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Opinion: Digital Health Precertification -- The Little Engine That Couldn't (Yet)

by Steve Silverman

In this op/ed, former US FDA device compliance chief Steve Silverman argues that while the agency's digital health precertification (Pre-Cert) pilot program failed to make much of a splash, the concept deserves a second look -- and more Congressional support.

This article proposes resurrecting the US Food and Drug Administration (FDA) digital health precertification (Pre-Cert) pilot program. First is a quick review of the Pre-Cert pilot: its beginning, its operation, and its current status.

The FDA launched Pre-Cert in 2017 as a pilot program focused on digital medical products, such as software as a medical device (SaMD). The FDA describes the Pre-Cert pilot as a new way to assess digital medical devices. Traditional device review is product-specific, which means that the FDA considers the safety and efficacy of particular devices before they come to market. Significant product change then requires safety and quality re-assessment before the change occurs.

By contrast, the Pre-Cert pilot focused on software device makers with strong quality cultures. Instead of evaluating specific devices, the pilot took a whole-firm approach. Firms that were judged to make safe and effective software devices and continuously monitor and improve these devices got a "fast-track" to market and could modify their devices without prior FDA review. This fast-track added to, but did not replace, standard device review. Critically, the Pre-Cert pilot was risk-based; higher-risk devices underwent traditional FDA review regardless of the safety and efficacy traits of the companies making them.

The Pre-Cert pilot generated positive reviews from FDA, device makers and technology innovators. The FDA touted the pilot's promotion of a regulatory model in which firms were rewarded for continuously prioritizing quality and organizational excellence. Industry praised the pilot for keeping pace with digital-health innovation.

Still, the pilot's impact has been anemic. This is because the FDA was required to operate the pilot using its current limited regulatory authority. A true fast-track approach fell away, with the FDA relying instead on its device de novo review process. The problem is that de novo review, while faster than other premarket review types, is too limited for the Pre-Cert pilot. It cannot support the fast-track approach originally envisioned for the pilot. That, taken with the few Pre-Cert pilot participants and the inability to limit de novo benefits to those participants, meant that the pilot underperformed.

Pre-Cert Is A Good Idea.

Despite these disappointing results, Pre-Cert makes sense. Digital devices like SaMD require new regulatory models aligned with the distinct ways that these devices evolve. This is evident when considering how traditional and digital devices are designed. Traditional devices use a "locked" design model in which product characteristics are developed, evaluated and fixed in place. By contrast, digital devices evolve continuously and iteratively. Locked design is too cumbersome for digital devices; it stifles the agility and innovation that characterize these products.

The Pre-Cert pilot avoids such slowdowns with a creative space for the FDA and stakeholders to imagine and design new regulatory paths. No surprise, the Pre-Cert pilot found that, to thrive, digital devices need systems-based assessments to support market entry. That is, FDA can offer streamlined product reviews for firms committed to organizational excellence and quality. When most successful, pilots like Pre-Cert underpin such new regulatory approaches, which promote innovative technologies while assuring product safety and efficacy.

The FDA's commitment to these new regulatory approaches is evident in its Digital Health Center of Excellence (DHCoE). Started about two years ago, the DHCoE considers how to improve digital health regulation to quicken access to safe and effective digital devices. In the short time since its launch, the DHCoE has promoted digital technology through publications explaining SaMD, resources on artificial intelligence and machine learning, and similar innovation-focused strategies. The FDA's support is equally evident in its real-world evidence (RWE) initiative, which considers data sources like product claims and billing records to supplement or even replace traditional clinical-trial data. RWE is vital to digital devices as the FDA considers new ways to bring these devices to market.

What Went Wrong?

Everyone agrees that shaping regulation to support device innovation is a good idea. So why did the Pre-Cert pilot falter? The answer is that the FDA did not adequately recognize and account for a key constituent: Congress.

Think about who was at the pilot "table." The FDA was all-in, along with stakeholders like the device industry, technology companies and patient groups. Everyone gave a thumbs-up -- but where was Congress?

Before getting to that question, here's an equally important one: Why is Congress a key stakeholder? The answer comes down to authority. The FDA lacks authority to streamline regulatory requirements in the ways that Pre-Cert envisioned. As proof, one need look no further than the *2018 letter* to the FDA from US Senators Elizabeth Warren, D-MA, Patty Murray, D-WA, and Tina Smith, D-MN, which chided the FDA for exceeding its regulatory powers in establishing the Pre-cert pilot. In response, FDA tied the pilot to the agency's de novo process, which diluted its impact. FDA ultimately agreed that it would need new regulatory authority to keep abreast of software development. (Also see "*Software Pre-Certification Program Highlights Needs For Legislative Change, FDA Says*" - Medtech Insight, 27 Sep, 2022.)

So, the FDA could only establish a weak pilot program. To fully power it, the FDA needs statutory authority, which comes from Congress. But Congress didn't know about the Pre-Cert pilot and the FDA is not asking Congress for new authority. Nor will Congress unilaterally grant this authority. That creates a canyon-sized gap between what the FDA needs to make Pre-Cert work and the resources that Congress is willing to provide. So far, nothing has bridged that gap.

Now What?

The FDA recently concluded the Pre-Cert pilot and gave responsibility for it to the Medical Device Innovation Consortium (MDIC), an FDA-sponsored private organization that works on initiatives that the agency cares about. The group likely will convene stakeholders to find ways to revitalize the Pre-Cert pilot, plugging some of the gaps that limited its initial success. That's good. MDIC has the capacity, talent and energy to advance the Pre-Cert pilot, addressing the limits of FDA's de novo authority.

Still, for MDIC's work to succeed, the FDA must stick around. The agency must be a primary, visible and active sponsor of MDIC's efforts. The reason is that Pre-Cert pilot improvement requires the FDA to refine agency processes like premarket product review. The FDA must help develop process changes and it must implement them.

The FDA is necessary for these changes to happen, but it's not sufficient. Congress is an equally critical stakeholder. Congress must participate in Pre-Cert discussions about expansion of the FDA's regulatory authority. This is not to say that Congress should join brainstorming sessions (unless it wants to). But Congress must be consulted, it must have the chance to ask questions and give feedback, and its statutory powers must be respected. Put differently, the FDA must sell the Pre-Cert program to Congress, and that sale must occur while the program is being redesigned, not when it's a done deal.

Will these things happen? No time soon. The recently concluded device user-fee negotiations left a host of legislative imperatives on the table (think cybersecurity, clinical-trial diversity and in vitro diagnostic device oversight). These priorities come first, and they will take time. But even so, there's value in pushing the Pre-Cert pathway. There must be new regulatory models that match and promote device innovation. Stakeholders like industry, patient groups and even

Congress must help shape these new approaches. And this collaborative model must complement the FDA's own capabilities, including by granting the agency regulatory authority that it currently lacks.

This collaborative approach will take time, but so what? Questions like the ones raised here – how are digital devices different, how should the FDA accommodate these differences, how will FDA get new authority to innovate – need answers. Convening a wide-ranging, interested and empowered group to answer these questions makes sense.

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