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ANALYSIS

Part 1: Exploring Cost and the Emerging Landscape of Naloxone Competition

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ISSUES: **HARM REDUCTION**, **OPIOID HARM REDUCTION**

With [opioid](#) overdoses taking tens of thousands of American lives each year, continuing to improve layperson [access](#) to the overdose reversal medication, naloxone, is essential. Over-the-counter (OTC) naloxone prices are higher than [out-of-pocket consumer costs](#) for insurance-paid prescriptions but lower than what uninsured people would have paid for the medication when it was still only available by prescription. Some experts and advocates suggest that the change in status [will do little to reduce cost barriers](#) to the life-saving medication. Others argue that increased market competition [could drive prices down](#), making naloxone more affordable as more products are approved.

How Competition Affects Medication Prices

In a free-market economy, [competition can benefit consumers](#) by improving quality while keeping costs low. When it comes to health care, however, this process is more nuanced. For example, while [innovation has enabled](#) some exceptional medical technologies, costs associated with such interventions often remain prohibitively high.

The role of competition in reducing medication costs is mixed. A [review of research from 1990 to 2019](#) found that making multiple brand-name products available within a particular drug class generally does little to reduce prices. What it does tend to do is establish a ceiling for new products entering the market, and in some cases—such as the [hepatitis C treatment](#)—innovation of novel medications has worked to drive prices down.

Intranasal Naloxone and Competition

First approved by the U.S. Food and Drug Administration (FDA) for [opioid overdose reversal](#) in 1971, naloxone does not see a considerable amount of competition in terms of actual drug

alternatives. It is highly effective and incredibly safe. And because it has been around for so long, there are plenty of generics on the market. Naloxone itself is, in fact, very affordable, but the user-friendly intranasal products approved for OTC sales are pricey—especially for the people at highest risk for overdose. Fortunately, three factors in the naloxone landscape may begin to drive prices down: generics, a nonprofit pharmaceutical company, and a state-manufacturer partnership.

The Emergence of Generics

Patents provide patent holders with [exclusive rights](#) to make, use, import, or sell an innovation, typically for [about 20 years](#). Although patent law originated as a means of incentivizing innovation, it can also prevent new products from coming to market, thereby stifling competition and its potential cost benefits. In 1984, recognizing a need to cut pharmaceutical prices to benefit health care consumers, Congress passed the Hatch-Waxman Act, a law that “[aimed to inject competition into the pharmaceutical market by opening the market to generic drug manufacturers](#).” A 2009 law extended this benefit—namely, an abbreviated approval process for generic versions of a drug when the patented version comes off patent—to biosimilar drugs. As of 2021, 91 percent of U.S. prescriptions were for generic drugs, saving Americans \$373 billion.

There are now [five approved OTC naloxone products](#), including at least two generics. Indeed, the presence of generics on the OTC naloxone market may drive prices down, or at least give consumers a slightly more affordable option. Whereas the national brand-name 4-milligram (mg) nasal spray generally sells for [\\$45 or more](#) (depending on retailer markup) for a two-dose package, the [generic alternatives](#) are roughly \$10 less expensive.

Innovative Production Alternatives

In addition to generics, the reach and persistence of the opioid overdose crisis has sparked a couple of unusual manufacturing pathways specifically aimed at making the medication more affordable.

Harm Reduction Therapeutics (HRT) was [founded in 2017](#) in response to then-increasing naloxone prices and the FDA’s call for manufacturers to develop an OTC option. Unlike the vast majority of other pharmaceutical companies, HRT operates as a nonprofit. Rather than relying on venture capitalists, the organization got its start thanks to [approximately \\$30 million](#) in grants and donations, with much of the funding coming from Purdue Pharma settlements. The lack of profit motive and a cost offset allow the company to sell its two-pack of 3-mg intranasal naloxone for [roughly \\$36](#) and donate about 10 percent. HRT prioritizes harm reduction organizations, public health departments, and other organizations directly serving people who use drugs.

California has brought another innovative price-reduction strategy to the OTC naloxone access challenge. Leveraging their bulk purchasing power, the state is partnering with the manufacturer of a generic OTC naloxone product to [buy its own version](#) of the medication. A two-dose package will sell for \$24 under the [CalRx® Naloxone Access Initiative](#).

The Persistent Cost Challenge

These growing market pressures do appear to be [driving OTC naloxone prices down](#) somewhat, providing more affordable options at retailers and for bulk purchasers. Nonetheless, at least three additional barriers to affordability persist. First, national brand naloxone is still [not sold consistently](#) in all markets (let alone any additional competitors), so market pressure may vary accordingly. Second, all currently available OTC intranasal products rely on the same [nasal spray device](#). This likely creates a cost “floor” and limits any manufacturer’s ability to reduce prices until the FDA approves additional device options (and competition has the time to act at this upstream stage in the access chain). Third, retailer markups can be quite hefty—[almost 400 percent](#) on common OTC medications—so product competition will only reduce prices by so much, especially in [pharmacy deserts](#) that disproportionately affect people living in rural and low-income areas.

Until we see competition throughout the OTC naloxone supply chain, it is unlikely that prices will fall to the levels necessary to drastically improve access for the individuals most likely to experience or witness an overdose. Therefore, policymakers should continue to look to solutions that ensure permissions for harm reduction organizations in their states; focus overdose prevention money (such as opioid settlement dollars) on naloxone bulk purchasing; and update their Good Samaritan and [naloxone access laws](#) to remain in line with current best practices.