwarth, MD, Chief Executive Officer, American College of Radiology Subcommittee on Labor, Health and Human Services, Education and Related Agencies House Appropriations Committee

In Support of FY 2025 Appropriations for the National Institutes of Health and the Advanced Research Projects Agency for Health

Chair Aderholt, Ranking Member DeLauro, and members of the Subcommittee, I am Dr. William T. Thorwarth, Chief Executive Officer of the American College of Radiology (ACR), a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists. On behalf of the ACR we are honored to present this testimony in support of robust appropriations for biomedical research at the National Institutes of Health (NIH) and urge the Subcommittee to provide at least \$51.3 billion to the NIH for fiscal year (FY) 2025. Additionally, the ACR asks the Subcommittee to support a continuation of funding from FY 2024 levels for the Advanced Research Projects Agency for Health (ARPA-H), providing \$1.5 billion in FY 2025. It is vital that ARPA-H funding is maintained as a separate appropriation outside of the NIH base budget.

As a specialty with a long history of innovation, we know that strong and predictable funding for NIH and our national research infrastructure allows for the continued advancement of scientific discoveries and breakthroughs, improving the lives of patients with a wide spectrum of diseases and disorders, many of whom depend on radiology and imaging tools for prevention, detection, diagnosis, and treatment of disease. ACR is grateful for the Subcommittee's past support of NIH and encourages the continuation of advancing biomedical research in radiology and imaging science, including within institutes such as the National Cancer Institute (NCI) and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). Additionally, we encourage support of ARPA-H, as we continue to engage with the agency regarding potential partnerships with ACR-collaborative, managed, led, or sponsored research entities and programs to address the nation's greatest healthcare challenges. In this testimony I will briefly describe examples of how robust NIH and ARPA-H funding has improved radiology patient care.

Leading Health Innovation, Impacts on Clinical Trials, and the Future of Medical Imaging

ACR has historically been a leader in the radiology clinical trial space, helping to develop and implement new prevention, detection, diagnosis, and treatment approaches at a faster pace for a variety of diseases and disorders. The newest public health federal agency, ARPA-H, has presented a multitude of opportunities for imaging advances, including clinical trials.

In FY 2024 ACR joined the ARPA-H established nationwide health innovation network, ARPANET-H. ACR became a member of the Customer Experience Hub, which intends to ensure that future healthcare advancements are patient-centric and deliver improved outcomes for all Americans. ACR is poised to serve as a resource and leading voice in the Hub's Advancing Clinical Trial Readiness initiative, which seeks to improve the nation's ability to conduct clinical trials safely, quickly, and equitably. ACR has also been selected as a member of the ARPANET-H Investor Catalyst Hub, which fosters collaboration between researchers, entrepreneurs, and investors to commercialize technologies and provide support in healthcare innovation. ACR sees a potential to engage through the Hub's Sprint for Women's Health initiative, an effort to fundamentally change the trajectory of women's healthcare research and radically accelerate the next generation of discoveries through areas of interest including making care available at home through home testing and monitoring, ovarian health, and imaging methods that would help assess brain lymphatic function.

Serving as a member in both ARPANET-H Hubs offers ACR the opportunity to provide input on ARPA-H challenge areas and priorities. ACR is poised to serve in both Hubs through its vast expertise in clinical trials including registries, as well as the commitment to create resources that make imaging safe, effective, and accessible for all.

Making Imaging Data Available for New Opportunities

Another example of an ACR collaboration with ARPA-H is through the agency's Biomedical Data Fabric (BDF) Toolbox. The ARPA-H BDF Toolbox will help make research data easier and more reliable to use, reduce effort for data integration, and enable new capabilities and models that can be applied across disciplines and generalized across disease domains.

The ACR co-led Medical Imaging and Data Resource Center (MIDRC), funded through the NIBIB, was selected to provide domain expertise and database technology development in medical imaging to the BDF. The BDF is an initiative to de-risk technologies for an easily deployable, multi-modal, multi-scale connected data ecosystem for biomedical data. ACR's COVID-19 Imaging Research Registry[™], included in MIDRC, established a growing network of sites that, to date, have ingested, curated, and transferred more than 84,000 imaging studies and data from 37,000 patients to MIDRC to help researchers develop machine learning (ML) and artificial intelligence (AI) tools for COVID-19 care. Additionally, the ACR supported MIDRC goals to develop collaborations with other organizations by establishing partnerships resulting in a transfer of more than 10,000 COVID-19 imaging studies to ACR for processing and ultimately contribution to MIDRC.

