United States Senate
WASHINGTON, DC 20510

October 10, 2018

Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration
10903 New Hampshire Avenue
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Dear Commissioner Gottlieb and Director Shuren,

We are in a new era of digital products that are providing unprecedented amounts of health information directly to consumers and providers. In a recent statement, Dr. Gottlieb applauded the release of two new, FDA-cleared mobile medical apps developed by Apple for the company's Apple Watch product.[1] With one app creating electrocardiograms and another analyzing pulse rates, it's clear that these products have the capacity to transform the way health care is delivered.

Given that patients and providers will likely be relying on these new products when making health-related decisions, we believe that these products must meet the gold standard of safety and efficacy. At the same time, we recognize that these novel technologies and their rapid rate of change may require a new regulatory paradigm.

In July of 2017, the U.S. Food and Drug Administration's (FDA) launched the "Pre-Cert for Software Pilot Program," which is part of the agency's broader effort to modernize its regulatory approach to digital health devices. We write to request information on this program to gain a better understanding of how the agency plans to use this precertification pilot to inform its efforts to regulate digital health products and to improve its post-market surveillance system for medical devices.

FDA Regulation of Digital Health Devices

Digital health devices – such as mobile health apps, medical software, and health information technology – are innovative, transformative products that have the power to fundamentally alter America's health landscape.[2] To help streamline FDA's review of certain

[1] U.S. Food and Drug Administration, "Statement from FDA Commissioner Scott Gottlieb, M.D., and Center for Devices and Radiological Health Director Jeff Shuren, M.D., J.D., on Agency Efforts to Work With Tech Industry to Spur Innovation in Digital Health," September 12, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620246.htm.
[2] U.S. Food & Drug Administration, "Medical Devices," https://www.fda.gov/medicaldevices/digitalhealth/.

low-risk digital health products, such as electronic health records and fitness tracking software, Congress exempted certain types of low-risk devices from device regulation in the *21st Century Cures Act.*[3] However, FDA has further concluded that its existing review process is "not well suited for the faster iterative design, development, and type of validation used for software-based medical technologies" and could "impede or delay patient access to critical evolutions of software technology."[4]

As a result, in July 2017, FDA released a *Digital Health Innovation Action Plan*, which outlines the agency's plans to further streamline its process.[5] A central component of FDA's innovation plan is a pilot program designed to "develop a new approach toward regulating [digital] technology – by looking first at the software developer or digital health technology developer, not the product."[6] FDA officially launched its Pre-Cert for Software Pilot Program (Pre-Cert Pilot) in July 2017,[7] and selected nine participants in September 2017.[8] In June 2018, FDA issued the latest working model for the Pre-Cert Pilot that expounded on the agency's current thinking and asked dozens of questions of stakeholders to provide feedback on the direction of the program.[9]

The stated goal of the Pre-Cert Pilot is to "reduce the time and cost of market entry for software developers that FDA determines manufacture high-quality, safe and effective digital health devices while providing appropriate patient safeguards." It will test the feasibility of a "precertification" system for developers, in which FDA reviews a company's software design, validation, and maintenance systems to "determine whether the company meets the necessary quality standards" for precertification. Ultimately, the agency envisions a regime in which "pre-certified companies could submit less information to [FDA] than is currently required before marketing a new digital health tool."[10]

We support FDA's efforts to update the medical device review regime to better accommodate digital health devices and believe that it is an important step in ensuring that America remains an innovative, cutting-edge producer of medical devices. However, it is

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[3] 21st Century Cures Act, H.R. 34, https://www.congress.gov/bill/114th-congress/house-bill/34/text.

[4] Scott Gottlieb, M.D., "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare," July 27, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/. U.S. Food & Drug Administration, *Digital Health Innovation Action Plan*, July 2017, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

[5] U.S. Food & Drug Administration, *Digital Health Innovation Action Plan*, July 2017, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

[6] U.S. Food & Drug Administration, *Digital Health Innovation Action Plan*, July 2017, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf.

[7] Scott Gottlieb, M.D., "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare," July 27, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/.

[8] U.S. Food & Drug Administration, "FDA Selects Participants for New Digital Health Software Precertification Pilot Program," September 26, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577480.htm.

[9] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf.

[10] Scott Gottlieb, M.D., "FDA Announces New Steps to Empower Consumers and Advance Digital Healthcare," July 27, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/07/fda-announces-new-steps-to-empower-consumers-and-advance-digital-healthcare/.

essential that changes to FDA's regulatory framework are done in compliance with the current statutory framework and do not compromise public safety.

