### Written Statement

Dr. Dana. H. Smetherman, 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 2026 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. Dana. H. Smetherman, Chief Executive Officer of the American College of Radiology (ACR), a professional association representing more than 40,000 physicians practicing diagnostic radiology, interventional radiology, radiation oncology, and nuclear medicine, as well as medical physicists. On behalf of the ACR, I am honored to present this testimony in support of robust appropriations for biomedical research at the National Institutes of Health (NIH) and the Advanced Research Projects Agency for Health (ARPA-H). For reasons I will describe in this testimony, I urge the Subcommittee to continue fiscal year (FY) 2026 funding at FY 2025 levels - with at least \$51.3 billion to the NIH and \$1.5 billion to ARPA-H (which is funded as a separate appropriation outside the NIH base budget).

Radiology is a specialty with a long history of innovation. Since its first National Cancer Institute (NCI) grant in 1968, ACR-collaborative, managed, led, or sponsored research entities and programs have been involved in over 500 NIH funded studies in diagnostic and interventional radiology, radiation oncology, and nuclear medicine. As a result, the ACR recognizes the need for strong, predictable funding of our national research infrastructure to enable scientific discoveries and breakthroughs. These advancements ultimately improve the lives of patients, who depend on radiology and imaging tools for the prevention, detection, diagnosis, and treatment of a vast array of diseases.

The ACR greatly appreciates the Subcommittee's past support of research in radiology and imaging science, including studies performed in NIH institutes such as the NCI and the National Institute of Biomedical Imaging and Bioengineering (NIBIB). In addition, we recognize the importance of ARPA-H in addressing the nation's greatest healthcare challenges, and we continue to explore potential partnerships between ARPA-H and ACR-collaborative, managed, led, or sponsored research entities and programs. In this testimony, I will provide examples of how robust funding of NIH and ARPA-H initiatives can positively impact radiology patient care.

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

For many years, ACR has been a leader in radiology clinical trials. We have helped develop and implement new, more rapid approaches to prevention, detection, diagnosis, and treatment of a variety of diseases and disorders. As the newest public health federal agency, ARPA-H has also presented many important opportunities, including clinical trials, to advance the science of imaging.

The ACR is particularly excited about the development of the ARPA-H ImagiNg Data EXchange (INDEX) project. In collaboration with the Food and Drug Administration, INDEX aims to create an exchange platform that connects medical imaging data providers, users, and services with robust and trustworthy artificial intelligence (AI) tools for radiology, pathology, and surgical imaging. The INDEX platform will offer access to medical imaging data and resources for image processing and ML algorithm development. The platform will also include tools to assess algorithms at multiple stages of their lifecycles, which will simplify and accelerate development, testing, and deployment. Due to our expertise in clinical trials (including registries), ACR is poised to be a development partner in this endeavor and is committed to creating resources to make AI in imaging safe, effective, and accessible for all patients.

## Making Imaging Data Available for New Opportunities

ACR and ARPA-H currently collaborate on the agency's Biomedical Data Fabric (BDF) Toolbox. The ARPA-H BDF Toolbox will 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. At this time, the BDF Toolbox project is under development and has been granted an extension to ensure completion in 2025.

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 initiative will de-risk technologies to provide an easily deployed, multi-modal, multi-scale connected data ecosystem for biomedical data. ACR's COVID-19 Imaging Research Registry<sup>™</sup>, included in MIDRC, established a growing network of sites. To date, more than 84,000 imaging studies with data from 37,000 patients have been ingested, curated, and transferred to MIDRC to develop machine learning (ML) and AI tools for COVID-19 care. Additionally, the ACR supported MIDRC's goals to collaborate with other organizations. As a part of the MIDRC project partnerships, more than 10,000 COVID-19 imaging studies were transferred to the ACR for processing.

# Identifying Breast Cancer through Customized Screening

The ACR is a longstanding collaborator with the NIH and many of its Institutes and Centers (ICs). As one example, I would like to highlight the ACR driven, NCI-funded Tomosynthesis Mammographic Imaging Screening Trial (TMIST). TMIST is a current study to determine the best way to find breast cancer in asymptomatic women.<sup>1</sup> In December 2024, TMIST not only completed but surpassed its participant accrual goal, with over 108,508 women recruited from 133 study sites around the world. TMIST also provides an example of clinical trial diversity and includes women from around the globe; 48% of TMIST participants are Hispanic or Latino<sup>2</sup>, and nearly 21% of US women in the study are African American<sup>3</sup>.

