FDA Chief: AI Holds ‘Enormous Promise’ for Tomorrow’s Health Care

But it can’t be scaled without “a vote of confidence that it protects and promotes patients."

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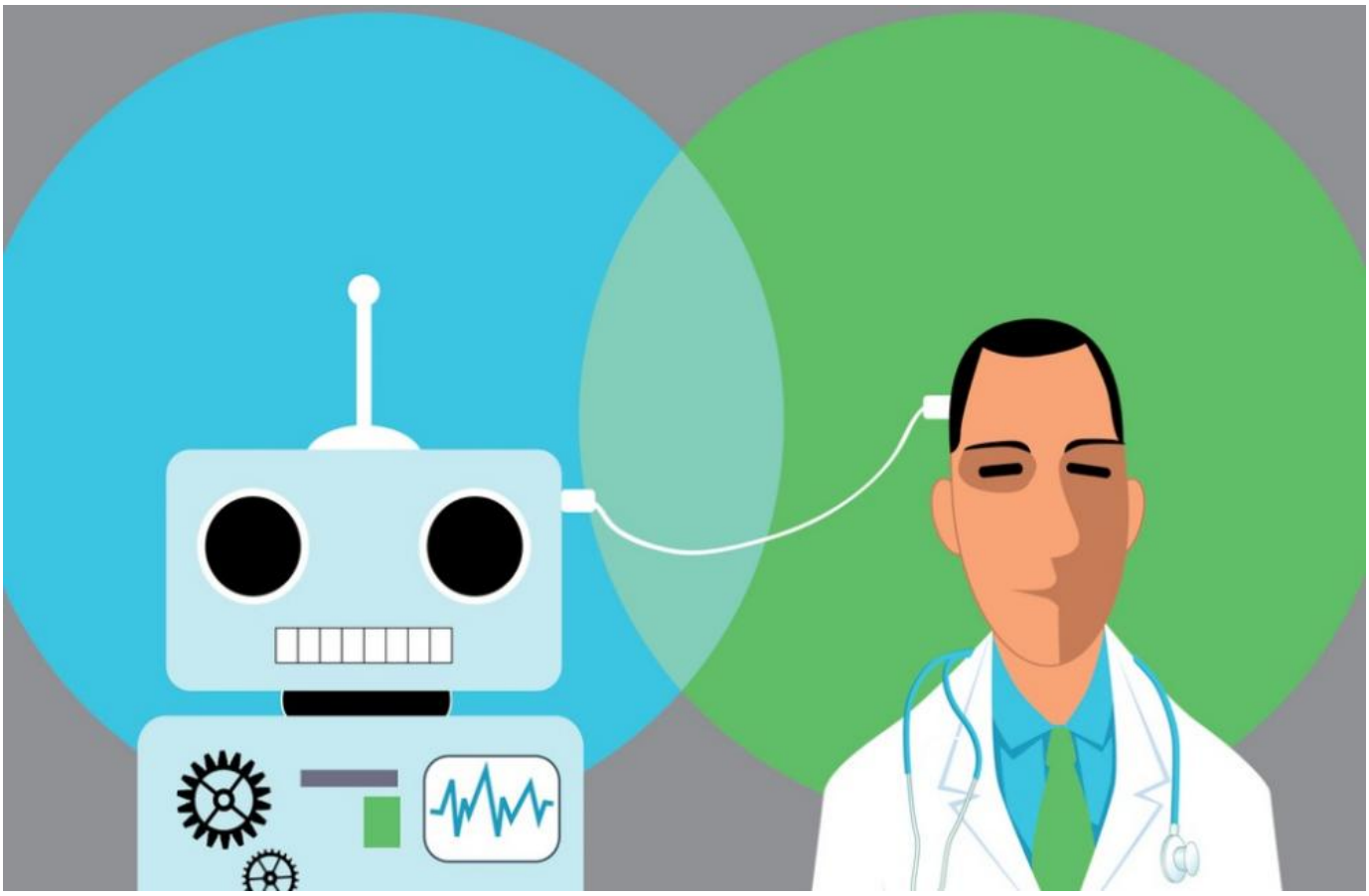

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Digital health tools have and continue to radically change how care is delivered and provided, helping with early detection and cutting costs. Wearable devices, telemedicine and mobile apps already enable patients to be more proactive with their health, and help care providers better tailor individual care.

But what’s the most promising tech transforming health care right now?

“Artificial intelligence, particularly efforts to use machine learning . . . holds enormous promise for the future of medicine, and we’re actively developing

regulatory framework to promote innovation and the use of AI-based technologies," said Food and Drug Administration Commissioner Scott Gottlieb. He spoke April 26 at the Health Datapalooza in Washington, D.C., organized by Academy Health.

"We know that to support the widespread adoption of AI tools, we need patients and providers to understand the connection between decision-making in traditional health care settings and the use of these advanced technologies," Gottlieb said.

FDA's approach to AI regulation must establish appropriate guardrails for patients, he said, "and even as we cross different tiers in innovation, we must make sure these novel technologies can deliver benefits to patients by meeting our standards for safety and effectiveness."

But technology can't be scaled without "a vote of confidence that it protects and promotes patients," he added.

FDA will be working with AI experts with experience from the finance sector, where AI platforms are widely used for fraud detection. Developing new policies should address how these technologies — including AI — can be validated, reliable, unbiased and help improve health outcomes. The agency's AI approach will also look at how real-world data flows, including unstructured and structured data from pathology slides, electronic medical records, wearables and insurance claims data, according to Gottlieb.

"In time, AI might even be taught to explain itself to clinicians," he said. This field has already advanced faster than anticipated, and "we expect AI tools become even more predictive as additional real-world data is fed into algorithms, and this technology has the potential to significantly reduce costs from complications of chronic disease."

In early April, FDA approved the first medical device that combines a special camera and AI to detect greater than a mild level of diabetic retinopathy, a condition that damages the retina and is a leading cause for vision loss among adults with diabetes. The software program, called IDx-DR, has an AI algorithm that analyzes images of the eye taken with the Topcon NW400 retinal camera.

Early detection is key to preventing serious vision problems, Gottlieb said, so if the AI detects mild retinopathy, primary care physicians can refer patients to an eye care specialist. Eventually, AI tools can be integrated directly into smartphones and

wearables for myriad early-detection applications.

“These are no longer far-fetched ideas,” Gottlieb said. “We know that to keep pace with innovation in these fast-moving fields, FDA itself must do more to leverage digital health tools and analytics internally to help the agency develop new regulatory tools and advance its own work.”

These tools, Gottlieb said, include digital biomarkers for early-disease diagnosis and using data from electronic health records to enable pragmatic clinical trials and better care. Eventually, these tools could also help make drug and device development more predictable, efficient and "more reflective of patients’ real-world experiences,” Gottlieb added.

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