

# The iPill Dispenser

**MISSION STATEMENT:** Development of combined digital health-medical devices to securely store, safely dispose and actively control opioid dispensing and reduce diversion and monitor abuse.

**Introduction:** After the government made pain the “5th vital sign”, opioid prescriptions soared. “Uncontrolled” access to “controlled” substances resulted in double digit increases in the overdose death rate every year for the last 20 years. Government policy to limit opioid access ignited the Heroin/ Fentanyl crisis. 135 people now die a day from opioid overdoses.

**Problem:** Opioids are dangerous drugs. In hospitals, opioids are securely dispensed by nurses supervised by pharmacist. 1,000 people still die a year. For home, patients receive a bottle of pills with a child-resistant cap. Patients easily abuse or divert them to family or friends. 3.3 billion pills unused opioids enter our communities every year. 47,600 people died of opioid overdoses in 2017 alone and the child overdose rate has rose 268.2% in the last 9 years. The child-resistant cap isn’t working for adults or our children.

**Solution:** The iPill system is a secure storage safe disposal solution that actively controls opioid dispensing to prevent diversion and abuse. It grants access only to the patient prescribed opioids and will destroy pills within the iPill if tampered or 90 days of the prescription date. It is the first integrated solution with a “wearable” sensor that calls 911 if respiratory distress is detected, a cognitive behavioral therapy module and data collection in a blockchain tree on for predictive analytics. Validation of the iPill solution came from the FDA. The iPill was selected a winner in the 2018 FDA Innovation Challenge for the Treatment and Prevention of Opioid Use Disorder. iPill has officially been designated as a “Breakthrough Innovation” medical device making it eligible an expedited review.

**Market/Competition:** The dispenser market was \$1.755 Billion in 2016 and expected to grow to \$3.023 Billion by 2023. CAGR is 7.3% There are many dispensers on the market but none are tamper-resistant design that can destroy contained opioids. None offers safe disposal. iPill will be the first-to-market active control opioid secure storage safe disposal dispenser integrated with home respiratory monitoring designed to prevent diversion and abuse. Market exclusivity for 3 years is granted by the Hatch- Waxman Act. The iPill, as a “Breakthrough Innovation” medical device will go through the De Novo 510K Class II approval path and set the standard by which the FDA evaluates other products. A functioning has prototype has already been built.

**The Value Proposition:** Saving lives and reducing healthcare cost is compelling. The iPill cost is minor compared to \$12,000 per ER visit, \$32,000 per hospital stay, or \$128,000 per rehab stay. When pre-marketed as a way decrease member costs to PBMs, dentists, CROs, and an insurer, all indicated that they would participate in pilot step studies. A reduction in the \$635 billion/year costs associated with opioid abuse and worker productivity losses would be desired by the government and insurers. Our manufacturing strategic partner is Ennoconn/Foxconn.

**Intellectual Property** iPill patent granted October 1, 2019 . USPTO no. 10,426,707

**Opportunity:** \$3 million is requested from an investor / partner to complete development and finish FDA regulatory approval. A future Round A raise of \$7 million will be for manufacturing and supply chain structure.

## **Team**

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