



California Consortium of
Addiction Programs and
Professionals

Progressive Early Interventions in Prescription Drug Abuse

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A Tale of Two Toddlers...in a Family without Fathers



My Daughter Jane



Her Cousin John



Overview

- **Prescription Drug Abuse and Policy Interventions**
- **Cost and Extent of Problem: Pre- and Post-Covid**
- **Early Intervention: Access Control and Efficacy**
- **Pending Policy Developments**



Prescription Drug Abuse & Policy Interventions

Prescription Drug Abuse is an Index Source for Illicit Drug Use – Far more than Marijuana



80%

Of heroin users
START with a
prescription **OPIOID**

90%

Of abusers **START**
in their **TEENS**

#1

Source for **TEEN ABUSE**
is **PILFERING** from the
family medicine cabinet

Epidemiology: Diversion = Transmission

Locker Room Values

Oxy 10 - \$80

Xanax "Bar" - \$40

~700,000 Initiations Annually

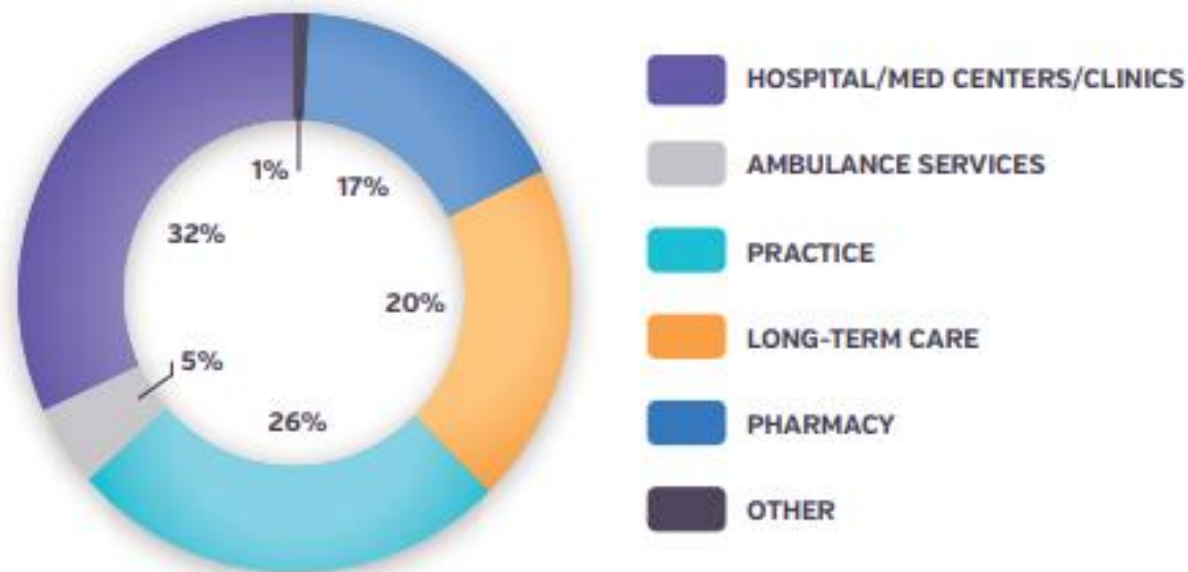


Other Diversion

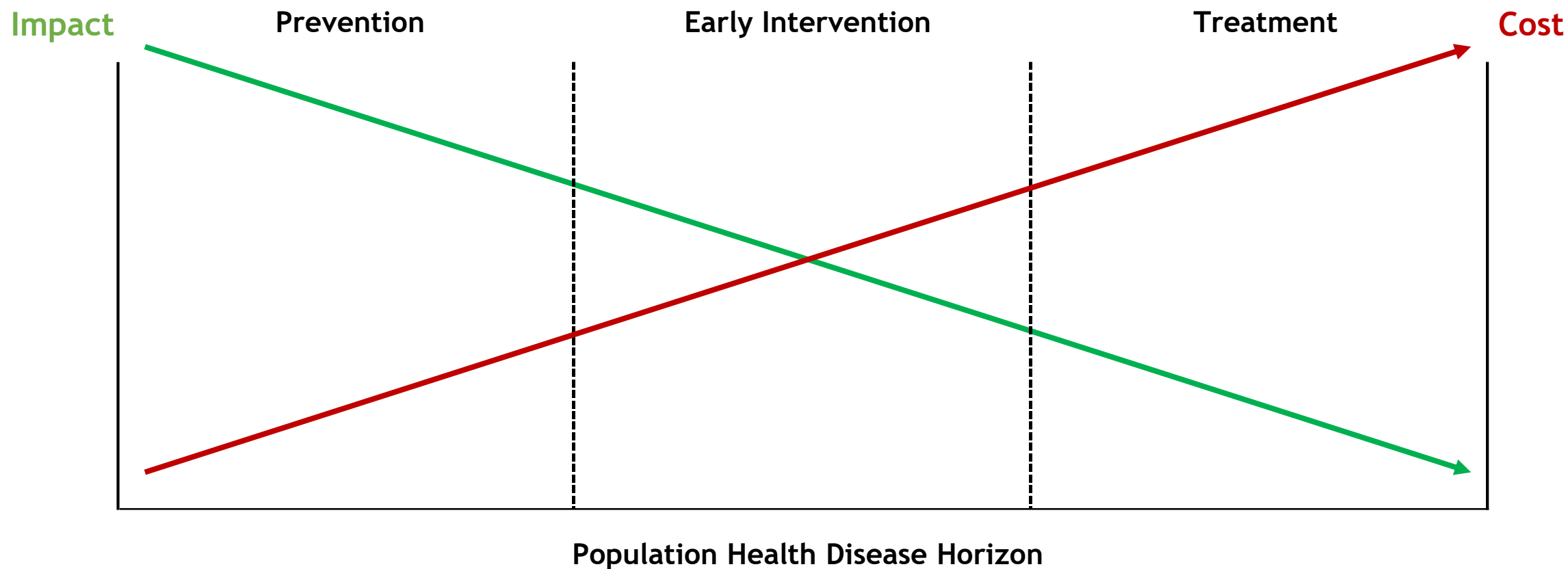
Nurse Who Stole Pain Medication From Her Elderly Patients at Two Area Nursing Homes Sentenced to Federal Prison

