

## Trump to the health and tech giants: AI is not your ‘cartel’

The Coalition for Health AI has enlisted big names in health and tech to evaluate artificial intelligence tools that are now mostly unregulated.

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The Trump administration has a message for the biggest names in health care and tech: You won’t control the development of artificial intelligence in medicine.

Top officials at the Department of Health and Human Services tell POLITICO that the administration does not support a multi-year quasi-regulatory effort by firms including Microsoft and OpenAI, and health systems including the Mayo Clinic and Duke Health, to pilot private-sector-led vetting of AI tools under the banner of the Coalition for Health AI.

“They don’t speak for us,” Deputy HHS Secretary Jim O’Neill said to POLITICO. The coalition, he added, threatens to become a “cartel” in which big companies squelch startups and corner the booming market for artificial intelligence in health care. He said he’s heard from industry “that if you want to work in the space, you have to be a member, and we just want to make clear that that is not the case.”

AI is transforming care. Hospitals are adopting high-tech systems to improve diagnoses and recommend treatments, but there’s little formal regulation. The Food and Drug Administration, which oversees some of the tools, may not have all of the authority it needs to monitor products that can evolve over time, as they take in more information, and would need a much larger staff to do so, former FDA Commissioner Robert Califf has said.

That’s one reason the Biden administration was enthused about CHAI, which promised to establish private-sector-led labs to test AI tools and advise doctors and hospitals on how they work. Two Biden administration officials served on CHAI’s board, lending it credibility with prospective private sector members. O’Neill’s concerns, which current FDA Commissioner Marty Makary shares, could make it more difficult for CHAI to follow through on its plans. With few other efforts afoot to evaluate AI tools, doctors and hospitals will continue to be on their own in determining whether they are safe and provide value.

CHAI CEO Brian Anderson said O’Neill’s mistaken if he thinks the group is trying to force any companies or health systems to join it.

“Everything that we do in CHAI is voluntary and not required,” he said, adding that he welcomes feedback, including from the Trump administration, and believes the group can be a resource as President Donald Trump considers how to handle AI’s growth.

CHAI has long been aware that Republicans in Congress weren’t comfortable with it, despite its private sector bona fides. House Energy and Commerce Chair Brett Guthrie (R-Ky.), along with Rep. Jay Obernolte (R-Calif.), who led a House task force on AI, have said they thought CHAI was providing cover for regulatory capture by well-heeled interests.

Earlier this year, CHAI hired Susan Zook, a former health care aide to Senate Finance Chair Mike Crapo (R-Idaho), to lobby. “We hired Susan because we wanted to build bridges into that community,” Anderson said. “I genuinely believe we are one of the best resources for our elected officials to have to be able to understand what’s going on out there in industry.”

But Anderson’s public relations problem has only gotten worse. O’Neill and Makary said they, too, believe CHAI is a Biden administration creation that aims to stifle health tech startups.

Micky Tripathi, Biden’s national coordinator for health information technology, and Troy Tazbaz, a top tech official at the FDA, were non-voting members on the organization’s board before resigning last year, citing potential conflicts of interest.

During President Joe Biden’s administration, HHS officials vocally supported the concept of private-sector-led assurance labs. Last year at a conference, Califf spoke about the challenges of regulating AI and raised the lab idea. Tripathi, Tazbaz, and Anderson, along with other CHAI members, called for a network of assurance labs to vet AI in the *Journal of American Medical Association* two years ago.

Anderson says CHAI now has 3,000 members that include not only big players in health and tech, but startups and smaller providers.

CHAI has backed Trump administration initiatives, including its AI Action Plan and the Centers for Medicare and Medicaid Service’s health tech ecosystem.

CHAI’s own plans for vetting AI are still in development. CHAI has published various guidance on the responsible use of AI in health care, but has only certified two assurance labs to vet a limited array of AI tools. This year it struck a relationship with the Joint Commission, an Illinois based organization that sets standards within the health care industry. They’ve since released guidance on AI.

O’Neill said the administration doesn’t support it. “No one should really feel compelled to submit their work for the analysis of their competitors or people that are entangled with their competitors,” he said. He added that he would like an array of institutions to take

on the job of vetting AI, not just one, and doesn't want anyone to think CHAI is backed by the government.

Trump has said he wants the U.S. to be the global leader in AI and promised a laissez-faire approach to regulation. On his second day in office, he signed an executive order calling on regulators to roll back rules finalized during the Biden administration.

O'Neill said he's big on transparency, and that HHS wants to share its data on AI tools so that buyers evaluating them can make informed decisions. He said the health agencies are also exploring whether they need to collect more or different kinds of data to better regulate AI — something he'd like to hear directly from industry on.

This week, the FDA published a request for information asking patients, doctors, tech companies, and others for feedback on how medical AI performance should be measured and evaluated.

In the meantime, CHAI may be parting ways with some of its largest tech members. Microsoft Chief Scientific Officer Eric Horvitz just stepped down from the board. Anderson said it was a time-limited position.