

iPill Dispenser

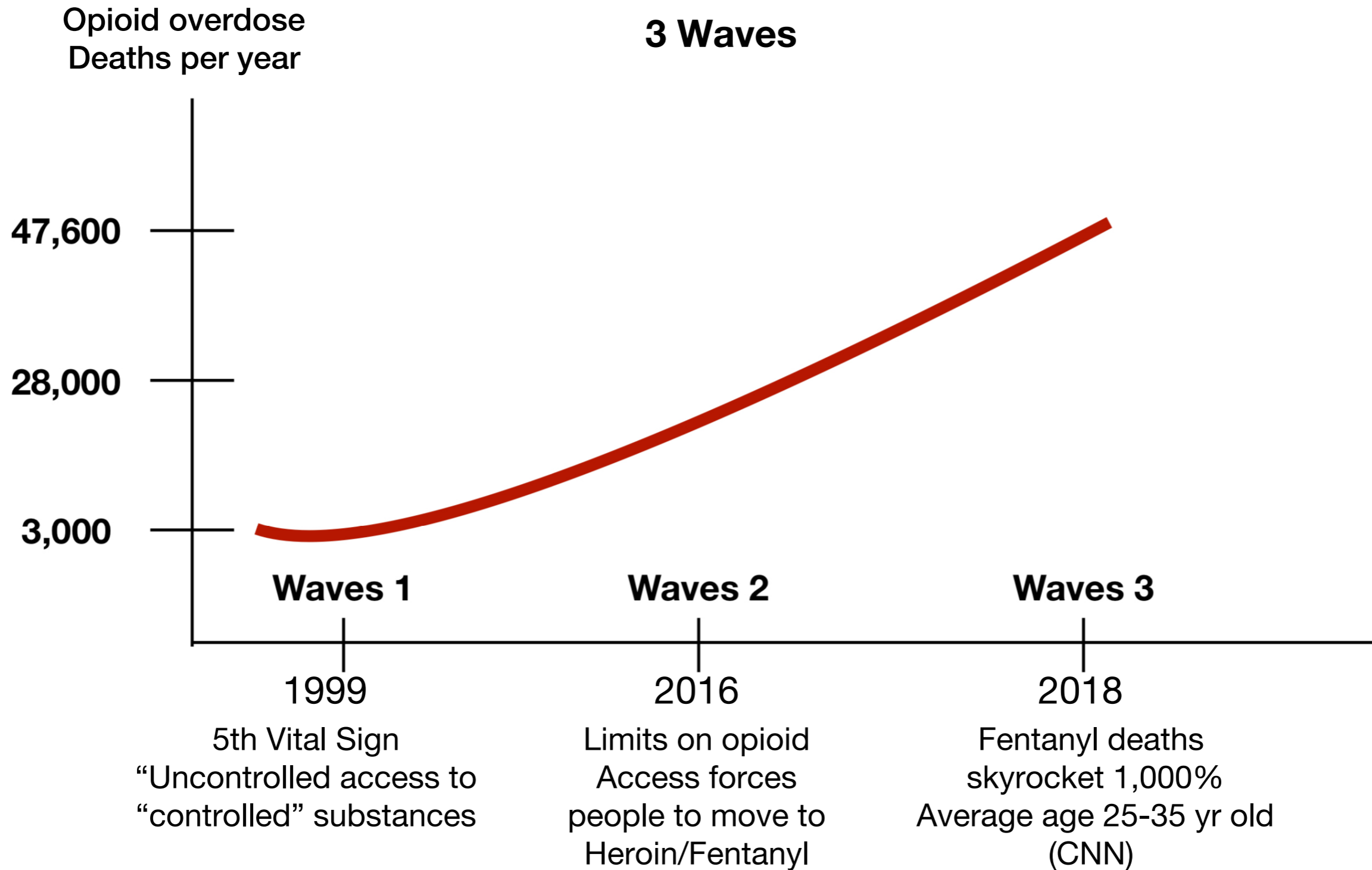
An innovation to prevent opioid abuse
from diversion and overconsumption



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The Problem

Opioid Crisis in the US



The Problem

Every 9 minutes someone dies of an opioid overdose
Every 25 minutes a baby is born suffering opioid withdrawal
100 million people take opioids daily



