

Cambridge Judge Business School

Case study

CIVICA RX: COLLABORATING TO DISRUPT HEALTHCARE

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“The fact that in such a short period of time Civica medicines are treating millions of patients is eye-opening. It shows the power of collaboration and the promise of this organization and its many partners to help millions and millions more people. I am so proud of the Civica team for all they have accomplished.”

Dan Liljenquist, Chairman

For Dan Liljenquist and Martin VanTrieste, respectively the founding Chairman and President & CEO of Civica Rx (see **Exhibit 1** for biographies), the three years since launching Civica had been the realization of very personal journeys to ensure that necessary medicines in short supply were available at affordable prices. They had taken a broken system and, along with the Civica team and all the partners, had developed a solution to create systemic change in the accessibility of generic medicines. Civica Rx was a collaboration of member hospital systems funded by those members and producing essential pharmaceutical drugs, often those in short supply, for its members at the lowest possible cost. Members had foregone short-term strategic advantages to embrace a long-term societal perspective, which sent a strong message to pharmaceutical companies that hospital systems would no longer tolerate a system of high prices due to the lack of governmental regulation in the market. Civica had also endured the stress on its capacities during the COVID-19 pandemic and found its Health Care Utility model well able to weather such an external shock.

As they looked forward to a future of further expansion, with more than 1,500 member hospitals and 50 drugs available, Liljenquist and VanTrieste reflected on how they and other founders had built Civica into a powerful public asset—and wondered in what other markets this model could create value for society rather than only for shareholders.

A Broken System

It was not common practice in the U.S. to formally regulate pharmaceutical drug prices, unlike in many developed countries with managed healthcare systems. In the U.S., it was the pharma companies themselves who set prices. One study found that the difference in prescription drug prices in the U.S. was more than 250% higher and for brand-name drugs 344% more, compared to 32 other countries.¹ While free market pricing was generally accepted in the U.S., it led, on some occasions, to individuals and companies gaming the system and inflating prices. One example in 2015 was the drug *Daraprim*, which was used to treat patients with toxoplasmosis, a parasite that could cause blindness, miscarriage or stillbirth, birth abnormalities, and lead to death, particularly in people with weakened immune systems. Martin Shkreli, (now former) CEO of Turing Pharmaceuticals, bought the company producing *Daraprim* and overnight massively increased the price from \$13.50 to \$750 per tablet.² The cost of producing *Daraprim* was about a dollar.³ Shkreli argued that the drug was a small market (circa 2,000 Americans per year need it)⁴ and of little interest to generics competitors. He suggested that the revenues from the price hike, estimated conservatively jumping from \$667,700 to \$300,000,000 per annum, could be used to develop better drugs to treat toxoplasmosis. While Shkreli ended up in prison for fraud – completely unrelated to the price rise of *Daraprim*, and Turing reinvented itself as Vyera Pharmaceuticals – the price did not

reduce and Vyera created the ‘Daraprim Direct Program.’ Through the program, uninsured lower-income patients could receive the drug for no cost, while commercial/privately insured patients “may pay as little as \$0 out-of-pocket” although limitations applied. Patients with Medicare or Medicaid were directed to independent co-pay¹ foundations and state programs but otherwise had to pay the inflated prices.⁵ Similarly, Valeant Pharmaceuticals hiked the prices of two heart drugs, *Nitropress* and *Isuprel*, immediately raising the cost to hospitals by millions.⁶



The discovery of insulin is commemorated on Canadian currency.

A further example was the cost of insulin in the U.S. The rights to insulin, discovered in 1923, had been sold to the University of Toronto for \$1 in the hope all those who needed it would have access.⁷ In 2017 a lawsuit filed in Massachusetts accused Sanofi, Novo Nordisk, and Eli Lilly of conspiring to drive up prices. The lawsuit described several examples of patients using expired insulin or starving themselves to control their blood sugar, while others intentionally fell into the potentially fatal diabetic ketoacidosis in order to get insulin

from treatment at hospital’s emergency room,⁸ with some patients flying to Mexico or crossing the border into Canada to buy insulin to keep themselves alive,⁹ rather than pay up to \$900 a month. Price hikes continued into 2018 but when the U.S. Congress and media were alerted, price hikes stopped, although the prices did not reduce.¹⁰ Liljenquist explained:

“This behaviour appears to be more and more common...there have been two factors that have led to a consolidation of the generic drug market, particularly around some of these older and essential generic drugs... where the price has gone up substantially. Either there is one producer for a long period of time who acted responsibly but then sold off the product and someone else took it and leveraged the ownership of that product to dramatically increase the price, or we’ve seen just an overall shakeout of the market for essential generic medications where there used to be multiple producers and now there are one or two who have a dominant market position. Every major health system in the country uses these and to make matters worse, the product is harder to get. We’ve seen that across literally dozens of drugs that we rely on every day.”

