Tech companies criticise health AI regulations

Efforts in the USA to strengthen oversight of AI in health are being resisted by industry. Paul Webster reports.

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As artificial intelligence (AI) spurs a new era in medicine, numerous US medical professional associations, including the American Medical Association (AMA), are calling for bolstered regulation of AI to protect patients and clinicians. Meanwhile, however, numerous AI-oriented industry associations representing medical technology and informatics companies and medical device manufacturers, as well as associations representing hospitals and health insurers, alongside prominent companies such as Amazon Web Services, are warning that a big new batch of US Government regulatory proposals might threaten the clinical utility of medical AI, while also trespassing on their intellectual property rights.

This message has been echoed in several industry responses to a call for consultations on proposed new regulations crafted by the US Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) earlier this year.

The ONC's proposed new regulations are intended to "improve transparency, promote trustworthiness, and incentivize the development and wider use of fair, appropriate, valid, effective, and safe" predictive decision support intervention technologies, it says. AI tools are being widely used to develop new drugs, guide physicians in clinical care including surgeries, and enable sophisticated predictive disease diagnostics on the basis of complex genomic and other data inside and outside electronic health records systems (EHRs).

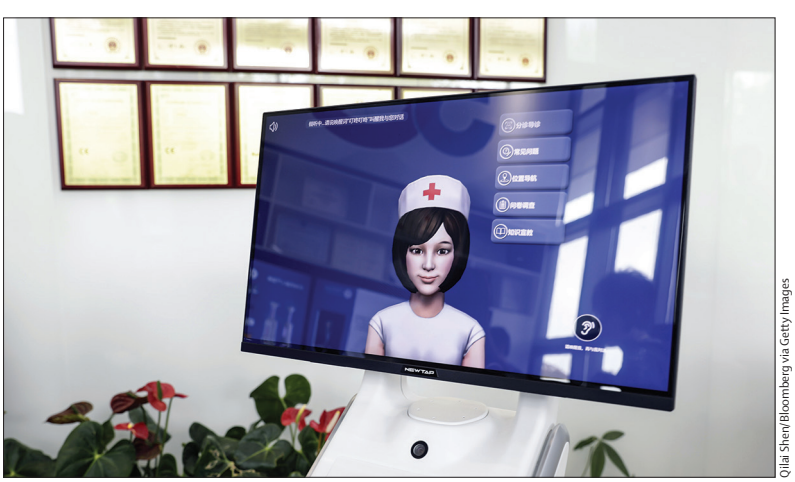
After it tabled its sweeping set of proposed regulatory measures on April 18, 2023, the ONC called for consultation. 234 responses have now been posted online by the agency. Well before the ONC released its regulatory proposals, a group of AI-oriented medical and tech companies (including Bayer and Roche) formed the Alliance for AI in Healthcare, which says that "AI will never replace human intuition in medicine".

Alex Zhavoronkov, the group's co-founder, is CEO of Insilico, a fast-growing new company that uses AI technology for drug development. Zhavoronkov takes a sceptical view of some of the ONC's regulatory proposals. "To me, the Food and Drug Administration is the ultimate authority, and it would be difficult to do it better than them", he says. Zhavoronkov also says the ONC's proposals for better patient data protection and greater transparency might go too far. "The risks of the harms are overstated", he insists. "If you restrict access to data, and require greater transparency from AI developers, it will kill innovation among startup companies that can't afford compliance."

Small tech companies are not the only ones complaining: Amazon Web Services, the massive online retailer of health-care-related services, reacted with hostility to the ONC's call for a plain language description of the rationales and sources on which medical AI technologies base their clinical suggestions. In its comment on the ONC's proposal, the company insists that "any transparency requirements should not require disclosure of intellectual property or trade secrets, and should balance disclosure of confidential business information against other methods to mitigate risk".

Many of the industry responses to the ONC's proposed new regulations seek to exempt significant areas of health-AI development from regulation. For example, the Federation of American Hospitals, which represents more than 1000 public and private hospitals and health systems, expressed concern about the application of "transparency requirements to tools that hospitals and health systems develop for use within their own organizations. To avoid unnecessary burden, we recommend that ONC specifically carve out tools developed by health systems that are not commercially available".