61% of overdosed patients did not have an opioid prescription

Opioid Prescriptions At Home

Self-Medicate
No secure storage
No safe disposal
No monitoring
No one can help



235% increase in children overdosing on their parents opioids

The iPill Opportunity

229 Million Opioid Prescriptions per year
100 million take opioids per day
53 million surgeries
6,210 US Hospitals

What is the issue

Excess opioids
Overconsumption
9 million units loss/year¹

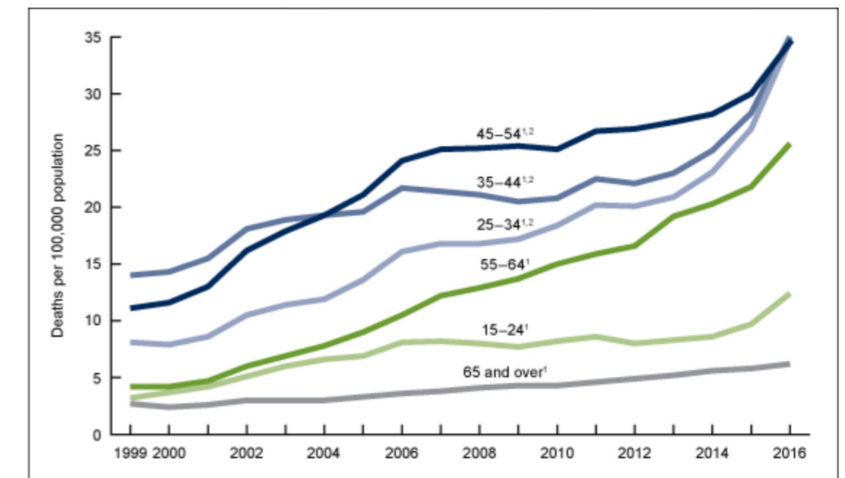
What's been tried

Limit Opioid Access
Put doctors in Jail
Narcan for already overdose
Suboxone for already addicted

All gov't interventions
have failed

Deaths keep Rising

Figure 2. Drug overdose death rates, by selected age group: United States, 1999-2016



Abuse starts in the youth

The iPill Opportunity to Save the Next Generation

- (1) 2018 DOJ DEA report on opioid abuse in the US
- (2) Nearly half of [40-54 year-old patients](#) with leftover pills kept them in their home, an age group that typically has teenage children – one of the most at-risk groups for misusing opioids
- (3) In 2016, overprescribing of postsurgical opioids resulted in [3.3 billion](#) unused pills flooding into communities 2017 IQVIA

The Solution

The iPill Dispenser

At Hospital



1,000 people die per year
Secure dispensing from nurses
Supervised by pharmacists

Why???

Opioids
Are
dangerous
Drugs

What is Needed?

A Secure Storage Safe Disposal dispenser
Monitoring for the home just like the hospital

