



Active controlled opioid  
dispensing – a patented FDA  
Breakthrough Product





# Opioid Crisis

128 people die  
everyday from an  
opioid overdose



1 in 4 opioid  
overdoses is now  
children/teens

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>

# The Problem: Starts in Your Medicine Cabinet at Home



Hospitals  
Pharmacies



Opioids are  
locked in safes



HOME



The same Opioids  
are not locked

## Abuse



## Sharing



## Addiction Overdose



# Secure Opioids at Home with Medication Adherence



- No unauthorized access
- Only the prescribed patient has access at only the prescribed dose
- Disposes unused opioids

# The Product

iPill Dispenser

Drug  
Vault



Destroys pills  
Disposes unused pills

iPill APP

Biometric  
Key



Reduces abuse  
Reduces sharing



# Operation

## Registration

### Step #1



Pharmacy fills iPill for patient

### Step #2



Scan QR code downloads iPill app

### Step #3



Fingerprint & Personal code

## Dispensing

### Step #1



Authenticate fingerprint & personal code

### Step #2



Dispense opioid



# Product Line

## FDA Class I

510K exempt



i Pill dispenser  
3 Moving Parts  
Simple to Manufacture

## FDA Class II

Future

Expected Q1 2022

Respiratory  
Biosensor



i Pill App



Calls 911



- ◆ If in respiratory distress
- ◆ Stops opioid dispensing





# i Pill Disposition

## Drug Supply Chain Security ACT

Any container that comes in contact with opioids must be single use only



- 120 pill capacity
- Tamper-resistant
- Safe disposal



## Resource Conservation and Recovery Act (RCRA) Laws



- i Pill is non-toxic
- Discarded after use

## 3 Granted Patents

PCT Patents EU, UK, Canada

### FDA Class I Registration

(May 9, 2020)

### FDA Class II Breakthrough Designation

(May 8, 2019)

**Medicare/Medicaid announces  
reimbursement for FDA  
breakthrough products (MCIT)**

(January 12, 2021)

iPill Class II - Only Dispenser covered by insurance



# Value Proposition of iPill: Cost Containment

## Current Treatment Costs



\$166-\$570 medication cost per month<sup>1</sup>

\$14,000-\$27,000 inpatient treatment cost per month<sup>2</sup>

\$5,000-\$10,000 outpatient treatment cost for 3 months.

After 4 months of treatment, relapse rate is still 50%+

## Using iPill



**iPill cost of \$600 per year prevents:**

\$19,333 mean annual cost per patient for addiction

\$1.8 million annual cost per death

\$696 billion annual cost to the US economy

Drugs.com. (2020). Suboxone prices, coupons, and patient assistance programs.  
<https://www.rehabs.com/addiction/how-much-does-rehab-cost/>  
<https://www.whitehouse.gov/articles/full-cost-opioid-crisis-2-5-trillion-four-years/>  
<https://www.optum.com/business/resources/library/managing-opioid-costs-managing-risks.html>  
<https://www.hindawi.com/journals/jad/2016/7620860/>



