



iPill Platform

A Patented FDA
Breakthrough Product



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The Problem — **Uncontrolled Access to Controlled Substances**

People take drugs

28,000 adults die from an opioid overdose per year

Child-resistant cap is the weak link



1 in 4 overdoses now involves **children** and **teens**



iPill Team

Management



- ◆ **John Hsu MD,**
Anesthesiologist
- ◆ **Pain management for 28 years**



- ◆ **James Yang, BS,**
Software Engineer,
- ◆ **Ticketmaster and Hilton Hotel apps**



- ◆ **Bruce Sargeant, BSEE**
Hardware Engineer
- ◆ **Developer of Velodyne**

Advisors



Daniel I. Sessler, MD, Professor Cleveland Clinic editor of Anesthesiology



Brian Harvey MD, PhD, Former CDRH Dir. of FDA

Board



- ◆ **Sherie Hsieh, BS Co-Founder**
◆ **Clinical Toxicologist**



- ◆ **Nick Spring**
◆ **Exited from medical device and biopharma company**



- ◆ **Peter Weinstein, PhD, JD**
◆ **IP Attorney, Baxter**



Jared Adams, MD, PhD
SelfCare Catalysts



Robert Nickell, PharmD
FDA pharmacy Regulations

iPill's Market Opportunity

There's a **\$9.2 billion*** annual recurring revenue opportunity to prevent addiction using a tech-enabled dispensing system

\$3 billion*

< 26 year olds

\$3.5 billion*

26-54 year olds

\$2.7 billion*

55+ year olds

- 60 million opioid RX for 104 million people
- **Highest rate of prescription opioids used and abused**

- 71 million opioid RX for 122 million people
- **Highest overdose death rate** of the age groups
- In 2014, those aged 25-64 had the **highest rates of inpatient stays,**

- 44 million opioid RX for 93 million people
- **1st Time Treatment opioid used disorder (OUD) in Adults Age 55 have almost doubled since 2007**

*Represents a price point of \$50 per iPill dispenser per opioid RX

iPill — Market Segmentation and Unit Economics

Total US opioid prescriptions were 185 million in 2019

	<26 y/o	26-54 y/o	55+ y/o	Total
Number of People in US	104 million	122 million	93 million	319 million
Number of Opioid Scripts in US	60 million	71 million	54 million	185 million
iPill Sales Opportunity (\$50/unit)	\$3 billion	\$3.5 billion	\$2.7 billion	\$9.2 billion
iPill COGS (\$15/unit)	\$0.9 billion	\$1.1 billion	\$0.81 billion	\$2.8 billion
iPill Gross Margin (\$35/unit)	\$1.4 billion	\$2.8 billion	\$2.1 billion	\$6.4 billion

1% penetration would represent \$92MM in sales and ~\$64MM in gross margin (not accounting for improvement in COGS manufacturing scale)

iPill Market Roadmap - 3 Key Stakeholders

Dental Practices targeting <26 yos

- Short-sales cycle
- iPill serves as a tool to prevent addiction for the treatment of post-op pain with opioids
- Dental practice can market it has processes in place to prevent opioid addiction in adolescents/young adults
- Represents \$250 million+ sales opportunity

Addiction/Rehab Centers targeting 26-55 yo

- Short-sales cycle
- 3.7 million people received treatment across 1,450 centers throughout US
- Public/State-owned Clinics: iPill serves as a tool to reduce drug related incarceration rates (State Judiciaries would provide iPill + ankle bracelet under home arrest)
- Private Clinics: iPill serves as a tool used to transition clients from a lower margin inpatient service to a higher margin outpatient service, and could improve relapse rates
- Represents \$150 million+ sales opportunity

