ConnectedHealthInitiative

March 9, 2022

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Commissioner Califf:

The Connected Health Initiative (CHI) congratulates you on your recent confirmation as Commissioner of the U.S. Food and Drug Administration (FDA). CHI is driven by a diverse steering committee that spans the digital health community and represents a broad consensus of healthcare and technology leaders who seek a policy environment that responsibly welcomes new digital health tools and services into the care continuum. Specifically, we encourage the use of connected health innovations such as remote patient monitoring and support improvements in patient and consumer health. Leveraging such tools are also critical in meeting the Administration's priorities, such as reducing disparities in healthcare.

As FDA Commissioner, you have the opportunity to advance the agency's patient safety mandate through enabling the responsible use of cutting-edge digital health tools. CHI is committed to work with you to improve FDA's policies and processes, bringing new and more efficacious medical devices into the marketplace to benefit countless American patients. The FDA's approach to emerging technologies will also continue to influence the wider healthcare ecosystem that is working to shape new coverage policies, developing clinical practice guidelines, and pioneering new software-driven medical tools that save lives.

As you shape the agenda for your administration, CHI encourages you to take several actions that will provide a pathway for the benefits of connected health tools to be realized by clinicians and patients throughout the care continuum while also enhancing patient safety. We offer the following recommendations for your consideration:

- **Support the Digital Health Center of Excellence:** CHI supports the creation of the FDA's Digital Health Center of Excellence (CoE) as the central place within the agency for the advancement of digital health technology such as mobile health devices, software as a medical device (SaMD), wearable medical devices, and technologies used to study medical products. We urge you to prioritize the Digital Health CoE as it continues to build capacity and expertise.

Digital health policy is most appropriately dealt with by the Digital Health CoE with Center for Devices and Radiological Health's (CDRH). CHI, therefore, remains concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the Prescription Drug-Use-Related Software (PDURS) that departs from the CDRH work to modernize the FDA's approach to the regulation of SaMD. We recommend that PDURS policy development be primarily led by the Digital Health CoE to ensure alignment with the widely-supported approach developed by CDRH for SaMD.

- **Improve the Medical Device Regulatory Process While Protecting Patient Safety:** CHI commends the FDA's risk-based approach to the regulation of medical devices. Specifically, CHI applauds the FDA's use of enforcement discretion for low-risk devices. We support the FDA pursuing all opportunities to modernize and streamline the medical device approval process, particularly for SaMD. For Americans to benefit from the latest advancements in medical devices, there must be enhancements to the FDA's approval process so there is a reduction in time-to-market while still ensuring patient safety and caregiver trust. The FDA has made significant progress in crafting the Software Pre-Certification Pilot Program (in which CHI members participate) based on extensive public input at multiple stages, public workshops, and the experiences from the pilot program. It is essential that the FDA continue to support and build on its significant investment in this important effort under your administration, laying the groundwork for a full Software Pre-Certification Program. CHI commits to support you moving the Software Pre-Certification Pilot Program forward in order to effectively and responsibly speed time-to-market for trusted developers of SaMD.

  CHI also commends FDA's continued development of digital health-related guidance documents and urges for continued consultations with impacted stakeholders as they are developed.

- **Deliver the Promise of Artificial Intelligence and Machine Learning-Enabled Technology to American Patients:** Artificial/augmented intelligence (AI) and machine learning (ML), powered by streams of data and advanced algorithms, have incredible potential to improve healthcare, prevent hospitalizations, reduce complications, and increase patient engagement. Yet, applications of AI in healthcare have also given rise to a variety of potential challenges for policymakers to consider, including quality assurance, adaptiveness, ethics, oversight, notice/consent, and data bias. The FDA must take a leading role in responsibly bringing AI medical devices to the marketplace, and we support FDA's continued leadership to develop a governance framework for AI meeting the definition of a medical device under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