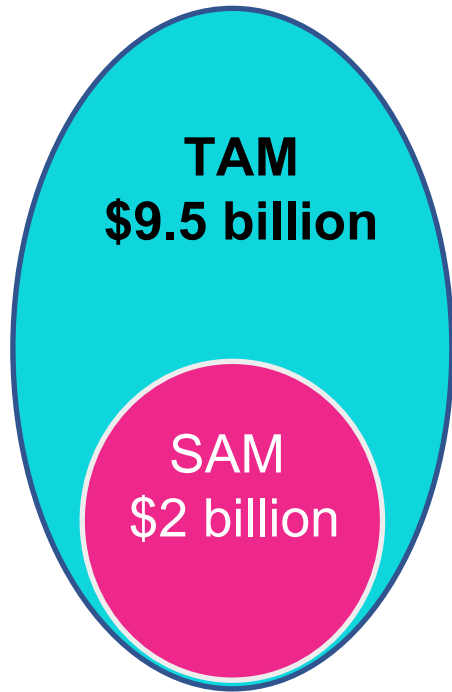
# The Market

Focus is on opioid segment  
Highest overdose deaths

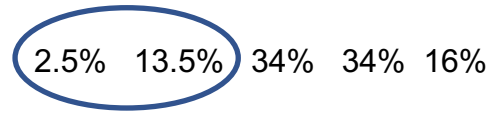
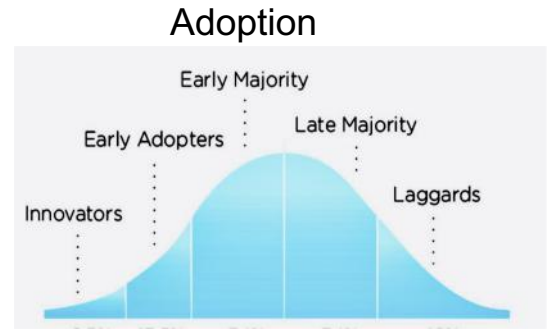
## Addictive drugs

2018 Prescriptions

- Tranquilizers 75 million
- Stimulants 42 million
- Sedatives 16 million
- Opioids 191 million



US opioid prescriptions:  
191 million in 2018



1. [iPill retail at \\$50](#)
2. <https://clincalc.com/DrugStats/>
3. <https://simplicable.com/new/adoption-rate>
4. <https://www.statista.com/statistics/261303/total-number-of-retail-prescriptions-filled-annually-in-the-us/>



FDA Class I  
Registered May 9, 2020

Addiction Centers  
\$2.0 billion  
SAM

- 40.7 MM units for 3.7 MM patients per year

Cash based  
Short-sales cycle

2 purchase agreements

## Addiction Centers

- Wheeler (June 19, 2020)
- Scale: 13 clinics in Connecticut
  
- Aspire-365 (Sept. 9, 2020)
- Scale: 4 locations in 4 states
  
- **\$7.7 MM annual sales opportunity** (SOM)
  
- **14,500 clinics in the US**



# Competitive Analysis: FDA Class I 510 Exempt



+



iPill  
\$50

Resistant  
Cap  
\$0

TAD  
Est.\$200

Medica  
Safe  
Est.\$250

Med  
Smart  
\$589.99

**Price**

**Biometric authentication**

**Destroys unused pills**

**Medication adherence**

**Controlled dispensing**



1. [Drug Supply Chain Security Act](#)
2. <https://www.massdevice.com/cms-agrees-to-cover-breakthrough-medical-devices/>



# Competitive Analysis: Future FDA Class II iPill

iPill will be the only dispenser covered by CMS under the MCIT program



iPill  
\$50



Hero  
\$399



Protex  
RX  
\$189



Med  
Time  
\$289



Auto  
Pill  
\$69.95



Med  
Ready  
\$179



Med  
Smart  
\$589.99



TAD  
Est. \$200



Medica  
Safe  
Est. \$250

Prescription adherence	✓	✓	✓	✓	✓	✓	✓	✓	✓
Abuse Deterrence	✓		✓	✓		✓	✓		
Secure storage	✓		✓				✓		
Destroys drug (tampering or prescription expiration)	✓								
Removes Unused Opioids From Circulation	✓								
Reduction in Healthcare cost	✓								
Reduction in Provider liability and Manufacturer (Pharma) liability	✓								
FDA Breakthrough Designation	✓								
Eligible for Reimbursement Coverage through CMS based on Recent Ruling	✓								



