

Remedy Alliance FTP

A Thousand Ways to Say “No” to Naloxone

October 26, 2021

Every 5 minutes someone in America dies of an overdose. The single greatest barrier to increasing naloxone access is FDA’s designation of naloxone as prescription-only. For the first time, we highlight how prescription-only status cascades into myriad unexpected legal and practical barriers. We ask Congress and FDA to remove generic naloxone’s prescription requirement for Harm Reduction programs, so that we may prevent overdose deaths more effectively and affordably.



Naloxone kits in an outreach bag, ready to hit the streets.

Remedy Alliance (For The People) operates the Opioid Safety and Naloxone Network (OSNN) Buyers Club, established in 2012. The Buyers Club is a collective of over 100 harm reduction programs who distribute naloxone directly to people who use drugs, their loved ones and community. Remedy Alliance is a non-profit organization.

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Summary

This month the US will surpass a once-unimaginable milestone: over 100,000 people dead from overdose in the past year. Over 70% of these deaths are caused by opioids and many of them are preventable with the rapid administration of naloxone. Community-based naloxone distribution is a rigorously evaluated, evidence-based intervention.

States have done everything they can to increase naloxone access, passing laws and executive orders to greatly simplify *prescribing* and *distribution*. FDA has clearly signaled their willingness to consider over-the-counter status for naloxone. However, significant legal barriers to *purchasing* of naloxone by community-based programs stem from FDA's continued designation of naloxone as "prescription-only."

As long as generic naloxone remains prescription-only at the federal level, corporate and local government compliance officers will adhere to the most risk-averse position, even if that contravenes State legislative intent. We have been told "No" at every level of the supply chain. The reason is always: "Naloxone is a prescription drug."

We provide 7 specific examples across every level of the supply chain. The Cascade of Consequences severely curtails naloxone expansion and public health innovation.

We recognize that FDA does not factor cost when considering regulatory decisions. However for naloxone, cost, availability, and lives saved are intimately linked. When \$2.50 generic naloxone cannot be purchased because of fear of FDA enforcement, public funds are spent on a \$75 branded version. That equates to 30-fold fewer naloxone kits distributed.

The discrepancy between state medical/pharmacy practice vs. federal interstate commerce regulation, requires urgent resolution and forms the basis for immediate Congressional intervention. We are ready to work with FDA and Congress to eliminate the Cascade of Consequences stemming from naloxone's prescription-only status. We share the sincere goal of reducing overdose deaths immediately. We have faith that the federal government will respond favorably to this new information about barriers to naloxone access.

We Are Ready To Talk

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Policy Landscape

In April 2021, the Biden Administration stated it will: “Examine naloxone availability in counties with high rates of overdose and identify opportunities to expand access in targeted areas among pharmacies, clinicians, peer support workers, family and community members, and PWUD.” ([source](#)) In this document we provide previously undisclosed information to aid the Administration in finding solutions to the overdose death epidemic.

We invite FDA to work with us, and the US Senators we have already engaged, to clear the single largest barrier to wider naloxone access: [prescription-only status](#).

Harm Reduction programs are our first line of defense to preventing overdose deaths. They are adept at reaching marginalized communities that mainstream medicine and public health cannot. They have distributed naloxone that laypeople have used to reverse hundreds of thousands of overdoses. Unfortunately, their ability to quickly and effectively get naloxone to the people who are most likely to reverse overdoses continues to be hampered by legal and regulatory barriers. These barriers slow down, and sometimes prevent entirely, purchases of naloxone. Even though purchasers have money and vendors have product, public health programs find FDA’s prescription-only designation a fatal impediment.

State legislatures and health departments have clearly expressed intent that naloxone be deregulated and treated as OTC under their authority over medical and pharmacy practice. All 50 states, DC and Puerto Rico have done what they can, passing laws and issuing executive medical orders enabling naloxone to be sold and/or distributed without a prescription. ([source](#))

Similarly, FDA has clearly stated its intent to consider OTC naloxone, through statements and publications by the [current](#) and [previous three Commissioners](#). FDA convened [Public Workshops](#) on April 2012 and July 2015, and an [Advisory Committee Meeting](#) in December 2018, where we described the need for OTC naloxone in detail. Unfortunately, FDA has not taken the next logical step: Moving one or more formulations of the medication OTC.

