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The FDA's Emergency Guidance for Mental Health and How Digital Health Manufacturers Are Responding

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May is mental health awareness month, as federal agencies and experts are seeing increasing rates in mental health problems associated with the coronavirus pandemic.[1] More and more Americans are experiencing anxiousness, loneliness, sadness, fear, stress from social isolation, and financial issues. Many are struggling with adjustments to the new circumstances and having to face many unknowns.

The National Alliance on Mental Illness (NAMI)[2] saw a 41% increase in calls, texts, and emails to its HelpLine due to the pandemic. In a recent poll by the American Psychiatric Association,[3] 36% of U.S. consumers say the pandemic has had a serious impact on their mental health, and 59% say it has had a serious impact on their day-to-day lives. Similarly, the use of drugs for treating depression, anxiety, and insomnia spiked 21% between mid-February and mid-March, according to an Express Scripts survey.[4] And Mental Health America (MHA), since the beginning of the year, has seen a 70% increase in the number of people screened for anxiety and a 64% increase in the number of people screened for depression.[5]

The Food and Drug Administration (FDA) plays an important role during this pandemic, protecting the United States from not only infectious diseases, but also from a mental health crisis. On April 14, 2020, the FDA attempted to address the concerns of patient mental health due to the coronavirus pandemic by issuing an *Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* (Emergency Guidance).[6] The Emergency Guidance relaxes certain regulatory requirements for digital health therapeutic devices for psychiatric disorders. The policy will remain in effect "only for the duration of the public health emergency related to COVID-19."

The Emergency Guidance applies to two groups of products: (1) computerized behavior technology devices (defined in 21 C.F.R. § 822.5801; product code PWE) and other digital health devices for psychiatric disorders; and (2) low-risk wellness and digital health products for mental health or psychiatric conditions.

The Emergency Guidance covers prescription-only computerized behavioral therapy devices designed for the treatment of psychiatric disorders. Before COVID-19, these tools typically have been used during in-person treatment sessions, such as cognitive behavioral therapy (CBT) and acceptance commitment therapy (ACT). The Emergency Guidance applies to devices used for treatment of both pre-existing and new diagnoses of conditions. These conditions include obsessive compulsive disorder (OCD), generalized anxiety disorder, insomnia disorder, major depressive disorder, substance use disorder, post-traumatic stress disorder (PTSD), autism spectrum disorder, and attention deficit hyperactivity disorder (ADHD).

The Emergency Guidance also provides some clarification regarding low-risk wellness and digital health products, which do not require FDA oversight. Low-risk wellness digital health products do not include software used for videoconferencing or telemedicine. The Emergency Guidance also does not include general wellness software not related to a specific disease or condition (e.g., promoting relaxation, mindfulness, or meditation; reducing stress, fatigue, or feelings of isolation; sleep-related wellness; positive mental outlook exercises; and reminders to promote social distancing practices), which remains subject to FDA's General Wellness Policy.[7]

Additionally, the Emergency Guidance does not apply to software functions for the treatment of a specific psychiatric condition, such as one that intends to increase abstinence from substance abuse.

There are also software functions that may still be subject to FDA enforcement, such as products implementing the software functions that:

- promote, track, and/or encourage choices to help with reducing the risk of certain chronic psychiatric diseases or conditions;
- help patients with diagnosed psychiatric conditions maintain behavioral coping skills;
- help patients or users self-manage their conditions without providing specific treatment or treatment suggestions; and
- guide a user through questionnaires or checklists of signs and symptoms for a psychiatric disorder.

The relaxed requirements discussed in the Emergency Guidance are that:

1. manufacturers do not need to submit a premarket notification under Section 510(k);
2. manufacturers do not need to report corrections or removals required in 21 C.F.R. § 806;
3. there is no 21 C.F.R. pt. 807 requirement to register or list products with the FDA; and
4. the products do not have to comply with the Unique Device Identification (UDI) requirements in 21 C.F.R. pt. 830 and 21 C.F.R. § 801.20.

The FDA still recommends that product labeling include 15 elements:

- a clear statement that the patient contact a physician before using the device;
- information about how to access additional resources related to the treatment of psychiatric conditions;
- a clear description of the device's indication, including the psychiatric condition or disorder the device is intended to treat;
- a description of the therapeutic method;
- a clear description of the recommended duration and frequency of use;
- user instructions;
- a summary of the clinical testing with the device;
- a description of the method of determining any treatment recommendations;
- a prominent notice that recommendations provided by the device are adjunctive;
- a warning that the device does not represent a substitution for the patient's medication;
- a statement as to whether the device is available with or without a prescription;
- instructions on when to consult a health care provider;
- a clear statement of what to do if symptoms are not improving;
- instructions on what to do in case of a medical emergency; and
- a clear identification of any device indications and functions that are not FDA-cleared.

These circumstances may open up opportunities for digital health manufacturers. And, one month later, we are already seeing movement. On April 29, 2020, Pear Therapeutics announced the launch of its product candidate, Pear-004, for temporary and limited distribution.[8] Pear-004 is a potential treatment for people living with schizophrenia. It provides social skills training, CBT for psychosis, and illness self-management training.

Lief Therapeutics also utilized the opportunity. On May 5, 2020, Lief Therapeutics made available its Digital Anxiety Treatment product called Downtime.[9] Downtime is an adjunct treatment that works with its wearable electrocardiograph (ECG) device, Lief Rx Smart Patch. Lief Rx Smart Patch is designed to help reduce anxiety by increasing heart rate variability (HRV). Downtime can provide patients with personalized biofeedback exercises, and health care providers can remotely monitor biomarkers and provide support through the mobile app.

Another manufacturer that recently made its product available under the Emergency Guidance is Akili Interactive. Akili Interactive released a computer game called Endeavor that aims to improve the attention function in children ages 8-12 who have inattentive or combined-type ADHD.[10]

Digital health technologies can provide tools for helping with the current mental health crisis. Some digital health manufacturers are already taking advantage of the opportunity the FDA has provided. The relaxed regulatory requirements compliment the recent FDA efforts to promote development and innovation in the digital health space,

but timing for new developments may be critical due to the transient nature of the Emergency Guidance.

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