

Non-Confidential

iPill Dispenser

A digital health - hardware Innovation to improve prescription adherence and safety by reducing opioid diversion and abuse



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The Problem

The Child-Resistant cap no longer protects children from drug overdoses



Drug overdoses in children
rose 268.2%
between 1999-2016

The Child-Resistant cap was never meant to protect adults;
More than 49,600 adults died of a drug overdose in 2016



3.3 BILLION unused opioids and 9 million stolen opioid units
flood our communities every year for diversion and abuse

The Result

- Too many unused opioids
- No Control of Dispensing
- No Secure Storage
- No Safe Disposal
- No Monitoring

The Solution – the iPill Dispenser



- Improved Safety :
 - Prescription Adherence
 - Secure storage safe disposal for opioid drugs
 - Tamper resistant design
 - Contained pills destroyed if tampered
 - Unused pills automatically destroyed at 90 days
- Reduced Costs :
 - Prescription Adherence
 - Reduction of loss of workers' productivity
 - Reduction of insurers' member costs from opioid abuse and addiction
 - Reduction of opioid overdoses and death

Why Now?

We have no effective solution.

- Ever increasing child and adult overdoses.
- Ever increasing Heroin and Fentanyl overdoses.
- Government Policy has not been effective.
- Narcan is for those already overdosed.
- Suboxone is for people already addicted.



FDA is looking for a solution.

- The iPill Dispenser was named a winner of 2018 FDA Innovation Challenge for the Treatment and Prevention of Opioid Use Disorder .
- The iPill Dispenser was designated a 2018 “breakthrough” innovation medical device by the FDA.
- The iPill was then designated for the de novo FDA approval path.



iPilltm 5 year Forecast Market Potential

Year	TAM*	# of Expected Units (SOM**)	Gross Revenue
1	18 million	92,000	\$5 million
2	20 million	147,000	\$9 million
3	22 million	282,000	\$17 million
4	24 million	543,000	\$32 million
5	26 million	1,045,000	\$62 million

- ❖ Assumptions: Growth rate of prescription is 8.2% (1)
- ❖ Forecast includes sales of iPill dispenser only. Revenue from the revenue sensor, remote monitoring, data and app subscriptions

*TAM – Total Addressable Market. **SOM Serviceable Obtainable Market

iPill™ Competitive Landscape



Opioid Storage	Secured	Not Secured	Not Secured
Safe Disposal	Destroys on tampering Automatically at 90 days	Sometimes	Sometimes
Tamper resistance	Safe	No	No
Opioid Prevention	Yes	No	No
Cognitive behavioral therapy	Integrated	Not Included	Not Included
Monitors respiration	Integrated	No	No
Calls 911	Integrated	No	No
Remote physician access	Integrated	No	Sometimes
Blockchain technology	Yes	No	No

