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FDA approves first digital pill with sensor - Abilify MyCite

By Ananya Mandal, MD Nov 14 2017

The United States Food and Drugs Administration (FDA), for the first time has approved a digital pill system. The novel pill comes with an in-built sensor that transmits information to a remote location after a person has taken it. Experts believe this is a huge step towards digital medicine and opens new avenues for therapy and diagnostics.

The pill that has been approved is called Abilify MyCite – a product of Japan-based Otsuka Pharmaceuticals. It contains the drug Aripiprazole – a drug used in schizophrenia, bipolar disorder and also as an add-on drug for depression used in adult patients. Abilify contains this miniscule sensor that is the size of a grain of sand embedded in it. This is made by Proteus. As soon as the pill is ingested and it reaches the stomach, contact with the gastric acids activates the sensor and sends information to a detector about the date and time the drug has been taken. The detector and recorder of these signals is placed within a patch that the patient wears on his or her person. This patch sends the information about whether and when the drug is taken to a smartphone app that can share the information with care givers and assigned family members.

Experts believe that one of the biggest problems with several health problems such as high cholesterol, high blood pressure, mental health disorders etc. is non-adherence to medications and prescribed drugs. Non adherence or non-compliance leads to failure of therapy, accidents due to break through of disease symptoms as well as long term worsening of the disease condition. This digital pill system that reports the time when the drug is ingested so that an app can keep tabs on usage of the drug can not only help prevent non-adherence to medications but also help detect non-adherence early.

According to Mitchell Mathis, M.D., director of the Division of Psychiatry Products in the FDA's Center for Drug Evaluation and Research, “Being able to track ingestion of medications prescribed for mental illness may be useful for some patients… 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.

The FDA statement that was issued on 13th November 2017, mentions that the manufacturers have put in labelling information on Abilify MyCite saying that the product has not yet shown better compliance of the patients and improved adherence to therapy. The statement also warns that this detection app is not to be relied upon in case of an emergency as it may delay judgement.

Abilify MyCite also carries a boxed warning on its labels that states that older patients who suffer from psychosis that is associated with dementia may be at risk with the use of this drug – with or without the sensor. It can also lead to suicidal thinking and tendencies among young adults, teenagers and children when given alongside antidepressants. Common side effects seen with this agent even without the sensor include nausea, vomiting, constipation, dizziness, anxiety, loss of sleep, restlessness etc. The patch of MyCite may also lead to skin irritation in some patients. Patients must consent to its use before it is administered to them says the FDA statement.

One of the concerns raised by many experts is the invasion into patient privacy. In addition there is the concern about cost of the medication rising due to the insertion of this sensor. Abilify pills without sensors cost around $891 a month. The injection form of this medication costs at least $1,478. The price for the digital version is not yet released.

Abilify MyCite approval has been given to Otsuka Pharmaceutical Co., Ltd. And the sensor and the wearable patch approval is given to Proteus Digital Health.

Reference: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584933.htm