

The Food and Drug Administration (FDA) has approved a digital pill for the first time that will serve as a medication with a built-in sensor that can provide information to doctors when a patient takes their medicine.

Abilify MyCite (aripiprazole tablets with a sensor) has an indigestible sensor embedded in the pill that will record and monitor medicine-taking and addresses the problem of millions of patients who either do not take what is prescribed or take their medication incorrectly.

This issue has been estimated cost around \$100 billion a year in medication costs, most of it due to patients getting sicker and needing additional treatment or even hospitalization.

"Being able to track ingestion of medications prescribed for mental illness may be useful for some patients," said Mitchell Mathis, M.D., director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research. "The FDA supports the development and use of new technology in prescription drugs and is committed to working with companies to understand how technology might benefit patients and prescribers."

This new product is approved for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar I disorder, and for use as an add-on treatment for depression in adults.

It works by sending a message from the pill's sensor to a wearable patch that then sends information to a mobile application so that patients can track the ingestion of the medication on their smart phone. Patients will be able to grant access to caregivers and family. Physicians are able to access the information through a web-based portal at any time.





Due to digital tools being required, like the use of an app or wearing a patch, some experts believe that the digital pill will be most welcomed by older people who want help remembering to take pills and by people taking finite courses of medication, especially for illnesses where nurses often observe patients taking medications anyway.

In the future, it is hoped that this technology is used to monitor whether post-surgical patients take too much opioid medication or if clinical trial participants correctly take the drugs being tested.

At some point, insurers might even incentivize patients with discounts on copayments. However, there is a massive debate regarding ethical issues arising from the technology being incentivized as it could be considered coercion.

Another controversial topic surrounding the new product is it might be used as a requirement for parole or patients released from psychiatric facilities.

Abilify MyCite is a collaboration between Abilify's manufacturer, Otsuka, and Proteus Digital Health, a California company that created the sensor.

The sensor contains copper, magnesium, and silicon, which are all safe ingredients that can be found in our foods. These substances are able to generate an electrical signal when splashed by stomach fluid. After several minutes, the signal is detected by a patch that must be worn on the left rib cage. The patch is then able to send the date and time of pill ingestion and the patient's activity level via Bluetooth to a cellphone app. The app allows patients to add their mood and the hours they have rested. It can then transmit the information to a database that physicians and others who have the patients' permission can access.



Even though this new invention sounds a little like a biomedical "Big Brother is Watching You", it will hopefully help reduce the number of relapses, overdoses, and any unnecessary hospital re-admissions.

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Summary



Article Name FDA Approves the First "Digital Pill"

Description

The FDA has approved a digital pill for the first time that will be used to monitor a patients intake of prescribed medication.