FDA and Artificial Intelligence in Digital Health Innovation

FDA is taking steps to embrace and enhance innovation in the field of artificial intelligence. It has already permitted the marketing of an AI-based medical device (IDx-DR) to detect certain diabetes-related eye problems, a type of computer-aided detection and diagnosis software designed to detect wrist fractures in adults (OsteoDetect), and most recently, a platform that includes predictive monitoring for moderate to high-risk surgical patients (HemoSphere).

FDA also embraced several AI-based products in late November when the Agency chose several new technologies as part of a contest to combat opioid abuse which it launched in May 2018. FDA's Innovation Challenge, which ran through September 30, 2018, sought mHealth (mobile health) technology in any stage of development, including diagnostic tools that identify those with an increased risk for addiction, treatments for pain that eliminate the need for opioid analgesics, treatments for opioid use disorder or symptoms of opioid withdrawal, and technology that can prevent the diversion of prescription opioids.

The opioid crisis continues to ravage cities and towns across America. The selection of AI-based devices by FDA to aid in the opioid crisis is important as it shows

- FDA's commitment to its Action Plan to address the opioid crisis
- FDA's recognition that AI is an important technology that it must address and encourage;
- FDA's willingness to work with developers of AI devices to establish new pathways for approval and
- The need for FDA to clarify its understanding of AI and how it will guide and regulate industry moving forward.

FDA received over 250 entries prior to the September deadline. In each proposal, applicants described the novelty of the medical device or concept; the development plan for the medical device; the team who would be responsible for developing the device; the anticipated benefit of the device when used by patients; and, the impact on public health as compared to other available alternatives. Medical devices at any stage of development were eligible for the challenge; feasibility and the potential impact of the FDA's participation in development to expedite marketing of the device were factors considered when reviewing the submissions.

A team from the FDA's Center for Devices and Radiological Health (CDRH) evaluated the many entries and chose eight of them to work with closely to accelerate develop and expedite marketing application review of innovative products, similar to what occurs under its Breakthrough Devices Program.

Several of the selected entries involve pattern recognition, whether by predefined algorithm or machine learning, to prevent, detect or manage and treat opioid abuse. For example, Silicon Valley-based startup CognifiSense is developing a virtual reality therapy as part of a system to treat and manage pain. CognifiSense uses a software platform that provides

psychological and experiential training to chronic pain patients to normalize their pain perception. Another FDA chosen product, iPill Dispenser, uses fingerprint biometrics on a mobile app that aims to cut over-consumption by dispensing pills based on prescriptions, and which permits physician interaction with usage data to adjust dosing regimens. Yet another, Milliman, involves predictive analytics and pattern recognition to assess a patient's potential for abuse of opioids before prescribing as well as detection of physician over-prescribing.