Former doctor who practiced in Roslyn sentenced for illegal opioid distribution

Chicago pharmacy technician sentenced to five years in prison for stealing opioids and selling them for profit

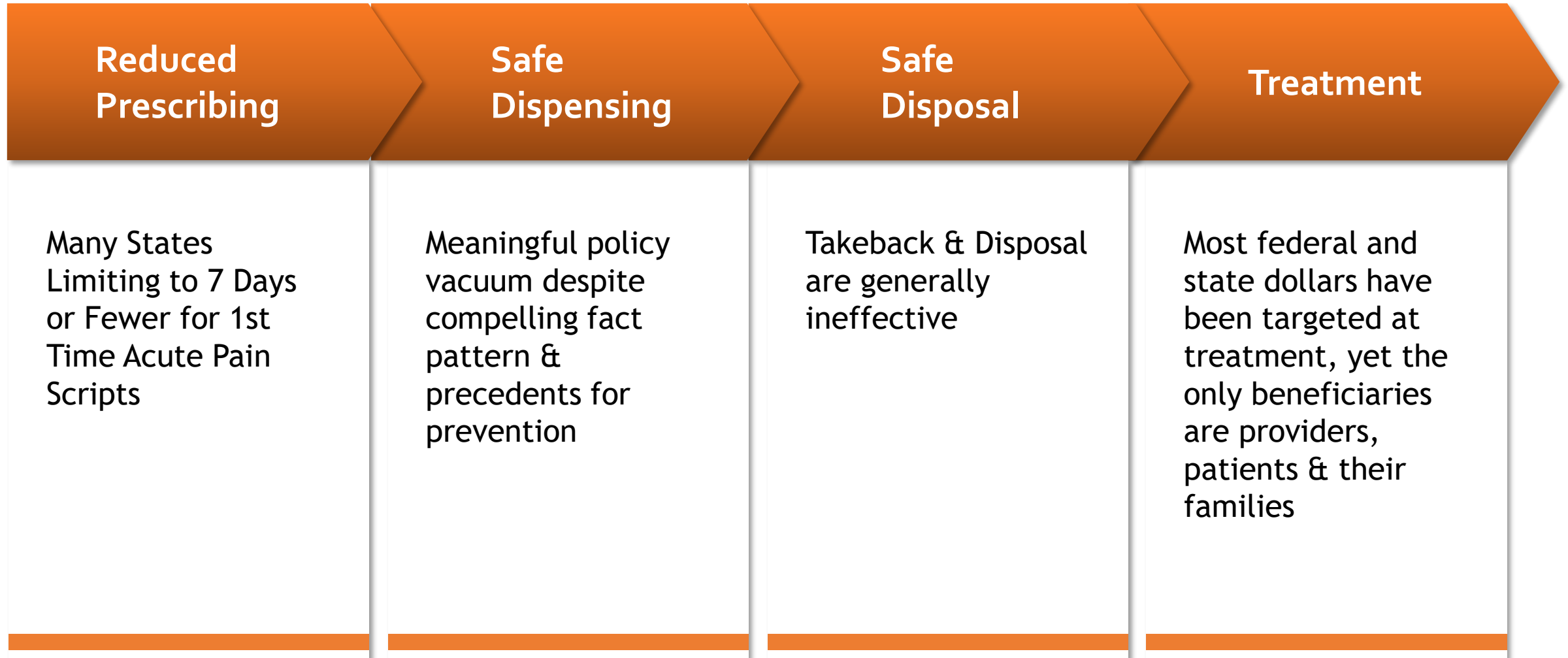


Policy Context: Population Health Management



Current Policy Continuum

There is a material void in safe dispensing - *the 2nd most effective policy after reduced prescribing, & most visible of solutions with constituents*



Cost & Extent of Problem

Composition and Total Cost of the Opioid Epidemic

Each year, opioid overdose, misuse and dependence account for:



