

TESTIMONY

of

Siemens Medical Solutions USA, Inc. (Siemens Healthineers)

before the

United States Senate

Committee on Finance

Re: “Artificial Intelligence and Health Care: Promise and Pitfalls.”

Presented by: Peter Shen, Head of Digital & Automation, North America

February 8, 2024

Summary

- Siemens Healthineers is a leading medical technology company with more than 120 years of history and experience bringing breakthrough innovations to market that enable healthcare professionals to deliver the best care for patients—from prevention and early detection, to diagnosis, treatment planning and delivery, and follow-up care. Our core portfolio includes imaging, diagnostics, comprehensive cancer care and minimally invasive therapies, augmented by AI.
- Siemens Healthineers has been working on applying AI into medical technology for more than 20 years.
- To ensure we develop reliable algorithms that are reflective of the patient populations they will be applied towards, we continually maintain a holistic view of the patient with high-quality training data. This training data is based on a balanced cohort of people of different ages, genders, ethnicities, healthy people, and those who are sick.
- We recently partnered with the American College of Radiology (ACR) to improve transparency and patient care through the launch of the Transparent-AI program. We disclose detailed product information, including training data demographics and machine specifications, to help radiologists choose tools that meet their specific patient population needs.
- AI in health care can take two dominant forms – AI for operational or workflow improvements that help reduce physician burden and improve patient experience, and AI for clinical services. We refer to clinical AI as Algorithm Based Healthcare Services (ABHS), which are analytical services delivered by FDA-cleared devices that use AI, machine learning or other similarly designed software to produce clinical outputs for physicians to use in the diagnosis or treatment of disease.
- Siemens Healthineers has over 80 FDA-cleared products on the market that represent groundbreaking innovations for patients. One of our cleared products, AI-Rad Companion¹ is our dominant AI platform that highlights, characterizes, measures, and reports clinical abnormalities to aid the clinician in formulating a diagnosis and treatment.

¹ General Availability Disclaimer for AI-Rad Companion:

AI-Rad Companion consists of several products that are (medical) devices in their own right, and products under development. AI-Rad Companion is not commercially available in all countries. Its future availability cannot be ensured.

- AI has enormous potential to improve access to care, diagnose disease faster and more precisely, and enable physicians to make treatment decisions based on comprehensive access to patient data in real-time.

Chairman Wyden, Ranking Member Crapo, and distinguished Members of the Committee, on behalf of Siemens Healthineers, our 17,000 employees in the U.S., and approximately 71,000 employees in over 70 countries globally, thank you for the opportunity to testify today on the topic of Artificial Intelligence (AI) in health care. My name is Peter Shen, and I am the North America Head of Digital & Automation for Siemens Medical Solutions USA, Inc – also known as Siemens Healthineers. My career focus is on the introduction of new and emerging technologies in the healthcare market, including in imaging, data analytics, digital ecosystems, and AI. My degree is in Biomedical Engineering and Mathematical Sciences from Johns Hopkins University.

Siemens Healthineers is a leading medical technology company with more than 120 years of history and experience bringing breakthrough innovations to market that enable healthcare professionals to deliver the best care for patients—from prevention and early detection, to diagnosis, treatment planning and delivery, and follow-up care. Our core portfolio includes imaging, diagnostics, comprehensive cancer care and minimally invasive therapies, augmented by AI. We focus on addressing the deadliest diseases impacting the United States (U.S.), including cancer, neurovascular, neurodegenerative, and cardiovascular diseases. We partner with more than 90 percent of providers in healthcare and in addition to the medical devices we provide, we also work to address population growth and chronic disease prevalence, healthcare workforce shortages and lack of access to care in underserved areas throughout the U.S., and globally. Given the depth and diversity of our product portfolio, we have the distinction of being the only medical technology company in the world capable of end-to-end cancer

care – from diagnosis and screening to treatment and survivorship. This is a responsibility we take very seriously, and we keep patients at the center of everything we do.