At Home



47,600 people die per year
Unsecure self dispensing
Self medicating

The iPill Solution

iPill App



Secure Storage
ID Authentication
No Diversion

Wearable
Respiratory
Monitor

App Calls 911
if no breathing
is detected

Remote
Physician Access
BlockChain

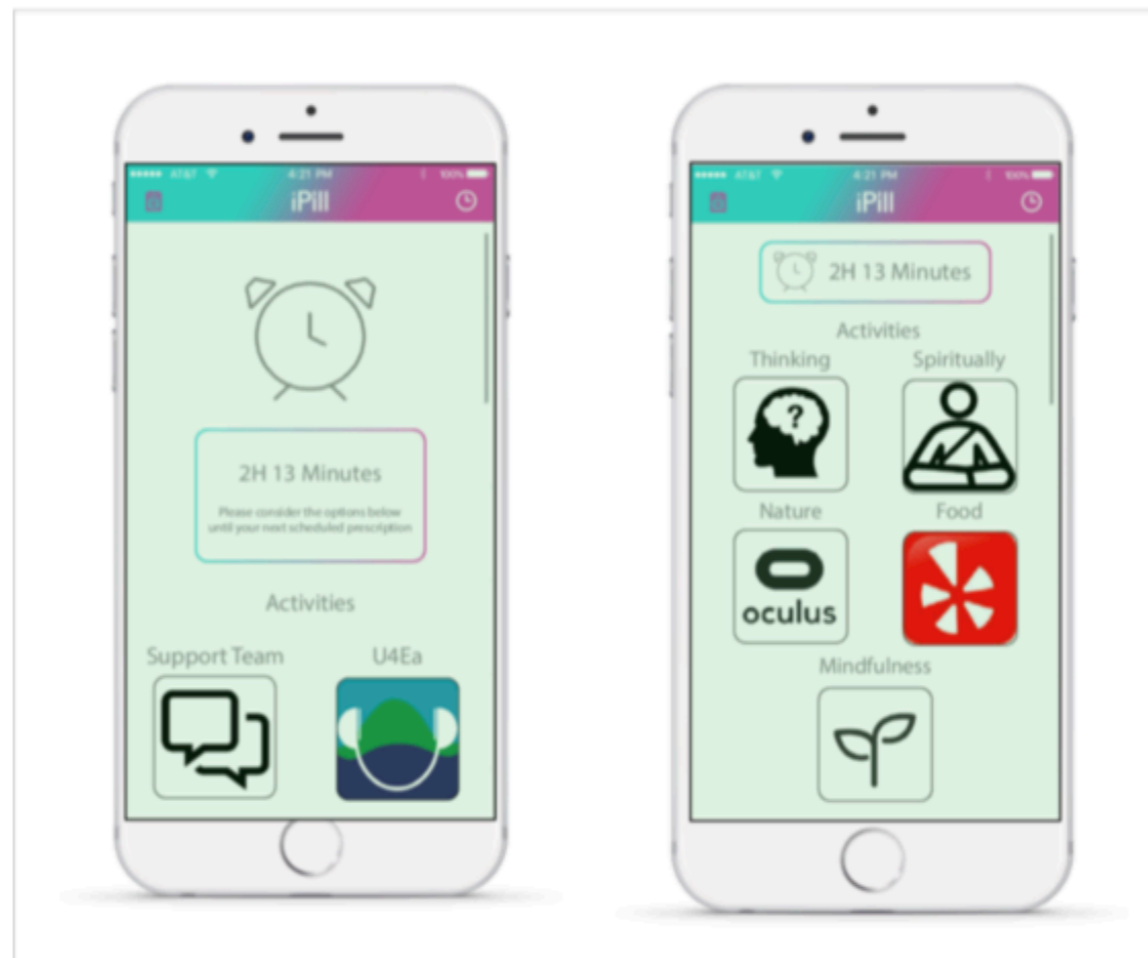
iPill dispenser



iPill App With Behavior Modification

AI avatar Cheri empowers patients to pursue more balanced behaviors

Virtual community links with social media and support groups



Collects Non-Opioid Intervention Data

AI predictive analytics

Shared with public health agencies and insurance companies

Winner of the FDA Innovation Challenge



The iPill Dispenser was the only dispenser/medical device chosen by the FDA in the FDA Innovation Challenge: Devices to Prevent and Treat Opioid Use Disorder ⁽²⁾

Advantage over competition

1. Designated a “breakthrough” product by FDA
2. FDA collaboration to shorten time to market

FDA Mandate for secure storage and safe disposal of **ALL** opioid prescriptions?

(2)<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhinnovation/ucm609082.htm#background>

iPill Dispenser a FDA mandate?

1970

Market is 229 million opioids

2019???

27.06.2018

FDA requirements for child-resistant packaging

In their draft Guidance for Industry "Child-Resistant Packaging Statements in Drug Product Labeling" the FDA has defined how medicinal products need to be labelled in the USA if their packaging is child-resistant. It is aimed at applicants, manufacturers, packing operations and wholesalers.

The "Poison Prevention Packaging Act (PPPA)" was implemented in the USA in 1970 in order to protect children under the age of five from unintended intake of substances in the household. This includes food products, cosmetics and pharmaceuticals. Until 1973, the FDA had been responsible for the enforcement of this law and after that, the "U.S. Consumer Products Safety Commission (CPSC)".

There are different approaches to making packaging materials child-resistant, e.g. by utilisation of a child-resistant closure such as a safety cap or by using certain single-dose blister packaging like peel-push blisters.

Child-resistant packaging is regarded as an important public safety measure through which the harmful and unintended intake of medicinal products by children is to be prevented.

When processing authorisation applications, the FDA evaluates various details about the containers and closures. This includes the type of packaging material which is to be used, the product's stability inside this packaging material and whether the closure design is suitable for the product. However, die FDA's assessment does not include the testing and assessment for whether or not a product complies with the provisions of the "Poison Prevention Packaging Act (PPPA)".

Since persons involved in health care and patients cannot see directly whether packaging is child-resistant or not, this information is supposed to be added to the labels in the future. The guideline therefore includes specific examples for the correct labelling of prescription and non-prescription drugs.