Encouraging Customized Breast Cancer Screening

The ACR is a longstanding collaborator with the NIH, and a multitude of its Institutes and Centers. An ACR driven, NIH-funded, clinical trial I would like to highlight for the Subcommittee, is the Tomosynthesis Mammographic Imaging Screening Trial (TMIST). TMIST is a current study that will help researchers learn the best way to find breast cancer in women who have no symptoms.¹ This trial compares two types of mammograms, the standard digital mammograms (2-D) and a newer technology called tomosynthesis mammograms (3-D). This study focuses on detecting breast cancer before it becomes advanced, aiming to reduce the morbidity and mortality of women who develop breast cancer. TMIST is a multi-faceted study that uses integrated diagnostics to attempt to predict the likelihood of breast cancer in an individual. Family history, age, genetic markers, and breast density are examples of the data collected in this study to learn the behavior of breast cancer, with the intent to customize breast cancer detections strategies. We are pleased that approximately 21% of TMIST enrolled individuals are African American.

¹ <u>https://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/tmist</u>

Creating a Central Public Repository of Medical Images

Another example of an ACR and NIH partnership is with the NCI and Booz Allen Hamilton project to develop an NCI-designated central public repository of medical images and associated clinical data from lung cancer screening patients. This will be used in artificial intelligence (AI) algorithm development and validation within the research community. A comprehensive "AI ready" dataset to use for algorithm training and validation is currently absent, particularly one that collects diverse, high-resolution annotated images accompanied with patient demographic characteristics, clinical history, cancer status, and CT imaging parameters. This repository will provide an opportunity for the development of new AI and machine learning algorithms beyond single institution experiences and will enable enhancements to equitable clinical care, leading to improvements in the diagnosis and treatment of lung cancer. The ACR also has developed a large (over 20,000 sites) network via "ACR Connect" that will allow testing of AI algorithms on site, thus limiting transfer of patient data ensuring broad geographic and institution-type diversity in testing.

ACR will facilitate collection and harmonization of images and corresponding data from a total of 15,000 lung cancer screening patients from up to 15 clinical sites within the United States. NCI has set specific requirements for subject level representativeness for race and ethnicity. Socioeconomic status variables will also be collected, which will expand the breadth and application of the dataset, provide downstream AI and social science research applications, and lay groundwork for future data collection efforts and collaborations.

Summary and Conclusion

Radiology and medical imaging are critical components of healthcare for a wide array of diseases and disorders, impacting at some level, all Americans. The use of imaging tools stretches farther than the examples described for lung cancer, breast cancer, and COVID-19. Radiology and imaging are essential in almost all aspects of early detection, diagnosis, and treatment, and should be included in all of NIH's Institutes and Centers, as it is in NCI and NIBIB. Radiology and imaging are used as risk estimate tools, impacting a patient's quality of life, and reducing the likelihood of suffering. The tools used in radiology may recommend clinical practice adaptations, such as avoiding an unnecessary surgery or procedure, thus altering the experience and risks and outcomes for patients.

Strong and predictable funding for NIH and ARPA-H is crucial to ensure continued advancements in biomedical research discoveries, including those in radiology. In addition to funding fundamental basic research, NIH research results in novel innovations and patents, and the potential creation of new commercial entities, benefiting and growing the U.S. economy. For example, each \$100 million in investment to the NIBIB results in \$3.3 billion in downstream research and development (R&D) investment, making it one of the most productive appropriated federal R&D programs. Furthermore, NCI funded research has generated the highest number of patents out of all NIH Institutes and Centers (IC), over 2.5 times higher than the average IC budget's production.²

ACR is grateful that NIH has received longstanding, bipartisan support from the Subcommittee and thanks the Subcommittee for the continued support of biomedical research.

² https://media4.manhattan-institute.org/sites/default/files/MI-NIH-0617.pdf

Our continued collaboration will ensure breakthroughs and discoveries in radiology and other areas of medicine are possible. On behalf of ACR, we urge you to continue your strong support of NIH funding and appreciate your consideration of least \$51.3 billion in FY 2025, and \$1.5 billion in FY 2025 for ARPA-H.