November 26, 2021

Via Docket Submission

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Notice to Public of Website Location of CDRH Fiscal Year 2022 Proposed Guidance Development
Docket No. FDA-2012-N-1021-0072

Dear Dockets Management Staff,

On behalf of the Digital Therapeutics Alliance (DTA), we are pleased to submit the below comments related to the Food and Drug Administration's "Notice to Public of Website Location of CDRH Fiscal Year 2022 Proposed Guidance Development," published by the FDA on October 26, 2021.

DTA is a global non-profit trade association of industry leaders and stakeholders with the mission of broadening the understanding and adoption of digital therapeutics (DTx) into healthcare. We work across numerous geographic regions to enable expanded access to high quality, evidence-based digital therapeutics for patients, clinicians, and payors to improve clinical and health economic outcomes.

As the FDA continues to provide crucial guidance to the industry related to new technologies coming to the market and next steps related to the Covid-19 pandemic, DTA appreciates the work that staff members within the Center for Devices and Radiological Health (CDRH) are undertaking to publish critical guidance documents in FY2022.

Reliable Access to Digital Therapeutics

Specifically related to the **A-list** (prioritized guidance documents the FDA intends to publish during FY2022), DTA reaffirms that the development of the draft guidances, "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," and "Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," are given high priority in FY2022.

The FDA issued the guidance, "Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," (EUA) in April 2020 to help expand the availability of digital therapeutic devices for psychiatric disorders to facilitate consumer and patient use, while reducing user and healthcare provider contact and potential exposure to Covid-19 during the pandemic. This policy is intended to remain in effect for the duration of the Covid-19 public health emergency, as declared by the Department of Health and Human Services (HHS).

A significant number of patients with behavioral and mental health conditions now have reliable access to DTx therapies through this EUA. It is therefore critical that next steps related to this guidance are well-designed – including extending key components of the current EUA through the remainder of this pandemic and ensuring that reliable access to safe, effective DTx products remains open through the post-pandemic period. These actions will help alleviate the ongoing impacts of the current mental health crisis, in addition to supporting and supplementing the significant demand for mental health care that is exceeding presently available professional resources.

The use digital therapeutics has already impacted adolescent depression, for example, during the current pandemic period and will continue to do so post-pandemic, should the Agency allow.

Over the past year, it has become clear that the psychological impact of the pandemic will persist long beyond any future official declaration of the pandemic ending. Indeed, during the pandemic, psychiatric conditions such as depression, anxiety, and substance use, as well as suicidality and suicide attempts have increased at an alarming rate, especially among America's youth, whereby emergency departments and acute hospital beds are inundated with children experiencing these conditions. The situation has become so dire that The American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, and the Children's Hospital Association in recognition of the pandemic's intensification of the mental health crisis, issued a joint declaration of a "National State of Emergency in Children's Mental Health".

In the case of adolescent depression, under the April 2020 EUA, safe and effective digital, non-pharmacological therapies are now available across the nation for patients, caregivers, and clinicians to use. Since their launch, digital therapeutics have received resounding support and adoption from providers who are eager to incorporate this therapeutic modality into their treatment programs. DTx products are also offering instantaneous, discrete, effective, and self-guided treatment programs that adolescents tend to favor.

It is therefore crucial for any next steps related to the proposed A-list draft guidances ensures that reliable patient access to safe, effective DTx therapies continues, particularly in light of the expanding national emergencies regarding pediatric and adult mental and behavioral health.

Formally Defining Digital Therapeutics

In the aforementioned April 2020 EUA, the FDA directly acknowledged the value that digital therapeutics provide to patients, caregivers, and clinicians. However, the FDA has not taken the important step of officially recognizing and defining digital therapeutics in formal guidance. The Agency is already viewed as a leader in the DTx industry. By formally defining and recognizing digital therapeutics in this capacity, the Agency can more clearly communicate and expand its current efforts related to the review and clearance of DTx products.

Whether this is achieved through the FY2022 **B-list** draft guidance topic, "Risk Categorization for Software as a Medical Device: FDA Interpretation, Policy, and Considerations," or a more appropriate guidance, it is becoming increasingly important for the FDA to formally recognize the specific types of products that qualify as a digital therapeutic.

We ask for the FDA's serious consideration of these requests, not only to provide greater clarity within the DTx industry, but also for the direct benefit of:

- *Clinicians and healthcare providers*. As the DTx industry continues to expand, there is an increased need for clinicians to understand the regulatory frameworks surrounding these technologies, especially as clinicians determine whether/how to integrate digital therapeutics into practice. When clinicians understand how to define these products, properly assess evidence requirements, and know when to prescribe versus recommend various DTx products, patients will increasingly gain access to high-quality interventions that are rooted in evidence and have undergone the appropriate levels of regulatory oversight.

- *Patients and caregivers*. Patients deserve transparency regarding the specific attributes and requirements that qualify a product as a DTx, standards DTx products are subject to, and whether products are able to deliver on the claims being made. It is currently difficult to understand the varying levels of risk, clinical evidence, and regulatory oversight requirements digital therapeutics are required to meet compared to other digital health technologies. Until patients can distinguish between products that are – and are not – therapeutic, the current lack of clarity from FDA surrounding digital therapeutics may have negative downstream impacts on patient safety and disease state outcomes.

- *Government agencies*. Greater clarity surrounding digital therapeutics would support the Federal Communications Commission (FCC) and Federal Trade Commission (FTC) in enforcing regulations related to digital health technology product claims. Ideally, this will further protect patients and clinicians from accessing products with false or unsupported claims that lack the necessary scientific evidence and regulatory oversight.

The effort to recognize and define digital therapeutics is not intended to replace currently existing frameworks within the Agency, but to provide greater clarity on how these products relate to the FDA's existing rules, guidance, and frameworks.

Thank you for the opportunity to provide commentary on this process. We look forward to ongoing conversations regarding this and other related efforts.

Sincerely,
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Vice President, Global Policy
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