We are committed to creating jobs in the U.S. and fostering community engagement. Our U.S. headquarters is in Malvern, Pennsylvania. Our global headquarters for diagnostics is in Tarrytown, New York, and we have laboratory diagnostics manufacturing facilities that serve customers worldwide in both Walpole, Massachusetts and Glasgow, Delaware. Our global headquarters for molecular imaging is in Hoffman Estates, Illinois. Cary, North Carolina is home to our training center, where we train thousands of engineers annually, including active service members. Our AI research and development team is housed in Princeton, New Jersey. Our Varian business is headquartered in Palo Alto, California. We also have manufacturing, engineering and research and development sites in Washington, Indiana, Tennessee, Nevada and Colorado.

Each day, an estimated five million patients benefit from our 600,000 cutting-edge technologies and services worldwide. Data, digitalization, and AI to improve patient care is at the core of the work we do every day, and who we are as a company.

Siemens Healthineers AI Experience & Algorithm Development

Siemens Healthineers has been working on applying AI into medical technology for more than 20 years. At our Big Data Office in the U.S., we created and maintain one of the most powerful supercomputing infrastructures dedicated to developing algorithms. This infrastructure allows our research scientists to collect, prepare and organize correct and secure medical data – including more than 2.1 billion curated images from more than 200 clinical providers and partners – needed to train and deliver accurate AI.

From its inception, we created and maintain a quality assurance process, which involves clinical validation to both understand the treatment outcomes associated with the curated data as well as guarantee the data being used to train our algorithms is accurate for diagnosing and treating disease. To ensure we develop reliable algorithms that are reflective of the patient populations they will be applied towards, we continually maintain a holistic view of the patient with high-quality training data. This training data is based on a balanced cohort of people of different ages, genders, ethnicities, healthy people, and those who are sick. From the inception of data collection, we work to build algorithms that are reliable, accurate, unbiased, and protect the patient.

We take great pride in the work we do to develop reliable AI and have company-wide guardrails for AI that I have included in an addendum to this testimony. In addition, we have recently partnered with the American College of Radiology (ACR) to improve transparency and patient care through the launch of the Transparent-AI program. We disclose detailed product information, including training data demographics and machine specifications, to help radiologists choose tools that meet their specific patient population needs. ACR's public website includes comprehensive information on our FDA-cleared AI imaging products.

Partnering with physicians is essential to the adoption of AI, and its ability to be a powerful clinical tool to drive better patient outcomes.

Regulation

Our algorithms go through a regulatory approval process with the Food & Drug Administration (FDA). We follow all AI/Machine Learning (ML)-enabled medical device regulatory requirements for

premarket review and postmarket surveillance to ensure the safety and efficacy of our devices. We also engage with the FDA regularly on AI/ML and provide feedback on ways to ensure the continued safe and effective application of these technologies. In this regard, our AI is distinct from unregulated AI products.

With the rapid acceleration in development and innovation of AI, the need for the regulatory environment to be able to balance safety, effectiveness, as well as update and improve functionality, without hampering innovation and adoption is critical. While we believe the current regulatory framework is sufficient to support AI innovation, we support the continuation of flexibility in the approval process, as a one-size-fits-all approach could seriously inhibit the potential of AI, as well as efforts to facilitate global harmonization and the development of appropriate international consensus standards.

Additionally, Siemens Healthineers recognizes the importance of continuing to address unintentional potential bias in AI. We feel that these concerns are currently addressed for applications in medical devices and mitigated under existing risk management processes, quality systems, and compliance with regulatory requirements from the FDA and other regulators.

The Patient Journey

The patient journey is at the heart of Siemens Healthineers AI work. AI is already improving care for patients. Patients undergoing a CT (Computed Tomography) scan for lung cancer screening can be better positioned in the CT scanner to help optimize the resulting generated images, while minimizing the time the patient spends in the scanner. This is done by AI that is built into our CT scanner

technology that allows our machines to identify human anatomy. Radiologists reviewing the resulting lung cancer screening CT images can utilize our AI-guided computer software as a companion to the clinician to identify small nodules and other abnormalities, including the ability to measure the density and characterize the size of suspicious nodules that were previously not possible to visualize without the assistance of AI.