This trial compares standard, planar digital mammograms and a newer technology, digital breast tomosynthesis (sometimes referred to as "3-D mammograms"). The study focuses on early detection, aiming to reduce the morbidity and mortality of women who develop breast cancer. TMIST is a multi-faceted trial intended to customize breast cancer detection strategies. Integrated diagnostics are used in an attempt to predict the likelihood of breast cancer in an individual. Family history, age, genetic markers, and breast density are among the data

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

<sup>&</sup>lt;sup>2</sup> <u>https://ecog-acrin.org/press-release-large-scale-tmist-breast-cancer-screening-trial-achieves-enrollment-goal/?cid=eb\_govdel</u>

<sup>&</sup>lt;sup>3</sup> <u>https://ecog-acrin.org/press-release-tmist-breast-cancer-screening-trial-enrollment-surpasses-100000/</u>

collected to better understand the behavior of breast cancer. The trial will show whether screening with tomosynthesis reduces the most dangerous kinds of cancers. Ultimately, the study will help improve treatments for both advanced and early breast cancer. TMIST is also developing the world's largest curated dataset of breast cancer screening images, clinical data, and biospecimens, which will be available to researchers for future use.<sup>4</sup>

## **Creating a Central Public Repository of Medical Images**

The NCI and Booz Allen Hamilton project is another example of an ACR and NIH partnership. This collaborative effort is currently developing an NCI-designated central public repository of medical images and associated clinical data from lung cancer screening patients. This information will be used to develop and validate AI algorithms within the research community. Currently, there is no comprehensive "AI ready" dataset to use for algorithm training and validation. In particular, there is no dataset available that collects diverse, highresolution annotated images accompanied by patient demographic characteristics, clinical history, cancer status, and CT imaging parameters. For this reason, NCI has set specific requirements for subject level representation of race and ethnicity. Socioeconomic status variables are also being collected. This approach expands the breadth and application of the dataset, provides downstream AI and social science research applications, and lays the groundwork for future data collection efforts and collaboration.

Presently, the ACR is facilitating the collection and harmonization of these medical images and the corresponding clinical data from 15,000 lung cancer screening patients from up to 15 clinical study sites in the United States. In the next year, the ACR plans to populate the central public repository with lung cancer screening images and data, which will be ready for use by AI developers. This repository will provide an opportunity to develop new AI and machine learning algorithms beyond single institution experiences. The project will enable enhancements to equitable clinical care and lead to improvement in diagnosis and treatment of lung cancer. The ACR has also developed a large network with over 20,000 clinical sites via "ACR Connect". This platform allows testing of AI algorithms at clinical sites, limiting transfer of patient data and ensuring testing occurs across a broad range of geographic areas and types of facilities.

## **Summary and Conclusion**

Radiology and medical imaging are critical components of healthcare. These technologies are used in a wide array of diseases and impact virtually all Americans. The utilization of imaging tools stretches far beyond the examples described above for lung cancer, breast cancer, and COVID-19. Radiology and imaging are essential in almost all aspects of patient care, including early detection, diagnosis, and treatment of disease, risk estimation, guidance for interventional procedures, and recommendations for clinical practice adaptations to avoid unnecessary surgery, treatment, imaging, and other procedures. Radiology and imaging care improve the experience, risks, quality of life, and outcomes for patients and should be included in all of NIH's ICs.

<sup>&</sup>lt;sup>4</sup> <u>https://ecog-acrin.org/press-release-large-scale-tmist-breast-cancer-screening-trial-achieves-enrollment-goal/?cid=eb\_govdel</u>

Strong and predictable funding for NIH and ARPA-H is essential to ensure stability of institutions and continued advancement in biomedical research discoveries, including those in radiology. In addition to support of basic research, NIH funding can result in novel innovations, patents, and the creation of new commercial entities, which benefit and help grow the U.S. economy. Each \$100 million invested in NIBIB results in \$3.3 billion in downstream research and development (R&D) investment, making NIBIB one of the most productive appropriated federal R&D programs. Furthermore, NCI funded research has generated the highest number of patents of all NIH ICs, over 2.5 times higher than the average IC budget's production.<sup>5</sup>

The ACR is grateful NIH has received longstanding, bipartisan support and again thanks the Subcommittee for its ongoing promotion of biomedical research. Our continued collaboration will ensure future breakthroughs and discoveries in diagnostic and interventional radiology, nuclear medicine, radiation oncology, and other areas of medicine. On behalf of the ACR, I encourage you to maintain your strong support and appreciate your consideration of the requested funding of at least \$51.3 billion for NIH and \$1.5 billion for ARPA-H in FY 2026.

<sup>&</sup>lt;sup>5</sup> <u>https://media4.manhattan-institute.org/sites/default/files/MI-NIH-0617.pdf</u>