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Medicine's Lessons for AI Regulation

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Regulation of artificial intelligence (AI) is imminent in the United States and much of the world. In October, President Biden issued an executive order on AI, and lawmakers hope to pass legislation soon. Several U.S. states have already taken action on AI oversight. The European Union issued draft rules, which will be adopted in the coming months, that differ substantially from U.S. proposals. This range of jurisdictions and rules suggests that there are various possible futures for AI regulation in the United States. The path forward will have important effects on medicine.

This is far from the first time the United States has written rules to safeguard the public as science reached new capacities. Next year marks the 50th anniversary of the National Research Act, which created rules for the treatment of human subjects in medicine. Like AI regulations, rules for the treatment of human subjects were put in place swiftly during a time of intense public scrutiny of unethical uses of science. In 1972, the racial injustices of the Tuskegee Study of Untreated Syphilis were revealed in the U.S. mass media.[1] Although this unethical research had been under way for four decades, with results published in scientific journals, Tuskegee's exposure in the popular press galvanized lawmakers to pass legislation on research with human subjects that had been in the works for years.[2] Moreover, like the use of AI today, human-subjects research in the 1970s was a long-standing practice that held new potential, had innovative applications, received unprecedented levels of funding, and was taking place on a new, larger scale. And like the use of AI today, research using human subjects in the 1970s was both exciting and risky, with many effects unknown — and unknowable.

Rules governing the treatment of human subjects have traveled a bumpy road since they were first passed in 1974. Their history holds insights for AI regulation that aims for efficiency, flexibility, and greater justice.

Formal rules for the treatment of human subjects had been debated among scientists and policymakers in the United States for decades before any were enacted. The core disagreement was less about the content of potential rules — what they should say — than about who should regulate: the government or professions. Henry K. Beecher is often celebrated as a founder of American bioethics, yet he opposed government regulation of human-subjects protections. Instead, Beecher and his allies advocated for a renewed commitment to professional ethics, which would involve scientists retaining the power to judge the moral acceptability of their own actions. As Beecher told his Harvard colleagues in 1958, "These matters are much too complex, it seems to me, to permit the establishment of rigid rules in most cases."[3]

Several years later, Beecher published his famous article "Ethics and Clinical Research." In it, he underscored his view that professional judgment, rather than government regulation, was the best mode of oversight. "A far more dependable safeguard than consent," he wrote, "is the presence of a truly *responsible* investigator."[4] At stake was scientific autonomy and the power of experts in a democracy. In practical terms, the issue was enforcement — specifically, whether rules regarding the treatment of human subjects would carry the force of law or only the soft discipline of colleagues.

Debates over AI have raised similar issues about the appropriate relationship between government and professional authority in the regulation of science. In July 2023, leaders of seven top AI companies made voluntary commitments to support safety, transparency, and antidiscrimination in AI. Some leaders in the field also urged the U.S. government to enact rules for AI, with the stipulation that AI companies set the terms of regulation. AI leaders' efforts to create and guide their own oversight mechanisms can be assessed in a similar light to Beecher's campaign for professional autonomy. Both efforts raise questions about enforcement, the need for hard accountability, and the merits of public values relative to expert judgement in a democracy.

Ultimately, Beecher and his supporters lost the debate over professional versus governmental oversight. In the years after Congress passed the National Research Act, administrators wrote the regulations that ushered in institutional review boards and formalized consent practices. The 1979 Belmont Report, which was mandated by the Act, established the philosophical underpinnings of the nuts-and-bolts regulation. The Belmont principles — respect for persons, beneficence, and justice — linked directly to regulatory requirements regarding consent documentation, risk–benefit calculations, and nondiscriminatory recruitment of subjects.

In each of these efforts, policymakers focused on the living people involved in biomedical studies — that is, "human subjects." During the same decade, projects involving human genetic material and genetic data were proliferating. Yet protections for people as "data subjects" were largely omitted from the regulations. In the 1990s, Indigenous communities led the way in protesting researchers' unethical extraction and use of genetic material. Such protests moved the government toward stronger guidelines for the data that underpin new science. In one landmark case, the Havasupai tribe in the U.S. Southwest sued Arizona State University for unauthorized use of members' genetic material to generate and share data beyond the terms of a consent agreement.[5] This case and many others signaled that use of human data had effects, including the production of commercial value, that exceeded the effects on people as they had conventionally been imagined as human subjects.