\$35 billion in health care costs

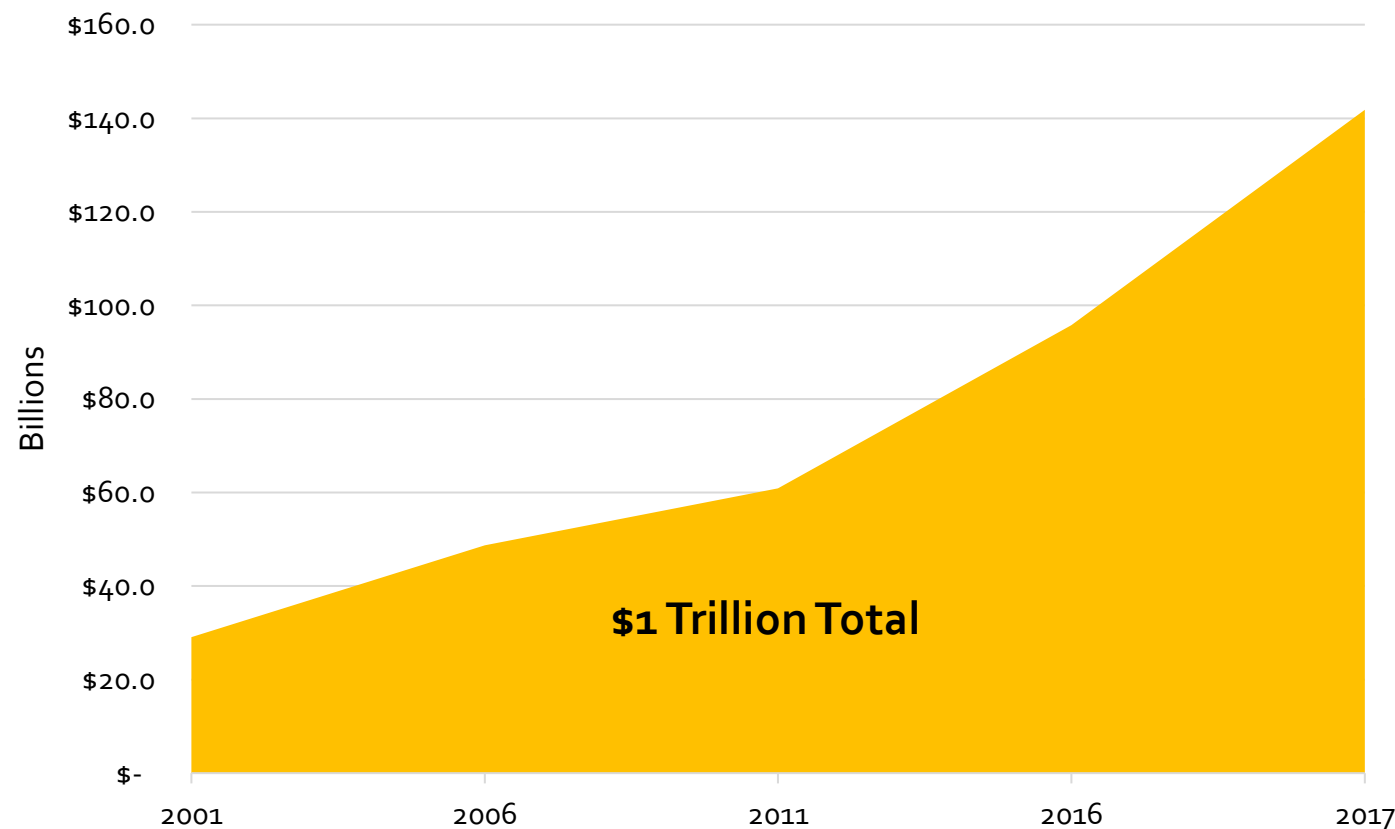


\$14.8 billion in criminal justice costs

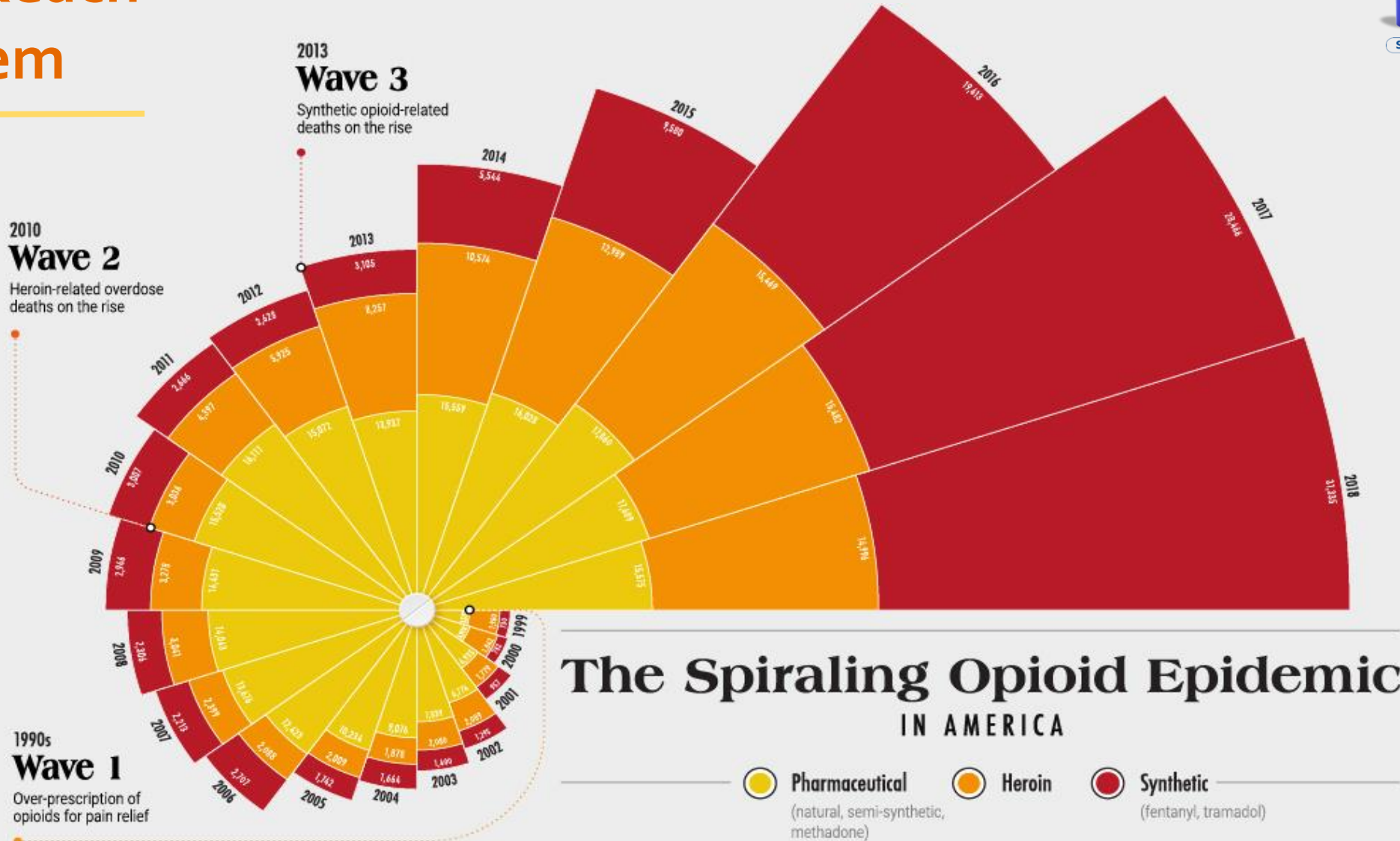


\$92 billion in lost productivity

Total & Projected Costs of the Opioid Epidemic



Extent and Reach of the Problem



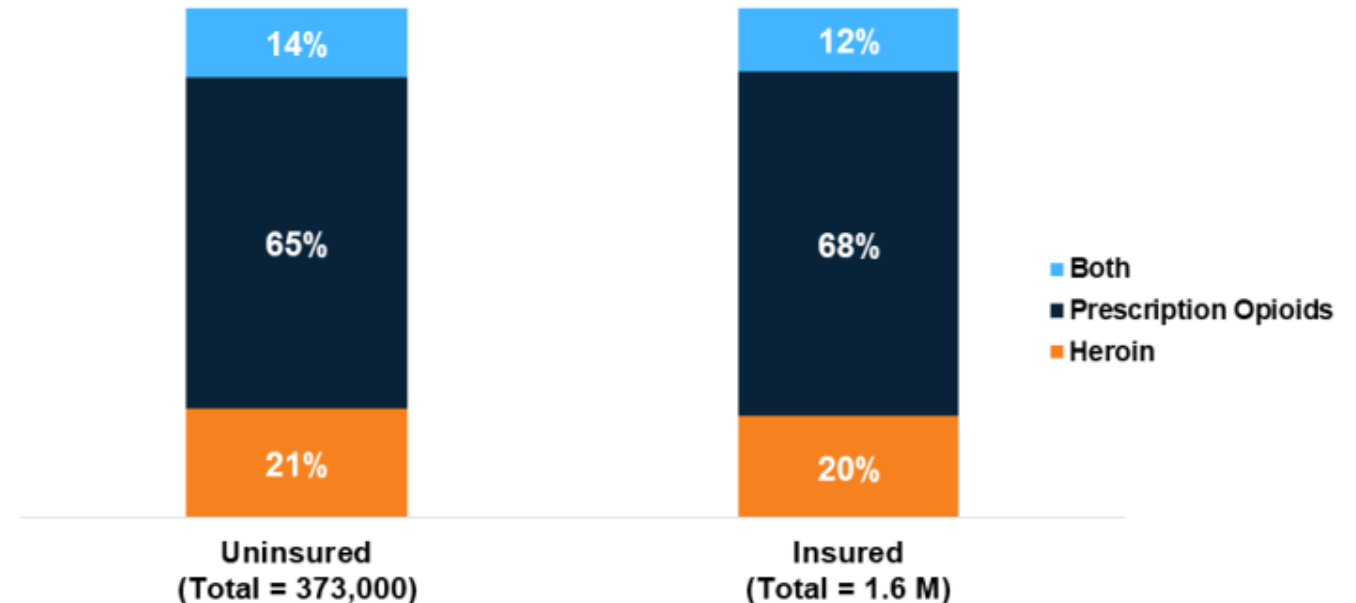
Economic Burden

Key Facts

- **1 in 5** adult opioid users are uninsured
- Between **54%-61%** of ED visits involving opiates resulted in a hospitalization
- Average Admission Cost is **\$14,235**
- Potential Economic Burden: **\$3 trillion**

Figure 3

Share of Uninsured Nonelderly Adults with Opioid Use Disorder, by Drug Type & Insurance Coverage, 2016-2017