The iPill

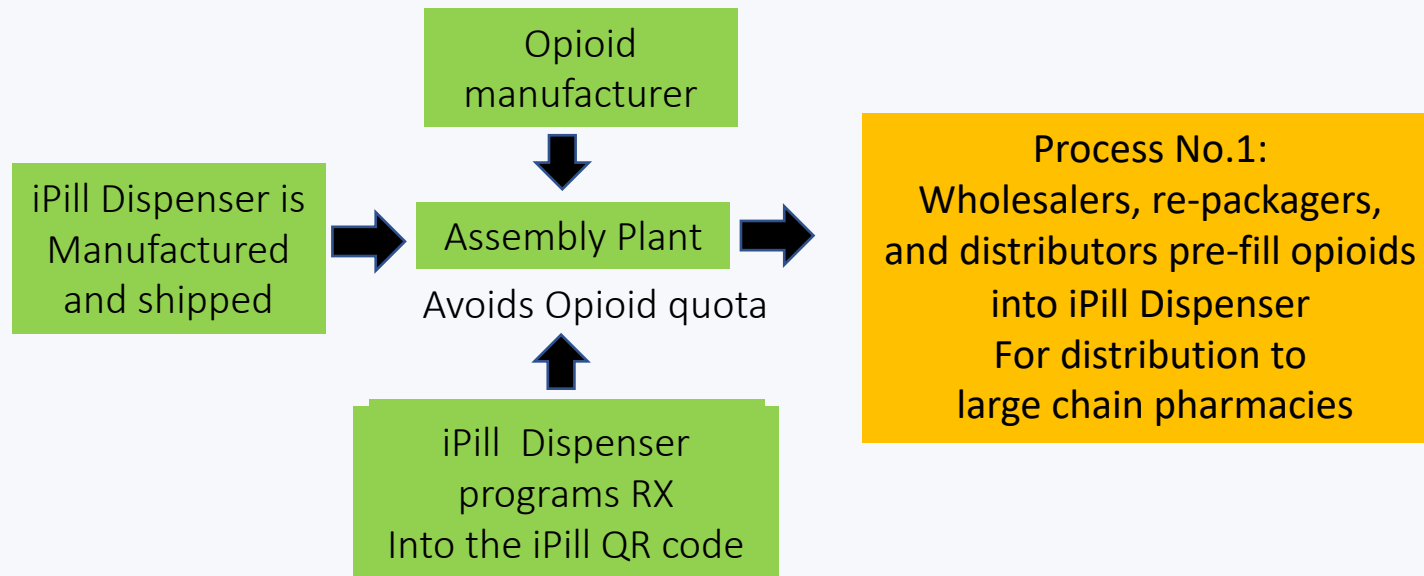


iPill Advantage over the Competition

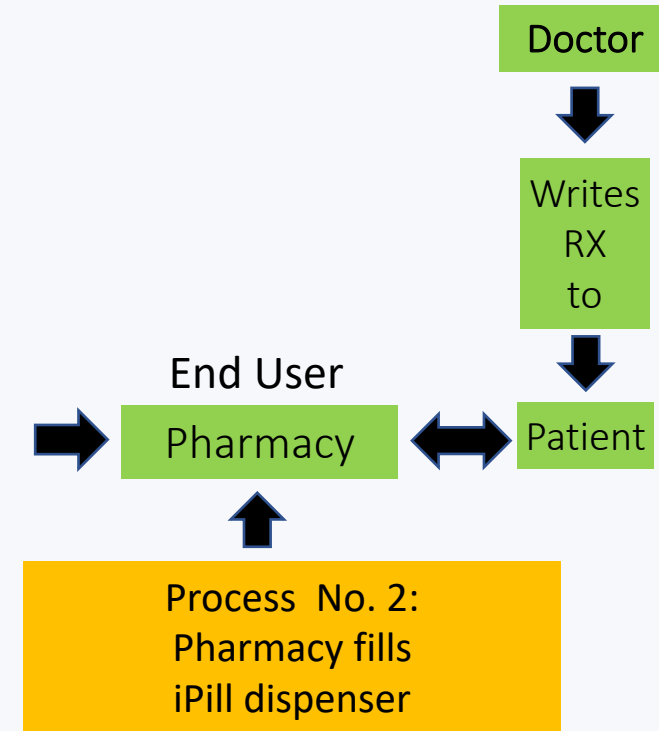
1. Secure storage and safe disposal.
2. Winner of the 2018 FDA Innovation Challenge for Treatment and Prevention of Opioid Use Disorder.
3. Designated as a “Breakthrough” medical device by the FDA.
4. Granted *de novo* 510K Class II expedited approval path.
5. Eligible for 3 years of market exclusivity through the Hatch-Waxman Act.