Suspicious lung nodules diagnosed to be cancerous by the clinician can potentially be treated by radiation therapy. To minimize the risk that healthy tissue around the cancer is not unnecessarily radiated, radiation physicists create a radiation treatment plan, which includes the tedious task of manually drawing the unique contours of the cancerous tumor. This manual contouring potentially delays the time to treatment for the patient. Our AI-enabled auto-contouring software can automatically detect these contours of the cancerous area, significantly speeding up the patient's time to treatment and potentially eliminating extraneous treatments.

Utilizing AI at each point in the process to screen, diagnose and treat lung cancer can reduce the time to treatment. This allows for a reduction in patient stress and anxiety, more precise and faster diagnosis, and more specialized treatment that we believe will improve patient outcomes.

Algorithm Based Healthcare Services (ABHS)

AI in health care can take two dominant forms – AI for operational or workflow improvements that help reduce physician burden and improve patient experience, and AI for clinical services. We refer to clinical AI as Algorithm Based Healthcare Services (ABHS), which are analytical services delivered by FDA-cleared devices that use AI, machine learning or other similarly designed software to produce

clinical outputs for physicians to use in the diagnosis or treatment of disease. They provide quantitative and qualitative analyses, including new, additional clinical outputs that detect, analyze or interpret data to improve screening, detection, diagnosis and treatment. ABHS are developing rapidly and represent an additional service provided to the patient to deliver the best care possible. These are clinical uses of AI that have a separate and distinct place within the healthcare AI conversation.

Siemens Healthineers has over 80 FDA-cleared products on the market that represent groundbreaking innovations for patients. One of our cleared products, AI-Rad Companion² is our dominant AI platform that highlights, characterizes, measures, and reports clinical abnormalities to aid the clinician in formulating a diagnosis and treatment. This ABHS supports physician decisions in diagnosing disease based on imaging scans.

For instance, ABHS can be an important service when used to diagnose neurodegenerative diseases. Brain morphometry, or changes in brain volume over time, can be a powerful predictor of neurodegenerative diseases, such as Alzheimer's, but neurologists are challenged with needing actionable, patient-specific volumetric data to diagnose and treat the patient more accurately. AI-Rad Companion (AIRC) Brain MR can automatically segment different structures of the brain on an MRI image, measure their volumes, and compare these volumes to data in a brain database from the Alzheimer's Disease Neuroimaging Initiative (ADNI). The AI-Rad Companion Brain MR feeds these comparative results into a report where deviations in volume from the norm are highlighted, enabling the

² General Availability Disclaimer for AI-Rad Companion:

AI-Rad Companion consists of several products that are (medical) devices in their own right, and products under development. AI-Rad Companion is not commercially available in all countries. Its future availability cannot be ensured.

radiologist to provide additional quantitative information to the neurology department, so that they can make a more accurate and informed diagnosis and treatment – resulting in better patient outcomes. AIRC Brain MR provides an additional service to the patient, and the physician receives essential information to diagnose neurodegenerative diseases that would be impossible without AI.

Another example of the benefit of ABHS is particularly relevant when discussing prostate cancer. Traditionally, a urologist identifies suspected areas of prostate cancer by manually reviewing written reports and pictograms of the prostate provided by radiology and as needed, acquires tissue samples from the areas in question using ultrasound-guided biopsy. We are developing an algorithm which is planned to be part of the AI-Rad Companion product family, which will automatically segment suspect areas of the prostate and characterize and measure suspicious lesions in the prostate from MRI images. This qualitative and quantitative analysis may support the urologist's decision on whether a tissue biopsy is additionally required for diagnosis or if such invasive procedure can be avoided, which is significant in managing a prostate cancer patient's well-being and minimizing unnecessary costs within the health system. This ABHS takes much of the grey area involved with prostate cancer, particularly when it comes to active patient monitoring, and provides a health care service through data that the physician would not otherwise have to allow a more informed diagnosis and treatment decision.