For more details please see the draft FDA Guidance for Industry "[Child-Resistant Packaging Statements in Drug Product Labeling](#)".

All opioids should have the iPill Dispenser???

FDA is focused secure storage safe disposal solutions

Dr. Scott Gottlieb
Current Commissioner FDA

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm582954.htm>

Dr. Douglas Throckmorton
Deputy Director
Regulatory Affairs FDA



NEW ENGLAND JOURNAL OF MEDICINE

The FDA and the Next Wave of Drug Abuse — Proactive Pharmacovigilance

Douglas C. Throckmorton
May 29, 2018 Original Article

In response to the opioid crisis, the Food and Drug Administration (FDA) has taken action on multiple fronts. We have approved better

IPill chosen 2018 FDA Innovation Challenge For Opioid Use Disorder

<https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhinnovation/ucm609082.htm#background>

iPill Management



**John Hsu MD,
CEO, co-Founder**



iPill



**Sherie Hsieh, BS
co-Founder**

Peter Weinstein, PhD, JD
Brian Harvey MD, PhD
Lacarya Scott, MS, MS, MBA
Ginger Cantor, RAC, MBA
Kyle Rose, MBA
Nisha Sawhney, B.Arch.M.ID
James Yang
Alfonso Limon, PhD
Jared Adams, MD, PhD
Robert Nickells, Pharm.D.
Tony Chang

Legal Counsel
Scientific Regulatory Advisor
Business Development / Auditor
Regulatory Consultant
Quality Systems Management
Engineering Design Consultant
Mobile App / Blockchain Designer
Engineering Design Consultant
Cognitive Behavioral App Design
Pharmaceutical Supply Chain
CDMO Ennoconn

The iPill Market

Global Automatic Pill Dispenser Market ⁽¹⁾

\$1.755 Billion in 2016

\$3.023 Billion in 2023

229 million prescriptions per year (NIH 2017)

100 million people take opioids daily

2018 FDA announcement: "Need a secure storage and safe disposal solution" ⁽²⁾

(1) (Report Buyer 2017)

(2) <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm582954.htm>

iPill Market Opportunity

Value Proposition

Gov't

**Private Insurers
PBMs**

**Dentists
Physicians**

CRO

**Reduction \$635 billion
Yearly Healthcare costs
from opioid
abuse/addiction**

**Savings of
\$12,000 ER visit,
\$28,000 hospital
visit, or \$128,000
rehab stay.**

**Safety for the
patient. Improve
patient satisfaction.
Improve business.
Decrease liability**

**Improve data in
Clinical studies.
Protection of
expensive drugs.
Offsite patient
Monitoring**

Who Pays for it

**For device "Reimbursement"
UDI Code with FDA
HCPCS code with HHS**

UDI - Unique Device Identification

HCPCS code - Healthcare Common Procedure Coding System code

HHS- Health and Human Services of Centers for Medicare/Medicaid Services

CROs - Clinical Research Organizations

PBMs - Pharmacy Benefit Managers

iPill Value Proposition

A cost-effective secure storage & safe disposal solution to actively control opioid dispensing

