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BY ELECTRONIC SUBMISSION

Re: Consumer Technology Association Public Comments in Response to Request for Feedback on Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning Based Software as a Medical Device Discussion Paper

Dear Bakul:

The Consumer Technology Association (CTA™) appreciates the opportunity to submit comments in response to the Food and Drug Administration (FDA) Request for Feedback to assist FDA in identifying an appropriate framework for modifications to artificial intelligence/machine learning (AI/ML) based software as a medical device (SaMD).¹

CTA™ is the trade association representing the \$398 billion U.S. consumer technology industry, which supports more than 18 million U.S. jobs. Over 2,200 companies – 80 percent of which are small businesses, startups, and others among the world’s best-known brands – enjoy the benefits of CTA™ membership including policy advocacy, market research, technical education, industry promotion, standards development, and the fostering of business and strategic relationships. CTA™ also owns and produces CES® – the world’s gathering place for all who thrive on the business of consumer technologies. Profits from CES® are reinvested into CTA™ industry services. At CES®, CTA hosts two digital health-related events. The first is the Digital Health Summit, a two-day showcase spotlighting the role technology plays in advancing and reforming medicine, health care, and wellness. The second is the Disruptive Innovations in Health Care Conference, a first-in-kind CME-

¹Docket ID: [FDA-2019-N-1185](https://www.fda.gov/oc/foia/FDA-2019-N-1185) (Posted April 2, 2019) [hereinafter Discussion Draft], last accessed June 3, 2019.

accredited conference aimed at clinicians which focuses on the latest technology innovations that are creating solutions for patient care.

On the policy front, CTA's™ Health and Fitness Technology Division strives to advance the use of consumer-based technology enabled health solutions to deliver better health outcomes and reduce overall health care cost. The Division, which includes some of the most well-respected thought leaders in the health care and technology sectors, oversees and provides CTA™ members with policy advocacy, health care market research, and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

Unlike most trade associations, CTA™ is accredited by the American National Standards Institute (ANSI) as a Standards Development Organization (SDO), and we have long history of voluntary national standards development. Among the wide range of topics addressed by our standards program are health, including fitness & wellness, video, and drones. Both CTA™ members and non-members can participate in the standards program. Just as significantly, CTA™ partners with other standards developers and organizations to develop joint documents and information sharing.

Over the past year, CTA™ has taken a proactive role in informing industry and promoting collaboration regarding AI in health care issues through the work of the Division Board and other CTA™ internal groups. In May 2017, we convened the AI Advisory Group under CTA's™ Technology Council, to oversee and help direct the technical direction of AI work within CTA™. As part of these efforts, in September 2018, CTA™ published, "What is Artificial Intelligence?", analyzing the definition, meaning and importance of cognitive technologies and their adoption in industry.² In November 2018, CTA™ published a companion document, "Use Cases in Artificial Intelligence. Understanding the Application of AI Across a Range of Industries," detailing AI's application in a range of industries and use cases, including health care.

Our work on the AI front convinced us that there was a gaping need for standards and guidelines regarding AI for both clinicians and consumers. As a result, earlier this year, more than 30 organizations – from major technology companies to health care industry leaders – joined forces to form a new initiative convened by CTA™ on AI in health care.³ The effort will serve as a platform for stakeholders across the tech and health care sectors to develop: (1) common terminology; (2) an analysis of what constitutes trustworthiness for AI in health care; and (3) develop best practices

²<https://www.cta.tech/News/Press-Releases/2018/October/All-About-AI-%E2%80%93-New-CTA-White-Paper-Explores-Cogn.aspx>, last accessed June 3, 2019.

³<https://www.cta.tech/News/Press-Releases/2019/April/CTA-Brings-Together-Tech-Giants,-Trade-Association.aspx>, last accessed June 3, 2019.

for data stewardship. The group aims to ultimately enhance health outcomes, improve efficiencies, and reduce health care costs while considering topics such as trustworthiness, ethics, and bias.

ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING TECHNOLOGIES

Advancements in artificial intelligence (AI) and machine learning (ML) promise to be transformational. Health care-related consumer technologies are integrating natural language processes, medical recognition, and algorithmic data analytics into everyday products and applications. Today, an average consumer smartphone has more computing power than Apollo 11 did when it reached the moon in 1969, or Voyagers 1 and 2 had combined.⁴ As a result, for example, a virtual assistant loaded onto a smartphone can facilitate a variety of health care functions for a patient or caregiver. Whether assisting a person to access sensitive personal health care data, easing the uploading of patient-generated images or videos to an electronic health care record (EHR), or enabling a telehealth video consult from virtually anywhere at any time – AI is beginning to understand contextual information from a person’s interactions and automate future services like never before.