While state laws and orders intend for naloxone to be treated as OTC, it remains regulated as prescription-only at the federal level, affecting interstate commerce. This discrepancy limits the ability of many organizations to obtain and distribute it. As illustrated in the following examples, the incongruity manifests as resistance from corporate and government compliance officers.

Cascade of Consequences

We provide 7 examples of structural barriers preventing naloxone access precipitated by prescription-only status. We can provide 993 more. While each problem is solvable in isolation, the collective impact is deadly.

1. Large pharmaceutical manufacturer

For Harm Reduction programs, Pfizer requires DEA registration of the prescribing physician even though naloxone is not a controlled substance. In their ordering system, one prescribing physician cannot provide their DEA authorization to multiple Harm Reduction programs, thus rendering statewide standing orders useless for naloxone procurement. **Prescription-only status forces highly restrictive corporate compliance interpretations.**

2. Small, generic pharmaceutical manufacturer

Hikma Pharmaceuticals (previously West-Ward) requires physicians working with Harm Reduction programs to sign affidavits clarifying that their naloxone prescription explicitly authorizes “purchase,” and not solely “distribution.” Corporate compliance officers require this burdensome paperwork to document the transaction out of fear of FDA enforcement. This applies even to states with standing orders, some of which explicitly forbid purchasing. **Prescription-only status conflicts with state laws, begetting burdensome paperwork, and curtailing naloxone distribution.**

3. Distributor

Distributors do not have a model for situations of state-OTC versus federal-Rx. For example, a convoluted fix was necessitated by the fact that the prescription product division (McKesson Pharma) is a separate commercial entity from the medical supplies division (McKesson MedSurg), and syringe service programs are ineligible for McKesson Pharma accounts because they are not pharmacies. Therefore, naloxone has to be transferred between these divisions, creating delays and additional supply chain vulnerabilities. McKesson sales reps are often uninformed about this arrangement, resulting in idiosyncratic order quotes or request denials. **Prescription-only status creates practical barriers and wasted time.**

As one corporate official put it:

“If FDA had intended for naloxone to be easy to get, they would have made it OTC by now.”

4. Regional Public Health Organization

The Northwest Portland Area Indian Health Board serves 43 tribes in Washington, Oregon and Idaho. These rural and remote Native American communities have limited emergency medical care, and most have no access to in-person Harm Reduction. While the organization can purchase naloxone, a legal assessment has prohibited them from mailing naloxone across state lines because the status is prescription-only. **Fear of FDA action limits the lifesaving antidote from reaching rural Native American communities.**

Source: Jessica Leston, Clinical Programs Director, NPAIHB

5. Local Public Health Program

A public health initiative in Michigan purchased 15 vending machines to place free naloxone 24/7 in high overdose and service-scarce areas. Despite an enabling state standing order, the fear of federal enforcement by FDA killed many target locations. Lawyers and organizational general counsels stalled implementation because naloxone is prescription-only and several vending machines continue to sit in a storage room. The same is situation is occurring in Connecticut. **Fear of FDA enforcement of prescription-only status stifles overdose prevention innovation.**

6. Charitable Donations of Naloxone

In order to receive a charitable donation of no-cost naloxone, programs must meet compliance requirements dictated by prescription-only status. To receive free naloxone through Direct Relief (Pfizer's donation of 1 million doses), programs must: "comply with State Board of Pharmacy regulations in storing and dispensing medications; and have a Medical Director or Pharmacist with a valid state license." Recently, the Buyers Club received a separate commitment of a 50,000 dose donation for member programs, and *only three programs* were able to produce the required paperwork to receive an emergency donation. **Even when cost is not an issue, regulatory and compliance issues continually leave overdose prevention efforts stymied.**

7. Individual Level

Of the many tragic stories we have heard about the lack of naloxone access, perhaps most heartwrenching is that of Jack Fishman, who invented naloxone in 1961. His stepson died of a heroin overdose in Florida. Joy Stampler, Jack's wife at the time, said: "It was hard for Jack to get naloxone even though he invented it!" (source) **Prescription-only status leads to thousands of avoidable deaths.**

Naloxone Market

Despite the barriers, the Buyers Club accounts for a large proportion of all community-based distribution in the entire country. **Recent modeling has suggested that no state is giving out enough naloxone in the community.**

(There has been a dearth of public information on naloxone distribution channels, with higher volumes in recent years.)