Patients / Physicians

- Prevents addiction and risk of death
- Prescription adherence

Customers

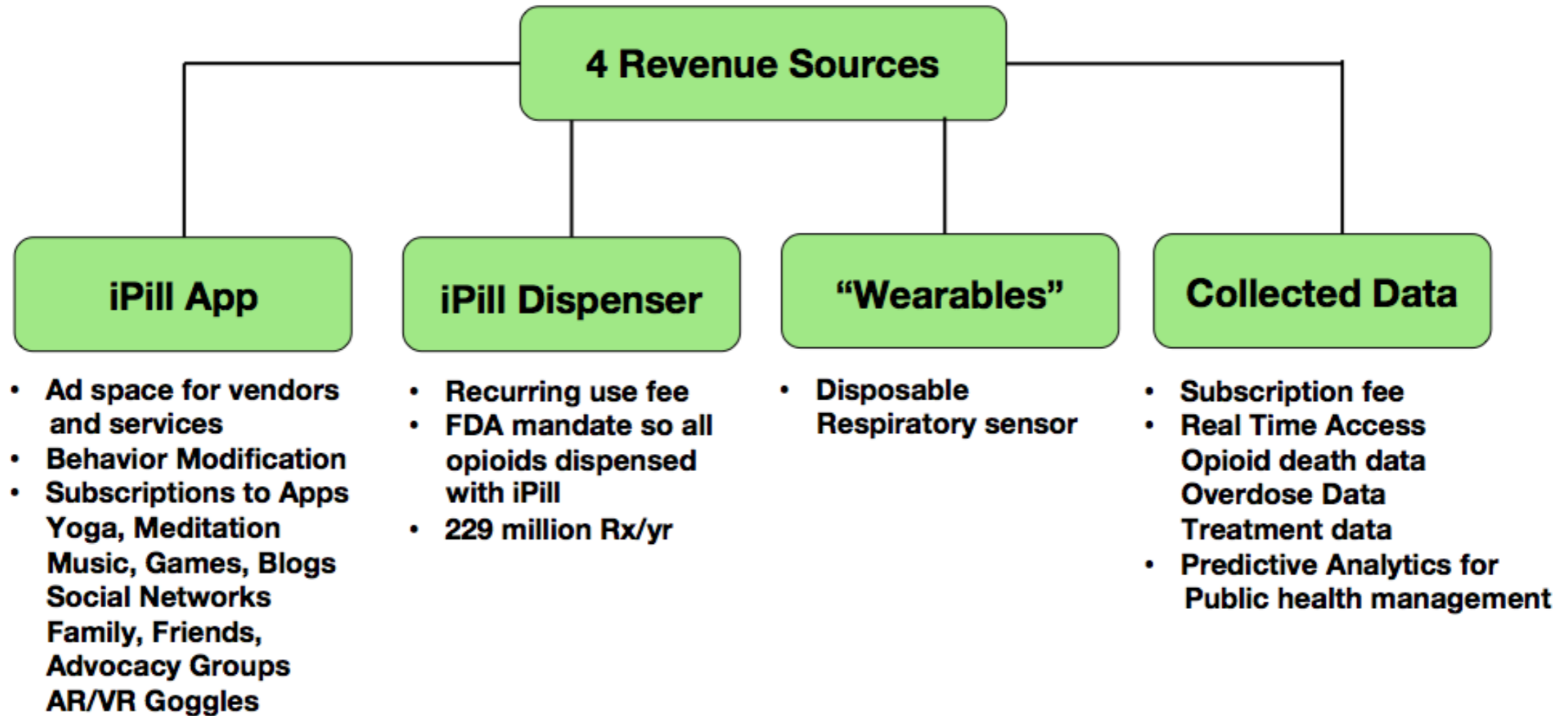
- Public health agencies
- Insurers, PBMs, CROs
- Valuable real-time data
- Predictive analytics
- Population Health management

Reduce healthcare costs

Prevent opioid-related
ER visits \$12,000
Hospitalizations \$28,000
Rehab Programs \$128,000
\$635 billion cost to GDP

A Healthier and Better Future

iPill Monetization



Premarketed to OPTUM, ExpressScripts, Anthem Blue Cross Connecticut
FDA, CDC, DOD, DEA, HHS, CMS, Clinical Research Organizations, Pharmacies

PBMs and insurers indicate desire to participate in
step studies to validate the value proposition

iPill Financial Projections

Market Share “%”	Year	No. of Rx	Retail Price	Revenues
Approval Process	2019			
1% of the Market	2020	2,290,000	\$40	\$91,600,200
2% of the Market	2021	4,580,000	\$40	\$183,200,000
3% of the Market	2022	6,870,000	\$40	\$274,800,000
5% of the Market	2023	11,450,000	\$40	\$458,000,000
10% of the Market	2024	22,900,000	\$40	\$916,000,000
100% of the Market		229,000,000	\$40	\$\$\$\$

“Base Case” scenario based on the following assumptions:

- **FDA places IR opioids into REMS (Done in September 2018).**
- **Advocacy and Physician groups make some recommendations for pain treatment which favor secure storage and safe disposal**
- **FDA considers all opioids to be dispensed in a secure storage safe disposal method (1)**

(1)https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm594443.htm?utm_campaign=01302018_Statement_New%20efforts%20to%20curb%20opioid...

iPill

Competitive Analysis



**Passive Control
Dispenser**



Pill Reminders



**Active Control
Dispenser**

Opioid Storage	Not Secured	Not Secured	Secured
Disposal	Sometimes	Unsafe	Safe
Tamper Resistant	No	No	Yes
Diversion Prevention	No	No	Yes
Cognitive Behavioral Therapy	Not Included	Not Included	Integrated
Monitors Patient Respiration	No	No	Integrated
Calls 911	No	No	Integrated
Remote Physician Access	Sometimes	No	Yes
Blockchain technology	No	No	Yes