The agency should be focused on ensuring it has the tools and capacity to guarantee that software products that perform medical device functions are safe and effective and to hold companies that skirt the rules accountable. Instead, the Pre-Cert Pilot focuses heavily on the potential of standards for design, validation, and maintenance of software and the ability to capture post-market data to reduce premarket review time or eliminate the need for premarket review all together.

The remainder of this letter describes our concerns in greater detail and asks FDA to respond to a series of questions about the precertification program.

Statutory Framework for Precertification

FDA contends that "application of the FDA's longstanding regulatory framework to software can impede access to new and improved software-based medical products." Consequently, the agency is pursuing the development of "an agile regulatory paradigm," a "regulatory model more tailored than the current regulatory paradigm," and a program that can "provide more streamlined and efficient regulatory oversight" of software-based medical devices.[11]

These are worthy goals; however, the statutory basis for FDA's deployment of this more agile, tailored framework is unclear in several important respects. First, FDA's timeline aims to launch pilot testing of precertification by 2019, but the working model for the precertification program also states that FDA "will consider appropriate mechanisms for establishing the program within FDA's current statutory and regulatory authorities."[12] It is unclear from FDA's working model what specific statutory and regulatory authorities FDA is utilizing to conduct the precertification program or whether FDA anticipates needing new statutory authority to pre-certify entities outside of a pilot.

We are also particularly concerned that, as part of a set of "challenge questions" related to the development of the precertification program, FDA has asked for public feedback on whether there should be "phased market authorization" of a Software as a Medical Device (SaMD), in which "some elements are reviewed premarket and other elements are gathered through real world evidence to support full market authorization."[13] The challenge question document also refers to "phased market authorization" as "preliminary' market authorization." It is again unclear what statutory authorities FDA would rely on to establish a "phased market

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[11] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 5.

[12] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 3, 5.

[13] U.S. Food and Drug Administration, "Challenge Questions," https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM605686.pdf

authorization" program that allows SaMDs to be legally marketed without sufficient evidence to support full market approval. Notably, FDA has stated that conditional approval – a regulatory pathway for certain animal drugs that allows these products to be legally marketed for a period of time without meeting the "substantial effectiveness" standard while the company continues to collect efficacy data – is not appropriate for human medical products, including SaMDs.[14]

1. **The precertification working model states that FDA "will consider appropriate mechanisms for establishing the program within FDA's current statutory and regulatory authorities."[15]**

    a. **What statutory and regulatory authorities is FDA utilizing to conduct the Pre-Cert Pilot program?**

    b. **Does FDA anticipate needing new statutory authority to pre-certify entities outside of a pilot?**

    c. **How does FDA plan to communicate statutory needs to Congress? Does FDA plan to use the upcoming renewal of the Medical Device User Fee and Modernization Act (MDUFA V) to address these issues?**

2. **FDA does not have the authority to grant "preliminary" or "phased" approval of medical devices and has publicly stated that conditional approval pathways are not appropriate for human medical products.[16]**

    a. **Does FDA envision supporting "phased" approval of SaMDs?**

    b. **If so, when does FDA plan to submit this legislative proposal to Congress for consideration?**

    c. **If so, why does FDA now believe that a conditional approval pathway is appropriate for medical devices?**

Qualification for Precertification

FDA's goal in designing a precertification program for SaMDs is to "create a regulatory environment" that enables "timely access to technologies that are built by excellent organizations."[17] The working model and its accompanying challenge questions solicit extensive feedback on how to define and assess multiple dimensions of organizational "excellence." FDA

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[14] Letter from FDA Commissioner Gottlieb to Senator Murray and Senator Alexander, July 31, 2018.
[15] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 3.
[16] Letter from FDA Commissioner Gottlieb to Senator Murray and Senator Alexander, July 31, 2018.
[17] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 7.

acknowledges that "the underlying principles of the excellence appraisal need to be consistently interpreted and applied across industry." At the same time, FDA states a belief "that there should be flexibility in the specific mechanisms by which excellence can be demonstrated."[18] While it is entirely appropriate for FDA to solicit this feedback, we are concerned that the standards of excellence the agency is considering and the process for assessing this excellence may not establish sufficiently rigorous criteria for qualifying for a streamlined review.

