



# Project Seven-0

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Executive Summary

June 28, 2025

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## Project Overview

The industry advocacy organization, HART sought an independent analysis addressed to federal and state legislators on the impact of expanded access to 7-hydroxymitragynine (7-OH)

- The client seeks to utilize Marwood's value story to defend their efforts to combat restriction of 7-hydroxymitragynine sales (i.e., not scheduled, not restricted in place of sale and not restricted in volume of purchase)
- The output is a value story informed by an overview of the state & federal policy landscape and analysis of the scientific literature in the space

### Disclaimer

*Marwood does not endorse or recommend 7-hydroxymitragynine. The slide may contain general information relating to various medical conditions and their treatment. Such information is provided for informational purposes only and is not meant to be a substitute for advice provided by a doctor or other qualified health care professional. Patients should not use the information contained herein for diagnosing a health or fitness problem or disease. Patients should always consult with a doctor or other health care professional for medical advice or information about diagnosis and treatment.*



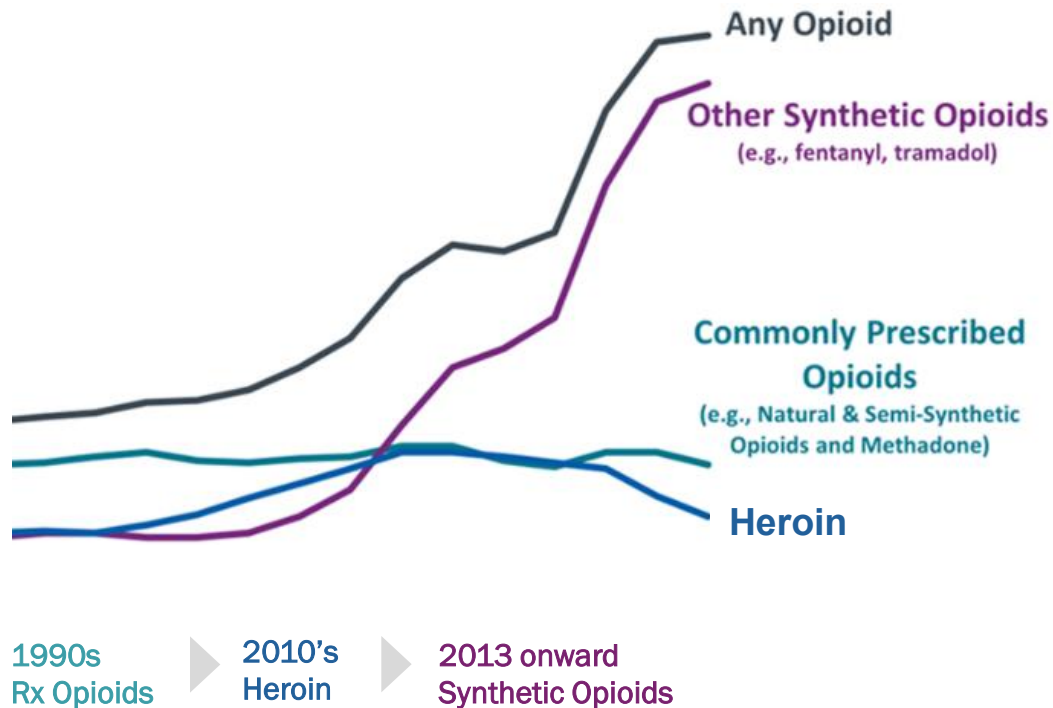
# 1 | Value Story

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# In An Epidemic Characterized By Three Successive Waves Of Abuse-Related Deaths, The Alkaloid 7-Hydroxymitragynine (7-OH) Is Structurally Distinct From Opioids

Opioid-involved Deaths Have Increased Substantially  
In 3 Successive Waves Since The 1990s



7-OH Has A Low Adverse Event Incidence;  
Particularly Compared To Opioids

There is limited preclinical or clinical data connecting 7-OH with overdose deaths, in sharp contrast to opioids

- A scan of the FDA Adverse Event Reporting System since 2023 reveals no deaths associated with 7-OH alone (a mere 2 cases when including polydrug overdose deaths) despite upwards of 1 million consumers; a fraction of the 201 kratom-associated deaths and >100-fold less per 100,000 lives than the >3 million overdose deaths associated with synthetic opioids in that time period<sup>1</sup>
- 7-OH has a low likelihood to molecularly signal respiratory depression – a cause of mortality among other opioids<sup>2</sup>
- 7-OH in poly-drug abuse, a contributor to overdose deaths, is relatively minimal in comparison to synthetic opioids like fentanyl and other natural and semi-synthetic opioids<sup>3</sup>

Sources: 1) FDA.gov 2) Todd et al. (2020) Nature 10(19158)

3) Krotulski et al. Temple University. Presentation. [https://www.cfsre.org/images/K52\\_AKrotulski\\_Polydrug\\_Use\\_ToX\\_Perspective\\_REDUCED.pdf](https://www.cfsre.org/images/K52_AKrotulski_Polydrug_Use_ToX_Perspective_REDUCED.pdf)