CTA’s™ white paper on use cases for artificial intelligence provided a great example of an AI use case in the health care context. CarePredict, an AI-driven digital health company focused on seniors, has developed an integrated solution consisting of a wearable device, smart remote sensors, and a deep learning platform to provide insights around seniors’ health. The wearable collects data autonomously that today is normally only observable by a human. Machine Learning and unique kinematics algorithms are used to quantify activities performed by the human body such as drinking, eating, sleeping, walking, bathing, etc. These unique and rich data sets are used to train the deep learning neural nets to surface insights like self-neglect due to depression, unusual toileting patterns due to a urinary tract infection, or increased fall risk due to malnutrition, lack of rest, and dehydration. These insights are generated without any self-reporting by the senior. The power of these unique data sets coupled with AI essentially provides a 24/7 net of continuous observation for the senior – giving caregivers great insight regarding the evolving health of the senior.⁵

As FDA continues to clear and subsequently approve AI/ML-based SaMD devices intended for use in medical practice and by health care professionals, we appreciate the Agency’s outreach to request

⁴<https://insights.samsung.com/2018/08/09/your-phone-is-now-more-powerful-than-your-pc/>,
https://www.nasa.gov/mission_pages/voyager/multimedia/vgrmemory.html#.XNg8SaQpBPY, last accessed June 3, 2019.

⁵<https://www.cta.tech/News/Blog/Articles/2018/October/This-Digital-Health-Company-is-Using-AI-to-Improve.aspx>, last accessed June 3, 2019.

public feedback regarding its regulatory approach. CTA™ recognizes the need to address complex issues associated with the use and application of AI solutions in health care. As AI and ML continue to proliferate into everyday consumer technologies and clinical practice, CTA™ is committed to drive industry consensus and standardization on definitions and characteristics of AI. It is through CTA's™ role as a convener that we offer the comments below for FDA's consideration.

GENERAL COMMENTS

The Discussion Draft Should Rely on a Broader, Richer, Timelier Group of Sources

FDA seemingly relies upon a single source from 2007 regarding the science and engineering associated with making intelligent machines and intelligent computer programs. With so many advancements over the past twelve years in computer processing power and the massive amounts of data accumulated, we encourage FDA to expand its sources. In the past few years alone, there have been a variety of robust health care AI-related efforts seeking to define “artificial intelligence,” as well as its computational sources, subsets, parameters, outputs, boundaries, trustworthiness, biases, market segments, and the ethics in this exciting space.

CTA's™ AI initiative participants and Staff are actively participating in and tracking other aligned efforts such as the Xavier Health Continuous Learning Systems Working Group, International Standards Organization JTC1 SC42 (AI standardization effort), IEEE (P2801 quality management of AI, and P2802 safety of AI), numerous international regulatory guidance development efforts by governments in China, Korea, and Japan, the App Association's Connected Health Initiative dialogue on AI, Partnership for Artificial Intelligence, Automation and Robotics in Healthcare (PATH HEALTH), the International Telecommunications/World Health Organization AI4H (AI for Health initiative), and augmented intelligence policy development efforts by the American Medical Association.⁶ We strongly encourage FDA to consider as many viewpoints and authorities as possible in their definitions of key terms such as “AI,” “ML,” and other subsegments of the science supporting these technologies.

⁶<https://www.xavierhealth.org/xavierai>, <https://www.iso.org/committee/6794475.html>, <https://www.itu.int/en/ITU-T/AI/Pages/default.aspx>, <https://www.mhlw.go.jp/content/11123000/000335173.pdf>, <https://www.cmde.org.cn/CL0004/18639.html>, https://www.mhlw.go.jp/stf/shingi2/0000213176_00008.html, https://www.mhlw.go.jp/stf/shingi/otherkousei_408914_00001.html, <https://www.iso.org/committee/6794475.html>, <https://www.techrepublic.com/article/ieee-announces-3-ai-standards-to-protect-human-well-being-in-the-robot-revolution/>, <https://actonline.org/2019/02/06/why-does-healthcare-need-ai-connected-health-initiative-aims-to-answer-why/>, <https://pathhealth.com/>, <https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx>, [AAMI/BSI/ https://www.ama-assn.org/amaone/augmented-intelligence-ai](https://www.ama-assn.org/amaone/augmented-intelligence-ai), last accessed June 3, 2019.

Given the breadth and diversity of the stakeholders involved in CTA's™ AI in health care workgroup, and the fact that we are ANSI-accredited, and, therefore, can develop voluntary national consensus standards, we invite FDA to join CTA's™ AI in health care workgroup. Participation by FDA would enrich the dialogue for all parties involved. The group meets regularly and has had active dialogue with other federal agencies that have pledged interest and support for the initiative.

Reliance on Untested Regulatory Proposals

The concept of the total product lifecycle (TPLC) and its regulatory approach is one borrowed from FDA's Software Precertification Pilot Program (Pre-Cert) where FDA seeks to facilitate a rapid cycle of product improvement for SaMD. At a minimum, the Pre-Cert Program seeks to develop a tailored, pragmatic, and least burdensome regulatory oversight structure to assess organizations that establish trust with FDA. Trust would be demonstrated through capabilities based on a culture of quality and organizational excellence. The program targets entities who meet or exceed existing FDA standards of safety and effectiveness to build, test, monitor, and proactively maintain and improve the safety, efficacy, performance, and security of their medical device software products. Such entities proving organizational excellence will be assumed to develop reliable SaMD products with top performance across the entire lifecycle of development through a proven and robust TPLC, and in turn be rewarded with a streamlined premarket review and a unique postmarket method to verify the safety, effectiveness, and performance of their SaMD while in commerce.

