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FDA Announces Approval of a Digital Pill that Tracks Pill Consumption

On November 13, 2017, the *Food and Drug Administration* (FDA) announced the approval of the first "*digital pill*" – a drug that will track medication ingestion by a patient.[1] Specifically, this pill is a digital version of *Abilify*, an antipsychotic used to treat conditions such as schizophrenia, bipolar and depression, otherwise known as *Abilify MyCite*.[2] Patients can sign a consent waiver allowing a physician and up to four other people to view electronic data on a smartphone application related to the date and time the pill was taken, and viewing permissions can be revoked by the patient at any time.[3] The pill was designed to address the issue of nonadherence to medication regimens, which is an issue for many diseases, including psychiatric disorders that Abilify treats, e.g., schizophrenia and bipolar, as well as chronic conditions such as hypertension and high cholesterol.[4] Many patients, such as the elderly, may find the digital pill consumption tracking useful, as they may be prone to forget to take their medication.[5] However, the emergence of the pill is not without controversy, as both physicians and patients have concerns related to the potentially coercive nature of medication-consumption tracking.[6]

The digital pill is embedded with a sensor that is the size of a grain of sand and is made of copper, silicon, and magnesium; the pill is activated when it comes into contact with stomach fluid.[7] Once activated, the sensor transmits a signal to a Band-Aid-like patch, which is worn on the left side of the patient's torso and must be replaced every seven days.[8] The patch then sends the date and time that the pill was ingested to a smartphone application that is viewable by anyone to whom the patient designates access.[9] This is the first approved drug to have a sensor embedded in the pill itself; prior to the creation of this pill, sensors could only be placed inside capsules.[10] Although the digital pill was designed to address the issue of patient non-compliance, the effects on health outcomes, due to increased prescription adherence, has not yet been determined.[11] However, encapsulated ingestible sensors previously have been proven to be effective at increasing medication regimen adherence for patients experiencing uncontrolled hypertension.[12] The use of other pharmaceutical technologies to track medication ingestion showed promising results when used to promote treatment adherence for schizophrenia and tuberculosis patients, such as AiCure, a smartphone-based visual recognition system that documents patients' medication consumption.[13]

The pill prompts discussion over ethical issues surrounding patient autonomy. Both experts and patients have expressed concerns that the digital pill could become coercive in nature, e.g., the government could use the pill as a condition for parole, or for the release of a patient committed to a psychiatric facility.[14] *Otsuka*, the manufacturer of Abilify, asserts that the assumptions underlying this concern are flawed because the pill's consumption-tracking technology only works if the patient is compliant with wearing the associated patch.[15] However, some patients who participated in the drug's clinical trials stated that the idea of pill-consumption tracking was "*overbearing*" and "*unnecessary*."[16] Despite apprehensive attitudes toward drug consumption-tracking, the FDA affirms that this technology may benefit some patients,[17] such as those who tend to forget to take their medication, or those wanting to be held accountable for taking their medications.[18] Further, caregivers and family members may benefit from consumption-tracking technology if they are concerned as to whether the patient has taken their medication.[19]

Many health experts have expressed surprise that the first digital pill was created for a drug that treats disorders like schizophrenia, given that many schizophrenia patients have delusions and paranoia about being watched.[20] It is worth noting, however, that this technology can be applicable to the treatment of other diseases, especially those requiring strict medication regimens, such as heart disease, stroke, and *human immunodeficiency virus* (H.I.V.).[21] Medication consumption-tracking technologies are still limited in their commercial use, but this may change in subsequent years due to the fact that several pharmaceutical companies are investing in and manufacturing their own digital pills, including etectRx, a Florida company that designed the ID-Cap, an ingestible sensor that is currently being tested with opioids and other drugs.[22] Before the use of these technologies becomes widespread, more research may be needed to determine their ability to improve health outcomes, and concerns may need to be addressed related to patient privacy, convenience, and cost.[23]

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1 "FDA Approves Pill with Sensor that Digitally Tracks if Patients have Ingested their Medication'" U.S. Food & Drug Administration, U.S. Department of Health and Human Services, Press Release, November 13, 2017, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm584933.htm (Accessed 11/28/17). Note: To gain FDA approval, a drug manufacturer must provide the FDA with sufficient data illustrating safety and efficacy of the drug. "About FDA" U.S. Food and Drug Administration, April 4, 2017, https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (Accessed 12/15/17).

2 U.S. FDA, November 13, 2017; Abilify MyCite was produced by Otsuka, Abilify's manufacturer, and Proteus Digital Health, a California company that created the sensor.

3 "First Digital Pill Approved to Worries About Biomedical 'Big Brother'" By Pam Belluck, The New York Times, November 13, 2017, https://www.nytimes.com/2017/11/13/health/digital-pill-fda.html?emc=edit_na_20171113&nl=breaking-news&nlid=16865964&ref=headline (Accessed 11/28/17).

4 "FDA Approves First Digital Pill That Can Track Whether You've Taken It" By Laurel Wamsley, National Public Radio, November 14, 2017, https://www.npr.org/sections/thetwo-way/2017/11/14/564112345/fda-approves-first-digital-pill-that-can-track-if-youve-taken-it (Accessed 11/28/17).

5 Pam Belluck, November 13, 2017.

6 *Ibid*.

7 Laurel Wamsley, November 14, 2017.

8 Pam Belluck, November 13, 2017.

9 U.S. FDA, November 13, 2017.

10 Pam Belluck, November 13, 2017.

11 U.S. FDA, November 13, 2017.

12 Pam Belluck, November 13, 2017.

13 *Ibid*.

14 *Ibid*.

15 *Ibid*.

16 *Ibid*.

17 U.S. FDA, November 13, 2017.

18 Pam Belluck, November 13, 2017.

19 Laurel Wamsley, November 14, 2017.

20 *Ibid*.

21 Pam Belluck, November 13, 2017.

22 *Ibid*.

23 Laurel Wamsley, November 14, 2017.

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