NOTE: Nonelderly adults are 18 to 64 years. In this analysis, fentanyl, a common synthetic opioid, is included as a prescription opioid; therefore, the misuse of illicitly manufactured fentanyl may not be fully captured.
SOURCE: KFF analysis of 2016 & 2017 National Survey on Drug Use and Health (NSDUH).

COVID-19 Impact: Syndemic



When a Pandemic Collides with an Epidemic

"We're seeing more overdose cases going straight to the morgue rather than to the emergency department."

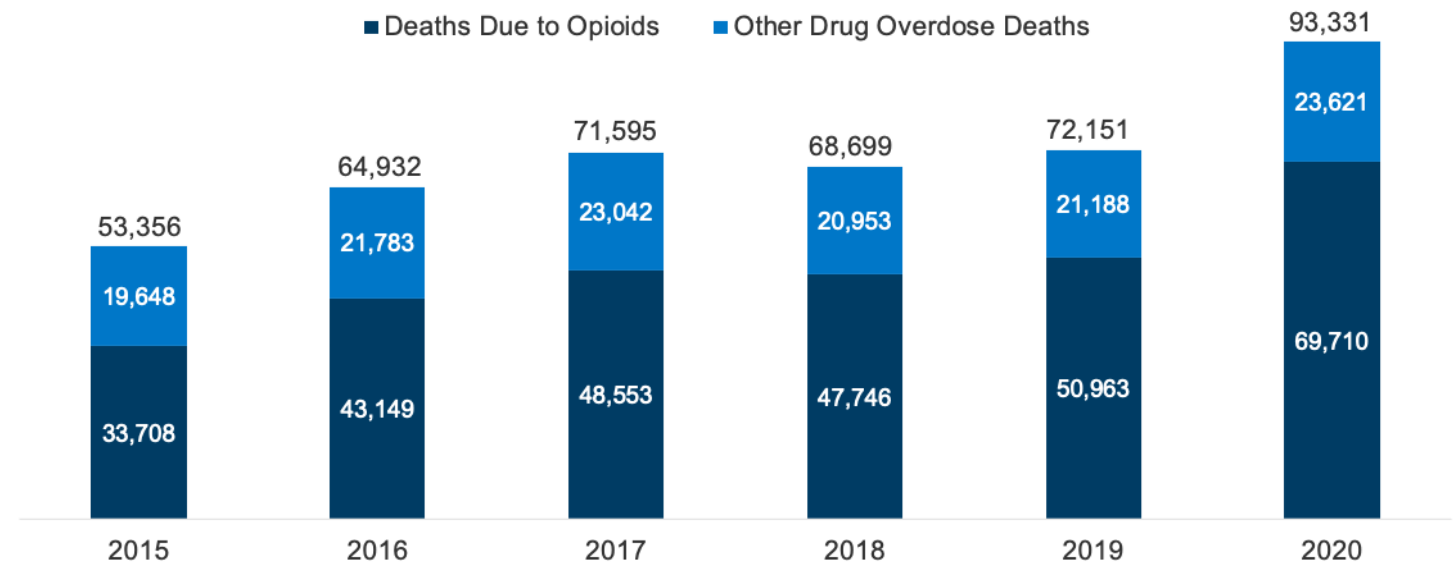
Daniel Buccino - Clinical manager of the Johns Hopkins Broadway Center for Addiction

"The opioid crisis hasn't just gone away. It's not solved. It's been shoved into the background by the 24/7 COVID-19 news cycle."

