Patient Controlled Dispenser & Deactivator of Liquid Oral Pain Medication

PCDD
Empowering Patients with a Sip

jinlei.li@yale.edu | daniel.wiznia@yale.edu | claudia.see@yale.edu
Pain Management: A Universal Issue
The Problem: 100 million patients need postoperative pain control, but current modalities are flawed

Nurse-Dispensed Pills
- Staffing costs
- Opioid diversion

Intravenous (IV) Patient Controlled Analgesia (PCA) Pump
- Invasive
- Not indicated for most patients

Pill PCA
- Side effects
- Opioid diversion
Co-Founder Team

Jinlei Li, MD, PhD FASA
- YSM Associate Professor
- YNHH Director of Regional Anesthesia
- Nationally known Acute Pain Expert
- Inventor of Yale Cocktail

Daniel Wiznia, MD, FAAOS
- Yale Assistant Professor of Orthopaedics and Mechanical Engineering
- Former McKinsey Consultant
- Quik-Clot / Z-Medica startup

Claudia See, BS
- 4th-yr MD-MBA Student at Yale ('24)
- Former R&D Engineer at Medtronic
- Yale College '17 (BS in Biomedical Engineering)

Advisors: Yale Ventures, Yale Center for Clinical Investigation, Saul Ewing Arnstein & Lehr LLP, regulatory consultants
How It Works

**Steps:**

1) Patient will press a button to dispense a dose.

2) The PCA pump will pump this dose into the medicine cup.

3) The patient will be able to drink this dose by sucking out of a straw.

4) Any excess medicine left over will be deactivated in the waste reservoir using activated charcoal & solidifier.
PCDD Revolutionizes Pain Management

**Personal:** Only unlocks with patient's RFID fingerprint

**Safe:** Eliminates need to return unused medicine

**Customizable:** Smaller dosing at higher frequency

**Trackable:** Real-time remote monitoring of consumption
Patients and Nurses Prefer Medication on Demand

**Patients**

"I prefer to use this device because I am an independent person."

“For my c-section, I was pleased with my PCA. I did not have to call and it was there.”

- 57% called nurse for pain meds 4-6x daily
- 34% receive delayed medicine
- 71% would prefer or be interested to try PCDD

**Nurses**

“Change of shift is when patients can wait 1 hour for medicine.”

"All we do is pass pain meds.”

- 47% of their time is spent managing pain
- Rate PCDD 6.4 out of 10 over pills
Many Organizations Value PCDD

Opioid Diversion Committee and Stewardship Committee
Patient Family Advisory Committee
Pharmacy Investigational Drug Service
<table>
<thead>
<tr>
<th>Category</th>
<th>Product</th>
<th>Low Nurse Staff Requirement</th>
<th>Low Cost (compared to IV pump)</th>
<th>Ease of Use</th>
<th>Patient Pain Control Satisfaction</th>
<th>Diversion Control (compared to pills)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse Dispensed Pills</td>
<td>NA; Standard of Care</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCA Pump</td>
<td>CADD-Solis: Traditional IV Pump</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PCoA Acute (Dosentrx)</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pill PCA</td>
<td>Avancen Corporation Medication on Demand (MOD)</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ReX (Dosentrx)</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid PCA</td>
<td>PCDD</td>
<td></td>
<td></td>
<td>✔</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Welcome to PCDD

Here's how much medicine you have taken so far:

<table>
<thead>
<tr>
<th>Days After Surgery</th>
<th>Medicine Consumed (mL)</th>
<th>Pain Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>30</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>40</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>50</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>60</td>
<td>6</td>
</tr>
<tr>
<td>7</td>
<td>70</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>80</td>
<td>8</td>
</tr>
<tr>
<td>9</td>
<td>90</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td>100</td>
<td>10</td>
</tr>
</tbody>
</table>

Please select your pain level to receive a titrated dose.

