Health Regulation for the Digital Age — Correcting the Mismatch

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In January 2018, Amazon, Berkshire Hathaway, and JPMorgan Chase announced that they would be teaming up to "disrupt" the health sector.[1] The news set the health policy world abuzz, overshadowing reports that many tech companies were already entering the health sector. Apple, for example, unveiled an iPhone feature that enables patients to download their medical records. Microsoft announced an initiative using machine-learning tools to increase patients' adherence to their care plans. And an Alphabet subsidiary said it's developing wearable devices that will monitor vital signs to detect the onset of illness. Imagining these and other possibilities, *New York Times* reporter Tiffany Hsu wrote an article entitled "Dr. Alexa, I've Been Sneezing and My Throat is Sore."[2]

Many of these technologies are promising, some might meaningfully transform the way we think about health care, and all have been greeted by a population eager to see improved care delivered at reduced cost. But one major concern plagues many of these initiatives: Can they obtain regulatory approval?

Current law requires regulators to ask some difficult questions. For example, are health tracking apps and wearables "medical devices"? If so, they require approval from the Food and Drug Administration (FDA) before they are marketed. And when artificial intelligence software offers medical guidance, is it "practicing medicine"? If so, it might violate laws that prohibit the corporate practice of medicine, and its developers could be subject to state licensing restrictions. Some observers have recognized the regulatory hurdles that confront emerging products, with CNBC reporting last year that Alexa does not comply with privacy requirements under the Health Insurance Portability and Accountability Act (HIPAA) (the article noted that "Amazon acknowledges the problem"[3]).

As new products and systems emerge, the health policy community faces a basic question: If these technologies are at odds with current regulations, does that reveal a shortcoming in the technologies or a shortcoming in the law? Does it make sense that Alexa can remind me when I need to purchase more cereal but not when I need to take my insulin?

Rather than applying current laws to emerging technologies, requiring innovations to meet the regulatory demands placed on other health care services and providers, policymakers might do better if they recognize that the digital age presents a mismatch problem. Current regulations were built for a traditional health care delivery system and are ill suited to new technologies.

Historically, health care was delivered in person, by physicians and by means of medical and pharmaceutical interventions. To ensure that care is delivered by competent people, we have laws requiring that it be provided only by licensed professionals at accredited facilities. To ensure that such care is of appropriate quality, malpractice law applies the standards embraced by other local professionals. When health care requires ingesting a substance or using a device, it must first be approved by the FDA. The law presumes that health care flows downward, in person, from a professional and through approved channels, which is indeed how most current health care was designed.

The digital age has introduced algorithms, automated products, and massive data storage into health care. In doing so, it has simultaneously undermined some core presumptions of health care regulation. With information being automated and democratized, physicians are no longer the only repositories of medical knowledge. The convenience and effectiveness of virtual visits have overcome geographic constraints and called into question the centrality of in-person visits. Accurate diagnoses and effective health care regimens no longer need to flow from the top; they can instead — or will one day be able to — emerge from laypeople using intuitive software that accesses a wealth of data.

Of course, digital health care interventions and services must meet acceptable quality standards. But assessing them effectively will mean discarding traditional guidelines and inherited legal categories, instead recognizing the needs they aim to meet, the realistic dangers they introduce, and the new models of care they offer.

Health care regulators have not been blind to these challenges. Many have grappled with adapting their governing authority and regulatory frameworks accordingly. For example, under the 21st

Century Cures Act, some software does not qualify as a medical device subject to FDA regulation. And the FDA has been "actively developing" a regulatory framework for artificial intelligence.[4] But despite some commendable foresight, substantial mismatch problems remain. It is useful to consider how, if we were to start from scratch, we would regulate health care in a digital age.

To start with, regulatory policy could be tailored to the needs of digital medicine. For example, the FDA is charged with assessing the safety and efficacy of digital apps, treating them as medical devices, while the Centers for Medicare and Medicaid Services determines whether mobile apps violate HIPAA's privacy rule, as it does for hospital electronic health record systems. Interagency communication can partially bridge this divide (and has done so),[5] but a better approach would be to construct a regulatory regime that is tailored to these new technologies. Mobile medical apps are neither medical devices nor hospital EHR systems, and regulation is compromised by treating them as either one.

Payment reform could also be considered within this broader regulatory view. If digital technologies make the patient, rather than a provider, the primary point of contact, we might need to overhaul the way we pay for care. We are already in a transition away from fee for service, but in the digital age, the most effective interventions may not require any encounter with medical personnel at all. The prevailing policy response has been to expand payments for certain digital technologies, for example by providing payment "parity" for telehealth services, but a broader reorientation may be necessary. Public and private payers can revamp payments to encourage effective use of digital technologies, in some cases potentially bypassing traditional providers altogether.

Digital medicine might also require rethinking more fundamental elements of health care regulation. We continue to regulate quality through a medical malpractice regime, in which physicians remain the focus of scrutiny. A key question in determining responsibility is whether a doctor–patient relationship has been created; if so, we evaluate a physician's conduct by comparing it with that of similar physicians. In a digital world, patients might be under the care of a physician they have never met, and the professional standard of care is elusive if algorithms are either extensions of or competitors with physicians. A better approach might be to abandon the traditional malpractice regime for enterprise liability or product liability, since these legal rules are designed for industries that issue goods and services to the general population and the broader flow of commerce.

Finally, the "practice of medicine," which is controlled by state medical boards, has to be rethought at the highest levels. The current regulatory regime issues local licenses to individual professionals to practice medicine and prohibits everyone else from doing so. But a hallmark of digital medicine is the blurring of boundaries between providers and products, and a licensure regime that empowers only individual professionals will appear silly to the next generation of patients. Board certifications and licensure will retain an important role, but they could be rethought in accordance with the skills and expertise that will advance high-quality health care in the digital age.

In sum, new technologies are stretching health care regulatory categories beyond recognition. A better approach might be to change the law to meet the needs of the public and the industry, rather than the other way around.

Doing nothing would not be disastrous. Law, like medicine, is often as much art as science, and rigid legal categories rarely dictate outcomes. Common sense usually wins out, and the law tends not to prohibit best practices. But if the law is used with foresight, it can help enable Americans to benefit from the promise of new digital technologies.

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

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DOI: 10.1056/NEJMp1806848