Pharmacy-Insurer- Providers targeting all patients

- Long-sales cycle
- 191 million prescriptions/year for opioids
- Major reduction in cost to treat patients post-addiction for payers
- Represents \$9.15B sales opportunity

iPill Go-to-market Roadmap – Current Market Traction

Dental Practices targeting <26 yos

- Dental consortium (320 practices across 20 states) has agreed to moved forward for a pilot study
- Pilot (initial PO) - 100 dispensers at \$50 will be given to patients after dental procedures
- Pilot study goals [Completion Dec 2020]:
 - Patient acceptance
 - Patient usability
- Upon successful pilot study, opportunity with Dental Consortium represents a **\$4.1MM annual sales opportunity**

Addiction/Rehab Centers targeting 26-55 yo

- First purchase order received (June 19, 2020) from a CT-state funded addiction treatment center
- Pilot (initial PO) - 100 dispensers at \$50 will be given to addicts transitioning from in-patient to out-patient
- Pilot study goals [Completion Nov 2020]:
 - Patient acceptance
 - Patient usability
- Upon a successful pilot study, State of CT Judiciary Treatment Pathways Program would order the iPill solution (dispenser + app) for all addiction clinics in the State (13 Clinics)
 - **\$7.8MM annual sales opportunity**
- Other states would also be able to place orders (do not need to go through a separate process in each other state)

Pharmacy-Insurer- Providers targeting all patients

- In discussions with a large pharmacy-insurer and hospital system (behavioral health department) for coverage at \$50 per dispenser
- Pharmacy-insurer dispenses 23 million opioid prescriptions per year
- Represents **\$1.2B annual sales opportunity**

The Solution **iPill platform**

Tech enabled device to reduce addiction risk

iPill APP

Actively controlled
dispensing

Prescription adherence

- ◆ Only the prescribed person can access pills
- ◆ Only at the prescribed dose



iPill Dispenser

Secure storage
Safe disposal

Tampering

- ◆ Destroys contained pills by dissolution
- ◆ Unused pills automatically destroyed at 90 days

Bluetooth Connection

iPill Patient Experience - Actively controlled dispensing

Patient Registration

Step #1

Patient gets
prefilled iPill



Step #2

Scans QR code

- Automatically downloads iPill App



Step #3

Registers in app

- name
- birthdate
- face / fingerprint
- personal code



After Registration For repeated doses

Step #1

Authenticate ID

- Face / fingerprint & personal code



Step #2

Dispense opioid





Support Mental Health

iPill App



Cognitive Behavioral Therapy (CBT)

1. Wellness
2. Anti-anxiety/Antidepression
3. Opioid reduction
4. Telehealth to behavioral therapist



Backend Data Collection



Cloud Computing

Predictive analytics
Population health management



Hardware become a SaaS / PaaS Company

Revenue Steams

Now

Future

iPill
Dispenser

\$\$

\$\$

iPill
Dispenser



\$\$

CBT

- 1. Wellness
- 2. Anti-anxiety/Antidepression
- 3. Opioid reduction
- 4. Telehealth to behavioral therapist

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Data

Predictive analytics
Population health management



Go to Market Strategy: Target Population of Youth < 26 y/o

High risk population

- ◆ Start of addiction risk
- ◆ Reduce acute use opioids turning into a chronic risk problem