These Siemens Healthineers AI healthcare services provide clinicians with otherwise unavailable quantitative and qualitative clinical data that allows them to make a more informed decision, resulting in better patient outcomes. However, these ABHS are not consistently reimbursed by the Centers for Medicare and Medicaid Services (CMS). Guaranteeing a consistent reimbursement process would empower providers to invest in AI confidently, ensuring their services are appropriately reimbursed.

Without this financial support, these providers will face difficulties in embracing and integrating AI technologies, ultimately potentially denying revolutionary services to patients.

Current AI Adoption Challenge and Solution

CMS stated in its CY2023 OPPI/ASC Final Rule that, “Novel and evolving technologies are introducing advances in treatment options that have the potential to increase access to care for Medicare beneficiaries, improve outcomes, and reduce overall costs to the program.” Furthermore, CMS also asked for input and suggestions from the public on a specific payment approach they might use for these services as AI becomes more widespread across health care.

While CMS has recognized the value and the complex nature of ABHS, the agency’s reimbursement decisions have not uniformly and consistently ensured appropriate levels of payment for these services. This inconsistent, unpredictable approach stifles adoption by providers, especially in rural and underserved areas, and therefore, restricts patient access to new and innovative diagnostic tests and treatments. We support a solution that ensures a predictable and consistent approach by CMS—an approach that recognizes the costs to develop and integrate AI into the clinical setting and reimburses for the distinct service that provides otherwise unavailable quantitative and qualitative clinical data, with a temporary and separate payment, for five years, based on manufacturer-supplied cost data. We believe this will allow for better adoption of AI to help CMS collect more data to evaluate the overall value of ABHS to patients. We also believe that more data will demonstrate ABHS’s ability to increase access to care and improve outcomes for all patients.

The Future of AI in Healthcare

AI has enormous potential to improve access to care, diagnose disease faster and more precisely, and enable physicians to make treatment decisions based on comprehensive access to patient data in real-time. Siemens Healthineers is researching a patient companion tool to synthesize this data and apply AI to look for patterns and detect the potential for disease much earlier. In addition, we are working to create a digital twin of the patient that would allow a physician to perform an interventional procedure, say for a heart procedure, on a digital replica of a patient's heart to test how that patient will react and respond to a specific course of treatment before it is applied to the individual. The digital twin will minimize unintended consequences and provide more personalized, precision medicine for the patient. We are excited about what the future holds for AI in healthcare.

Conclusion

In closing, thank you for the opportunity to testify before you today on AI in health care. While there are many forms of AI applications in health care to reduce physician burnout and streamline operational complexities, we believe the highest value of AI in health care comes in the form of ABHS, and that this will revolutionize health care services for patients. Siemens Healthineers is a market leader in researching and training AI in medical technologies and welcomes the opportunity to continue this discussion. It is critical that we all work together to ensure we create trust with consumers and build ethical, transparent, and accessible AI in health care to improve patient outcomes. Again, thank you for the opportunity to testify. I look forward to your questions.

Addendum

We use a set of guardrails to guide the way we develop and implement AI in healthcare:

- We believe that healthcare professionals, backed up by AI solutions, make a strong team.
 - Our AI solutions learn from the best: Siemens Healthineers collaborates with a huge network of world-class clinicians, where we combine our research and development (R&D) capabilities with our customers' clinical expertise. The results of this collaborative process are powerful, clinically proven AI companions for decision-making that help to provide better patient care at lower cost. Humans and artificial intelligence have vastly different abilities. We believe that the future of medicine lies in combining the strengths of these capabilities. Such systems will provide healthcare professionals with tools to meet the rising demand for diagnostic imaging and actively shape the transformation of radiology into a data-driven research discipline. Moreover, AI algorithms are expected to help speed up clinical workflows, prevent diagnostic errors and reduce missed billing opportunities, thus enabling sustained productivity increases.
- We believe the level of autonomy of AI solutions needs to be balanced with ethical expectations and human values.
 - Societies are currently discussing the extent to which AI solutions could be a vital part of everyday human life. Depending on the area of life, society allows and strives for lower or higher levels of autonomy. In this regard, healthcare is a special area, as patients benefit from and rely on the trusted doctor-patient relationship. A high degree of autonomy of an AI solution substantially impacts this relationship. In healthcare areas, where the personal and trusted patient-doctor relationship is key to the success or course of the treatment, we believe that the autonomy of AI solutions needs to be well-balanced. Therefore, we develop AI

