With artificial intelligence being implemented across the health care continuum, FDA and other agencies find themselves contending with the prospect of regulating a moving target.

From smartphones to self-driving cars, artificial intelligence continues to influence nearly every aspect of modern life. Health care is no exception. Use of artificial intelligence systems promises better health care management for patients and faster, more accurate diagnoses for doctors. But FDA’s traditional regulatory framework will require major changes in preparation for the advances on the horizon. John J. Smith, M.D., J.D., partner in Hogan Lovells’ Medical Device practice, believes that companies pursuing AI technologies must realize that while the health care industry is embracing this technology, the regulatory landscape is still finding its footing.

“AI is a technology that has come of age,” says Smith. “There’s been talk of using machine-based algorithms [in health care] for decades. (Until now) the results have been disappointing, largely because the technology was not up to the level necessary to really analyze the tremendous amounts of data that are in the health sciences or medical space. That’s not the case anymore.”

Smith says that as computing power has caught up to the dream of automating more systems in health care, the full potential of this technology is creating exciting new use cases. “It (AI) can alert someone to the presence of an abnormality, identify it, and even diagnose it,” he says. “From analyzing radiographic images to images from endoscopies, these algorithms can be applied to any number of different health systems, depending on the specific clinical need.”

But even as AI continues to evolve, regulators are still figuring out how to adapt. The industry’s current regulatory paradigm – in use since 1976 – isn’t suited to regulate the rapid pace of AI innovation. Much of FDA’s early regulation is based on evaluation of specific medical devices, each of which must be individually assessed. That creates issues when an algorithm might be applied to multiple devices and/or serve different purposes. “You can see the tension between a fast-moving, broad-based technology and something that is looking at clearance for a specific condition or a specific type of application,” says Smith.

“As you extend this technology to more hospitals using a mix of technologies, it may be difficult to apply [regulation] to them broadly,” he continues. “For example, FDA just cleared something
called ‘IDX’ which looks at retinal photography and detects diabetic retinopathy. But the AI was only cleared for use with *one* retinal camera. FDA maintained that differences in imaging (between cameras) could affect the algorithm's output."

FDA is making strides to address these issues through a new pre-certification program that Smith believes should lower the overall regulatory burden for device makers. “Under current regulation, [device manufacturers] can't just change their product at will as long as the basic concept remains the same,” he says. “With the pre-certification program, as companies modify their algorithms for new devices, they potentially won't have to file brand new marketing submissions, meaning they can get their products to market faster.”

As new regulation around AI continues to take shape, Smith advises companies pursuing the technology to think carefully about their approach and seek outside counsel in order to fully understand the changes that are coming. “The worst outcomes I've seen are (those) where companies do not anticipate to what extent [their product] will be regulated by FDA,” he says. “Some companies simply don't realize the regulatory implications of their products...Understanding where (your device) fits into FDA's regulatory paradigm and how that paradigm will continue to shift over time is critical for a successful long-term strategy.”

Watch the video for more insights from Smith about how companies can navigate the rapidly evolving regulatory landscape for AI.

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