FDA's view of the types of products and organizations eligible for precertification is extremely broad, raising questions both about how the agency will effectively determine excellence and about the conditions under which SaMDs developed by so-called "excellent" organizations would ever be subject to full review by FDA. FDA indicates that "all software that meets the definition of device" in the Federal Food, Drug, and Cosmetic Act could be eligible for precertification.[19] According to the June working model for the precertification program, even moderate or high-risk devices could be eligible for streamlined review if they were developed by a pre-certified company. Furthermore, FDA states that "any organization that intends to develop or market regulated software in the United States" could be eligible for inclusion in the precertification program.[20] This is a more expansive view of potential eligibility than was envisioned in FDA's April version of the working model, which proposed using past experience of successfully marketing and maintaining medical devices as an appropriate metric for demonstrating organizational excellence.

Finally, FDA envisions software developers being evaluated for eligibility for the precertification program "by FDA or an accredited third party." The use of third-party review to qualify companies for participation in the precertification program could mean that SaMDs could be legally marketed without FDA ever reviewing either the medical device software developed by a company or the company itself. FDA has not yet articulated the statutory authorities it would rely on to utilize third party review in this manner or identified circumstances where such review may be inappropriate.

3. FDA states that there should be "flexibility in the specific mechanisms by which excellence can be demonstrated."[21]

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[18] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 7.

[19] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 8.

[20] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 13.

[21] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 7.

a. **Who determines the most appropriate demonstration of effectiveness for a specific entity? The organization being evaluated or FDA?**

b. **What does FDA believe the limitations of flexibility should be?**

c. **Does FDA plan to define various mechanisms for demonstrating excellence? If so, how many?**

d. **What principles will FDA use to define appropriate mechanisms? What type of data or evidence would be appropriate – and inappropriate – to demonstrate excellence?**

4. **One of the stated program goals is to "[leverage] transparency of organizational excellence and product performance across the entire lifecycle of an SaMD."[22]**

   a. **Does "transparency" in this case refer to greater insight by FDA into companies and their products or to public transparency?**

   b. **How will FDA define whether companies have met the excellence principle of transparency with all stakeholders? What are the metrics by which adherence to this principle will be measured?**

5. **FDA anticipates pre-certifying at a business unit or center of excellence level, rather than a corporate level, and notes that the "boundaries of a 'business unit' should be clearly determined by the company itself prior to participating in the precertification process."[23]**

   a. **How does FDA view the differences between these levels of organizations, and how does it plan to define and limit a unit within a corporate entity that has several business divisions developing SaMD?**

   b. **How does FDA plan to oversee and enforce these boundaries?**

6. **FDA states its "belief that an organization of any size without a medical device or SaMD currently on the market should have the opportunity to deliver products for medical purposes as a pre-certified organization."[24]**

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[22] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 6.

[23] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 13.

[24] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018,

a. **What is the public health justification for that belief?**

b. **What is the agency's justification for proposing to apply a Level-1 precertification for an entity with no track record in developing SaMD?**

c. **Why has FDA not chosen to limit precertification eligibility to entities with demonstrated success in marketing medical devices?**

d. **When an entity applying for precertification has little or no track record with FDA, how does FDA propose to evaluate their capacity? What data or evidence will FDA collect in order to evaluate whether they remain in compliance with agency requirements?**

7. **FDA proposes utilizing third parties to conduct precertification assessments, meaning that FDA will not be reviewing all SaMD products, nor reviewing the entities themselves.**

    a. **What existing third party entities does FDA believe have the capacity and expertise to conduct such assessments?**

    b. **What statutory authority is FDA utilizing to allow third party review?**

    c. **Are there cases where FDA feels it would be inappropriate for a third party to conduct a review?**

    d. **Will FDA create a new third party accreditation program or rely on existing accreditation programs? Do existing accreditation programs have the expertise necessary to evaluate SaMDs?**

    e. **Will FDA conduct inspections or audits of third party organizations assessing SaMDs? If so, what funds will FDA use to support this work, and how many inspections or audits does FDA estimate conducting per year?**

8. **Pre-certified entities will qualify for streamlined or no pre-market review for an SaMD, even for an SaMD that is moderate or high-risk.**

    a. **Does FDA envision any product requiring a non-streamlined review?**

    b. **What is the public health justification for FDA to abandon its authority to conduct a full review for a high-risk product?**

9. **Who will review the definition statement and risk categorization framework definitions chosen by product developers to characterize their product?**

Effective Monitoring and Post-market Surveillance

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https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 19.

