ConnectedHealth

January 17, 2019

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

Dear Commissioner Hahn:

ACT | The App Association's 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, our advocacy encourages the use of connected health innovations such as remote patient monitoring and supports improvements in patient and consumer health. Our members' products enable the American healthcare system to deliver high quality care at lower costs, supporting American economic prosperity and job creation.

As FDA Commissioner, you have the opportunity to advance the Agency's patient safety mandate through enabling the responsible use of cutting-edge connected health tools. CHI is committed to work with you to improve FDA's policies and processes through key guidance documents and proposed regulation. As a result, this will bring new and more effective medical devices into the marketplace, which benefits countless American patients. Further, the FDA's approach to emerging technologies will 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. We offer the following recommendations for your consideration:

- **Protect Patient Safety and Improve the Medical Device Regulatory Process.** CHI commends the FDA's risk-based approach to the regulation of medical devices. Specifically, the CHI applauds the FDA's use of enforcement discretion for low-risk devices. We support the FDA pursuing any and all opportunities to modernize and streamline the medical device approval process, particularly for

software as a medical device (SaMD), as well as medical devices that utilize software and internet connectivity. As an example, CHI recently shared comments with FDA on the Clinical Decision Support (CDS) Software Draft Guidance. We support FDA's attempt to clarify CDS but offered substantive feedback on the agency's reliance on the International Medical Device Regulators Forum and our belief that FDA should further clarify terms associated with device CDS intended for healthcare professionals, and patient decision support (PDS). 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 can be reduced while still ensuring patient safety and caregiver trust. The FDA has made incredible 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.

- **Lead the Charge to Bring the Promise of Artificial and Augmented Intelligence-Enabled Technology to American Patients.** Artificial/augmented intelligence (AI), powered by streams of data and advanced algorithms, has 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 U.S. policymakers to consider including quality assurance, adaptiveness, ethics, oversight, notice/consent, bias, and other concerns. The FDA must take a leading role in standardizing what software capabilities fit the criteria of AI and responsibly bringing locked AI medical devices to the marketplace. Currently healthcare AI systems may inform real-world workflow and evidence, reflect human-centered designs, contain usable principles, and provide for end-user needs to facilitate the "Quadruple Aim."[1] However, policymakers should begin to address the role of AI in healthcare. CHI's AI Task Force developed a set of healthcare AI policy principles[2] that addresses the range of opportunities and challenges associated with AI in healthcare and propose the appropriate role of government regulations. CHI urges the FDA 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. Industry, and software developers in particular, will benefit from the FDA directly addressing AI and machine learning in this proposed guidance.

[1] https://www.ama-assn.org/system/files/2018-11/playbook-resources-step-3-quadruple-aim-value.pdf.

[2] https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf.

- **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 monitor post market safety and adverse events, as well as to make regulatory decisions. CHI members widely use RWD and RWE to support product design, clinical trials, and studies to innovate. We encourage FDA to fully leverage this important data by engaging our members in its processes. Noting our appreciation for the 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.
- **Revisit the FDA's Proposed Approach to Prescription Drug-Use-Related Software (PDURS).** CHI remains concerned with the Center for Drug Evaluation and Research's (CDER) proposed approach to the Prescription Drug-Use-Related Software (PDURS) in Draft Guidance,[3] which would depart from the Center for Devices and Radiological Health's (CDRH) work to modernize the FDA's approach to the regulation of SaMD. For example, CDER's approach to PDURS would take a situation-based approach, as opposed to the CDRH's risk-based approach to SaMD. Further, CDER's proposed approach to PDURS would expose software developed by a drug company to significantly longer approval timeframes, placing PDURS at an arbitrary disadvantage to SaMD overseen by CDRH. We recommend that the FDA's approach to PDURS be brought into alignment with its widely-supported approach developed by CDRH for SaMD.
- **Continued Leadership in the International Medical Device Regulatory Forum.** CHI supports FDA's efforts to ensure the safe, secure, and effective exchange and use de-identified data between devices, products, technologies, and systems. We believe that the FDA can and should lead in collaborative efforts addressing medical device interoperability between all stakeholders.
- **Continued Leadership in the International Medical Device Regulatory Forum.** CHI supports FDA's ongoing efforts to address emerging technology issues within the 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*[4]). As our members' new technologies begin to enter regulatory processes, the 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 the FDA to clarify IMDRF guidance and positions where consistent with U.S. law.

[3] *Prescription Drug-Use-Related Software; Request for Comment*, U.S. FOOD & DRUG ADMIN., 83 Fed. Reg. 58574 (Nov. 20, 2018).

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

Connected 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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