Current Status of iPill

Accomplished

1. Pre-marketed to PBM / Insurers / CROs
2. Prototype iPill App and iPill Dispenser built
3. Patent Filed
4. Premarket collaboration with FDA for development
5. Designated as a breakthrough device by the FDA

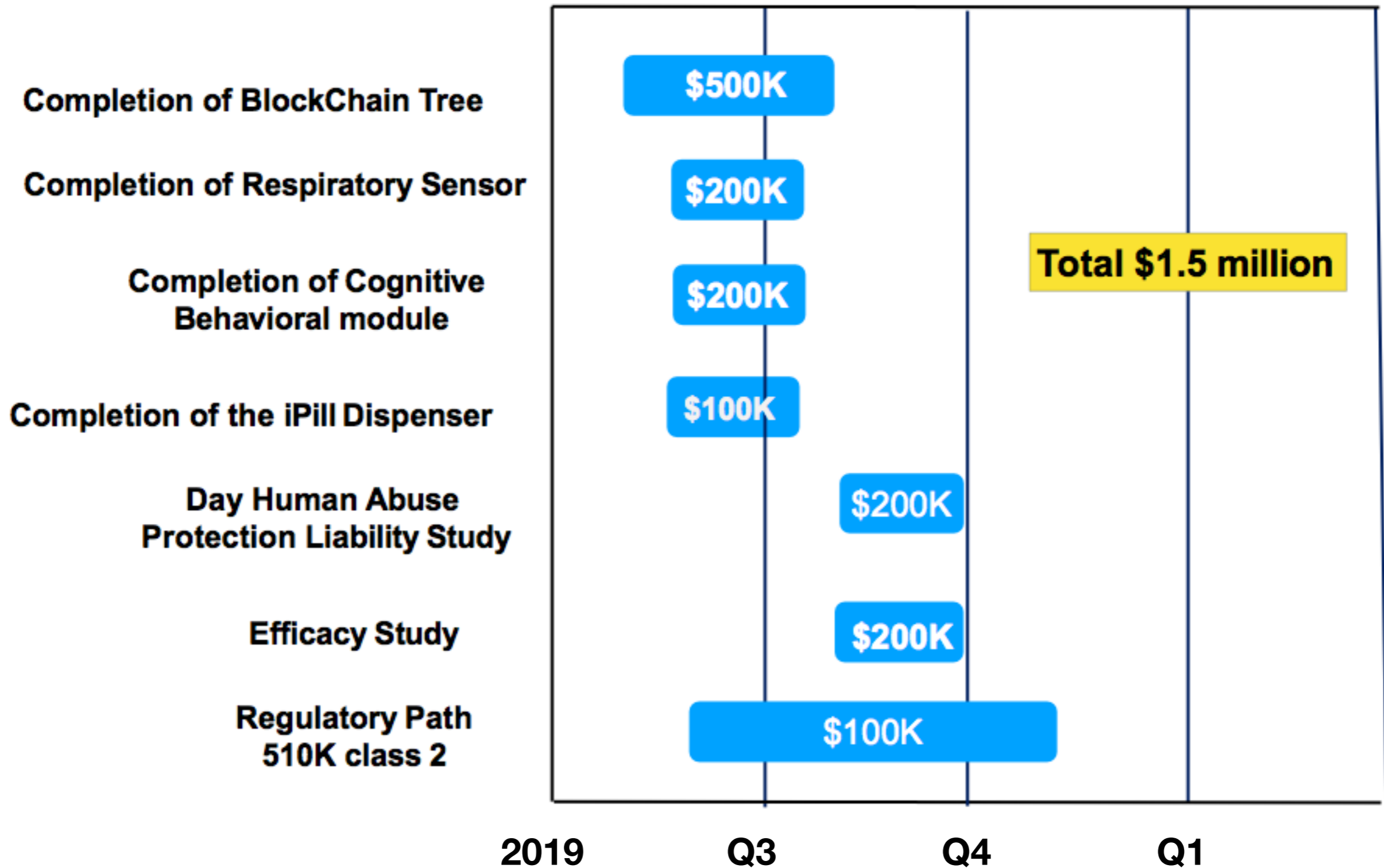
Notice of Allowance Granting of Patent 5-13-2019