iPilltm Accommodates Multiple Business Models

Manufacturing and Supply Chain

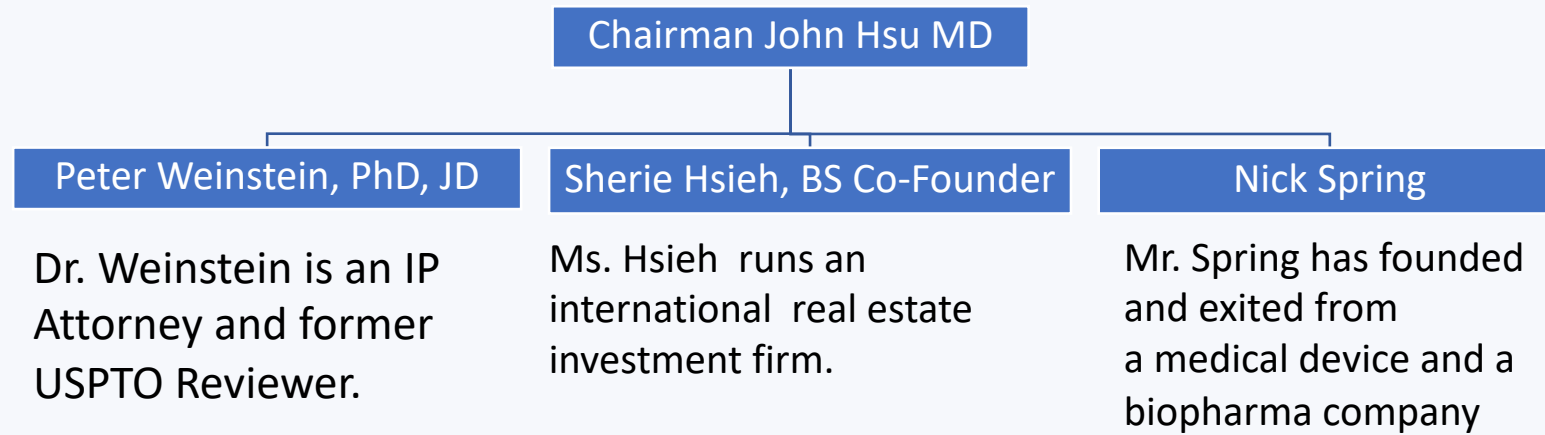


Prescription flow unchanged

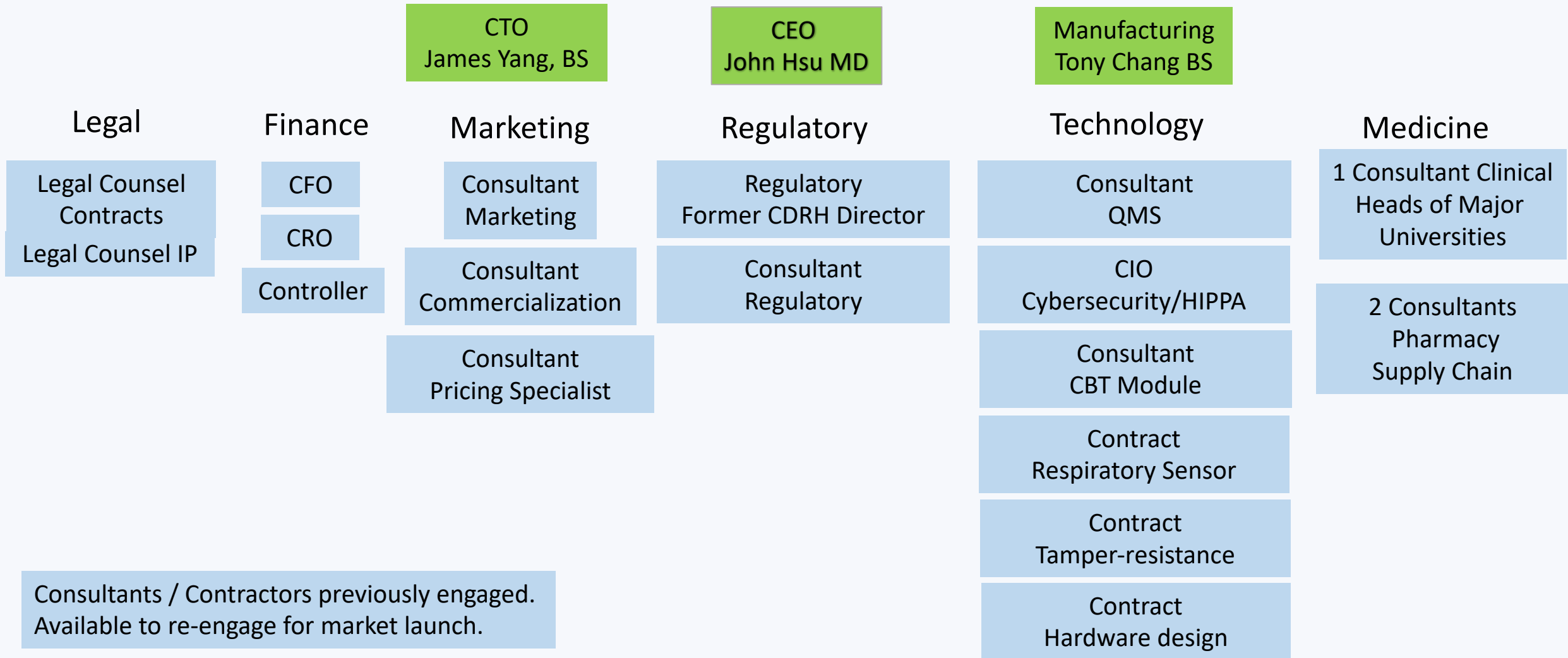


The iPill™ Board

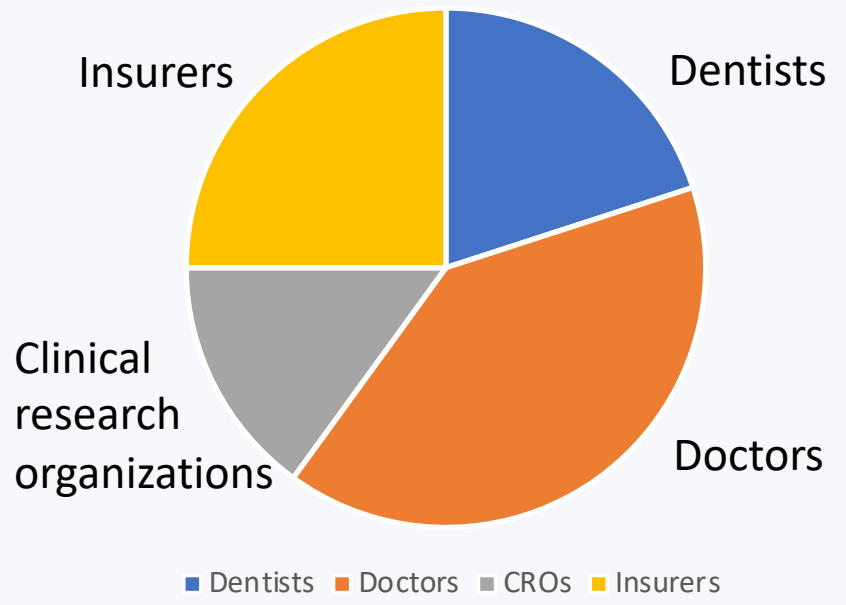
Experienced business executives



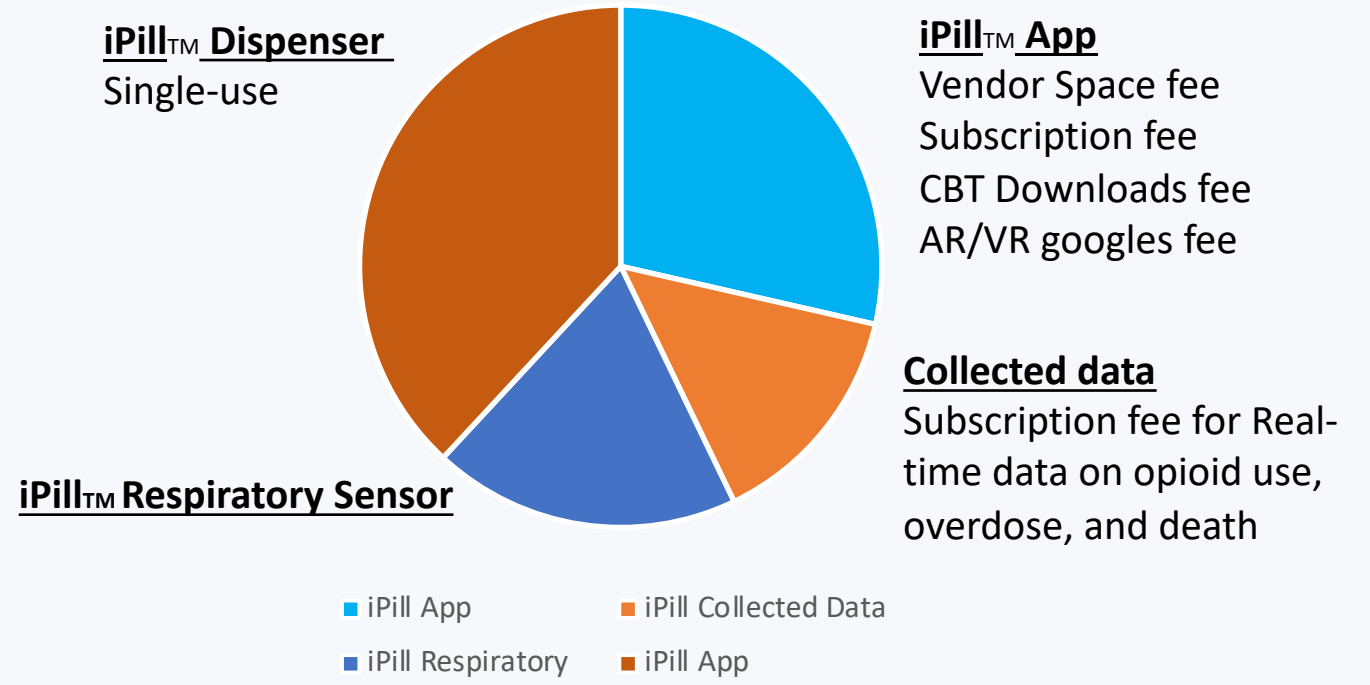
iPill™ Management



Customer Base



iPill™ - 4 Sources of Revenue



iPilltm Dispenser Expenditures

Already Done \$500K spent by founders
For proof of concept

- Premarketing to insurers
- iPill App prototype built
- iPill App QMS tested
- iPill Dispenser prototype built
- iPill Dispenser QMS tested
- Granted patent
- FDA registration Class I
- Team assembled not employed
- Customers identified

To be Done \$1.5 million request from investors
For FDA Registration Class I Approval

- iPill Dispenser Industrial design
- iPill Dispenser QMS tested
- iPill App completion
- iPill App QMS testing
- FDA Class I approval
- Injection mold tooling
- Logistics, Distribution, Marketing
