June 10, 2025

The Honorable Martin Heinrich
709 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Rounds
716 Hart Senate Office Building
Washington, DC 20510

Re: *Introduction of Health Tech Investment Act*

Dear Senators Heinrich and Rounds:

On behalf of the patients and patient advocates we represent, we sincerely thank you for your leadership in introducing the *Health Tech Investment Act* (S.1399). This landmark bipartisan legislation addresses a critical need by establishing a stable payment pathway for Algorithm-Based Healthcare Services—devices regulated by the Food and Drug Administration (FDA) that utilize Artificial Intelligence (AI) and Machine Learning (ML). By enabling broader adoption of these innovative technologies, this bill has the potential to enhance diagnostic accuracy, improve patient outcomes, and drive cost efficiencies across the healthcare system.

The potential of AI to transform patient care is immense, and its role in radiology offers some of the most compelling examples. AI-enabled tools are supporting healthcare professionals with interpreting medical images efficiently and accurately, aiding in the early detection of diseases and ensuring that patients receive timely and definitive diagnoses. From helping a physician identify polyps during a colonoscopy to prioritizing scans for emergency interventions, AI in medical imaging is not just a technological advancement—it represents markedly improved patient diagnostic care.

Despite its proven benefits, AI adoption faces significant barriers due to inconsistent reimbursement. Only a very small portion of FDA-approved AI-enabled medical devices receive reimbursement through the Centers for Medicare & Medicaid Services. The absence of payment predictability creates challenges for physicians seeking to integrate these advanced tools into their practices and thus prevents many patients, particularly those relying on Medicare, from accessing the benefits of AI-enabled medical devices.

Without Congressional action, AI-enabled medical devices may remain out of reach for many

Medicare beneficiaries, limiting access to devices available today and stifling future innovation and new applications. This legislation is designed to bridge that gap by ensuring physicians can integrate FDA-regulated AI/ML-enabled medical devices into standard care pathways. Moreover, it will ensure equitable access for both patients and physicians. Every physician, regardless of their practice size, financial resources or geographic location should have the opportunity to utilize these innovative technologies.

We strongly urge Congress to prioritize and pass this legislation, recognizing its transformative potential for the health and well-being of patients while fostering innovation in healthcare. Thank you for your commitment to improving patient care and advancing groundbreaking solutions. We look forward to working alongside you to ensure the successful passage of this bill and enhance the health of all Americans.

Sincerely,

AdvaMed
Alliance for Aging Research
Alzheimer's Association
American Society for Gastrointestinal Endoscopy
Arthritis Foundation
Be Still Foundation
Brem Foundation to Defeat Breast Cancer
Breast Friends
EGFR Resisters
Focused Ultrasound Foundation
Global Colon Cancer Association
HealthyWomen
Heart Valve Voice US
National Health Council
National Psoriasis Foundation
ONE CANCER PLACE
Ovarian Cancer Research Alliance
Patients Rising
Prevent Cancer Foundation
Right Scan Right Time
Say YES to Hope
Spina Bifida Association
ZERO Prostate