- Buyers Club: 1.3 million doses in 2020, 4 million doses 2017 through 2020, entirely injectable, cheap, generic naloxone. ([source](#))
- Veterans Administration: 200,000 doses from May 2014 to September 2019 ([source](#)), or 31,000 doses per year.
- Retail Pharmacy: 336,100 doses in 2017 ([source](#)) and 556,847 in 2018 ([source](#)), including intranasal.
- Pfizer donation to Direct Relief: 1 million doses over four years, 2017 to 2021. ([source](#))
- In 3Q2018 Emergent BioSolutions reported sales of <250,000 doses per quarter ([source](#), slide 4), now surely million+ per year. However, this includes extensive sales to law enforcement and other venues with considerably lower naloxone utilization rates per unit dispensed.
- The largest state-based effort, by the California Department of Health Care Services, purchased 600,000 units of naloxone from 2018 to 2021 on behalf of programs, funded by SAMHSA. ([source](#)) But this volume was so inadequate that programs purchased *tens of thousands of additional doses* through the Buyers Club. **Cheap, generic naloxone via the Buyers Club is a backstop for inadequate federal funding.**
- The global naloxone nasal spray market is estimated to be \$351 million in 2021. ([source](#)) In contrast, if we tripled (3x) community-based distribution of generic naloxone in the United States, the naloxone product cost would be less than \$10 million.

On-the-ground Reality Check

October 2021, Denver, Colorado



Harm Reduction Action Center

October 12 at 11:43 AM · 🌐

...

This is our injectable Naloxone drawer. It is looking pretty sad and empty right now. We are experiencing a shortage in injectable Naloxone in Colorado and nasal Narcan is INCREDIBLY expensive at the moment. We're in the worst overdose crisis we have ever seen, and the very last thing we need is a shortage/unavailability of Naloxone. We are spending most of our money on accessing Narcan. Our folks need it. It's lifesaving!

So, what can you do to help? Because most of our money is going towards buying Narcan for our folks, we are quickly running out of money to purchase other necessary items like snacks, water, socks, hygiene, etc. Luckily, we have an Amazon wishlist of all the items we need! You can find our wishlist here: <https://a.co/2brD29C>

You can also donate directly to HRAC to help us purchase Naloxone TODAY:

<https://harmreductionactioncenter.wedid.it/>

❤️❤️ Please check out our wishlist link or donate directly if you are willing and able to help! ❤️❤️



Haven Wheelock and 57 others

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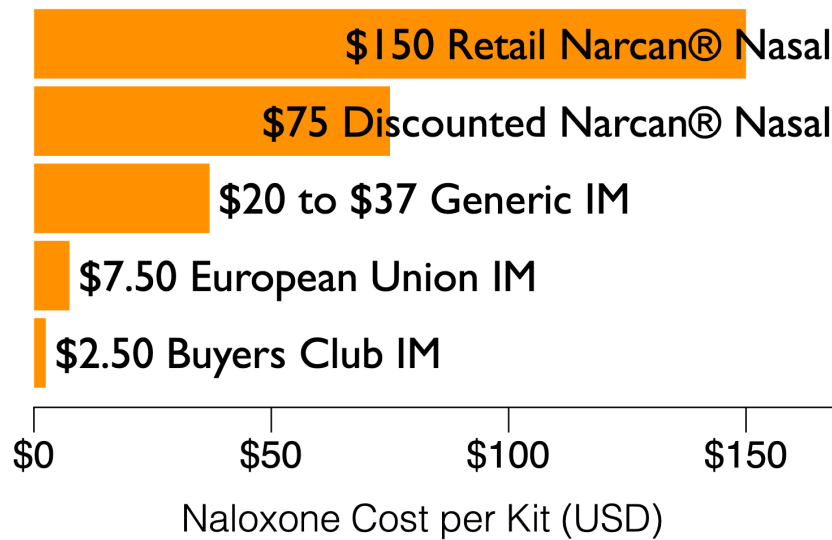
Naloxone Pricing

