

Groups make own drugs to fight high drug prices, shortages

August 10 2021, by Linda A. Johnson



In this June 23, 2021 photo provided by Civica Rx, foreground from left, Jason Winfield and Martin VanTrieste of Civica Rx and Petersburg Mayor Sam Pelham tour the construction site of the company's Essential Medicines Manufacturing Facility in Petersburg, Va. Civica Rx was started three years ago by a hospital consortium. It now provides over 50 generic injectable medicines in chronic shortage to more than 1,400 hospital members and the Veterans Affairs



and Defense departments. Credit: Paul Bacci/CRB Group/Civica Rx via AP

Impatient with years of inaction in Washington on prescription drug costs, U.S. hospital groups, startups and nonprofits have started making their own medicines in a bid to combat stubbornly high prices and persistent shortages of drugs with little competition.

The efforts are at varying stages, but some have already made and shipped millions of doses. Nearly half of U.S. hospitals have gotten some drugs from the projects and more medicines should be in retail pharmacies within the next year as the work accelerates.

Most groups are working on generics, while at least one is trying to develop brand-name drugs. All aim to sell their drugs at prices well below what competitors charge.

"These companies are addressing different parts of the problem and trying to come up with novel solutions" to produce cheaper medicines, said Stacie Dusetzina, a Vanderbilt University health policy professor. "People should be able to access the drugs that work for them without going broke."

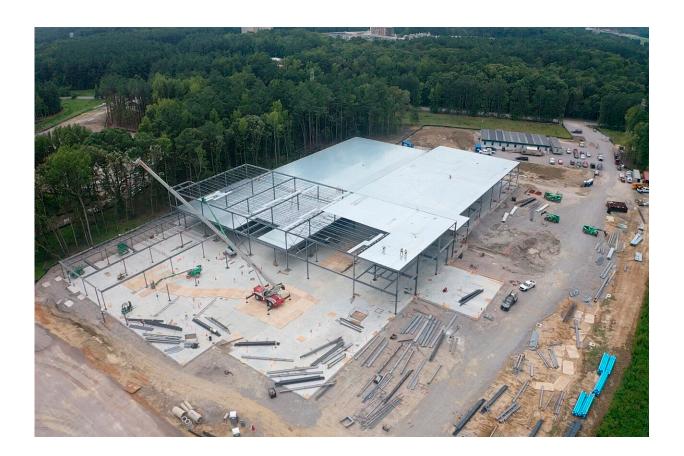
While some of the projects are solving supply problems and reducing medication costs for hospitals, <u>drug</u> price experts are split on how much consumers will benefit.

Dusetzina said the efforts could bring needed price competition, at least for some drugs.

Dr. Aaron Kesselheim, a Harvard Medical School researcher and price expert at Brigham & Women's Hospital in Boston, thinks for some drugs



these projects "can lower patients' out-of-pocket costs ... absolutely."



This July 21, 2021 photo provided by Civica Rx shows construction of their Essential Medicines Manufacturing Facility in Petersburg, Va. Civica Rx was started three years ago by a hospital consortium. It now provides over 50 generic injectable medicines in chronic shortage to more than 1,400 hospital members and the Veterans Affairs and Defense departments. Credit: Paul Bacci/CRB Group/Civica Rx via AP

But David Mitchell, founder of the independent consumer group <u>Patients</u> <u>for Affordable Drugs</u>, said the projects are workarounds that help in niches, but are "not enough to fix a broken system."



Civica Rx was started three years ago by a hospital consortium. It now provides over 50 generic injectable medicines in chronic shortage to more than 1,400 hospital members and the Veterans Affairs and Defense departments. It already has sold enough medication to treat 17 million people, including many hospitalized with COVID-19.

Now it's expanding to help patients directly, said chief executive Martin VanTrieste. Its new partnership with Anthem and Blue Cross health plans, CivicaScript, is picking six or seven expensive generic drugs to start. It will have contract manufacturer Catalent start producing those drugs to sell at 50,000 retail pharmacies starting in 2023.

Other "alternative drugmakers" include:

- —Two enterprises, from Premier Inc. and Phlow Corp., focused on providing their hospital members with affordably priced generics that are chronically scarce.
- NP2, which is about to start producing cheaper generic IV cancer medicines.
- <u>EQRx.</u> which is creating brand-name drugs for cancer and inflammatory disorders to sell at "radically lower prices" than rival brands.