Precertification will likely be a powerful label in the market that signals to investors, customers, and patients that FDA has faith in the organization. This label should be leveraged to ensure the agency is receiving the information it needs to ensure these products meet statutory standards of safety and efficacy. A successful precertification program for digital health devices must ensure that the performance of such devices can be evaluated throughout the device's total product life-cycle. It also must be designed to effectively monitor the organizations that are afforded precertification status.

The June working model envisions that "maintaining Pre-Cert status would be automated," suggesting that this status does not expire or need to be renewed by FDA.[25] According to the working model, tracking and monitoring "adherence to the excellence principles" that qualify an organization for precertification would be performed not by FDA on an ongoing basis, but by "organizational leadership." In other words, software companies could be allowed to use an entirely self-policing review system in order to maintain a status that affords them valuable access to a streamlined review process, even for high-risk software and even if they have no prior experience marketing medical devices. This approach raises serious concerns about how FDA would ensure compliance with the goals and requirements of the precertification program.

FDA states that "excellent organizations [. . .] grow and evolve based on lessons learned from real-world usage of their products after they launch" and that they "consistently collect and analyze post-launch data from diverse sources."[26] FDA also indicates that "precertified organizations would demonstrate a robust program for [. . .] sharing analyses of such data with FDA." It is unclear, however, whether the precertification would require organizations to share this data, the specific types of data that would be shared, and whether other entities such as the National Evaluation System for health Technology (NEST) would have access to data from these organizations.

In its *Digital Health Innovation Action Plan,* FDA linked the success of the Pre-Cert Pilot with the development of NEST, a collection of electronic health records, clinical registries, billing claims, and other data that FDA anticipates will be up and running by 2019.[27] Firms engaged in the pilot, FDA notes, "could collect real-world data post-market that might be used [. . .] to affirm the regulatory status of the product, as well as to support new and evolving product functions"—a stepping stone that would allow them to "take advantage of [NEST]" upon NEST's completion.[28]

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[25] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 19.

[26] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 29.

[27] Scott Gottlieb, M.D., "Fostering Medical Device Innovation: A Plan for Digital Health Devices," June 15, 2017, https://blogs.fda.gov/fdavoice/index.php/2017/06/fostering-medical-innovation-a-plan-for-digital-health-devices/.

[28] U.S. Food & Drug Administration, *Digital Health Innovation Plan* (2017) (online at https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/UCM568735.pdf).

However, the first pre- and post-market NEST pilots mandated under MDUFA IV and the FDA Reauthorization Act of 2017 are not due to begin until 2019 and August 2018, respectively, and will not be evaluated until the end of this user fee cycle. Given NEST's infancy, we are concerned about its readiness to support the type of hands-off approval and clearance process FDA is proposing for SaMDs.

10. **How does FDA propose to evaluate whether the reported intended medical purpose of SaMD is really the intended medical purpose and continues to be the purpose once a product is being used on the market?**

11. **What is the public health justification for not allowing an entity's precertification to expire and establishing a recertification or maintenance process?**

    a. **Why is an entity put in charge of monitoring its own adherence?**

    b. **What is the precedent for FDA to rely on self-monitoring of this sort?**

    c. **Will FDA be conducting inspections and audits to assure compliance? If so, what funds will FDA use to support this work, and how many inspections does FDA estimate conducting per year?**

12. **FDA expects that program participants "would demonstrate a robust program for [. . .] sharing analyses of such data with FDA."[29] However, the working model does not appear to require pre-certified organizations to share such data with FDA.**

    a. **Does FDA plan to require organizations to share data with FDA? If not, why not?**

    b. **With what other entities does FDA believe participants should be obligated to share data?**

    c. **Will precertification require sharing information with the NEST or another public entity? If not, why not?**

    d. **Will FDA allow the use of proprietary systems or require sharing using interoperable systems to encourage information sharing in the industry?**

    e. **If data sharing by program participants is optional, what incentives exist for companies to share this information?**

13. **How does FDA view the difference between real world performance analytics (RWPA) and real world evidence (RWE) in supporting preclinical product**

[29] U.S. Food and Drug Administration, "Developing Software Precertification Program: A Working Model (v0.2 – June 2018)," June 2018, https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM611103.pdf, p. 29.

clearance and post-launch product modification claims?

