The iPill Dispenser

MISSION STATEMENT: To develop digital health-hardware Innovations to improve prescription adherence and safety by reducing opioid diversion and 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 prescribed for 548 million dental procedures and 53 million surgeries floods communities. 47,600 people died of opioid overdoses in 2017 alone and the child overdose rate has risen 268.2%

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. FDA validates of the iPill solution. The iPill was selected a winner in the 2018 FDA Innovation Challenge for the Prevention and Treatment of Opioid Use Disorder and is FDA designated, 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 because they lack a tamper-resistant design are not not suitable for secure storage Schedule II opioids. None offers safe disposal. iPill will be the first-to-market active control opioid secure storage and safe disposal dispenser to reduce 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 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 .

Intellectual Property The iPill patent was granted October 1, 2019 USPTO 10,426,707

Opportunity: $4 million is requested from an investor / partner to complete development and finish FDA regulatory approval.

Team/Advisor/Consultants

John Hsu MD CEO Co-Founder

Sherie Hsieh, BS, COO Co-Founder
Lacarya Scott, MBA, CFO
James Yang, BS, CTO
Peter Weinstein, PhD, JD, Legal counsel
Brian Harvey MD, PhD Former FDA Director
Daniel Sessler, MD, Cleveland Clinic

Inquiries Please Contact:
John Hsu MD
john@iPillDispenser.com
626-695-5985

Revolutionary Prescription Safety