Walmart recently added insulin to its in-house brand of products for people with diabetes. It's selling its own version of the mealtime insulin NovoLog, in partnership with manufacturer Novo Nordisk, for less than half NovoLog's price.





This 2019 photo provided by Civica Rx shows a vial of vancomycin in Lehi, Utah. Civica Rx was started three years ago by a hospital consortium. It now provides over 50 generic injectable medicines in chronic shortage to more than 1,400 hospital members and the Veterans Affairs and Defense departments. Credit: Civica Rx via AP

Even entrepreneur Mark Cuban has jumped in, giving his name and money to a public-benefit company aiming to provide cheap alternatives to high-cost generic drugs at 15% above manufacturing costs, no insurance needed.

In January, Mark Cuban Cost Plus Drug Co. launched its first medication, a pill for parasitic worm infections that it sells through independent pharmacies for about \$40 per two-dose treatment, said



founder and CEO Dr. Alex Oshmyansky. The company is building a factory in Dallas but paying other manufacturers for now and aims to launch up to 100 more drugs by year's end.

Vanderbilt's Dusetzina sees Cuban's company as best positioned to cut out-of-pocket costs.

"It's a really nice project to go after products where there's little competition—and price gouging," she said.



This 2019 photo provided by Civica Rx shows vials of vancomycin in Lehi, Utah. Impatient with years of inaction in Washington on prescription drug costs, U.S. hospital groups, startups and nonprofits have started making their own medicines in a bid to combat stubbornly high prices and persistent shortages of drugs with little competition. Credit: Civica Rx via AP



Brand-name drugs get monopolies lasting up to two decades under U.S. patent law, so most of the alternative drugmakers are targeting certain off-patent medicines whose prices have risen dramatically in recent years.

Generics are usually cheap. But as buyers pushed for barely break-even prices on these drugs over the last couple decades, generic manufacturers consolidated. With fewer factories making certain generics, even temporary plant closures triggered lasting shortages. And the reduced competition led to big price hikes, often forcing doctors to try costlier, less-effective alternatives and hospital pharmacists to spend long hours seeking alternatives for drugs in shortage.

Those years-long shortages spurred Civica's formation. It also led a top hospital group purchasing organization, Premier Inc., to launch a program that has contractors making more than 60 products for about 850 member hospitals, said its chief pharmacy officer, Jessica Daley. The two groups say they've gotten numerous drugs off national shortage lists.

Phlow Corp., a public benefit drug manufacturer largely funded by government grants, partnered in March with 11 top children's hospitals to address shortages by making generic medicines in child-size doses for cancer and other life-threatening conditions. Phlow and Civica are building neighboring factories in Petersburg, Virginia.

Such efforts have been helping hospitals stock crucial drugs—sedatives, painkillers, antibiotics and respiratory medicines—needed for COVID-19 patients.

The alternative drugmakers are hiring U.S. contract manufacturers



whenever possible and getting drug ingredients here or in Europe, to diversify supply chains heavily reliant on China and India, which limited exports of drugs and ingredients early in the pandemic. The Biden administration also is working to increase domestic production of essential generic drugs.



This 2019 photo provided by Civica Rx shows vials of vancomycin in the pharmacy of the Riverton Hospital in Utah. Brand-name drugs get monopolies lasting up to two decades under U.S. patent law, so most of the alternative drugmakers are targeting certain off-patent medicines whose prices have risen dramatically in recent years. Credit: Civica Rx via AP

Harvard's Kesselheim foresees the new generic manufacturers helping to



boost supply and lower <u>prices</u>, but he thinks developing new brand-name drugs—as EQRx is trying to do—is tougher.

EQRx is currently testing 10 novel drugs that it licensed the rights to, for cancers and immunologic disorders like rheumatoid arthritis. One already in final-stage testing could launch within three years.

The company expects to start work on another 10 patented drugs in ultraexpensive categories in the next year and is collaborating with <u>Exscientia</u>, a firm that uses artificial intelligence to design drugs and speed up testing.

Insurers are among EQRx's early investors, said the company's president, Melanie Nallicheri. They expect the company to turn a profit, but they also support plans to price medicines at up to two-thirds off rival <u>brand-name drugs</u>, she said.

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