

ALERT

Health Care AI and Drug Prices: Highlights From Two Senate Hearings

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Health Care was a hot topic in the U.S. Senate on February 8, as two important Senate Committees – the Committee on Finance and the Committee on Health, Education, Labor, and Pensions (HELP) – held hearings, respectively, on the use of artificial intelligence (AI) in health care and the setting of drug prices in the United States.

The Senate Finance Committee hearing on “Artificial Intelligence and Health Care: Promise and Pitfalls” discussed the potential benefits and harms of using AI in health care. Committee Chairman Ron Wyden (D-OR) questioned medical and technical expert witnesses about the ways in which health care AI (and its algorithms) could be more transparent, accountable, equitable, and private.

- Transparency. In developing algorithms for AI, the witnesses said it should be clear what the algorithm is predicting. They added that the industry should be wary of algorithms that make predictions based on cost because of the implicit bias in the data used.
- Accountability. The witnesses testified that clinicians recognize the need to vet AI tools before use, but not many have the resources to do so. They urged industry to look at how AI would be best incorporated into workflow and said the government needs standards for adoption, but those standards need to be adaptable.
- Equity. Because historical data is the basis for AI algorithms, witnesses said there is a risk of bias, as AI tools learn and incorporate all the barriers and biases of the current system. The witnesses also noted that AI algorithms need to be rigorously tested, and the process of linking datasets together

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can highlight where there is a lack of information.

- Privacy. The witnesses said that data sharing is what will leverage the advancement of AI technology, and the industry needs to balance the need for large datasets with protection of individual patient data.

The witnesses discussed whether the Centers for Medicare & Medicaid Services (CMS) needed to provide more oversight to health plans incorporating AI, and whether CMS should reimburse not only for clinical care, but also for the use of an FDA-approved AI tool. As an example of an area for greater CMS input, witness Michelle M. Mello, JD, Ph.D., Professor of Health Policy and of Law at Stanford University, said CMS had not made the level of specificity for “meaningful human review” clear and stated that health plans may not adequately consider prior authorization denials made by AI.

In his closing remarks, Chairman Wyden said the industry needs “really strong guardrails” around the use of AI in health care.

Meanwhile on February 8, the Senate Committee on Health, Education, Labor, and Pensions (HELP) held a hearing titled, “Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?” featuring testimony from the CEOs of several pharmaceutical companies. Committee Chairman Bernie Sanders (I-VT) questioned the CEOs about drug price setting and compared pharmaceutical prices in the United States to other countries including Japan, Canada, and France. The CEOs testified that drug pricing in the United States is higher than in other countries due to increased availability and accessibility offered to patients in the United States. They further explained that their drug pricing is based on the value of the medication to patients and within the industry overall and that manufacturing costs are only one component in pricing drugs. The CEOs testified that increased research and development costs also explain rising costs to consumers.

In response to questions about shareholder dividends, the CEOs explained their duty to their investors and how payment of dividends ensures that a company can remain operational and sustainable. Various members of the HELP Committee, including Sens. Rand Paul (R-KY) and Mitt Romney (R-UT), accepted this explanation and acknowledged that returning dividends to shareholders is a priority of any company, not just pharmaceutical companies, when participating in a free market.

The CEOs continued to underscore their support of patient assistance programs, such as copay assistance programs (which can provide financial assistance to patients on certain high-cost drugs), and their support of rebates (which can be used to reduce prescription drug premiums) as demonstrations of their commitment to lower the price of drugs. Senators and witnesses did not address whether such programs contribute to rising drug prices. But the CEOs argued that the complexity of the U.S. health care system is an underlying factor in the high costs of drugs. For example, they said the role of third-party entities, such as pharmacy benefit managers (PBMs), can further complicate efforts to reduce costs for consumers.

Members of the Committee alluded to pursuing legislation to curb drug pricing, as well as legislation to regulate PBMs. Wiley will continue to monitor any such developments.

Wiley's multidisciplinary Health Care team of experienced attorneys and advisors is closely monitoring regulatory developments and is available to assist with contract review or any other questions. For more information about drug pricing and the use of AI in health care, please contact one of the attorneys listed on this alert.