

November 10, 2023

## Senate Health, Education, Labor and Pensions Committee Hearing on AI Policy Considerations in Health Care

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On Wednesday (November 9), the Senate Health, Education, Labor and Pensions (HELP) Subcommittee on Primary Health and Retirement Security held a hearing entitled, "Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence (AI) in Health Care."

The hearing centered on the role and scope of Congress in regulating AI use in health care and the need to strike the right balance between enacting safety guardrails around AI and enabling innovation. During the hearing, lawmakers heard testimony from a panel of witnesses who represented providers, academics, and patients who discussed the potential benefits, harms and use cases of AI in health care. Panelists all agreed that some form of regulatory oversight or AI guardrails are needed but differed on the scope. And while most of the providers spoke about ways AI could be harmful in health care in the future, the witness representing patients said AI is already being used in negative ways and that more human oversight is needed in initial claims decisions.

- For more information: <https://www.help.senate.gov/hearings/avoiding-a-cautionary-tale-policy-considerations-for-artificial-intelligence-in-health-care>

### Opening statements

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**Subcommittee Chairman Ed Markey (D-MA):** Subcommittee Chairman Markey spoke cautiously about the promises of big tech, citing research showing the impact social media has had on youth mental health. "When we talk about the promises of AI we also have to talk about its risks," Chairman Markey said. He stressed the importance of regulating AI, raising concerns that unregulated AI could contribute to the next pandemic, supercharge existing inequalities in our health care system, and misdiagnosis or mistreat patients, such as through inappropriate claims denials. Markey also raised concerns that health workers on the frontlines are implementing AI without evidence or understanding its true impact. He called for a comprehensive privacy bill of rights for youth and his bipartisan Children's Online Privacy Protection Act and the need for additional bills, such as the AI and Biosecurity Risk Assessment Act and the Securing Gene Synthesis Act to ensure that AI is used in a way that puts "people over profits."

**Subcommittee Ranking Member Roger Marshall (R-KS):** Subcommittee Ranking Member Marshall said, "AI has great potential to revolutionize health care by developing new cures, improving health care delivery and reducing administrative burden and overall health care spending" to ultimately enable the clinical workforce to go back to practicing medicine. He said that AI could help develop better standards for care and improve the effectiveness of treatments. Marshall said his "biggest concern is AI's application in biosecurity and how it could be used to enable bioterrorism." He said that AI could help us prepare or react to the next pandemic or it could also be used intentionally or unintentionally to develop novel pathogens, bioweapons, or chemical weapons. But Marshall said we need to look for "guardrails that protect Americans but at the same time promote innovation," citing Sen. Bill Cassidy's (R-LA) [white paper](#) on AI, which calls for striking the right balance in regulation and innovation.

### Witness testimony

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**Thomas Inglesby, Director, Johns Hopkins Center for Health Security:** In his testimony, Dr. Inglesby said that AI offers “enormous potential benefits” in health care, as well as “substantial potential risks that need to be addressed before and while realizing those benefits.” He highlighted two risks that he believes should be top priorities for Congress: 1) the potential for AI to accelerate or simplify the creation of dangerous viruses that are now extinct or only exist in research labs; and 2) the potential for AI to enable, accelerate or simplify the creation of entirely new biological constructs that could start a new pandemic. He praised President Biden’s recent executive order (EO) as a good first step and recommended that Congress build on it by 1) providing HHS with the authority and resources to require anyone purchasing synthetic nucleic acids in the US to only purchase from a provider or manufacturer that conducts sequence and customer screening irrespective of funding source; 2) Commissioning a rapid risk assessment to identify whether the EO will adequately address high-end biological risks or whether additional congressional action is needed in the near-term to prevent those threats; and 3) Requiring entities developing models with significant dual-use risks to red-team and evaluate their models, and task an agency with auditing those models and submitting a report to Congress with recommendations for new authorities that will be needed by the agency to take any appropriate remedial action should red-teaming, evaluations, or audits fail. [Full Statement](#).

**Kenneth D. Mandl, Harvard Professor and Director, Computational Health Informatics Program, Boston Children’s Hospital:** In his testimony, Dr. Mandl said, “With the release of sophisticated large language models like ChatGPT, AI will transform health care delivery sooner than anticipated.” He spoke about the ways AI is used and can be used in a doctor’s office and noted that currently there is “no oversight” of AI. As such, he said the US needs to “accelerate a system that meticulously tracks the real-world accuracy, safety, and effectiveness of not just AI, but also drugs, diagnostics, and devices, procedures, and models of care.” He praised the 21<sup>st</sup> Century Cures Act and the Office of the National Coordinator of Health IT for advancing interoperability through APIs and called on Congress to ensure appropriate enforcement and guardrails. [Full Statement](#).