solutions only for areas where they are ethically acceptable and beneficial to humankind and society.

- We develop AI solutions to support patients' desires for more personalized medicine.
 - An increasing choice of personalized therapies is leading to significantly improved outcomes in oncology, but personalized medicine is also gaining traction in other application areas. For physicians, however, it is becoming more and more challenging to keep abreast of the constantly expanding treatment options. With our AI solutions, we enable physicians to make more accurate diagnosis and treatment choices, based on comprehensive patient data and the ever-advancing wealth of medical knowledge. With our vision of the "Health Digital Twin" as a constantly updated virtual model of the human body, we strive to develop the next generation of systems for personalized medicine.
- We believe data handling in healthcare needs to focus on the individual.
 - We support patients, so they can share their health data safely and securely with physicians in health systems. Our e-health solution creates a decentralized electronic health record that enables patients to make their longitudinal health data accessible to physicians. The patient is in control and decides who to share their data with. We promote the vision of a "Health Digital Twin" in healthcare, which models and represents a human body based on a multitude of datasets like body composition and vital parameters. For both patients and healthy people, their digital twin will help physicians to diagnose complex systemic diseases earlier and find the best treatment available for the patient's given condition.
- We strive to develop AI solutions for both healthy people and sick people.
 - Our current portfolio focuses on diagnosing and treating patients. Yet, we believe that stewardship for a patient starts with prevention, and the predictive power of AI offers a

wealth of opportunities for us to help people stay healthy. In the future, we want to extend our portfolio to support health systems in their transformation from caring for the sick to proactively caring for the well.

- We work passionately to make AI solutions accessible to patients everywhere.
 - At Siemens Healthineers, we believe that every human being has the right to access high-quality healthcare, regardless of location, age, and social circumstances (in line with Art. 27 (1) Declaration of Human Rights "right to progress"). Thus, we support the United Nations' 3rd Sustainable Development Goal (SDG), which ensures healthy lives and promotes well-being for all at all ages. By providing powerful AI solutions, we contribute to better and more personalized healthcare that is accessible around the globe.
- We believe AI development needs to be transparent.
 - We openly communicate insights into underlying technology, training/test datasets, and quality assurance for our AI solutions. We carefully compile training and test datasets which we document to allow traceability and transparency. Specifically, we strive to free our data from bias and prejudice to enable equal treatment for all people.
- We measure ourselves against the highest scientific standards.
 - We aim to improve clinical outcomes with state-of-the-art technologies. We do not fuel technological hype; instead, we invest in science to improve technology and establish new standards. Our world-class scientists therefore critically evaluate and thoroughly assess our AI solutions with carefully designed evaluation studies for the respective target populations.
- We speak honestly about the capabilities of our AI solutions.
 - We are aware of the capabilities and limitations of our AI solutions and share these insights with our customers and users in order to promote the setting of realistic expectations.

Expectations of any technical system need to be realistic to prevent false hopes, misunderstandings, and errors in judgment. Healthcare professionals need to be aware of the capabilities of an AI solution, so that they can make an informed decision in line with applicable best practices and guidelines and advise patients accordingly.

Data Privacy - we believe that to fully realize the potential of digital transformation, people need maximum confidence in the processes, institutions, and technologies used.

