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Coronavirus is Deregulating Healthcare One FDA Guidance At a Time

One unintended consequence of COVID-19 has been the paradigm shift within the healthcare industry which has turned to prioritize value-based, patient centric remote monitoring solutions and non-contact technologies. COVID-19 has created a demand for digital health technologies to provide relief for public health professionals and individuals alike. This is not to say that digital technologies have not been in existence, because they have. Rather, according to a 2019 Price Waterhouse Cooper survey, 94% of participants pointed to data-protection and privacy regulations, the Health Insurance Portability and Accountability Act (HIPAA) and the expansion of HIPAA rules and penalties under the Health Information Technology for Economic and Clinical Health (HITECH) Act as factors limiting implementation of digital technologies. This blogpost will explain the significant de-regulation efforts enacted by the Federal Drug Administration (FDA) to ultimately conclude why it is such an important time for the private sector to invest in digital health technologies.

Historically, venture capitalists and businesses looking to build and invest in digital health products and services have viewed the FDA as being "closed for business when it comes to innovation."[1] However, the COVID-19 pandemic has drastically changed the regulatory giant's approach to healthcare related products and services. At the end of March 2020, the FDA created the Coronavirus Treatment Acceleration Program (CTAP) to provide regulatory advice, guidance and technical assistance to potential sponsors seeking to develop drugs and biologic therapies for COVID-19. The FDA's new approach is to accelerate the investigation of safe and effective therapies that could benefit people affected by the COVID-19 pandemic.

On May 11, 2020, the FDA finally issued two guidances intended to ease the regulatory burden of developing drugs and biologics to treat or prevent COVID-19. The first guidance document is titled, "COVID-19, Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products" (Pre-IND Guidance). The Pre-IND Guidance directs sponsors to "initiate all drug development interactions for COVID-19 related drugs through Investigational New Drug (IND) meeting requests," instead of submitting a pre-emergency use authorization (pre-EUA) requests. The Pre-IND Guidance highlights the importance of putting together a quality submission when engaging with FDA. Now, the pre-IND meeting request and package development process has been streamlined into a single step. This is especially important because the FDA will respond to a pre-IND meeting request as "written response only meeting," meaning that there may not be an opportunity to provide additional information. The goal of this guidance is to provide explicit direction in assisting drug manufacturers to get their products into clinical trials efficiently.

[1] Joseph V. Gulfo "Innovation Breakdown" How the FDA and Wall Street Cripple Medical Advances" (p 234).

The second guidance provides recommendations for clinical trial design for Phase 2 and 3 clinical trials intended to establish safety and efficacy for therapeutic or prophylactic drugs and biologics with the goal of potentially approving safe and effective drugs to address the COVID-19 pandemic. The guidance "strongly recommends that drugs to treat or prevent COVID-19 be evaluated in randomized, placebo-controlled, double-blind clinical trials using a superiority design." It also includes a list of what it believes to be important clinical outcome measures for treatment trials, including all-cause mortality, respiratory failure, need for invasive mechanical ventilation and sustained clinical recovery.

Additionally, the FDA has also started Emergency Use Authorization (EUA) as one tool to help make certain medical products become quickly available during COVID-19. The issuance of an EUA essentially allows access to medical products that can be used when there are no adequate, approved and available options. Under the EUA, the FDA authorizes the product's use based on the best available evidence. For example, after initial data from a clinical trial showed that remdesivir may benefit some patients with COVID-19, the FDA authorized remdesivir to be provided under the terms of an EUA to hospitalized patients with severe COVID-19.

We are seeing the fruits of this de-regulation. On June 6, 2020, the FDA authorized the first standalone at-home sample collection kit that can be used with certain authorization tests. The FDA issued an EUA to Everlywell, Inc. for the Everlywell COVID-19 Test Home Collection Kit. Individuals at home, who have been screened using an online questionnaire that is reviewed by a health care provider, can self-collect a nasal sample at home using the kit. The FDA also authorized two COVID-19 diagnostic tests, performed at specific laboratories, for use with the samples collected by individuals using the Everlywell kit. In the future, additional tests may be authorized for use with the kit. This exemplifies how de-regulation opens the door for innovative digital services that focus on public-private partnerships to deliver personalized, at home medical access. Currently, the Everlywell home-collection kit is the only authorized COVID-19 at-home sample collection kit for use with multiple authorized COVID-19 diagnostic tests.

Sadly, as of this writing we are seeing an uptick in the rise of confirmed COVID cases across the country. Given the FDA's loosened regulations, there is a greater potential to meet the continued need to bring digital health services, medical devices, and drugs to the market to safely and effectively prevent or treat COVID-19. Stay tuned for Vandenack Weaver's continuing coverage on the changing landscape of health-care law during this turbulent and historic time. Next week we will evaluate the changes related to certain device software functions and the shift to prioritize personalized-healthcare through post-acute care and interoperability.