<table>
<thead>
<tr>
<th>Pain Level</th>
<th>Dose (mL)</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>5</td>
<td>25</td>
</tr>
</tbody>
</table>

ALERT!
We've noticed you have rated 10/10 pain over the last 2 doses.
Our team would like to adjust your dosing.

Call Us: 888-888-8888

Dose has been dispensed!
Please provide your fingerprint to unlock the straw and sip your medicine.

Your next dose will be available in 2 hours at 4:00 PM
Remote Home Monitoring Data

1) Real-time opioid consumption data are continuously sent to both patients & physicians
2) Physicians can remotely modify prescriptions based on patient needs
Global Pain Management Market

TAM
Global Pain Management Market
$27B

SAM
Opioids $7.5B

SOM
Liquid Opioids
$4.4B

Market Opportunity

Beachhead Market:
Surgical patients who need high dose opioids for 12+ hours.
- Orthopedics
- Trauma
- General surgery
- Surgical oncology
- Cardiothoracic

Unit Economics Show $1M Savings with 380 Patients

Each PCDD saves ~$2,634 or 35% compared to pills

<table>
<thead>
<tr>
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<th>Medicine</th>
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<th>Patient Satisfaction</th>
<th>Risk of Increased Healthcare costs</th>
<th>Overhead Costs</th>
<th>Total</th>
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<tr>
<td>Pills (Status Quo)</td>
<td>$4.4K</td>
<td>$1.3K</td>
<td>$60</td>
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<td>$10</td>
<td>n/a</td>
<td>1.28x</td>
<td>$50</td>
<td>$7,463</td>
</tr>
<tr>
<td>PCDD</td>
<td>$3K</td>
<td>$900</td>
<td>$300</td>
<td>$30</td>
<td>$300</td>
<td>4%</td>
<td>n/a</td>
<td>$500</td>
<td>$4,829</td>
</tr>
</tbody>
</table>
Financials: PCDD to Earn $1.2M in 2029 Across the Northeast
PCDD to Launch at YNHHS in 2025

- Filed 2 provisional patents
- Built 3 prototypes
- Interviewed customers

SWIMMING WITH SHARKS AWARD

Swimming with Sharks Award from ASA

August 2022

- $150k YNHHS Innovation Award
- n=30 build with contract manufacturer
- Filed utility patent
- Yale SOM Award for Entrepreneurship

Spring 2022

- $30k Blavatnik Award
- YNHH clinical trial
- FDA Investigational Device Exemption & 510k submissions

Summer 2022

- Build 2nd gen device
- YNHHS device launch

Fall 2022

- YNHHS clinical trial
- FDA Investigational Device Exemption & 510k submissions

Summer 2023

- Build home version of device

2026
<table>
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<th>2024 Milestone</th>
<th>Cost</th>
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<td>Complete clinical trial at YNHH</td>
<td>$20k</td>
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<td>(funds to support research &amp; nursing staff)</td>
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<td>Complete FDA Q-submission to determine regulatory strategy</td>
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<td>FDA 510(k) application fee</td>
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**$30k Blavatnik Award Enables FDA Approval for PCDD**

- YNHH clinical trial
- FDA Investigational Device Exemption & 510k submissions

**2024 Milestone**
- Spring 2024
- Fall 2024

**2025 Milestone**
- Summer 2025
- Build 2nd gen device

**2026 Milestone**
- Fall 2026
- Build home version of device

**$30k Blavatnik Award**

- Enables FDA Approval for PCDD

**Cost**
- Complete clinical trial at YNHH: $20k
- Complete FDA Q-submission: $5k
- FDA 510(k) application fee: $5k
- YNHH device launch: $30k

**Other Milestones**
- Summer 2023: YNHH device launch
- Spring 2024: Complete clinical trial at YNHH
- Fall 2024: Complete FDA Q-submission
- Summer 2025: Build 2nd gen device
- Fall 2026: Build home version of device