What is unclear is how TPLC as envisioned in Pre-Cert, would be applied to entities developing AI/ML technologies who are not participating in the Pre-Cert Pilot program. It is also unclear how TPLC which is currently theoretical and aspirational, would work in practice. Aspects such as real-world performance (RWP) monitoring and performance analytics as described in the Pre-Cert Pilot Program, are still conceptual. Many of CTA's™ members have expressed concern over how daunting an endeavor that may be to adequately implement – both from the perspective of the petitioning entity and by FDA. Issues such as personnel, systems implementations, and security, are serious considerations, and FDA's ability to oversee RWP given its own resource constraints and lack of technical capabilities raise serious questions. Further complicating the proposed pathways, both the Pre-Cert Working Model and the AI discussion draft describe how these innovative approaches for software may admittedly “require additional statutory authority to implement fully.” FDA has stated it intends to implement these TPLC approaches using current authorities, and we urge FDA to primarily focus on what the agency is statutorily authorized to implement.

CTA™ ANSWERS TO FDA'S QUESTIONS

- Do these categories of AI/ML-SaMD modifications align with the modifications that would typically be encountered in software development that could require premarket submission?

CTA™ Response: As stated, FDA's AI discussion draft serves the purpose of eliciting stakeholder feedback on general categories of AI/ML SaMD modifications encountered in software development. Should final AI/ML guidance ever be created, FDA must clarify whether the AI/ML guidance will be a supplement to existing and established FDA guidance such as Deciding When to Submit a 510(k) for a Software Change to an Existing Device.⁷ This will help determine whether the existing categories of AI/ML SaMD modifications align or need to be further elaborated upon.

- What additional categories, if any, of AI/ML-SaMD modifications should be considered in this proposed approach?

CTA™ Response: FDA states that to date it has cleared or approved several AI/ML based SaMD that are “locked” (i.e., not autonomous and produce consistent outputs), as opposed to “unlocked” algorithms that are autonomous, can adapt over time and continuously learn from real-world experience (i.e., adaptive algorithms can produce varying outputs). These continuously learning, autonomous, and adaptive AI/ML algorithms created by highly iterative technologies will theoretically benefit from an untested TPLC, that facilitates rapid product improvements based on real-world evidence. It is unknown how adaptive technologies will impact patient experience, caregiver involvement, and professional and clinical practice. Understandably, we don't yet fully know the complexity or rapidity of software modifications for “unlocked” adaptive AI/ML SaMD. FDA needs to consider a thoughtful yet nimble approach to allow for additional software modification categories as necessary for adaptive “unlocked” AI/ML SaMD.

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device>, last accessed June 3, 2019.

- **Would the proposed framework for addressing modifications and modification types assist the development AI/ML software?**

CTA™ Response: Yes, albeit the proposed framework addresses device software modifications differently than typical design controls. FDA needs to reconcile how this approach will fit in with, and impact, existing quality systems for regulated products as well as Agency guidances.

- **How do manufacturers and software developers incorporate GMLP in their organization?**

CTA™ Responses to GMLP (broadly): As part of any medical device manufacturing, specification development, and SaMD production, the requirement to implement and follow good software practices are comprehensive and include aspects such as verification and validation (among other metrics) that are required by FDA.⁸ In addition, GMPL may consider areas such as data management, unintended data bias, active feedback, performance improvement, data integrity, and variability in data standards (a topic of interest being developed by CTA and it's multi-stakeholder initiative). We urge and welcome FDA to join CTA's™ AI in health care initiative to discuss these evolving topics.

- **What additional level of detail would you add for the described components of an ACP?**

CTA™ Responses to SPS and ACP (broadly): CTA™ proposes to work with FDA to develop several examples representative of how industry, the health care community, medical societies, caregivers, and patients best inform appropriate elements for the SPS, ACP, and additional components as needed.

- **What role can real-world evidence play in supporting transparency for AI/ML-SaMD?**

CTA™ Response: As SaMD sophistication improves, manufacturers and software developers will need to continue to use real-world evidence, including adverse events, reported device malfunctions and other consumer feedback to inform potential improvements to the SaMD. Important modifications to a product's intended use or functionality would be clearly

⁸ See 21 C.F.R. § 820.

communicated to consumers and patients as appropriate, particularly those that could affect device effectiveness or safety.

- What additional mechanisms might be needed for real-world performance monitoring of AI/ML-SaMD?

CTA™ Response: As user sophistication of SaMD products improve, reactions from patients and consumers and associated feedback may become an invaluable tool for manufacturers and software developers.

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CTA™ thanks FDA for the opportunity to comment, and we welcome discussing these issues in more depth. As discussed above, CTA™ would like to invite FDA to participate in its AI in health care initiative in any capacity the agency sees fit. FDA’s involvement would be invaluable for all parties involved, most importantly, the broader AI community. In the meantime, if you have any questions, please do not hesitate to contact us.

Respectfully submitted,

Consumer Technology Association

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