Public concern about AI has emphasized applications, such as the use of medical chatbots, which has drawn attention to effects on people as users of AI tools. But with increases in social-media content, use of personal electronic devices, and techniques such as data scraping, AI systems also have ample access to benchmark and training data generated by people in the course of their everyday lives. The history of human-subjects research shows that rules for AI would do well to prioritize protections and clarify rights regarding the data that underlie generative tools — in addition to protecting people from harmful effects of AI applications.

By the start of the new millennium, regulations from the 1970s governing human-subjects research fit awkwardly in a changed scientific landscape and political terrain. Federal agencies had smoothed minor differences among their rules in 1991 to create the unified "Common Rule," but the basic structure and requirements from the 1970s remained intact. In 2011, the U.S. government issued an Advance Notice of Proposed Rulemaking with a goal of updating human-subjects protections for 21st-century science and reducing the regulatory burdens that had emerged since the 1970s. After 6 years of drafts, public comment, and widespread debate, the federal government issued revised rules for the treatment of human subjects in 2017, which accounted for the use of biospecimens, cooperative research, and the need for input from tribal governments, among other issues. It was the first substantial update to the rules in 40 years.

The capacity of AI is rapidly evolving — as are public concerns about norms of use, corporate accountability, and effects on global security, labor, climate, and other areas. The history of human-subjects research suggests that it will be important to keep rules for AI as nimble as the science they regulate. Federal agencies, rather than Congress, typically lead the way in updating regulations using a process, known as retrospective review, that is con-

ducted when demanded by stakeholders. Yet regulation of AI is best envisioned as an ongoing project, to ensure that new rules emerge alongside new scientific possibilities and political contexts.

There are lessons to be learned from the past that are relevant to the future of AI. First, the history of human-subjects regulation shows that a core decision to be made relates to the role of professions in guiding or replacing government regulations. It will be important to focus on discussions of who, specifically, should have authority to establish and enforce rules for AI, with public values in mind. Second, attention to data ethics, including questions of how strenuously to regulate data collection and ownership, will be key to robust AI regulation. Third, the history of human-subjects regulation shows that for any fast-moving area of science, anticipating and planning for rule revision is necessary. AI's emerging properties and new use cases warrant clear, built-in mechanisms to allow speedy regulatory updates made with meaningful public input to support science, medicine, and social justice.

An audio interview with Laura Stark is available at NEJM.org

Disclosure forms provided by the author are available at NEJM.org.

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Preliminary Data on "Unwinding" Continuous Medicaid Coverage

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One of the most substantial changes to health insurance coverage since the Affordable Care Act was implemented will unfold during 2023 and 2024. In early 2023, the uninsured rate in the United States fell to a historic low,[1] in part because of increases in insurance subsidies enacted during the Covid-19 pandemic, but also because of a pandemic-era Medicaid policy — the continuous-coverage provision.

Starting in early 2020, states received additional federal program funding, under the condition that they pause eligibility redeterminations in Medicaid and the Children's Health Insurance Program (which we collectively refer to as "Medicaid" here), among other requirements. States couldn't remove enrollees, even if their eligibility would otherwise have lapsed. Nationally, enrollment in these programs swelled from 71 million people in February 2020 to 94 million people in March 2023.[2]

In April 2023, however, states were permitted to start disenrolling people from Medicaid if they were no longer eligible or didn't complete the redetermination process. States have 14 months to fully "unwind" the Medicaid continuous coverage provision. Supplemental federal funding decreased during 2023 and will return to prepandemic levels in January 2024.

Before terminating coverage, states must attempt an "ex parte" renewal, in which they check available sources of information (such as state unemployment and wage databases) to determine whether they can independently confirm an enrollee's eligibility. If ex parte renewal is unsuccessful, redetermination paperwork is mailed to the enrollee.

Enrollees may have their Medicaid coverage terminated if they submit their redetermination materials but are determined to be ineligible. Alternatively, coverage can be terminated for "procedural" reasons when states don't have enough information to make an eligibility determination. Procedural terminations often occur when enrollees don't successfully complete required paperwork — because they never received redetermination forms, didn't fill them out, or otherwise couldn't navigate the process.

Federal officials projected in 2022 that 15 million people could lose Medicaid coverage because of unwinding, with higher numbers possible under certain circumstances.[3] About 45% of enrollees losing coverage were predicted