**Additional Information**
- $30k Blavatnik Award
- Enables FDA Approval for PCDD
- Complete clinical trial at YNHH (funds to support research & nursing staff)
- Complete FDA Q-submission to determine regulatory strategy
- FDA 510(k) application fee
- Milestones
  - Spring 2024
  - Fall 2024
  - Summer 2025
  - Fall 2026

**Additional Costs**
- $20k Complete clinical trial at YNHH
- $5k Complete FDA Q-submission
- $5k FDA 510(k) application fee
- $30k YNHH device launch
Patient Controlled Dispenser & Deactivator of Liquid Oral Pain Medication

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# Unit Economics Show $1M Savings with 380 Patients

Each PCDD saves ~$2,634 or 35% compared to pills

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**Assumptions:**
1. Mean cost of $4,383 & 4.35 day length of stay (LOS) for opioid-related hospitalization (PMID: 30584350), ~3 day LOS for PCDD
2. Bureau of Labor Statistics hourly nurse and pharmacy costs (Nursing: $37/hr for 24 hrs for 4.35 vs. 3 days; Pharmacy: $37/hr for 1 vs. 5 hrs)
3. Estimated using GoodRx pricing for 40 hydromorphone tablets and 120mL hydromorphone oral solution
4. Estimated unit cost from $22,999 cost of BD’s automatic pill dispensing Pyxis machine vs. PCDD
5. 4% cost savings from 2018 study delivering integrative medicine to hospitalized patients (PMID: 29474095)
6. Estimated from 28% increased costs of Opioid Use Disorder (OUD) (PMID: 29764482) & 4% OUD prevalence in the US (PMID: 35783994)
7. Estimated unit cost to train nurses and pharmacists on the automatic pill dispensing Pyxis machine vs. PCDD
Financials: PCDD to Earn $1.2M in 2029 Across the Northeast

Expenses
- 1st Contract (30 prototypes): $120,000
- Regulatory: Phase 1: $30,000
- Regulatory: Phase 2 (510K): $30,000
- Costs of Goods Sold ($300/unit): $30,000, $150,000, $1,200,000, $1,800,000, $4,500,000

Total Expenses: $150,000, $30,000, $30,000, $150,000, $1,200,000, $1,800,000, $4,500,000

Revenue
- YNHHS Innovation Award 2022: $150,000
- Anesthesia Pitch Award: $1,000
- Yale SOM Award: $7,500
- Units sold ($400/unit): 100, 500, 4,000, 6,000, 15,000

Sales Revenue: $40,000, $200,000, $1,600,000, $2,400,000, $6,000,000

Total Revenue: $158,500, $40,000, $200,000, $1,600,000, $2,400,000, $6,000,000

Net Profit: $8,500, $-38,500, $-28,500, $21,500, $378,500, $221,500, $1,278,500
# PCDD 5-Year Financial Projection