John Kelly, PhD -Director of the Recovery Research Institute at Massachusetts General Hospital

Figure 1

Deaths due to Drug Overdose, 2015–2020



NOTES: Estimates are based on provisional data.

SOURCE: CDC, National Vital Statistics System. Available from: https://www.cdc.gov/nchs/nvss/mortality_public_use_data.htm.

KFF



COVID-19 Impact: Behavioral Health

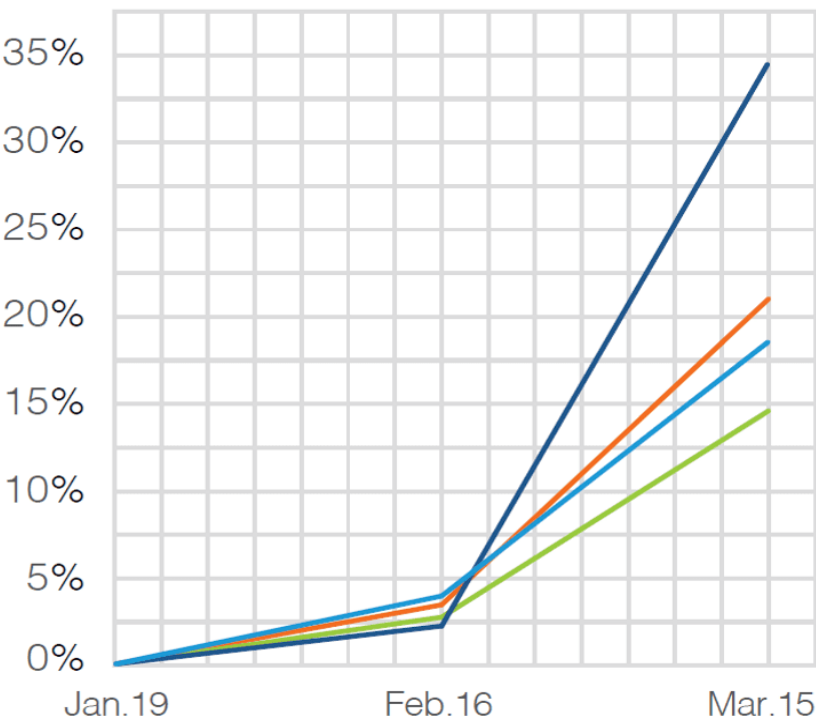
*Treatment for anxiety
insomnia and depression*

PERCENT CHANGE IN PRESCRIPTIONS FILLED PER WEEK FOR MENTAL HEALTH MEDICATIONS

By select weeks from January 19, 2020 to March 15, 2020

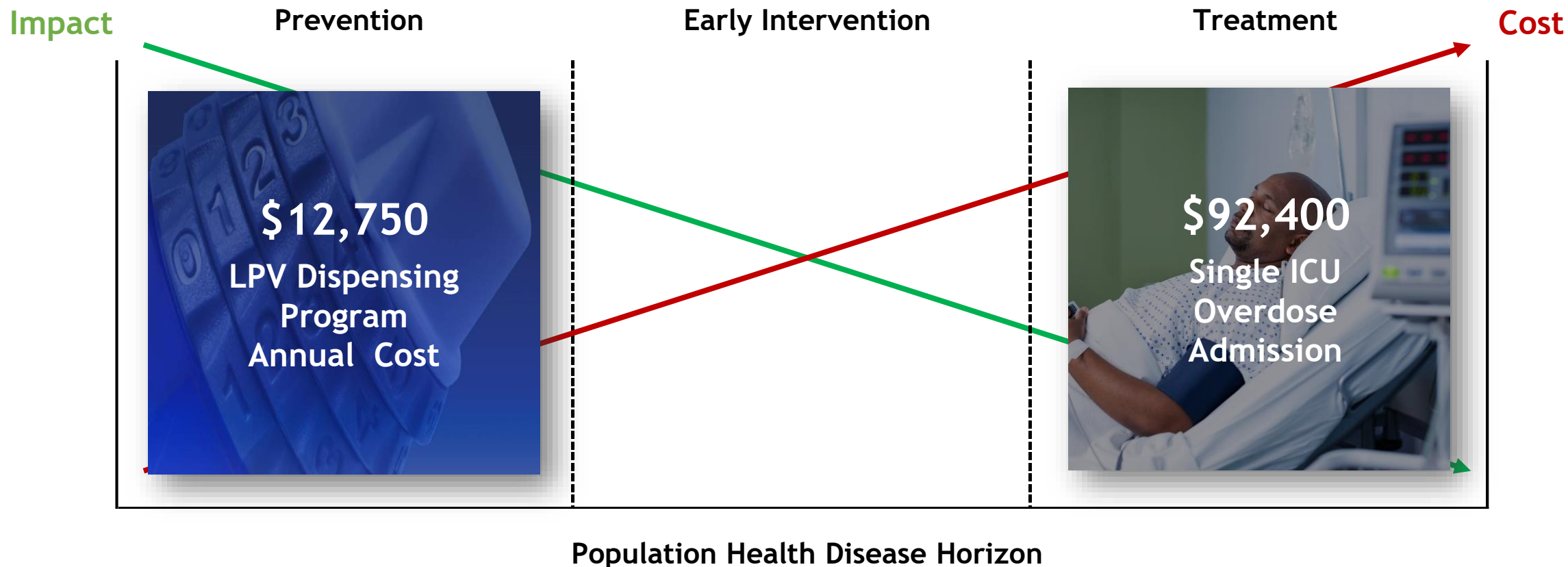


Depression Anxiety Insomnia Total



Early Interventions: Access Control and Efficacy

Policy Context: Population Health Management



1 in 5 opioid abusers is uninsured, generating substantial uncompensated costs of care

Precedents in Epidemiology: Controlling Transmission

Malaria & Nets

- Insecticide-treated nets can reduce deaths in children by 1/5 and episodes of malaria by half.
- Cost of net \$2.