**Christine Huberty, Supervising Attorney, Greater Wisconsin Agency on Aging Resources:** Ms. Huberty’s testimony focused on the ways AI use in health care can cause patient harm and administrative burden. She cited an example of a patient whose care was directed by AI and resulted in a claims denial, forcing the patient to shorten his stay at a skilled nursing facility against his medical team’s advice due to the cost. As a result, Ms. Huberty said the patient’s health suffered and his family was ultimately able to help him intervene and appeal the decision. She said in Wisconsin her agency has seen the number of claims denials increase from 1-2 per year to 1-2 per week, with a 90% success rate upon appeal. Ms. Huberty said facilities also are negatively impacted from the use of AI because they “must submit near daily updates to the subcontractors regarding the predicted discharge date and provide hundreds of pages of medical records when a patient appeals.” She added, “As a result, many facilities are refusing to take patients whose insurance uses this predictive technology due to the administrative burdens it creates,” which can disproportionately impact those in rural areas with limited care options. She said, “It is unrealistic to eliminate AI from the healthcare system. However, this algorithm has been used for years to direct patient care with devastating effects. ... patients should have, at a minimum, a clear view of its moving parts” and “when it is obvious that the algorithm got it wrong and issued an incorrect denial, patients need to be compensated, and insurance companies and their subcontractors must be penalized.” [Full Statement](#).

**Keith Sale, Vice President and Chief Physician Executive of Ambulatory Services, The University of Kansas Health System:** In his testimony, Dr. Sale said one of the best uses of AI is to prevent provider burnout and improve workflows by assisting with administrative and documentation tasks. He spoke about the evolution of provider documentation and the current role AI plays in provider note dictation and how it can evolve and learn a provider’s preferences over time. Dr. Sale said the AI tools available to him today can save him hours in end-of-day documentation and free him up to speak in person with his patients. He stressed that AI should be used as tool that assists physicians but does not dictate decision making for physicians. However, said it’s important that these

tools comply with existing privacy laws. He spoke favorably about the traceability and trackability of the information, noting that he can see in real-time where the AI tool retrieved its information to make the medical note. [Full Statement](#).

## Discussion Topics

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**Chair Markey** asked Ms. Huberty what lessons should be learned from patient stories. Ms. Huberty stressed the algorithms being used in claims decisions are not new and that they have years of examples of errors that occurred because there is not enough human oversight. In response to a question, Ms. Huberty said subcontractors who develop and use the AI should bear the burden of proof to ensure models work. Dr. Mandl said there is a need to educate the health care workforce on the AI tools and ensure AI tools are designed and implemented to improve workflows and not create new challenges, as the industry saw after the implementation of electronic health records. He said there also have to be legal and ethical safeguards to protect providers and ensure it is clear who is responsible if the AI makes a decision that is incorrect, as well as increased transparency to know how AI tools operate.

**Ranking Member Marshall** asked what Congress should avoid doing in order to protect innovation. Dr. Sale urged Congress not to limit physicians' use of AI tools, Dr. Mandl said he would avoid actions that would unintentionally create monopolies, and Dr. Inglesby said Congress should keep their eye on some of the most serious risks and build its expertise on AI to keep up with the rapidly developing field. Ms. Huberty said we have seen proven harm from AI and we are not addressing it. Marshall said he is concerned that imposing too many guardrails will cause the US to fall behind other countries, Dr. Inglesby said all countries in theory should be moving toward the same goal, but the US should be aware of the small area of science that could cause the biggest risk. Ranking Member Marshall said we need to teach our medical community that AI is one more tool but should not override the need to put the patient first.

**Sen. Tina Smith (D-MN)** asked about AI in drug and vaccine development and preventing biosecurity risks. Dr. Inglesby said AI tools can improve the speed and precision in vaccine development, but at the same time those same functions could unintentionally or intentionally be misused and that is why we need guardrails that focus on pandemic risks. He suggested one standard the government could create is for health care-related AI to be transparent and reverse engineered to understand how the models work.

**Sen. Maggie Hassan (D-NH)** asked about AI's role in addressing antimicrobial resistance (AMR). Dr. Inglesby said AI could be used to develop new therapeutic approaches and different combinations of therapies, as well as making predictions about the sequencing of pathogens and resistance. He said Congress can support AI's use in combatting AMR by ensuring BARDA, HHS, and FDA have the flexibility to pursue new therapeutic approaches and ensuring datasets can be anonymized and shared. In response to a question on needed standards, Dr. Mandl said the integration of AI and EHRs will be essential, and the US will need standards to ensure AI once deployed can be continually monitored to understand real-world performance.

**Sen. John Hickenlooper (D-CO)** spoke about his bill with Sen. Ted Budd (R-NC), the Gene Synthesis Safety and Security Act, to require federally funded gene synthesis providers to enact screening protocols and asked how Dr. Inglesby would assess the US' current level of risk. Dr. Inglesby praised the bill but urged lawmakers to go a step further and require all gene synthesis providers to enact screening protocols. He said the current risk is that a bad actor could create a virus that is now extinct in the US, such as smallpox. Sen. Hickenlooper also asked about ways to manage and protect large amounts of data that will fuel AI. Dr. Mandl said we need guardrails around AI used in a clinician's office to support patient care and to help advance real-time data sharing and analysis across the country.

**Sen. Mike Braun (R-IN)** spoke about a bill he is planning to introduce, the Medicare Transaction Fraud and Prevention Act, which would direct CMS to conduct a pilot program of enhanced oversight using tools that exist in other industries for two categories of historically high fraud: diagnostic testing and durable medical equipment. Dr. Inglesby and Ms. Huberty said they would support bills that aim to use fraud tools that exist in other industries to improve health care.

**Sen. Ben Ray Luján (D-NM)** raised concerns about the potential for bias and discrimination in AI, noting the lack of diversity in underlying data. Dr. Mandl said we need interoperability to ensure a robust and diverse dataset to better serve the full population and ensure data are trained using a diverse population.

*If you have questions, please contact [Heather Meade](#) or [Heather Bell](#).*

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