<table>
<thead>
<tr>
<th>Expenses</th>
<th>2023</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract Manufacturer: Initial contract for 30 prototypes to be used for initial pilot study</td>
<td>120,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract Manufacturer: 2nd contract to produce prototypes for phase II RCT study at limited delivery networks of YNH: YSC and SRC only</td>
<td>200,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contract Manufacturer: 3rd contract to produce first lot of products for market YNH system wide (estimated 100 units)</td>
<td>300,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory: Phase 1 (Initial Regulatory Plan)</td>
<td>30,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory: Phase 2 (510K submission to FDA)</td>
<td>60,000</td>
<td>20,000</td>
<td>20,000</td>
<td>20,000</td>
<td>20,000</td>
</tr>
<tr>
<td>Legal: Intellectual Property</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salary for 10 Personnel</td>
<td>500,000</td>
<td>500,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Trial at YNHH</td>
<td>75,000</td>
<td>120,000</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Prototyping Supplies</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
<td>$5,000</td>
</tr>
<tr>
<td>Form and continue LLC</td>
<td>$720</td>
<td>680</td>
<td>680</td>
<td>680</td>
<td>680</td>
</tr>
<tr>
<td><strong>Total Expenses</strong></td>
<td><strong>230,720</strong></td>
<td><strong>405,680</strong></td>
<td><strong>325,680</strong></td>
<td><strong>525,680</strong></td>
<td><strong>525,680</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Revenue (awards, grants, etc.)</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>YNHHS Innovation Award 2022</td>
<td>150,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anesthesia Conference Shark Tank 2022 Award</td>
<td>1,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Units sold ($200 per unit)</strong></td>
<td></td>
<td></td>
<td></td>
<td>100</td>
<td>200</td>
</tr>
<tr>
<td>Sales Revenue</td>
<td></td>
<td></td>
<td></td>
<td>$20,000</td>
<td>$40,000</td>
</tr>
<tr>
<td><strong>Total Revenue</strong></td>
<td><strong>151,000</strong></td>
<td><strong>0</strong></td>
<td><strong>0</strong></td>
<td><strong>20,000</strong></td>
<td><strong>40,000</strong></td>
</tr>
</tbody>
</table>

<p>| Expenses Less Revenue                                                   | 79,720    | 405,680   | 325,680   | 505,680   | 485,680   |
| <strong>Total Start-Up Costs</strong>                                                | <strong>2,013,440</strong>|           |           |           |           |</p>
<table>
<thead>
<tr>
<th>Classification Pathway</th>
<th>FDA Background Research</th>
<th>FDA Application</th>
<th>FDA Registration</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **Class 1: Low Risk of Illness or Injury** | Research and Device Classification | Exempt from Approval Process | Register the Establishment and List the Device | - Least regulatory scrutiny  
- Low risk devices require limited review |
| **Class 2: Moderate Risk of Illness or Injury** | Research and Device Classification | 510(k) Premarket Notification Application | Register the Establishment & List the Device | - Moderate regulatory scrutiny  
- If predicate (similar) device exists on the market, process is smoother |
| **Class 2: De Novo** | Research and Device Classification | 510(k) Premarket Notification Application | Register the Establishment and List the Device | - Moderate regulatory scrutiny  
- If no predicate, additional filing requirements needed |

Q-Submission needed (feedback ≤75 days) to determine regulatory path
$58 Billion Global Pain Management Market

2003 Inhalation: AERx (Aradigm)

2006 Intranasal: Rylomine (Morphine)

2007 Inhalation: AeroLEF for Fentanyl

2015 Sublingual Sufentanil Tablet System (SSTS, 1st Gen, Zalviso)

2016 Transdermal: Fentanyl Iontophoretic System (FITS)

2017 Oral: PCoA Acute (Dosentrx)

2017 Oral: Avancen Corporation Medication on Demand (MOD)

2018 Oral: ReX (Dosentrx)

Trend Towards Oral PCAs
Oral Liquid Format is Advantageous

PCDD design principals
- Oral liquid opioids exist for every opioid pill
- Similar bioavailability
- Patients like liquid format
- Pharmacy is very experienced with oral liquid opioids
PCDD Safety Features & Clinical Benefits

- Attaches to any PCA pump
- Tamperproof
- Secure straw and cup
- Empowers patient for improved outcomes
- Lowers side effects: overdose/euphoria
- Reduces nursing workload
- Digitizes opioid consumption in hospital
- Accurate estimation of discharge prescription need
- Deactivates left over medication
PCDD Tracks Medication at Home
PCDD Mitigates Diversion of Prescription Drugs

2020 opioid prescriptions dispensed:

- 43 M (30%) Fully Taken
- 99 M (70%) Not Fully Taken

>50% of misused prescribed opioids were obtained from family & friends

PCDD Improves Equity in Pain Management for African Americans, Low SES, and Females