  As part of its commitment to responsibly advance AI in healthcare, CHI has assembled a Health AI Task Force consisting of a range of innovators and

thought leaders. CHI's AI Task Force has developed a range of resources, including a position piece supporting AI's role in healthcare, a set of principles addressing how policy should approach the role of AI in healthcare, and a terminology document targeted at policymakers.[1] Even more recently, CHI's AI Task Force has developed good machine learning practices, specifically for AI development and risk management of AI meeting FDA's definition of a medical device,[2] as well as recommendations on ways to improve transparency for caregivers, patients, and others necessary for the appropriate uptake of AI tools across the care continuum.[3] We urge FDA to build on these digital health community consensus recommendations, and to directly address the role of AI in new standalone guidance providing a scalable, risk-based approach be taken when handling regulatory and enforcement discretion.

- **Fully Leverage Real-World Data (RWD) and Real-World Evidence (RWE) in FDA Processes and Decision-Making:** CHI stands in agreement with the FDA's public acknowledgement that RWD and RWE can and should play an important role in the FDA's efforts to address patient protection at the supplemental phase, monitor post-market safety and adverse events, and to make regulatory decisions. CHI members widely use RWD and RWE to support product design, clinical trials, and studies to innovate. The use of RWD and RWE has been critical to the response to the ongoing public health emergency. We encourage FDA to fully leverage this important data by engaging our members in its processes, particularly in the supplemental and post-market phases. Noting our appreciation for FDA's ongoing efforts with respect to RWD and RWE, FDA should prioritize widespread changes to processes and policies when it comes to using RWD and RWE to make timely informed decisions.
- **Advance Interoperable Data Exchange:** CHI supports FDA's efforts to ensure the safe, secure, and effective exchange using de-identified data between devices, products, technologies, and systems. We believe that FDA can and should lead in collaborative efforts addressing medical device interoperability between all stakeholders through collaboration with other federal agencies.
- **Continue the Development of Cybersecurity Best Practices for Medical Devices:** CHI supports FDA's continued efforts to guide medical device makers in addressing the cybersecurity threats faced by SaMD and software in a medical device (SiMD). We commend FDA's efforts to encourage the timely sharing of threat indicators between both the public and private sector so that new threats may be addressed rapidly and effectively. We encourage you to continue this

[1] The CHI Health AI Task Force's deliverables are accessible at https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/.

[2] CHI's good machine learning practices are available at https://bit.ly/3gcar1e.

[3] CHI's recommendations on necessary policy changes to enhance transparency for healthcare AI are available at https://bit.ly/3Gd6cxs.

work while ensuring that the distribution of critical security updates is not delayed by overly burdensome reporting requirements.

- **Maintain International Digital Health Policy Leadership:** CHI supports FDA's ongoing efforts to address emerging technology issues with other regulators[4] and within the International Medical Device Regulatory Forum (IMDRF), producing important frameworks for regulatory approaches that utilize a risk-based and scalable approach (such as the IMDRF's *Software as a Medical Device (SaMD): Clinical Evaluation*[5]). As our members' new technologies begin to enter regulatory processes, FDA's leadership in correlating this arena to existing domestic law and regulation is needed more than ever. We encourage you to continue the FDA's engagement in the IMDRF, and for FDA to clarify IMDRF guidance and positions where consistent with U.S. law.

CHI also appreciates FDA's commitment to driving innovation and patient protection by leveraging the public-private partnership model and welcomes such engagement. For example, we welcome FDA's participation in a new CHI dialogue on digital health and quality assurance aimed at bringing the ecosystem closer together in responsibly advancing the use of connected digital health tools, which will also feature digital health innovators, providers, payors, and patients that will share needs and expectations about new digital health technologies and what needs to be demonstrated to drive adoption in health systems and plans.

[4] *E.g.*, https://www.fda.gov/news-events/press-announcements/fda-brief-fda-collaborates-health-canada-and-uks-mhra-foster-good-machine-learning-practice.

[5] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf.

Digital health tools and services are essential to improving healthcare for all Americans while reducing rising healthcare costs. We appreciate your attention to these requests and look forward to collaborating on these vital issues. We welcome the opportunity to discuss our views in more detail.

Sincerely,

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