- Market Launch
- Personnel Employed

Appendix

iPill_{tm} Next steps for Future investors

- Aug 2019 In 2019 large Canadian pharmacy chain approached iPill_{tm} to be exclusive secure packager
- Dec 2019 FDA Class I Registration of iPill Dispenser
(iPill_{tm} Class I - Tamper-resistant design and CBT component)
- Dec 2019 Secure strategic partners / investor commitments
- Mar 2020 Build Business Team
- Apr 2020 Structure Manufacturing (Fortune 100 company has signed a MOU)
- Apr 2020 Structure Supply Chain/Distribution) (2 opioid packagers have signed a MOU)
- Apr 2020 Marketing
- May 2020 Logistics
- Jun 2020 FDA Class I Launch to market
- Future iPill Class II de novo regulatory path
(iPill_{tm} Class I also with, bidirectional physician remote access, a biosensor to detect respiratory depression Collection of data for Blockchain)

Intellectual Property Summary

- iPill Patent granted on October 1, 2019 as U.S. Patent No. 10,426,707
 - 21 years of IP Protection.
 - 3 years market exclusivity with the Hatch-Waxman Act.
- Trademark iPill, iPill Dispenser, iPill Smart Dispenser.
- www.iPilldispenser.com.

iPilltm Timeline and Milestones

Today

	2017	2018	2019	May	June	Sept	Dec	2020	Jan	June
Company history	Company started	Patent Filed	Patent published	Notice of Patent Allowance		Patent Granted				
IP Status										
Marketing	Clinical Studies Pilot studies with PBMs/insurers							Clinical Studies Pilot studies with PBMs/insurers		Market Launch
Regulatory status	Prototype iPill _{ym} App / Dispenser Built	FDA 2018 Winner Innovation Challenge Opioid Use Disorder		FDA Designates iPill tm Breakthrough Medical device			FDA De Novo 510K Class I Approval	FDA IDE Submission	FDA De Novo 510K Class II Approval	Post Market Surveillance
Industrial Design							Industrial Design DFX: 3-4wks EVT: 12 wks DVT: 8-12wks PVT: 4 wks MP: 2-3 wks iPill tm App Design completion			
Clinical Studies								Clinical Studies Efficacy Human Abuse Liability		

Who pays for the iPilltm?

