US AI regulatory rollback and health

Donald Trump has promised to create a pro-AI environment, but even tech companies are frustrated by federal cuts that hamper regulatory processes. Paul Webster reports.

For the **AMA survey** see https://www.ama-assn.org/practice-management/digital-health/2-3-physicians-are-using-health-ai-78-2023

For the **STAT investigation** see https://www.statnews.com/denied-by-ai-unitedhealth-investigative-series/#:~:text=This%20series%2C%20a%20Pulitzer%20Prize,ill%20older%20and%20disabled%20patients

For more on **reaction to Biden's regulatory requirements** see **World Report** *Lancet* 2023; **402:** 517–18

As the use of artificial intelligence (AI) in medical devices and health-care services rapidly increases, the US Food and Drug Administration (FDA) has struggled to implement safety regulations. Driven by technological disruption, competitive secrecy, and a libertarian aversion to government regulation, the AI industry's intersection with health care presents the FDA with an anarchic new marketplace unlike any it has ever encountered. Now, thanks to a series of steps by the Trump Administration to deregulate AI while downsizing the FDA, observers including David Blumenthal, National Coordinator for Health Information Technology in the Obama Administration, worry that the FDA might be losing control of health-care AI. "The message from the administration is they won't regulate AI," says Blumenthal. "The question is whether they will make any kind of exception for health-care-related AI, and particularly, clinical artificial intelligence?"

For regulators and industry alike, the stakes are high: start-ups have raised approximately $30 billion for health-care AI development over the last 3 years. A survey by the American Medical Association (AMA) found that two-thirds of phycisians used AI in their practice for, among other things, documentation of billing codes, medical charts or visit notes; creation of discharge instructions, care plans or progress notes; translation services; and assistive diagnosis. In a survey of executives by the Center for Connected Medicine at the University of Pittsburgh Medical Center (Pittsburgh, PA, USA) released last August, AI was ranked as the most promising emerging health-care technology for the fourth year in a row. The intersection of artificial intelligence, venture capital, and health care presents spectacularly rich opportunities for companies that pioneer ways to insert AI into the $5 trillion US health-care sector, many health-care executives now say.

Scores of tech companies—led by giants such as Amazon Web Services (Seattle, WA, USA), Apple (Cupertino, CA, USA), Epic (Verona, WI, USA), Google (Mountain View, CA, USA), Meta (Menlo Park, CA, USA), UnitedHealth Group (Minnetonka, MN, USA), and many others—are racing for stakes in this burgeoning market. Meanwhile, media reports of controversial use of health-care AI by some health-care technology companies indicate that patient safety could be increasingly at risk. To underline that point, in September, 2024, Robert Califf, then Commissioner of the FDA, warned at a press conference that if US health systems "don't step up" their involvement in health-care AI governance, "they're going to end up holding the bag on liability when these algorithms go wrong". There remain unresolved physician concerns with the design of health AI and the potential of flawed AI-enabled tools to put privacy at risk, integrate poorly with electronic health records systems, offer incorrect conclusions or recommendations, and introduce new liability concerns. "Increased oversight ranked as the top regulatory action needed to increase physician confidence and adoption of AI", AMA Immediate Past President Jesse Ehrenfeld said. An investigation by *STAT* found that UnitedHealth Group used an unregulated algorithm to over-ride clinicians' judgment and deny care to seriously ill older and disabled patients.

Until just a few months ago, health-care AI regulators could count on considerable support from former President Joe Biden, who ordered that developers of health-care AI systems share the results of safety tests with federal regulators within the FDA. It was, according to Blumenthal, "a pro-regulatory posture", albeit cautious and limited in many ways, including a failure to regulate generative AI systems that are capable of self-improvement and self-control and that are now being implemented widely in health-care settings. Even so, many health-care AI companies have stated that Biden's reporting requirements might threaten clinical utility while voicing concern about the impact on intellectual property rights.

During his electoral campaign, Donald Trump promised policies that would "support AI development rooted in free speech". After he was elected, the deregulation of health AI gained traction quickly. In December, 2024, after Trump's election but before he took office, a bipartisan Congressional committee on AI called for "collaboration among developers, providers, and regulators in developing and adopting AI technologies in health care where appropriate and beneficial". Examples included "voluntary standards for collecting and sharing data". This suggestion stood in sharp contrast to the Biden Administration's emphasis on a legally binding framework for health-care AI data sharing.