Cybil Roehrenback, Executive Director of the AI Healthcare Coalition, a Washington, DC-based association led by executives from several medical



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diagnostics companies, which aims to "define what it means to be an ethical creator of healthcare AI", says she hopes ONC will recognise the need for a "bright line" between areas of ONC and FDA regulatory purview. "ONC should engage in a formal cross-collaboration with other federal agencies and industry stakeholders to formulate a comprehensive, consistent approach", she suggests. Roehrenback's message to the ONC, which regulates certified health information technologies alongside the FDA (which regulates all US medical devices whether certified by the ONC or not), stressed that many rapidly evolving AI tools in health care promise to increase health-care accessibility and quality and reduce costs.

In September, 2022, the FDA released a 26-page *Clinical Decision Support Final Guidance* that specifies that all AI-assisted medical technologies—including ones not certified by the ONC—that are designed to assist physician decision making will have to be reviewed by the FDA. As of January, 2023, there were more than 500 FDA-approved AI medical algorithms available in the USA. The vast majority of these relate to medical imaging.

The FDA guidance warns strongly about the risks of automation bias, which it labels "the propensity of humans to over-rely on a suggestion from an automated system", and notes that "in situations that require urgent action, automation bias increases because there is not sufficient time for the user to adequately consider other information". In situations where health-care providers cannot "independently review the basis for the recommendations that the software function provides", says the FDA, the software function is deemed to be a medical device that requires regulatory review.

In this context, Roehrenback worries that the ONC's definition of "predictive decision support intervention" technologies that harness AI may be overly broad, "and will encapsulate nearly every technology that employs any type of data analysis tool or algorithmic capability. The definition would cover everything from spell check to an autonomous AI system for diagnosis of an illness."

Regarding the ONC's call for greater transparency from medical AI developers in providing information that might allow doctors to better assess the clinical appropriateness of their products, Roehrenback concurs with calls from other health information technology industry and research groups for ONC to require factsheets to be made available to doctors detailing how the algorithms were developed, and what scientific evidence they rely on.

This idea was detailed in a submission to the ONC from the Coalition for Health AI Transparency Working Group, which calls for the ONC to require medical AI technology "developers to enclose an intelligible end-user fact sheet that would disclose data used for training, potential risks, concerns for bias, performance, and generalizability, at a minimum. We liken this to a nutritional label or 'model card' that guides the user to the intended use and describes the key 'ingredients' and attributes that created the AI model."

The Biden Administration's push for tighter regulation of medical AI comes at a time when public concern about the issue is mounting. According to a Feb 22 Pew survey, there is doubt among Americans over the idea of AI being used in their own health care. Six in ten US adults say they would feel uncomfortable if their own health-care provider relied on artificial intelligence to do things such as diagnose disease and recommend treatments. According to the poll, however, nearly two-thirds of US adults say that they want AI to be used for their own skin cancer screening.

The White House is paying heed. In May and June, President Joe Biden and Vice President Kamala Harris met with AI industry leaders to explore regulatory measures. Biden also consulted with Responsible AI for Safe and Equitable Health, an initiative which is co-led by Lloyd Minor, Dean of Medicine at Stanford University.

Minor says the issues raised by industry voices about the ONC regulatory proposals have to balanced with the risks posed by unregulated medical-AI technologies, including patient confidentiality breaches, unreliability, and inappropriate usage. "I'm impressed and pleased regulators are taking advances in AI very seriously and are gathering a broad array of opinions", he added. On the subject of the intellectual property claims of algorithm developers, Minor said he thinks the ONC is acting appropriately to try to balance the need to enable better medical algorithm development with clinicians' need for transparent understanding of how these tools operate.

Medical associations want tougher measures compelling greater transparency about the clinical reliability of medical AI technologies, and much tighter protection of patient health data from potential misuse or unapproved use by AI-driven technologies.

"Transparency is a prerequisite for trustworthy AI", AMA CEO and Executive Vice President James Madara warned in a June 20 letter to the ONC that spotlighted the need for stricter control over AI algorithms that are embedded within EHRs. "The AMA urges ONC to ensure EHR developers do not use technical, financial, or contractual levers to influence or steer physicians' use of AI in EHRs", Madara said.

Patients and doctors need insight into whether their data will be used to develop and train AI tools, Madara added, while also stating that educational materials are needed "to help physicians interpret and act on information provided by AI and EHR developers."

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