Goal is to minimize additional patient burden on insurers

Insurers

- Each insured patient who abuses opioids costs the insurer an additional \$14,810 annually.¹
 - iPill can significantly reduce this cost, in part by being granted standard HHS HCPCS Code for insurance reimbursement
 - A similar device, Pacira's Exparel is labeled as an opioid reduction technology.
 - It uses HCPCS² code C9290 for insurance reimbursement
 - The iPilltm value proposition was pre-marketed to OPTUM, ExpressScripts, BlueCross all of which indicated an openness to participate in pilot studies once the FDA IDE is filed.

CMS

- CPT code for physician remote monitoring of chronic pain
 - iPill to bill and collect monthly codes 99190,99090,G2010,G2012.³

1. <https://www.jmcp.org/doi/full/10.18553/jmcp.2017.16265>

2. HCPCS – Healthcare Common Procedure Code

3. <https://currenthealth.com/remote-patient-monitoring-reimbursement>

iPill Team

CEO Cofounder

John Hsu MD was an anesthesiologist and pain management physician for 28 years.

Software Engineer for Mobile App and Blockchain

James Yang BS was the principal developer for Ticketmaster and Hilton Hotel Mobile app.

Manufacturing & Supply Chain Consultant

Tony Chang, BS, worked as sales director for Ennoconn corporation He discovered 2 companies that recently sold to Amazon for more than \$1 billion.

Science Advisory Board

Scientific Advisor

Daniel I. Sessler, MD, Professor Cleveland Clinic

Dr. Sessler was the Editor, *Anesthesiology* and Seven other editorial boards in 2012. He has authored more than 750 full research papers; including 12 in the *New England Journal of Medicine*, 6 in *The Lancet*, and more than 200 in *Anesthesiology*.

Scientific regulatory advisor

Brian Harvey MD, PhD, former CDRH director of the FDA and is an expert on regulatory affairs for biologics, drugs, and medical device development programs.

Software engineer cognitive behavioral therapy module

Jared Adams, MD, PhD.

Dr. Adams is the CMO, CSO and director of research and product development of Self Care Catalyst, which currently has 60,000 users.

Pharmacy Supply Chain and Manufacturing Consultant

FDA Pharmacy Regulatory Consultant

Robert Nickell, RPh. as Associate Professor of Pharmacy taught FDA pharmacy regulations at the University of Southern California the Pharmacy School .

Consultants / Contractors

Legal counsel

Peter Weinstein PhD, JD, is a former USPTO reviewer and senior Patent Counsel at Baxter Healthcare Corporation. He was responsible for managing legal and intellectual property matters for Baxter.

Consultant Pharmaceutical Distribution and Operations

Christian Baker, MBA, has more than 25 years' experience working in operations, finance and distribution within the healthcare and pharmaceutical industry, mostly at McKesson. He has led large-scale finance and accounting operations managing over \$200B in healthcare-related financial transactions annually.

Consultant Cybersecurity HIPAA Compliance.

Matthew Clark, BS, has a 19-year history of experience in Information Systems Management. As an expert on cybersecurity, HIPAA, compliance, and information systems management, and has been awarded nearly \$400 million in multiple NIH, DOD, and HHS grants.

Consultant Commercial Officer

Chris Buckley, BA, has long been a successful marketing and commercialization executive in the medical device sector, specifically drug dispensers. He worked for 15 years at Pyxis, the hospital version of an automatic pill dispenser and Livi, a home pill reminder for the elderly.

Consultant Corporate Finance

Lacarya Scott, MBA has 16 years' experience across life science research, life science buy-side and biopharmaceutical companies advising on M&A transactions.

Consultant FDA Regulatory

Ginger Cantor, MBA, is a certified Regulatory Affairs/Quality professional with 25 years' experience, mostly at 3M. She has focused on pharmaceuticals, medical devices, and biological products)

Consultant Quality Systems Management

Kyle Rose, MBA, is a medical Device expert and a certified quality auditor (CQA) with regulatory and submission experience for a variety of markets including FDA, CE Mark, Health Canada, and CFDA.

Consultant Engineer for the iPill Dispenser Hardware

Nisha Sawhney, M. Arch. is an expert in industrial Design who specializes in mechanical design and engineering, medical device manufacturing and IOT connected devices.

Consultant Hardware Engineer for the Respiratory Sensor

Alfonso Limon PhD, is a technical director with numerous medical device engineering designs and medical applications combining mathematics, physics and machine learning.