President Trump's deregulation drive began on his first day in office on January 20, 2025, when he scrapped Biden's October, 2023, executive order directing the US Department of Health and Human Services (HHS) and the Commerce Department's National Institute of Standards and

Technology (NIST) to regulate health AI. 3 days later, Trump issued a new executive order calling for a rollback of all "policies, directives, regulations, orders, and other actions taken under the Biden AI order that are inconsistent with enhancing America's leadership in AI".

Following Trump's dumping of the Biden executive order, "what policies, if any, will replace it remain unclear", says Blumenthal, while adding that Trump's "antiregulatory pronouncements, 'America First' ideology, and suspicion of international organisations make it less likely that the USA will work to harmonise cross-national regulation of health care".

The Trump Administration is now imposing sweeping cuts to the NIST, which Biden named as a centrepoint for health-care AI regulation alongside HHS (which includes the FDA). Many staff within the NIST's AI Safety Institute have reportedly been cut. That has not pleased all players in the health-care industry: on March 20, AI industry groups including the Center for AI Policy, which describes itself as a non-partisan research organisation "dedicated to mitigating the catastrophic risks of AI", issued a joint letter warning that as the "administration considers changes to personnel and programmes to better align agencies with priorities, we encourage a strategy that leverages NIST's leadership and expertise on standards development, voluntary frameworks, public–private sector collaboration, and international harmonisation".

The FDA's health-care AI regulatory efforts, says Blumenthal, are now experiencing similar turmoil to that experienced by the NIST. In late January, 2025, Troy Tazbaz, then Director of the FDA's Digital Health Center of Excellence, abruptly quit. In a social media post announcing his departure from the FDA, Tazbaz said that the agency had supported him in collaborating with industry "to ensure that AI and digital health technologies are developed, integrated, and managed with the safety, effectiveness, and responsibility required to enhance patient care while addressing other critical health-care challenges".

Tazbaz had been leading the FDA's regulatory strategies on AI-enabled software medical devices for 2 years, a period during which the FDA forged a set of important regulatory approaches based on a "total product lifecycle approach" to health-care AI. Tazbaz had also begun tackling regulation of adaptive AI models and generative AI systems that are capable of self-refinement, and which now remain largely unregulated, according to Blumenthal. In November, 2024, the FDA began soliciting advice from patients, physicians, and researchers on regulating generative AI, which resulted in a draft guidance outlining FDA requirements for AI health device submissions and transparency steps that AI health device companies can take.

> **"You don't want to reduce FDA staff in a way that makes the process less efficient,"**

On March 30, 2025, the ongoing tumult within the FDA—highlighted by the departure of scores of regulatory leaders like Tazbaz—triggered a number of executives from biotech and venture capital firms, many of which are deeply involved with health-care AI projects, to release an open letter explaining that "companies that happen to be engaging with the FDA right now are our leading indicators—and some of us have already encountered regulatory difficulties that we believe are the consequences of the FDA's loss of experienced staff".

The letter detailed that one unnamed California-based biotech company is now engaging the European Medicines Agency earlier in development than previously anticipated to mitigate concerns about the FDA's ability to meet development timelines. "We are now filing an investigational medical product dossier with the European Medicines Agency in order to enrol patients in geographies outside the USA to keep timelines," the letter added, while detailing worries "that the institutional knowledge that makes the FDA the world's leading regulatory body will be irretrievably lost due to the agency's recent reduction in force and wave of retirements". After warning that patients, industry, and biomedical leadership in the USA "will bear the consequences", the letter asks "agency leadership to possibly rehire key people who carry substantial institutional knowledge".

Alex Zhavaronkov, Chief Executive Officer of drug development company Insilico Medicine (Boston, MA, USA), says that although the regulation of health-care AI required extensive reforms aimed at modernisation, and reductions in regulatory burdens on innovators using AI to develop new drugs, he has "very mixed feelings" about the Trump policies. "You don't want to reduce FDA staff in a way that makes the process less efficient," he warns, especially for companies like his with products that require review by AI specialists with extremely precise skillsets. "Getting a meeting with multiple departments is very difficult and we will soon start to see if they all show up." An April 9 public notice from the FDA notes that it "continues to explore the potential of Gen AI to enhance the product review process".

