

# The iPill

**MISSION STATEMENT:** To develop secure storage and safe disposal solutions integrated with active control opioid dispensing, home monitoring and EMR connectivity to prevent diversion and abuse.

**Introduction:** When pain was declared the 5th vital sign and pharma said opioids were not addictive, opioid prescribing soared. “Uncontrolled” access to “controlled” substances resulted. The death rate from opioid overdoses increased by double digits for the next 19 years. Government limitations on opioids has not stemmed the death rate. 135 people now die a day from opioid overdoses.

**Problem:** In hospitals, opioids are securely stored and dispensed by nurses. The deadly opioid side effect of respiratory depression is closely monitored. Rescuers are close. For home, doctors write opioid prescriptions and patients get a bottle full of pills where children often get to the drugs. Absolutely nothing prevents patients from taking two pills, 20 pills or giving away pills to family or friends. No home monitoring of patients for respiratory depression occurs. No one is nearby.

**Solution:** The iPill App uses biometric authentication to operate a portable tamper-resistant iPill Dispenser to dispense opioids to treat pain and prevent overconsumption and diversion. Upstream blockchain bidirectional connections allows remote physician control and integration with EMR. Downstream monitoring for respiratory depression can autonomously contact 911 personnel. Cognitive behavioral therapy, integrated within the iPill App, adds another layer of abuse deterrence. The real power of the iPill app is in collection of near-death and opioid usage data with real time access for predictive analytics in management of population health.

**Market:** 229 million opioid prescriptions were written for 100 million people with acute, chronic or cancer pain. There is no alternative for opioids in the treatment of 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 FDA is leaning towards a secure storage and safe medical device for all opioid prescriptions. The iPill Dispenser was selected as a winner of the FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder. (Nov2018). The iPill Dispenser will be the first on the market.

**Value Proposition:** A cost-effective secure storage safe disposal solution to prevent diversion will lower healthcare costs and improve patient safety. Compared to 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 rehab stay, the proposition will be attractive to PBMs, insurers, 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 an active secure storage and safe disposal solution supported by the FDA. 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.

**Opportunity:** The iPill is seeking a total of \$1.5 million to complete final development for respiratory monitoring software, blockchain EMR connectivity and the cognitive behavioral therapy module.

## **The Team:**

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iPill

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