At Siemens Healthineers, our data vision is, “we use data responsibly to develop innovations in healthcare to help people live healthier and longer lives.” This vision has given rise to a set of data principles that guide our handling of very sensitive health data and the development of today’s and tomorrow’s digital health solutions:

- We use data for the benefit of the individual.
 - The purpose of our company is to advance human health. People should benefit from data-driven medical innovations through the prevention of sickness and best-in-class procedures and treatment. We invest in data-driven health solutions because we support the patient's desire for personalized high-precision medicine to live a healthier and longer life.
- We use data to drive healthcare innovation.
 - Data will become the key enabler for innovations in digital healthcare. Data-driven innovations are essential for medical research and progress. Our tailored and responsible use of data enables us to fill our innovation pipeline, push data-driven medicine and develop innovative procedures for patients.
- We are trustworthy and ethical in our handling of data.

- We only use data in a purpose-bound manner to develop medical innovations and to enable our data-driven products to perform according to their specified performance capabilities. We treat data responsibly, reliably, and securely.
- We apply proven and high data privacy standards worldwide.
 - We believe that trust and accountability are basic pillars for responsible data privacy management. Consequently, we apply high data privacy standards worldwide. Fundamental legal principles of the GDPR – including the legitimacy and lawfulness of data processing, purpose limitation, the need-to-know principle, data avoidance and data economy – are mandatory for Siemens Healthineers worldwide based on internal directives. In addition, we apply proven technical standards and organizational measures to ensure data security, authenticity, and confidentiality. Our ISO-certified cybersecurity management system follows a holistic approach and integrates information security management (ISO 27001) and privacy information management (ISO 27701).
- We support the advancements that enable individuals to have sovereignty and transparency over their data.
 - Every person should have sovereignty over their own health data. This includes transparency on what data is used on what basis and for what purposes, and the right to grant or revoke consent to the use of one's own data. This right should also include the freedom to donate one's personal data for the purpose of conducting research, advancing progress, and improving healthcare solutions. The processing of health data in private-sector research and development work also contributes significantly to advancing medical and technical progress. To safeguard this valuable contribution, we believe that private-sector research is also subject to the privilege of research, and that the development of medical devices or

artificial intelligence that facilitate(s) improvements in the early detection or treatment of illnesses, for instance, also serves the public interest and public health. We promote trust throughout society and among all patients for the application of digital technologies and support the exercising of their rights accordingly.

- We leverage data as a strategic asset.
 - Driving digitalization and promoting value creation from data are essential to advancing medical progress and providing efficient, high-quality healthcare. Leveraging this potential of data is strategically important to us. Besides developing data- and software-driven solutions for supporting decision-making, we continuously pursue efforts to further develop our portfolio by automating devices and workflows and expanding our use of predictive maintenance. The interoperability and connectivity of our products and solutions accelerates this development into a platform-oriented business.
- We use state-of-the-art technology to protect data.
 - We offer a state-of-the-art portfolio of secure products, cybersecurity services and consulting that helps to ensure optimum protection. We continuously improve our systems and processes and train our teams in aspects of cybersecurity and data protection to maintain a consistently high level of threat awareness. Our engineering practices include a secure development lifecycle (SDL) to ensure that high cybersecurity standards are implemented for every product and solution. Examples of our core development principles are the implementation of privacy by design and privacy by default.
- We support open standards for data interoperability.
 - The key to data-driven healthcare innovations is the ability to interconnect various health datasets. It is only through data integration and data interoperability that the value of data can

be fully utilized. We strongly support the standardization of healthcare data and data sharing. When designing our solutions, we aim to systematically include standardized interfaces such as DICOM5, FHIR6, and increasingly uniform APIs7.

- We invest in trustful partnerships to access data.
- Efforts to improve medical knowledge and to advance data-driven healthcare solutions depend on having rights to access health data from diverse, genuine sources. We believe that providing fair access to relevant data by all healthcare stakeholders and using this data responsibly to our mutual benefit will contribute to advancing medical progress. We therefore build our data-related partnerships on fairness and transparency.