Compared to the nasal sprays, naloxone purchased through the Buyers Club is 30x cheaper.

Intramuscular naloxone is the most cost efficient option for community-based programs. During 25 years of community-based distribution, the intramuscular naloxone formulation is considered highly acceptable among people who use drugs in syringe service programs.

In the graph below, naloxone costs assume 2.5 doses of intramuscular naloxone per kit, and 2 doses for nasal spray. These costs do not include distribution labor, packaging, and additional materials (approximately \$10-\$20 per kit).

Public funds wasted, more lives lost with a 30x price difference between brand name and decades-old generic.



Source: *The Guardian*, October 2021 and *Filter Magazine*, April 2021

Federal Financial Support for Naloxone

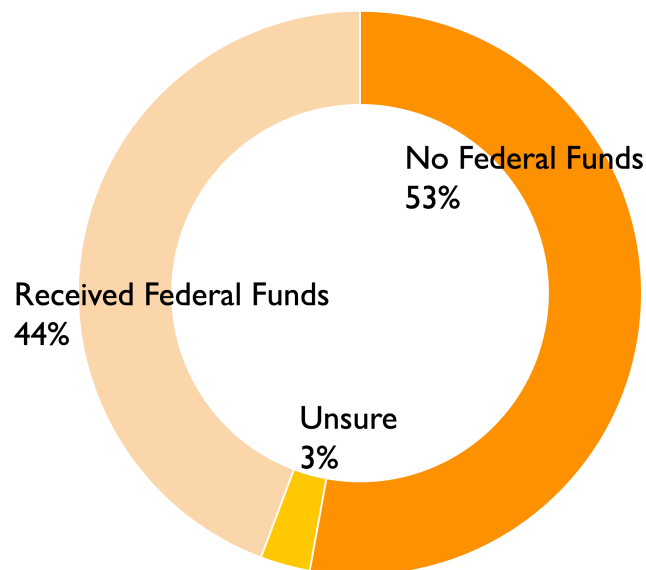
53% of Buyers Club programs receive no federal funds for naloxone.

Internal data from 2020 OSNN Buyers Club survey, n=70 programs responded.

Other Findings

- Half of Buyers Club programs report having to do fundraising to purchase naloxone. GoFundMe pages, t-shirt sales, and donations to overdose memorial funds are common.
- A quarter of programs (25.3%) report regularly rationing naloxone due to inadequate financial support from state and federal government.
- Half of programs do not receive any financial support to pay for staff time to distribute naloxone.

Sources of Funding for Naloxone among Buyers Club

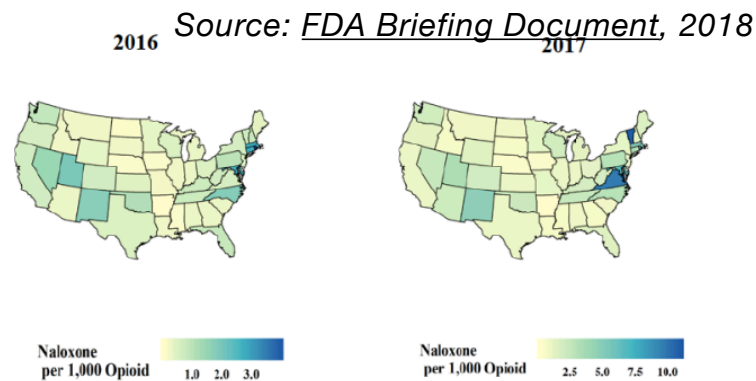


The backbone of naloxone distribution in the United States teeters on donations and volunteer time. With 100,000 overdose deaths each year, it's time to finally recognize the truth.

