March 23, 2022

Via Docket Submission

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

Re: Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 Public Health Emergency; Draft Guidance for Industry and Food and Drug Administration Staff; Comment Request

Docket No. FDA-2021-D-1118

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 "Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," published on December 23, 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, clinically evaluated digital therapeutics for patients, clinicians, and payors to improve clinical and health economic outcomes.

Enduring Impact of the Pandemic

The Agency implemented policies during the public health emergency (PHE) to directly facilitate the availability of devices used to diagnose, manage, and prevent COVID-19 and associated conditions. As the FDA transitions from enforcement discretion policies to normal operations, it is critical that each step prioritizes the protection and promotion of public health – including sustained patient access to certain technologies made available during the PHE.

DTA appreciates the FDA's recognition of the time device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and the Agency need to adjust to normal operations from the policies and operations implemented during the declared COVID-19 PHE. We were glad to see that the Agency proposed a multi-phased transition process for devices that fall within enforcement policies issued during the COVID-19 PHE. It is critical that the Agency revaluate some of the timelines included in its multi-phased transition and consider extending the Phase 2 timeline. Additional information about this recommendation is below.

Since the COVID pandemic and long-term sequela will continue to impact the U.S. population for years to come, it is important for the Agency to continue enabling the provision of medical products introduced

during the PHE to patients with chronic and mental health conditions. We need to ensure that patients can continue accessing currently available therapies that meet regulatory standards.

Phased Approach

"FDA believes a phased approach over the course of 180 days following the implementation date as set forth in this guidance can help foster compliance with applicable statutory and regulatory requirements once the relevant enforcement policies are no longer in effect."

We agree with the overall three-phase approach. However, we recommend the Agency implement a longer Phase 2 into Phase 3 transition period for applicable manufacturers and devices that meet pre-defined criteria, such as:

- Patients currently have access to the product (particularly important for vulnerable populations) under the current enforcement policy
- Product is actively conducting pivotal trials
- Product manufacturer has met with the Agency for a pre-submission meeting
- Manufacturer is actively pursuing marketing submission

Like many other areas of healthcare, our member company operations have been negatively impacted by the pandemic. For example, the pandemic has created barriers and delays in executing clinical trials, such as significantly longer institutional review board (IRB) times and difficulties conducting remote recruitment and enrollment. These factors may make the current Phase 2 timeline more challenging for our member companies to meet, potentially putting patient access to needed care at risk.

In addition, given the potential unexpected volume of incoming submissions and product reviews the FDA will be responsible for conducting – particularly since the Agency does not know how many products came on the market under these policies – we want to ensure that the Agency has sufficient resources and time to execute the steps laid out in the Guidance within 180 days of the implementation date.

It is important that: 1.) all deadlines and timelines account for the operational challenges our members are facing due to the pandemic; 2.) the potentially larger than expected batch of marketing submission applications the Agency will receive; and 3.) that the final guidance addresses how products found to be noncompliant, misbranded, or adulterated following the Phase 3 implementation date will be dealt with.

We support the FDA's proposal to implement the beginning of the transition (e.g., Phase 1) after the expiration of the COVID-19 PHE declaration. If enacted early, this would cause a significant disruption to patient care and product access pathways.

Additionally, Footnote 31 states: "FDA may consider future adoption of enforcement policies for certain devices that currently fall within an enforcement policy adopted during the COVID-19 PHE." Before adopting such a policy, FDA should open a docket and consider public comments.

Focus on Real-World Data

We appreciate the Agency's past work to include real-world data in clearance and approval decisions for drugs[1] and devices.[2] A key component of the 'Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the COVID-19 Public Health Emergency,'[3] focuses on the use of real-world data and evidence generation.

Given the unique circumstances of the pandemic, the Agency's enforcement discretion policies, and digital therapeutics' ability to collect safety and efficacy data at the patient and population levels, healthcare decision makers are able to leverage significantly more accurate, secure, and abundant insights related to regulatory and patient care pathways. The Agency should therefore rely more on real-world evidence (RWE) to:

- Determine clearance decisions and assess new indications for use
- Better understand patients who are being treated under the COVID-19 enforcement policy
- Develop new regulatory and approval processes

We encourage the FDA to learn from the COVID-19 PHE experiences and use real-world evidence to improve and adapt ongoing clearance and oversight efforts.

Defining Digital Therapeutics

As directly referenced in the April 2020 Enforcement Policy, we also request the FDA officially recognizes and defines digital therapeutics in formal guidance. Although the Agency reviews and clears DTx products through various medical device regulatory pathways, by formally defining and recognizing digital therapeutics in this capacity, the Agency will provide clarity for *patients* (i.e., transparency regarding DTx product attributes, quality standards, and claims), *clinicians* (i.e., evidence, safety, and prescription requirements to provide patient access), and *government agencies* (i.e., Federal Communications Commission and Federal Trade Commission enforcement of product claims).

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

Sincerely,
Megan Coder, PharmD, MBA
Chief Policy Officer

[1] https://www.fda.gov/media/154714/download
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-real-world-evidence-support-regulatory-decision-making-medical-devices
[3] https://www.fda.gov/media/136939/download