

# iPill Dispenser

**MISSION STATEMENT:** To develop medical devices to guarantee opioid prescription adherence, to protect patients from opioid overdoses, to provide home monitoring and to provide EMR connectivity.

**Introduction:** Pain was declared the 5th vital sign and the pharma industry said opioids were not addictive. Everyone was able to get opioids. “Uncontrolled” access to “controlled” substances resulted. Opioid prescriptions soared. The death rate from opioid overdoses increased by double digits for the last 19 years. The government fix to limit opioid access have caused a very deadly Heroin/ Fentanyl crisis. 135 people now die a day from opioid overdoses.

**Problem:** In hospitals, opioids are securely stored and dispensed by nurses. Respiratory depression, the deadly opioid side effect is closely monitored and rescuers are close by. For home, doctors write opioid prescriptions and patients receive a bottle full of pills to store in their unsecured home where children can get to the drugs. Absolutely nothing prevents or controls whether a patient takes one pill, 20 pills or gives pills to family or friends. Absolutely nothing monitors patients at home for respiratory depression and death in the event of accidental overdose. No rescuers are nearby. In fact, only 10% of patients are rescued with Narcan in the field.

**Solution:** The iPill App uses a biometric authentication process to operate a portable tamper-resistant device to ensure patient treatment for pain, prevent overconsumption and diversion of opioids. Upstream controls employ blockchain to allow bidirectional remote physician control and integration with EMR. Downstream controls monitor respiratory depression to prevent further opioid access, ring the patient or automatically contact emergency personnel. Cognitive behavioral therapy are integrated with the iPill App to deter overconsumption. The real power of the iPill app is in collection of overdose death and opioid usage data for real time application of analytics to manage population health.

**Market:** 239 million opioid prescriptions were written for 100 million people with acute, chronic or cancer pain. There is no alternatives for opioids for pain. 90% of patients who overdose on opioids are placed back on opioids after their overdose event. Abuse costs the country \$78.5 billion a year. The vision is to use the iPill App and iPill dispenser for all opioid prescriptions.

**Value Proposition:** A cost effective secure storage safe disposal solution to prevent diversion will lower healthcare costs and improve patient safety. Compared to extended release / abuse deterrent opioids, which cost hundreds to thousands of dollars per month, a \$12,000 ER visit, a \$28,000 hospital stay or a \$128,000 inpatient rehab stay, the proposition will be attractive to targeted clients including PBMs, insurance companies, and the government. The iPill dispenser, if mandated for all opioids prescribed, could reduce healthcare cost and save lives.

**Competition:** There are many pill dispensers on the market to remind patient to take drugs. They monitor pills and are not tamper-resistant or prevent diversion. The iPill will be first to market and first in class for its ability to prevent opioid overconsumption, monitor patients at home for respiratory depression, allow remote physician adjustment of drug dosages, allow blockchain EMR connectivity and physician remote access, have cognitive behavioral therapy, and collect data for real time access for population management. The Hatch-Waxman Act will provide market exclusivity for 3 years.

**Intellectual Property / Regulatory Path:** The patent pending iPill is going through a FDA 510(k) class 2 approval process. A functioning prototype has been built. The iPill was selected as 1 of 8 companies by the FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder. (Nov2018)

**Opportunity:** The iPill is seeking a total of \$1million to complete final development for respiratory monitoring software, blockchain EMR connectivity and the cognitive behavioral therapy module.

## The Team:

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