Marcello Ienca, who leads the Ethics of AI and Neuroscience group at the Technische Universität München's Institute for History and Ethics of Medicine (Munich, Germany), says that given that AI is "severely under-regulated worldwide", the regulatory torch for health-care AI will likely pass from the USA to Europe in the coming years. "The tech oligopoly is very aligned with Trump, and the trend is that the Trump Administration wants zero regulation for AI as a

whole, not just health-care AI," he argues. Paradoxically, says Ienca, although Europe lags behind the USA in AI innovation, it leads the USA on AI regulation. "I now expect Trump will demand Europe step back from this," he says.

Brian Anderson, Chief Executive Officer of the Coalition for Health AI, a non-governmental organisation with more than 3000 member universities, health systems, and companies that work on health-care AI safety and quality assurance guidelines for vendors and buyers, says that the FDA is "in a big period of transformation". But, he says, that is not necessarily a bad thing, and the Biden approach risked becoming "sclerotic". The FDA's new Commissioner, Martin Makary, "has an appetite for working with the private sector", says Anderson, to "avoid regulatory frameworks that are misinformed and ham-handed". Anderson also thinks that the FDA could conceivably begin regulating generative AI in the near future. "My personal opinion is that we need to rethink the software as medical devices regulatory framework," he says, "for one reason because of the growing number of generative AI use cases and the lack of the current framework's ability to contemplate where these products might fall—are they software as medical devices or not?"

Although the shape of things to come for health-care AI regulation remains uncertain, the Trump Administration is now firmly rooting out Biden-era barriers to unfettered adoption of AI within government operations. On April 3, 2025, the Office of Management and Budget issued a directive on "accelerating federal use of AI through innovation, governance, and public trust" for the heads of executive departments and agencies that charges them to "cut down on bureaucratic bottlenecks and redefine AI governance as an enabler of effective and safe innovation".

Federal agencies are charged with "breaking barriers to AI adoption". Importantly, statutory definitions for algorithmic discrimination, automation bias, and equity have been dropped. The directive specifically identifies health-care AI as a "high-impact" area for AI, with specific reference to "medically relevant functions of medical devices; patient diagnosis, risk assessment, or treatment; the allocation of care in the context of public insurance; or the control of health-insurance costs and underwriting". As a "high-impact" AI sector, the directive requires agency heads in health-care-related fields to implement "minimum risk management practices". These are described as including evaluation of "the quality and appropriateness of the relevant data and model capability, supported by a summary of the data used in the AI's design, development, training, testing, and operation and its fitness for the AI's intended purpose".

"AI can introduce and propagate bias, which may misclassify people's needs, negatively impact physical or mental health outcomes, and increase costs."

The softness of these regulatory directions stands in sharp contrast to a Strategic Plan for the Use of Artificial Intelligence in Health, Human Services, and Public Health issued by HHS in early January, 2025, shortly before Trump took office, which presents a detailed case—based on years of work by the HHS and FDA during the Biden era—for firm AI regulation in products such as drugs and devices, as well as in health-care settings.

This brand new, albeit now largely superseded, plan states that "AI has or will directly or indirectly affect every American's experience in health and human services", notes a doubling from 2022 to 2023 in "the number of regulations that mention AI", and warns that AI "also presents possible risks that could lead to adverse impacts and outcomes. Depending on the data and model quality, AI can produce outputs that are incorrect or incomplete. When important decisions are made in part or in whole based on AI that is not accurate, people can be harmed or denied access, and resources can be misused. Further, researchers have found that AI can introduce and propagate bias, which may misclassify people's needs, negatively impact physical or mental health outcomes, and increase costs."

In March, 2025, the Trump Administration announced that 20 000 jobs have been eliminated at HHS, with about 35% of that total coming from the FDA—or about 19% of the agency's workforce. On April 10, the health sciences publication *Stat* (Boston, MA, USA) reported that the White House Office of Management and Budget had recommended slashing overall discretionary funding for HHS to roughly $80·4 billion, down from its current $116·8 billion budget, while proposing to create a new HHS Office of the Chief Technology Officer with funding for the Assistant Secretary for Technology Policy, reduced to $9 million, compared with the $66 million appropriated in the 2023 budget.

HHS were unable to offer an interview before *The Lancet* went to press.

Isaac Kohane, Chair of the Department of Biomedical Informatics at Harvard Medical School (Boston, MA, USA), says that because Biden's recommendations "were very broad and not very precise", the USA requires a "dramatically different framework" for regulating health-care AI. However, Kohane says he is "concerned" that shutting down significant portions of the regulatory apparatus within the FDA and elsewhere might not achieve this. "We have to ask ourselves how we'll use AI safely," Kohane insists.

Paul Webster