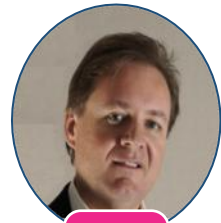


# Senior Management Team



CEO

**John Hsu MD**  
Co-Founder  
Anesthesia & Pain  
28 years



COO

**Christian Baker, MBA**  
Former VP McKesson  
26 Years



Interim  
CTO

**Aliasgar Morbi, PhD**  
Founder of GaitTronics  
12 years



CFO

**Lacarya Scott,**  
MS,MS, CFA, MBA



**Romy Seth, BAsC, BSc**  
Chief Corporate Strategy / Finance

# Team

## Board



Sherie Hsieh, BS Co-Founder  
Clinical Toxicologist



John Hsu MD  
Anesthesiologist  
Pain management



Peter Weinstein, PhD, JD  
Baxter, IP Attorney



## Advisors / Consultants



Brian Harvey MD, PhD  
Former CDRH Dir. of FDA



Daniel I. Sessler, MD  
Editor of *Anesthesiology*



Nick Spring, BSc  
TOPAZ PHARMACEUTICALS INC



## Vendor Partners



Robert Nickell, PharmD  
FDA pharmacy Regulations



Tony Chang, BS, E.E.  
Foxconn, Project Manager



Zachary Jensen, BS  
ASPIRE365



# iPill Platform



A Smart Dispenser for  
Revolutionary  
Prescription  
Safety

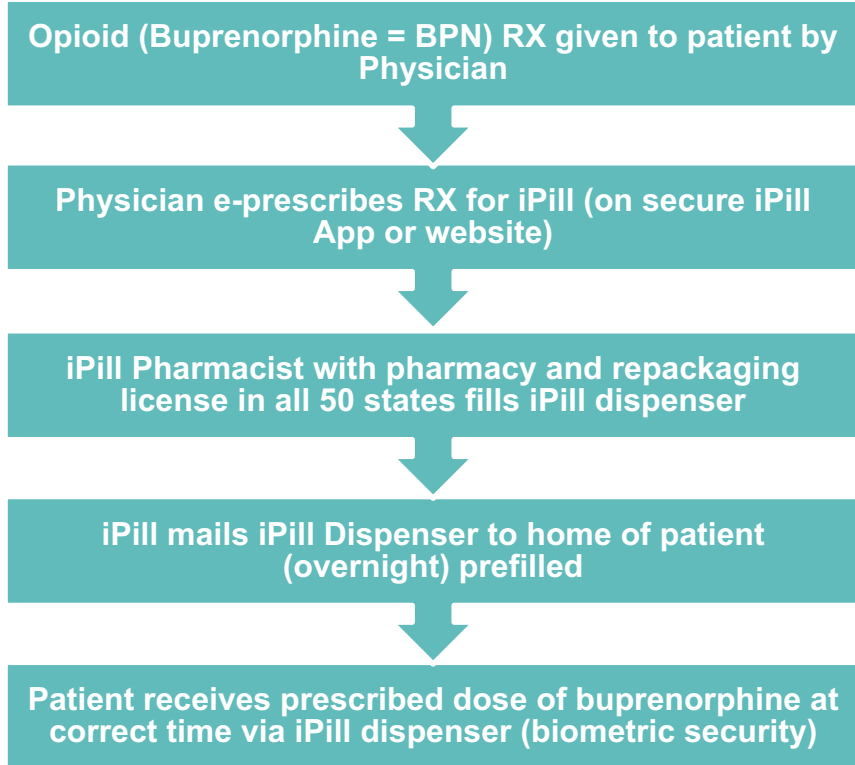
John Hsu MD

[John@iPilldispenser.com](mailto:John@iPilldispenser.com)

626-695-5985

*(Calendly.com/john-iPill)*


# How iPill Works – Simple Five Step Process



- Patients being discharged from the addiction clinic will receive a pre-filled iPill (with Buprenorphine) directly at home every 30 days
- Therefore, each patient would use 12 dispensers per year
- US Drug Supply Chain Act requires one time use of the device

# Business case



 15,000  
Opioid Rx  
per month

Medication  
treatment  
Management  
(MTM)



Know if patient  
took medications



180,000  
iPill dispenser units  
per year

\$9 million revenue opportunity



# Business case

## BD Pyxis and iPill Overview




Hospitals	6,200
Pharmacies	60,000
Addiction clinics	14,500

Home  
opioid  
security



HOME 191,000,000  
Opioid prescriptions

 Medication management  
Inventory management



Web based Data



Precision care  
Prediction of home  
opioid use