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FDA And Digital Health: Time For A Cultural Exchange

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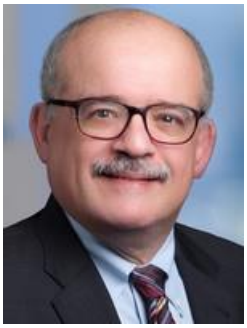
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The tech industry prides itself on both the volume and speed of the innovative developments emerging from its network of academic and corporate research enterprises and collaborations. One focus of all this innovative thinking is to develop products, services or business methods that "disrupt" existing practices or industries, so as to unlock efficiencies or create novel ways to achieve new and better results.

Health care, one of the most traditional and complex sectors of our economy, increasingly is becoming the target of tech industry disruptors. Under the rubric of "digital health," there is a wide array of ongoing activities at the intersection of health care products, medical services, data collection and analytics, and software design — tech meets medicine fueled by information.

But there is a potential clash of cultures because much of the health care industry is highly regulated and as we have seen in other contexts, evolving disruption and extensive regulation often do not mix. For example, digital health developers emerge from the tech industry, where products are launched at breakneck pace and then revised and updated over the life of the product, with light regulatory touch. In stark contrast, the U.S. Food and Drug Administration regularly serves as a market gatekeeper for medical devices and heavily regulates these products, generally requiring registration of manufacturers, premarket clearance or approval of medium- to high-risk devices before commercial distribution, reporting adverse events, and implementation of current good manufacturing practices.

The different backgrounds and expectations between the regulators and the regulated community in this space can lead to an unproductive atmosphere full of frustration. How can the two sides work toward a meeting of the minds and change this dynamic? To its credit, the FDA has tried to change that dynamic by issuing guidance that sets forth its plan to "exercise enforcement discretion" with regard to relatively low-risk digital health products by allowing those medical devices to go to market without prior FDA clearance or approval. But guidance technically is not legally binding and is subject to change, plus given the complexity of some these products or services, ambiguity, and therefore uncertainty, is inevitable in particular circumstances.

Two knowledge gaps exist that require narrowing before the FDA and the digital health community can work collaboratively to bring disruptive, innovative, safe and effective medical technology to the market. First, medical device reviewers and policymakers at the FDA must truly understand the science

and clinical implications of digital health. Second, digital health developers, such as software engineers and code writers, must learn the FDA regulatory landscape.

One way to expedite change is to create a cultural exchange. The cultural exchange would facilitate a conversation between the regulators and the tech industry so that the two sides can become familiar with each other, both from a technical as well as a mission perspective. If tech software engineers and code developers can participate in a cultural exchange at the FDA, they can share their practical concerns and help educate the agency about the technology, while at the same time gaining an understanding of the FDA's public health mission, the regulatory framework, and the agency's need to balance risks and benefits. Armed with this knowledge, upon their return from the exchange, digital health representatives can serve as regulatory translators for, or perhaps even ambassadors of, the agency to their tech colleagues.

A model already exists for such a cultural exchange. The National Science Foundation (NSF), one of the government's pre-eminent agencies dedicated to the furtherance of science, has an extensive "rotator" program where it relies on the Intergovernmental Personnel Act (IPA) to attract leading external researchers for temporary government service to augment and complement the agency's permanent staff. These "rotators," who are leading scientists, engineers and educators, generally serve one to two years, and provide a steady infusion of new ideas to keep the NSF informed of cutting edge developments in the nation's science and engineering facilities.

The IPA, plus other federal hiring programs, enables the NSF to structure a reimbursement package that makes it feasible to hire these leading experts for such temporary service. For example, under the IPA authority, the NSF is able to craft a compensation package that exceeds the federal pay ceiling so as to attract leading scientists, who often would have to maintain two households, interrupt research and teaching careers and forego consulting income to participate in the rotator program. The results speak for themselves — close to one-third of NSF's program directors are hired under the auspices of the IPA.

The FDA and Congress recognize the need for such a cultural exchange. Newly confirmed FDA Commissioner Dr. Robert Califf is on record calling for an influx of outside experts to enhance the current FDA workforce and has expressly noted the potential value of importing internet and technology expertise from Silicon Valley. One provision of the "21st Century Cures" legislation pending in Congress would give the FDA greater hiring flexibility to pay any "highly qualified scientific, technical or professional" employee up to the same amount as the president's salary, currently $400,000 annually.

But that proposal is directed at the agency's permanent workforce and it ultimately may not be enacted into law. The FDA does not need to wait for that new statutory authority to augment its expertise. The agency should rely on existing hiring provisions and programs to create its own "rotator" program to bring in tech researchers to help ease the transition for both sides in the emerging digital health area.

Given the concerns over conflicts of interest, an FDA rotator program likely would have to be limited, at least at the outset, to digital health experts from academia and the nonprofit sector. Over time, as knowledge management and exchange in this area is more widespread, there may be less of a need for an influx of new ideas into the agency. But there is a generational shift occurring and it is imperative that the FDA take advantage of current tech thinkers to facilitate that shift. In this circumstance, familiarity will not breed contempt, but instead will foster understanding. An organized exchange program between the FDA and the tech community will benefit both the digital health enterprise and the public health.

—By Albert F. Cacozza Jr. and Abram S. Barth, Ropes & Gray LLP

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