14. **We appreciate that FDA speaks to the need for an iterative learning process regarding the parameters of a RWPA framework; however, regulated entities need to have clear rules of the road. When does FDA expect the iterative process to end and the active regulatory compliance work to begin?**

15. **Does FDA view the precertification program as way to apply the least burdensome principle to SaMD review? If so, why does FDA believe it is necessary to reconsider the least burdensome standard in the collection of RWPA within the precertification program?**

16. **What other postmarket surveillance mechanisms does FDA plan to use to assess SaMDs, other than NEST? Does FDA plan to mandate postmarket studies? How frequently does FDA plan to require submissions of adverse event reports from precertified entities?**

17. **Please provide an update on the current status of the NEST system, including the pre-market pilots mandated by the MDUFA IV letter and post-market pilots required by FDARA.**

FDA Capacity to Oversee Digital Health Products

FDA conducts ongoing oversight and compliance work related to digital health products that go beyond efforts to develop the precertification program. Although the Center for Devices and Radiological Health (CDRH) is taking the lead in the agency's digital health work, other centers within FDA are also engaged in issues and overseeing products with software components.

There is bipartisan support for FDA's oversight and compliance efforts, as evidenced by report language in the 2019 Senate agricultural appropriations bill, which states that the Appropriations Committee is "supportive of FDA efforts to increase oversight and enforcement over digital health products to assure that they are compliant with the appropriate regulatory frameworks.[30] However, we have been unable to locate any public records of FDA issuing a Form 483 – issued to firms when an inspector observes potential violations of the Federal Food, Drug, and Cosmetic Act – to a software company during 2017. This raises questions regarding whether FDA is indeed carrying out robust oversight of such firms.

Finally, FDA's plan to create a precertification program for software developers open to any organization and a wide range of SaMDs will have implications for the revenue available to

[30] Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2019, S.Rept.115-259, https://www.congress.gov/115/crpt/srpt259/CRPT-115srpt259.pdf. *Digital Health Products.*-The Committee is encouraged by the FDA's efforts to implement section 3030 of the 21st Century Cures Act regarding low-risk medical software and launch of the Digital Health Software Precertification [Pre-Cert] Program to learn from software developers about their products and quality processes. The Committee believes that digital health technologies are extremely promising and that consumers should have assurances that the products work as claimed. The Committee is supportive of FDA efforts to increase oversight and enforcement over digital health products to assure that they are compliant with the appropriate regulatory frameworks.

FDA to support its work on digital health. Current user fee programs are designed – and user fees are collected – based on the applications and approvals of individual products, not the pre-designation of organizations that could maintain an automatically-renewing certification of excellence allowing them to bypass certain FDA review processes. If FDA intends to implement such a program beyond the pilot phase, this structure could reduce the amount of revenue available to support FDA work or require the development of new user fee programs specific to digital health.

18. **It is clear that CDRH is making major efforts to address the rapidly evolving digital health sector efforts. However, cross-center efforts are less clear.**

    a. **Who is coordinating digital health regulatory policy across FDA?**

    b. **Who is leading digital health regulatory policy in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER)?**

    c. **What work is being conducted in CDER to address clinical trial data generation through software and digital health products?**

    d. **What formal or informal guidance exists for drug developers on how to employ digital health technologies in the clinical drug development process?**

19. **How is FDA currently monitoring the software landscape to assure that SaMDs are compliant with medical device regulations?**

    a. **How many compliance staff at CDRH are dedicated to software, and what roles do these staff perform? How many compliance staff at CDER are dedicated to software, and what roles do these staff perform? How many compliance staff at CBER are dedicated to software, and what roles do these staff perform?**

    b. **Does FDA plan to modify the scope of its compliance work related to SaMDs in the future?**

20. **Does FDA propose user fees be associated with obtaining a precertification?**

    a. **How does FDA plan to fund the post-approval clearance or post-marketing activities of precertified products that are not reviewed or cleared, given that current user fees are statutorily precluded from supporting that work?**

    b. **Does FDA plan to submit a budget request or negotiate a new fee structure related to these products in MDUFA V?**

21. **How does FDA plan to financially support iterative review of product-specific regulatory information throughout the development process? How does the agency plan to meet current MDUFA goals with these additional review processes?**

Conclusion

FDA has outlined an ambitious set of goals for establishing a precertification program for SaMDs. We appreciate that FDA continues to gather stakeholder input on the design of this program; however, we have a number of concerns with the vision of the program laid out over the past year.

We request answers to the questions in this letter no later than November 9, 2018. Please do not hesitate to contact Beth Pearson in Senator Warren's office, Elizabeth Letter in Senator Murray's office, or Beth Wikler in Senator Smith's office with any questions or concerns.

Sincerely,

Elizabeth Warren
United States Senator

Patty Murray
United States Senator

Tina Smith
United States Senator