ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6115 Majority (202) 225-3641 Minority (202) 225-2927

December 20, 2023

Mr. Peter Shen Head of Digital Health – North America Siemens Healthineers 40 Liberty Boulevard Malvern, PA 19355

Dear Mr. Shen:

Thank you for appearing before the Subcommittee on Health on Wednesday, November 29, 2023, to testify at the hearing entitled "Understanding How AI is Changing Health Care."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on Friday, January 5, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Sather

Brett Guthrie Chair Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

The Honorable Mariannette Miller-Meeks

- 1. We currently have a regulatory structure in place where some AI technologies, such as clinical decision support software, have to go through multiple agencies in order to reach providers. While I believe AI should be used to augment patient care for providers, do you believe this regulatory environment is sustainable? And what are some ways Congress can work to foster safe and effective deployment of AI technologies at the point of care to give every patient access to the highest quality care?
- 2. Healthcare systems who adopt autonomous AI need to see sustainable, well founded fee-forservice payment mechanisms. How do the existing Medicare pathways for reimbursement limit patient access to innovation that promise to improve treatment decisions and patient outcomes and what can be done to improve payment pathways?

The Honorable Anna Eshoo

- 1. I'm concerned about vulnerable patients particularly children not benefiting from advancements in AI technology for medical imaging. Few medical devices using AI specify whether they've been tested or trained on pediatric populations.
 - a) Please explain why AI is such a critical tool for improving medical imaging.
 - b) What should Congress be doing to make sure children are benefiting from the AI revolution in medical imaging? What measures have you instituted to ensure human oversight of AI technology?
- 2. Several large companies currently represent the majority of the market for AI used in medical imaging. Siemens Healthineers is one of those companies.
 - a) How does Siemens Healthineers work with other companies to ensure medical data, such as MRI or CT scans, can be reviewed in different systems?
 - b) How are your systems interoperable with others in the industry?
- 3. I introduced the *CREATE AI Act* (H.R. 5077) to give medical researchers in all sectors of society, including academia, small businesses, nonprofits and government agencies equitable access to resources needed to develop AI technology. In no industry is equitable access to innovative technologies as important as the health care industry, where the lives of patients are on the line every day.
 - a) Do you support this bill?

The Honorable Nanette Barragán

1. Latinos are at greater risk of dementia and certain types of cancer compared to non-Hispanic white people. Early detection is critical to increase success of treatments or slow progression of these diseases. Can you explain how improving Medicare reimbursement of AI innovations, such as the utilization of AI in medical imaging, could help achieve health equity in early detection of diseases such as Alzheimer's and cancer?