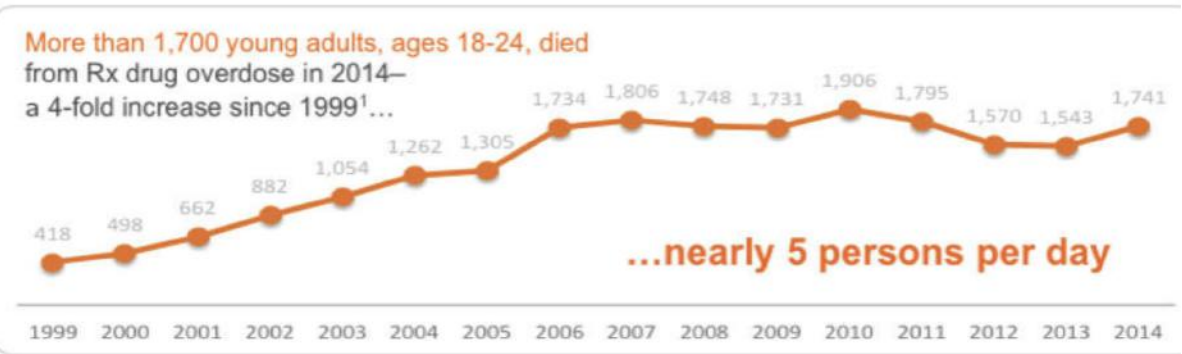
Lowest barrier to entry

- ◆ Familiar with apps/devices
- ◆ Parental guidance

Highest cost to society

- ◆ Long term addiction cost
- ◆ Greatest loss of worker productivity

CONSEQUENCES



Among young adults, for every death due to Rx drug overdose, there were:

119

Emergency Room Visits⁶

&

22

Treatment Admissions⁷



iPill — External Validation: Reduced Project Risk

2018

- ♦ A winner **FDA Innovation Challenge** for the Prevention and Treatment of Opioid Use Disorder

2019

- ♦ Designated **FDA** breakthrough product.
- ♦ Granted **US Patent**
- ♦ **PCT** patents **EU, UK, Canada**

2020

- ♦ A winner of the **Hartford InsurTech Hub**
- ♦ A winner of the **American College of Cardiology** Digital Health Innovation Challenge
- ♦ **FDA Class I Registration May 8, 2020**
- ♦ **Paid pilot study at Rutgers's Dental School** supported by a NIDA / NIH grant
- ♦ Pilot UConn/ Hartford Healthcare
- ♦ Purchase orders from Connecticut Clearinghouse





Strategic Partners

iPill





Competitive Analysis



iPill
\$50



Child
Resistant
Cap



Hero
\$399



Protex
RX
\$189



MedT
ime
\$289



Auto
Pill
\$69.95



Med
Ready
\$179



Med
Smart
\$589.99



TAD
Est. \$200



Medica
Safe
Est.\$250

Prescription adherence	✓		✓	✓	✓	✓	✓	✓	✓	✓
Deterrence	✓			✓	✓		✓	✓		
Secure storage	✓			✓				✓		
Destroys drug	✓									
Removes Unused Opioids From Circulation	✓			<p>The iPill superiority</p> <ul style="list-style-type: none"> • Lower price • 2 point authentication • Destroys pills • Incorporated cognitive behavioral therapy 						
Reduction in Healthcare cost	✓									
Reduction in Provider liability	✓									
Reduction in Manufacturer liability	✓									15



Barriers to Market Entry



Other devices are an expensive easy-to-bypass child-resistant cap

1. No secure storage
2. No active control dispensing
3. No destruction of unused pills
4. No insurance coverage
5. Limited CBT
6. Limited return on investment for pharmacy-insurers



Secure Dispensing



Bank ATM

1. Pharmacy-insurer buy in
2. Work Comp buy in
3. Improve care, save lives, reduce healthcare costs
4. Applications for reimbursement codes submitted



Financial Overview

Software plus Hardware

**Bootstrapped
\$500,000
Invested by founders**



	Year 1	Year 2	Year 3	Year 4	Year 5
Revenue	\$3.2 M	\$6.7 M	\$14.1 M	\$29.3 M	\$60.7 M
Expenses	\$5.1 M	6.4 M	\$5.5 M	\$5.8 M	\$5.0 M
Net	(\$1.9 M)	0	\$8.6 M	\$23.5 M	\$55.7 M

Break even point

Point of Profitability



1Q21

- “Breakthrough” designation for reimbursement codes (for Medicare and Health and Human Services)

4Q20

- Pilot with UConn/Hartford Healthcare
- Pilot with Rutgers Dental School

3Q20

- ✦ Market Launch Class I product
- ✦ Working with Foxconn to shrink the iPill

2Q20

- ✦ FDA Class I registration May 8, 2020



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A Smart Dispenser for
Revolutionary
Prescription
Safety

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