COVID-19 & Masks

- If most people wear a mask in public, the transmission rate can stop the spread of COVID-19.
- Cost of mask \$2.



Access Control Precedent: 1970 Poison Prevention Packaging Act

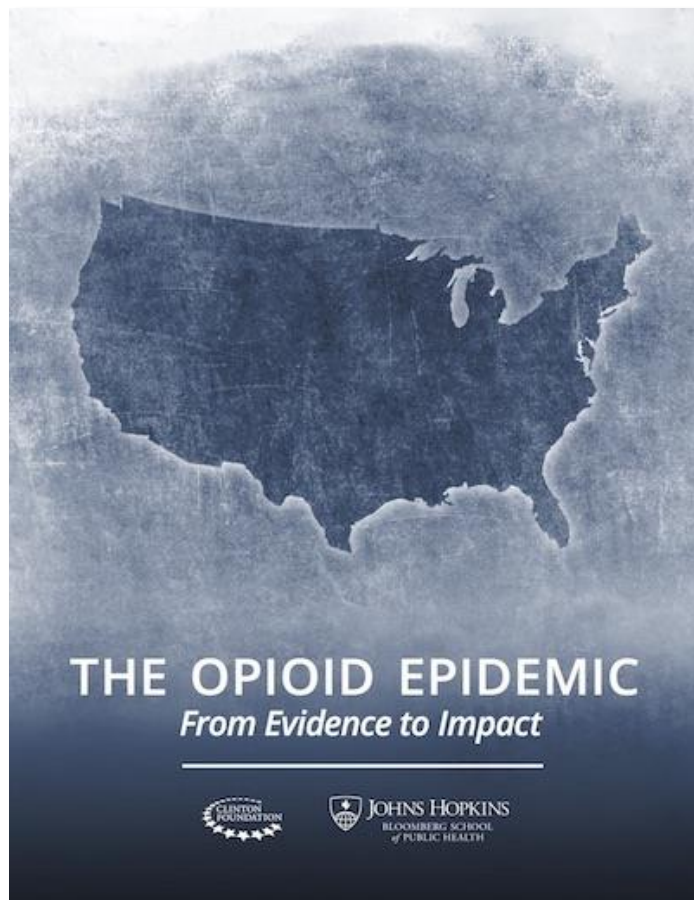


85% ?



45%

2015 Bloomberg School Report: Update Packaging



Expert Support for Improved Packaging

LIVE
9:37 am PT

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

JOHNS HOPKINS
BLOOMBERG SCHOOL
of PUBLIC HEALTH

OPIOID EPIDEMIC

ANDREA GIELEN
Johns Hopkins Center for Injury Research & Policy
Director

C-SPAN
c-span.org
@cspan

"The time has come for more secure packaging"

Safe Rx Locking Prescription Vials (LPVs)

Vials with a 4-digit combination to prevent unintentional or unauthorized access to others' medications



Sturdy Polypropylene Bottle



Amber Large and Small

Multi-Use Encoder



Encoder

Locking Cap with 4-digit code



Blue Large and Small

Solution: Locking Prescription Vials



LPVs are a low-cost, highly effective early intervention, with established precedents and a significant impact on public health outcomes



10 Year Impact of Eliminating Pilfering of Opioids Alone

Excess
Healthcare Cost
Savings:

\$30.0B

Teen Drug
Initiation
Preventions:

7.0M



10 Year Impact of Eliminating Pediatric Poisonings from Drugs & Supplements

Excess
Healthcare Cost
Savings:

\$3.7B

Pediatric
Hospitalization
Preventions:

4.3M

Feedback from parent following teen pilfering

“This product was just what I was looking for. I have pain medication that I needed to protect from a teenager who had been stealing them from my pill bottle while I slept. I couldn't prove he was stealing but was sure they were missing. I found this bottle and it has solved my problem. He can no longer open my bottle and take pills. The only way this would not work would be if he took a hammer to the container and smashed it, but then, I would know who did it and why. If you need to protect your medication from unauthorized use or theft, this is just what you need. I like that you can either get a randomly selected combination or select your own at the time of order. Very cool product and good quality. I am recommending this to my family members who are in an assisted living center where the employees are not always the most honest.”