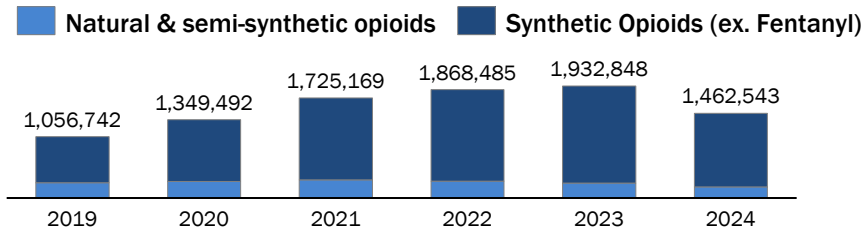
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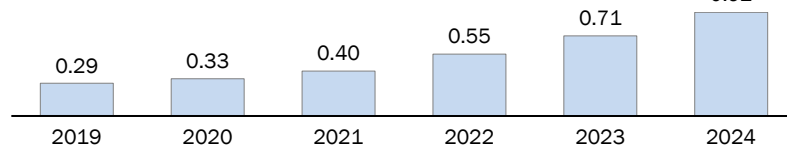
# 7-OH Consumption Has Increased Concurrent To A Decrease In Opioid Overdose Deaths; Trends In Naloxone Availability Alone Are Insufficient To Explain This Trend

## National Opioid Overdose Deaths Have Declined Since 2023

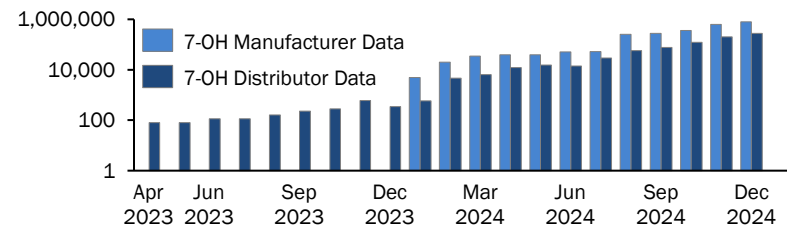
### Opioid Overdose Deaths<sup>1</sup>



### Naloxone Dispensing Rate (Rx/100) persons<sup>1</sup>



### 7-OH Consumers Per Month<sup>2</sup> Since 2023 (Est From Units)



## 7-OH Sales Have Increased Opioid-Related Deaths Have Declined

### Overdose control and substitution may both be contributing to a decline in opioid-related deaths

- Naloxone dispensing alone has been insufficient to explain the sudden reversal in opioid deaths
- Illegally manufactured fentanyl has declined in quantity and quality, due to increased enforcement
- As the quality of fentanyl has declined under pressure, researchers note that users are seeking out alternatives<sup>3</sup>

### 7-OH provides an alternative to fentanyl and other opioids, without the withdrawal symptoms seen with Kratom, in preclinical studies

- 7-OH produces comparable pain control to strong opioids such as morphine<sup>4</sup>
- 7-OH exhibits cross-tolerance with other mu-opioid receptor agonists; this would indicate opioid users could cross over to 7-OH<sup>4</sup>
- 7-OH is a partial opioid agonist that binds to the mu-opioid receptor, distinctly from full opioid agonists such as morphine and fentanyl<sup>5</sup>

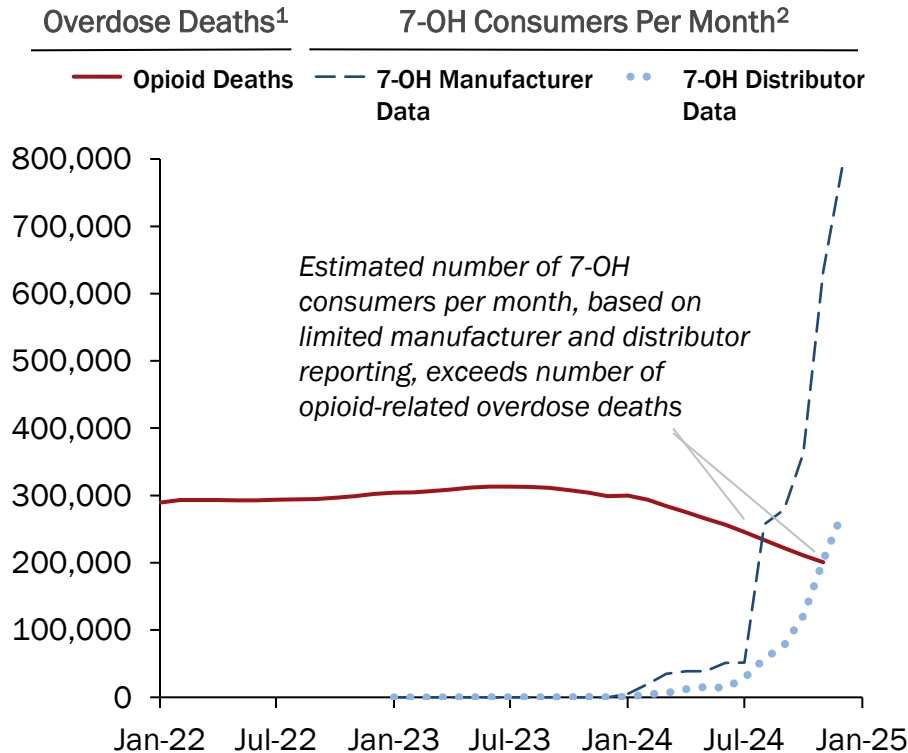
**Sources:** 1) CDC.gov 2) Estimate based on limited reporting of 7-OH manufacturer/distributor data 3) [npr.org/transcripts/1210938287](https://www.npr.org/transcripts/1210938287) 4) Matsumoto et al. (2005) Life Sciences 78 (1): 2-7. 5) Todd et al. (2020) Nature 10(19158)

