CLOSER LOOK

MEMORANDUM

FDA announces exciting PreCert program for digital health companies, with potential for faster reviews and less regulatory burden; applications open August 1, public workshop in January 2018 - July 31, 2017

Executive Highlights

- On Thursday, FDA Commissioner Dr. Scott Gottlieb shared an encouraging blog post announcing an important new FDA pilot: Digital Health Software Precertification (PreCert) Program." PreCert will allow FDA to first look at the company, rather than primarily at the product being submitted. This "firm-based approach," sort of like a 'TSA Pre-Check' for digital health submissions, is intended to expedite product reviews from vetted companies - either minimizing the burden of submissions or eliminating them in some cases.
- PreCert applications open tomorrow (August 1), and the pilot will initially include nine "software firms of various sizes." The program will start rapidly on September 1, and FDA plans to hold a public workshop in January 2018 to report on and review initial findings. A webinar tomorrow (August 1) from 1-2:30 PM EST will share more information.
- Given the blazing pace of digital health innovation, we're thrilled to see a more streamlined FDA process in the works. We see high potential in diabetes/digital health for faster reviews, more iteration, and smarter use of FDA's limited resources.
- CDRH has also released an eight-page Digital Health Innovation Action Plan, announcing plans to publish five guidance documents in the next half-year.

On Thursday, an inspiring blog post from FDA Commissioner Dr. Scott Gottlieb announced a big development for digital health regulation with potential benefits for diabetes technology. The pro-innovation post, "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare" announced a new FDA pilot called "Digital Health Software Precertification (PreCert) Program."

The idea of PreCert is to first look at the company, rather than primarily at the product being submitted (as FDA currently does for traditional medical products). This "firm-based approach," sort of like a 'TSA Pre-Check' for digital health submissions, has a lot of potential wins - once pre-certified, companies could submit less information to the FDA than is currently required before marketing a new digital health tool. In some cases, a submission from a pre-certified company wouldn't be needed at all, and companies could simply collect data in the post-market setting. The hope is to speed up review cycles for digital health products and allow vetted companies to innovate more quickly with less FDA regulatory burden. Nice! Dr. Gottlieb's post is well worth a read, noting the "revolutionary" potential of digital health and that FDA's "traditional approach to medical devices is not well suited to these products."

FDA will begin taking PreCert applications tomorrow (August 1) and will initially accept nine "software firms of various sizes" for the pilot - application details are in the Federal Register here. The PreCert program will begin very quickly with the initial nine companies chosen and starting on September 1. Notably, FDA plans to hold a public workshop in January 2018 to report on and review initial findings. A webinar tomorrow (August 1) from 1-2:30 PM EST will share more information. Wow is there seriously fast movement on this!

Digital health is of course a difficult field to regulate, and we salute the FDA for coming so far so fast in recent years. Focusing first on the company, rather than the product, seems like an excellent solution to us - in diabetes, this could allow pre-certified device/data management companies to iterate far more quickly on connected products, particularly for apps related to CGM, BGM, pumps, and insulin dose titration. As long

as the companies are experienced in software and use best practices, we see high potential for faster innovation, quicker iteration based on users' needs, far better devices, and less FDA burden to evaluate every single tweak.

In tandem with the PreCert pilot announcement, CDRH also published a succinct eight-page Digital Health Innovation Action Plan. The document notes five upcoming draft/final guidance documents:

- **A general 21st Century Cures Act implementation guidance by the end of 2017** (potential implications for diabetes, including mobile medical apps and medical device data systems [MDDS]);
- **Clinical Decision Support Software draft guidance in 1Q18** (to delineate the software that is no longer under FDA's jurisdiction - unclear implications for diabetes, since things like insulin dosing software would presumably still be regulated);
- **Multifunctionality draft guidance in 1Q18**, pertaining to software with both (i) functions that fall under FDA's medical device oversight; AND (ii) functions that do not (possible diabetes implications here, since most diabetes apps have low-risk wellness features and then potential higher-risk functionality);
- **Final guidance by the end of 2017 on Deciding When to Submit a 510(k) for a Software Change to an Existing Device** (definite diabetes implications here, at least for BGMs, pumps, and software); and
- **Finalize the International Medical Device Regulators Forum approach to clinically evaluating Software as a Medical Device (SaMD)** - FDA expects this international committee to finalize this in September. If that happens, the Agency intends to issue final guidance (possible diabetes implications here, though we're not sure what this entails).

To ramp up digital health efforts, CDRH is also hiring new staff for its Digital Health Program and launching an Entrepreneurs in Residence program in the fall, crowdsourcing insight from leaders in the software development field on how best to build a flexible digital health infrastructure within the CDRH. Amazing!

Dr. Gottlieb's post summed things up well: "We need to make sure our approach to innovative products with continual updates and upgrades is efficient and that it fosters, not impedes, innovation." Hear, hear! The FDA is also encouraging input through a public docket (FDA-2017-N-4301).

While many would agree the FDA is not the most significant barrier to bringing digital health tools to market, it's outstanding to see the continued commitment given the lightning-fast speed at which the field is growing - Rock Health recently reported a staggering $3.5 billion invested in digital health during 1H17, up ~50% from 1H16. We'll continue to follow this for more specific takeaways for diabetes players.

- **Dr. Gottlieb's post emphasized that the nine selected companies for the PreCert pilot will reflect the diversity of digital health companies, ranging in size, structure, and product offerings. We wonder if any diabetes companies will be chosen.** The end-game is to determine pre-certification criteria, presumably for a broader rollout across the field. We'll be fascinated to hear the early experience in the January 2018 Public Workshop.

Close Concerns Questions

Q: How might PreCert affect the diabetes technology field? How significantly could this speed up submissions, approvals, and iteration (if at all)? Will PreCert de-risk the field and encourage more ambitious work in diabetes and digital health?

Q: How hard will it be for a diabetes tech company to become pre-certified with FDA? Will any of the initial nine companies be chosen from diabetes?

Q: Will any of these upcoming guidance documents change the regulatory evaluation of diabetes and digital health products? What product areas are the toughest for diabetes tech companies to navigate right now?

Q: Will it be hard for FDA to draw the lines on risk in diabetes? When will submission be required vs. not required? How will this evolve as the field expands into insulin dose titration in the coming years? How will patients' baseline risk - on open-loop dose titration - be considered?

Q: Will the pilot program address the issue of certifying new companies, including those with just one product? Or will this program mostly pertain to larger, more established companies?

Q: Will there be any sort of expiration timeline for pre-certification? Will a company's status need to be re-evaluated after a certain time period to ensure consistent quality and standards?

-- by Maeve Serino, Adam Brown, and Kelly Close