Review from Son of Senior cared for at home



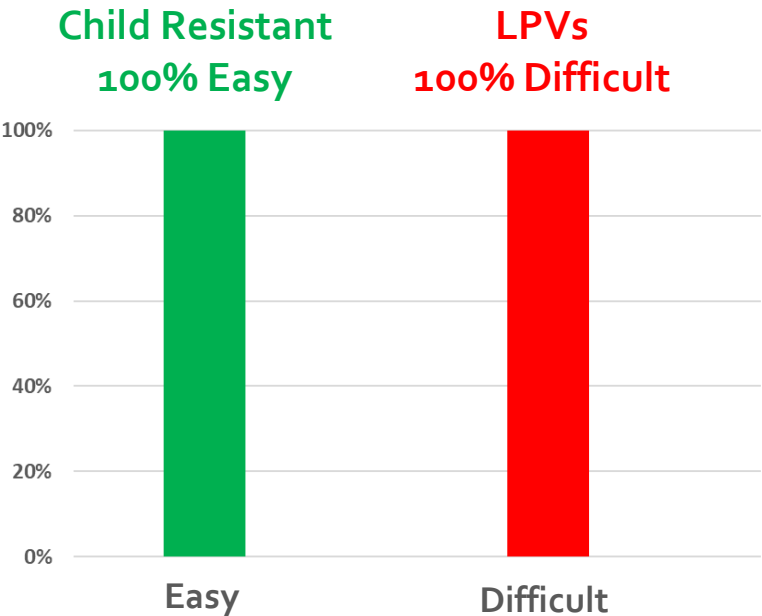
“This bottle is amazing! Why wasn’t it invented 8 years ago when I really needed it to protect my mother’s oxycodone Rx? Pills started disappearing from the bottle that was kept on her kitchen counter with her other Rx. I suspected they were being stolen by one of her 9 caregivers. Obviously, I could not tell my mom...Had to secretly install a \$700 security system, with a ‘smoke detector’ camera, until I finally found the culprit - the condo’s maintenance man! A ‘nice guy’ I knew for almost 15 years! With an HD video of this guy’s third theft, I got him arrested and convicted of robbery, harming a senior, etc. Then the MD who prescribed the pills refused to provide replacement pills since he didn’t want to lose his license for over medicating my mom. My only alternative if she was in pain was to take her to the ER! What a horrible time! Never had time to remove the camera system that was 2,000 miles away from my home. Then another bunch of pills disappeared 6 months later. This time it was a visiting nurse who stole them! With yet another HD video of theft in hand, I got her arrested and convicted. Plus, I got the state of Florida to permanently pull her RN license! If I had these locking pill bottles, I would never have had even one pill disappear. Gonna now use them to protect my pills from potential misuse of meds...Glad that SafeRx was invented!”



Proven Efficacy & Expert Support

LPVs have been proven effective and more secure packaging has very broad expert support as a key solution to the opioid epidemic

Ease of Pill Theft



Ease of Adolescent Pill Theft
% of respondents aged 12 - 25 in household with LPV Study Patient (a)

Expert Support for Improved Packaging



(a) Survey data from 2016 company pilot studies of LPV dispensing in selected Colorado and Nebraska independent pharmacies. Results also indicated dramatic increases in patient awareness of pilfering risk, patient awareness of medication risks, and packaging impact on each.



Impact & Efficacy Data from Early Dispensing Studies

Dispensing with Locking Pill Vials (LPVs) versus Child-Resistant (CR) Vials

Studied Effectiveness to:

- Prevent Teen Pill Theft
- Raise Awareness of Pill Theft Risk
- Raise Awareness of Medication Risks



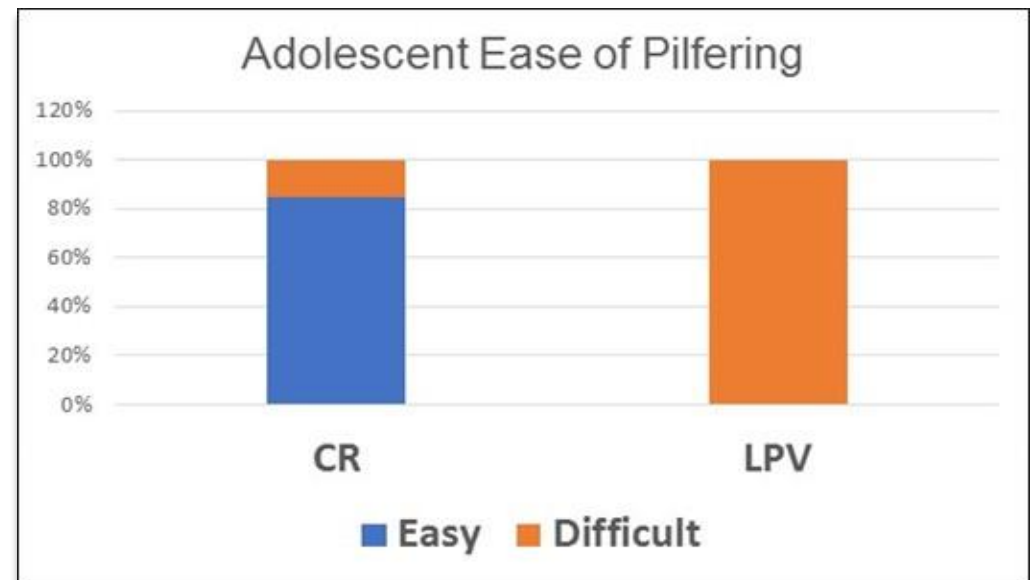
LPVs are Effective in Preventing Teen Pill Theft