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# 7-OH Consumption Has Increased Concurrent To A Decrease In Opioid Overdose Deaths; Testimonials Concur With Studies On 7-OH As A Substitute For Powerful Opioid Agonists

## National Opioid Overdose Deaths<sup>1</sup> Have Declined; 7-OH Doses Have Increased, Since 2023



## Testimonials – An Alternative To Street Drugs

*7-OH is the only reason I didn't go to the streets. I could be dead from a **fentanyl** overdose. Banning this would be killing a lot of people.*<sup>4</sup>

*Since I found 7-OH I always have it to go to instead of the **hard drugs**... [it] has help me and so many others, having a viable option to turn to.*<sup>3</sup>

*7-OH makes my life manageable and my **addiction** **tameable**. It's just like taking suboxone once daily.*<sup>4</sup>

*7-OH saves [lives]! [It has] kept me **drug free** and a functioning member of society for years now...I had a crazy dope addiction... it worked for me.*<sup>4</sup>

*7-OH isn't kratom...I've been taking it for over two years, and it has **kept me clean**.*<sup>4</sup>

*So **easy to taper off** and withdrawal is child's play compared to **fentanyl**.*<sup>4</sup>

**Sources:** 1) CDC.gov 2) Estimate based on limited reporting of 7-OH manufacturer/distributor data; 3) Industry-provided testimonials; 4) Marwood-identified testimonials from internet blog sites.

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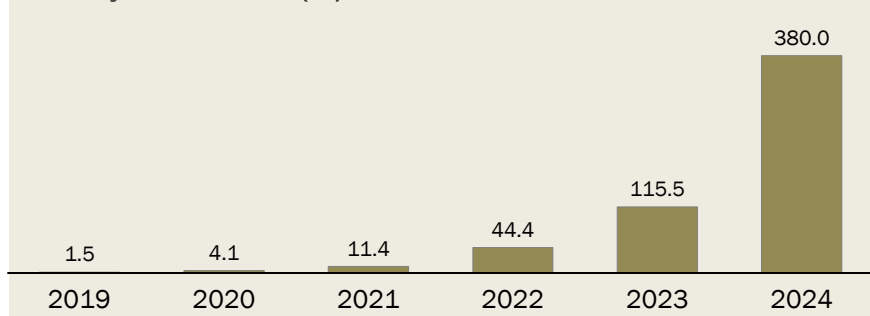
# Strictly Manufactured, Dosed And Labeled 7-OH Is A Standardized Alternative To Illegally Manufactured Fentanyl Products

## Laced Synthetic Opioids Are A Growing Threat To Public Health

### Constrained supply has led to inconsistently formulated and often laced illegal fentanyl products

- >40% of illegally manufactured fentanyl products contain a potentially fatal dose<sup>1</sup>
- With expanding seizures, reduced fentanyl supply has led to an increasing number of illicit drug mixtures
  - The DEA has reported widespread threat of fentanyl mixed with non-opioid sedatives such as xylazine<sup>1</sup>

Fentanyl Pills Seized (M)<sup>1,2</sup>



Sources: 1) DEA.gov 2) NIDA.NIH.GOV

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## 7-OH Manufacturers Provide A Standardized Alternative

### The 7-OH industry seeks consistent and compliant manufacturing, labeling and sales, maintaining access to those most in need

- Holistic Alternative Recovery Trust (HART) member companies offer to comply with all laws and regulations applicable to the marketing, distribution and sale of 7-OH:
  - **Good Manufacturing Practices (GMP)** for dietary supplements to ensure products are free from contaminants and consistently meet quality standards
  - **Testing** to verify the consistency, purity, and potency of 7-OH products, with test results made publicly available.
  - **Strict labeling and safe packaging** of 7-OH products to include labeling of 7-OH content, recommended serving sizes, daily intake limit recommendations, appropriate warnings, and usage instructions as well as child safety packaging
  - **Health-related claims substantiated** by credible scientific evidence and complying with FTC truth-in advertising requirements