To be Completed

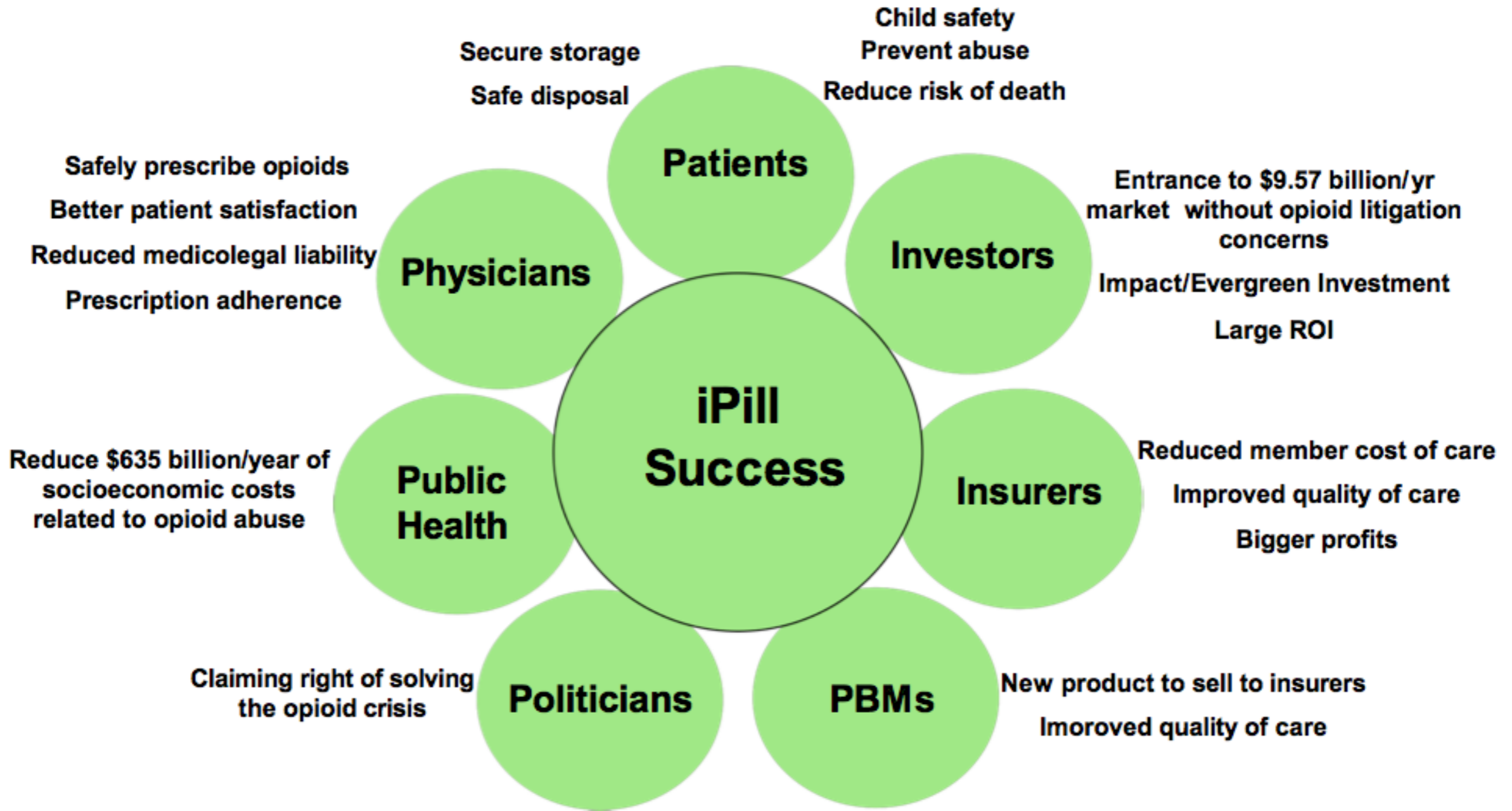
1. Respiratory Sensor Software
2. BlockChain Tree development
3. Cognitive Behavioral Module
4. ~~Patent granted~~
5. HAP Liability Study
6. Efficacy Study
7. 510K Class 2 approval

iPill TimeLine and Use of Funds



Alignment of Stakeholder Goals

iPill Benefits All Stakeholder





Thank you



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