100% of teens indicated that pill theft would be **difficult** with LPVs

50% of teens indicated that it would be **very difficult** with LPVs

85% of teens indicated pilfering would be **easy** with CR vials

62% of teens indicated pilfering would be **very easy** with CR vials

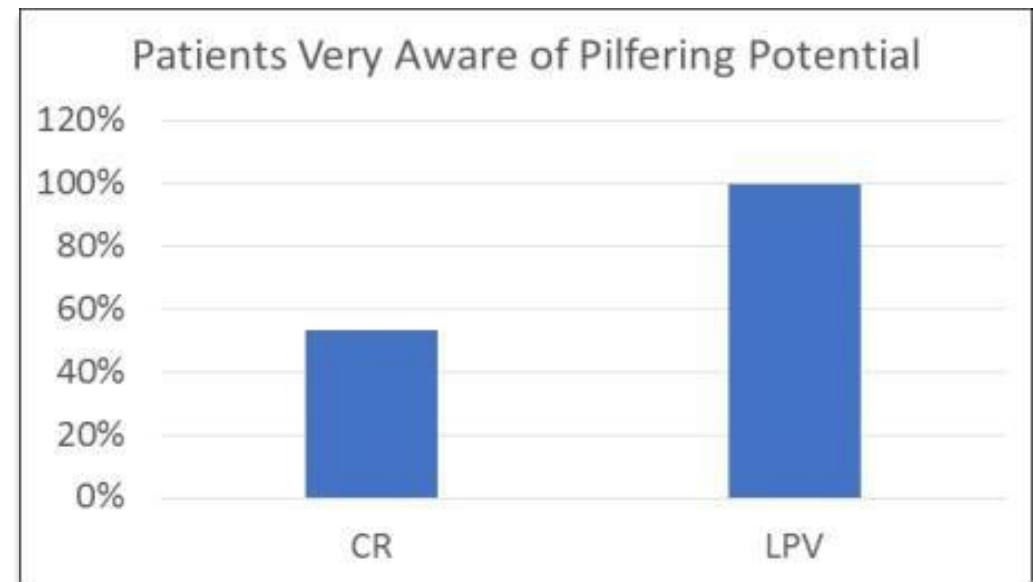




LPVs Significantly Raise Patient Awareness of Pill Theft Risk

53% of patients were **very aware** of the potential for pill theft using CR vials

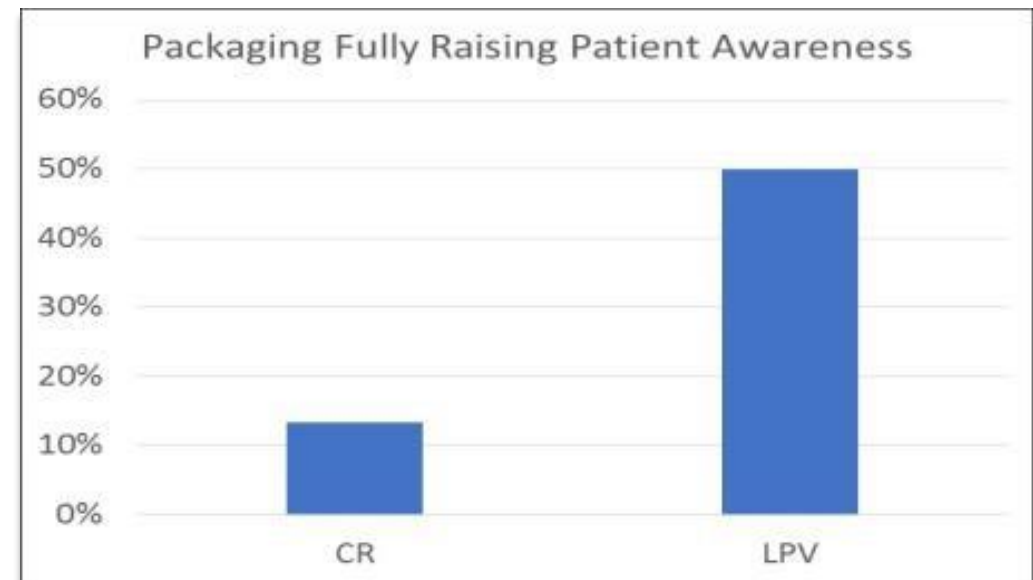
100% were **very aware** after using LPVs



Raises Awareness of Medication Risks

50% of patients indicated that LPV packaging **fully raised** their awareness of medication risks

Only 13% of patients indicated that Child Resistant packaging **fully raised** their awareness



The Power of One Thousand Bottles

Summary Statistical Estimates



Prevention Estimates per 1,000 LPVs	
# of Pilfering Events	8.5
# of Addiction Disorders	0.8
# of Heroin Transitions	0.42
# of Fatalities	0.002

For every million units dispensed, 800 new addiction disorders will be averted, and 2 lives saved

If used for all Schedule IIs Nationwide: 200,000 new addiction disorders and 500 lives annually



Five Pending Pilots To Validate Reimbursement

Ohio Statewide

\$2M appropriated & to be supplemented by litigation settlements & federal stimulus

Montana Statewide

Coalition Anchored by Blue Cross Blue Shield MT & and public sector policy makers

Indian Health Service

Regional or Nationwide Pilot anchored by Salish Kootenai tribe (WA, ID, OR)

Veterans Administration

Championship: VHA Innovators Network & Veterans Affairs Committee Chairman Jon Tester

North Carolina

Coalition Anchored by Old North State Medical Foundation



Ohio Pilot Overview

Pilot Overview

- Administered by Ohio Department of Mental Health Addiction Services (OhioMAS)
- Pharmacies will be paid an extra dispensing fee to fill c2s in locking vials
- Expect 2nd bill on system using 3rd party copay card provider
- Data collection and analysis by expert 3rd party CRO

Pilot Funding & Timing

- **\$2M** already allocated in the 2022 budget, with additional funds pending
- **Additional funding pending** from federal and state sources
- **Expected to start in early 2022** for up to two-years duration

Safe Rx LPV Program

- **Safe Rx is lobbying for a fee of \$4.00 or more** so pharmacies make 61% blended fill margins using its LPV program

California Pending Legislation

Mandating LPVs for all Schedule II Programs

Mandates the use of locking vials for all Schedule II fills

Expecting passed by **June '23**

Bill passed Policy Committees by **13:4** and **8:2** majorities

Domain Expert Sponsors



Rep. Joaquin Arambula, MD
ER Physician



Sen. Thomas Umberg
Former Deputy Drug Czar (Clinton)

Federal Agencies with Statutory Authority



DEA



CPSC

Safe Rx Impact to-date



Drug Abuse: Cumulative Mission Impact on Public Health & Cost of Care

	Preventions	Cumulative Monetary Impact ⁽¹⁾	Uncompensated Care Component ⁽²⁾
# of Pilfering Events	1,059		
# of Addiction Disorders	106	\$15.7 M	\$3.1M
# of Heroin Transitions	53	\$7.8M	\$1.6M
# of Fatalities	0.3	Priceless	

NOTES: Based on 125,350 bottles sold through 9/30/2021.

(1) Average cost per ER visit and hospital admission are \$1,840 and \$14,235 respectively. (2) 5.5% of children are uninsured.

The Time Has Come...



7,000,000