Retail Pharmacy: Marketing vs. Reality

The majority of community-based naloxone distribution to people who use drugs is hand-to-hand. It occurs far from retail pharmacy shelves. Yet, the main branded manufacturer (Emergent BioSolutions) has forwarded a narrative emphasizing retail pharmacy as the sole avenue for OTC, based on their expensive nasal spray; they have not extended an alternate price that Harm Reduction programs can afford. An [FDA analysis](#) suggests that retail pharmacy sales of naloxone are highly concentrated in a handful of states. During COVID, [retail pharmacy sales of naloxone declined 26%](#), while demand from Buyers Club programs [increased 29%](#).

Nationally Estimated Number of Naloxone Prescriptions per 1,000 Opioid Prescriptions Dispensed from U.S. Outpatient Retail Pharmacies in 2016 vs 2017 (48 contiguous)



Source: Symphony Health PHAST™ Prescription Monthly. January 2016-December 2017. Extracted October 2018. Files: 2018-1663 SHS FDA total naloxone by state 11-8-2018.xlsx; 2018-1663 SHS narcotic analgesic by state.xlsx

The truth is that injectable naloxone has been used successfully by people who use drugs since 1996. Research shows that people who use drugs are best-placed to reverse overdoses as they happen. ([source](#)) People who use drugs do not feel comfortable purchasing naloxone in pharmacies ([source](#)). **It is imperative that we find ways to get lifesaving medication into the right hands.**

Our experience and research from the United States, Vietnam, and Norway has shown that “Super-savers” naturally and consistently emerge during naloxone distribution. ([source](#)) These empowered and motivated individuals report reversing multiple overdoses, having gained a positive reputation. In one study, the “Super-saver” group made up 15% of the sample but contributed to 29% of take-home naloxone use. ([source](#))

Exclusive focus on retail pharmacy for OTC naloxone disadvantages those who are most likely to save lives.

Targeted Action

We request that FDA remove the prescription-only designation for generic naloxone. A narrower ask could be limited to syringe service and Harm Reduction programs. Since OTC status for all naloxone products is likely not acceptable to the Agency, we have come up with a **game changer solution**: A new, exclusive naloxone product, within an established restricted-access program. We have reached a contractual agreement with an existing manufacturer to create an exclusive 0.4 mg (in 1 mL vial) product (already approved), with a new NDC, for \$2 per vial. The Pfizer version could also be included. The existing Buyers Club access control program vets each member, ensuring that they are nonprofits serving a population comfortable using needles. FDA has new authority under the 2020 CARES Act to initiate OTC switches, through the OTC Monograph Reform Process. Thus far the agency has prioritized wart removers, ingrown toenail treatments, and anti-flatulent medications.

Waiting for a generic company to initiate an OTC switch for naloxone is tantamount to granting exclusive access to the OTC process to branded companies with more expensive products. FDA's decade-long exclusive endorsement of expensive branded nasal and auto-injector formulations has set an insurmountable precedent that no generic manufacturer we have spoken to is willing to challenge.

To our knowledge, FDA has not taken enforcement action against regulated industry or local programs around naloxone. *Nor has FDA formally stated its intention to exercise enforcement discretion.* The silence has a chilling effect.

Legislative Intervention

We will continue to pursue Congressional intervention. On October 20, 2021, Senators Tammy Baldwin (WI) and Tina Smith (MN) called for HHS action to increase intramuscular naloxone availability. Senators Bernie Sanders (VT) and Elizabeth Warren (MA) have proposed invoking Section 1498 Defense Production Act powers to compel a supply of affordable naloxone for Harm Reduction programs. (source) In additional conversations with some of these offices and those of Senators Cory Booker (NJ) and Angus King (ME), the question has not been *if*, but rather *how*, to move FDA to eliminate prescription status for Harm Reduction programs. If FDA is unwilling to act immediately, Congress could act to remove the prescription requirement for all naloxone products, or only the restricted-access version(s).