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Gottlieb's going. What's next?

FDA Commissioner Scott Gottlieb surprised the health policy world March 5 with news that he would resign in a month. But despite Gottlieb's broad popularity among industry, lawmakers and public health professionals, FDA's medical technology efforts will likely proceed unabated when he leaves the agency, reports [MedTech Dive](#). Center for Devices and Radiological Health Director Jeff Shuren, who has served at FDA for over 20 years in various roles, will maintain continuity in the agency's medical device oversight efforts and initiatives. Meanwhile, Principal Deputy Commissioner Amy Abernethy, who recently joined the agency from Roche unit Flatiron Health to help develop the agency's approach to real-world data, is rumored as a potential acting commissioner.

The FDA's secret cache of data

The FDA has built and expanded a vast and hidden repository of reports on device-related injuries and malfunctions, according to [Kaiser Health News](#). Since 2016, at least 1.1 million incidents have flowed into the internal "alternative summary reporting" repository, instead of being described individually in the widely scrutinized public database known as MAUDE. The hidden database has included serious injury and malfunction reports for about 100 medical devices, including surgical staplers, balloon pumps and mechanical breathing machines. The program has been so obscure that it is unknown to many doctors and engineers dedicated to improving device safety. Even a former FDA commissioner said he knew nothing of the program.

Artificial intelligence: Is it as smart as they say?

In a new book, "Deep Medicine: How Artificial Intelligence Can Make Healthcare Human Again," cardiologist Eric Topol says AI can do more than enhance diagnoses and treatments. It can also save doctors from such tasks as taking notes and reading scans, allowing them to spend more time with their patients, according to an interview in [The New York Times](#). When asked what areas AI shows the most promise, Topol was quoted as saying, "One is machine pattern recognition to promote the rapid and accurate reading of medical scans, slides, skin lesions, the pickup of small polyps during colonoscopy, and much more. Another is keyboard liberation, or using natural language processing of speech to synthesize notes and eliminate the ultimate source of distraction and dislike in medical encounters. A.I. can also predict key outcomes for both patients and clinicians to promote prevention."

Meanwhile, Amazon reported that its Amazon Web Services unit is working with a Harvard-affiliated teaching hospital in Boston to test how AI can simplify medical care, reports [Bloomberg](#). While the tech industry has high hopes that powerful computing tools can improve diagnoses and treatment, Beth Israel Deaconess Medical Center's first

projects with Amazon.com Inc. are more about making day-to-day tasks like patient scheduling more cost-effective. Amazon gave the Harvard Medical School teaching hospital a grant valued at as much as \$2 million to experiment with machine learning and AI. It's a new indication of the desire Amazon and its competitors have to grow in the U.S. health industry.

Speaking of artificial intelligence ...

AI – and its impact on medical technology -- will be just one of the forward-looking topics to be discussed at the upcoming IMDA/HIRA Conference, July 21-23 in suburban Chicago. The Conference, whose theme is “The Many Facets of Value,” will feature presentations and workshops around the theme of identifying and demonstrating value to healthcare professionals. Meanwhile, the Manufacturers Forum will offer manufacturers, dealers and representatives an opportunity to view and talk about new products and discuss business opportunities. The Conference will be held at the Eaglewood Resort in Itasca, Illinois. You should be there! For more information, visit www.imda.org or www.hira.org.