With the exception of Medicare — the government health insurance program for those over the age of 65 — the U.S. healthcare system is fragmented across states and other insurance product segments, leading to a lack of coordination around prices. At a federal level, the government was unlikely to materially intervene, given the market-based system and the historical precedent of the government not to directly regulate prices. The issue was the inelasticity of demand for these essential medicines, meaning, regardless of price fluctuations, demand remained relatively stable.

¹ Co-pay is an out-of-pocket payment that an insured person pays for a prescription. In the U.S., there are list prices – set by the pharma company and what uninsured people pay, net price is the profit the company receives for a drug, rebates are discounts for insurance companies, deductibles (which run into thousands) are what insurance policy holders must pay before the insurer starts to pay - <https://www.bbc.com/news/world-us-canada-47491964>.

Where a supplier was able to concentrate market power, it effectively had carte blanche to set prices. Healthcare providers and insurers were faced with a problem of how much they were willing or able to pay in order to secure these drugs for patients. With the second challenge of whether they could access them in the first place. The American Society of Health-System Pharmacists estimated that approximately 200 drugs faced shortages in 2022.¹² In addition, a study by Vizient suggested that drug shortages cost healthcare providers nearly \$360 million per annum in labour costs trying to work around the shortages.¹³ Compounding this problem of shortages was that hospitals would often hoard essential medicines, knowing they may be unable to access them. This meant less supply for hospitals which didn't hoard. There were no straightforward options to address the problem. Forming a private company to produce drugs was beyond the capabilities of both individual hospitals or new providers due to the economies of scale required and the sheer cost of setting up production. Added to this was that a new entrant would likely meet with retaliation from existing players and be exposed to predatory pricing.

Changing the Game

Dan Liljenquist, an economist and lawyer by education, executive at Intermountain Healthcare and former Utah State Senator, was planning to run again for office. He saw the unfairness in the system and his previous bid for U.S. Senate focused on a more equitable healthcare system, but he lost to a candidate who was heavily backed by Big Pharma. He was angry about the blatant exploitation of the market by Shkreli. Liljenquist believed in free markets but also knew that in situations of inelastic demand where one or two players met the entire market demand, inflated product prices were nearly unstoppable, as Shkreli had demonstrated. Expecting the federal government to regulate pharmaceuticals was unlikely as Big Pharma bankrolled political candidates and had very deep pockets. Liljenquist's mind kept returning to the subject. One day in August 2016, during his morning run, a glimmer of an idea came to him:



Dan Liljenquist holds the first vial of Civica Rx medicine.

“Rather than expecting miracles on the supply side, what if we organised the demand side of the equation and just created a new market? It was a moment of clarity – we need to create a new construct by creating a non-profit structure that nobody would own and would act like a democratised public utility. I called my wife and said, ‘I’m not going to run for office. I’m going to build this because I think we can do it!’ She replied it was the best idea she’d ever heard. But then I was like, ‘OK, what do I do?’ ”

Liljenquist shared his idea with colleagues at Intermountain and others, including Carter Dredge, Senior Vice President & Lead Futurist at SSM Health, whose own family members had suffered from the shortages and high prices of essential medicines. A couple months later, Liljenquist was on a four-hour plane trip and happened to sit next to Mike Leavitt, former Governor of Utah and former U.S. Health and Human Services Secretary. Liljenquist seized the opportunity and explained his idea. Leavitt connected him to a friend, Rick Gilfillan, CEO of Trinity Health, which was one of the largest healthcare systems in the U.S. Gilfillan then put Liljenquist in touch with the U.S. Department of Veterans Affairs, which is a federal government entity that provides medical care for U.S. military

service personnel and their families nationwide. Liljenquist discovered that everyone he spoke to loved the idea.

Other CEOs who led multi-billion-dollar organizations became involved, a courageous move in backing an unprecedented idea. One was SSM Health President and CEO Laura Kaiser, Dredge's boss, whose support and feedback was critical in helping the dream to become a reality. Another was Liljenquist's boss, Intermountain CEO Marc Harrison. In May 2017, Liljenquist sat down with Harrison, to present his idea in detail and update him on its progress:

“I said, if you were going to make the list of the top 100 things that Intermountain should do, this won't even make the list because it is not going to impact us much but we're the only ones who can do it. There's no white horse coming. I walked him through the fact that it would require health systems to organise it. That it would require some of my time, some of his time and some time from a couple of other people, but not the vast majority. But if we're the only ones who can do it and it needs to be done, don't we have an obligation to do it? Frankly, it was probably the most persuasive day of my life. Marc came out of our meeting saying, 'We're going to do this.' ”

They organised a conference in September in Salt Lake City and invited 20 experts from pharma manufacturing, three health systems, and Veterans Affairs. One of the attendees at the conference was Mo Kharbat, VP of Pharmacy Services with SSM Health, a multi-state health system which operated in Missouri, Illinois, Wisconsin and Oklahoma, who was invited by Dredge:

“Carter invited me and said it was highly confidential and then explained the idea. It had to be confidential not to tip off the market for two reasons. First, we didn't want big pharma dissuading health systems to join in, and second, if they knew what we were up to they would drop the price immediately and it wouldn't be feasible to make these products. But we knew that if that happened, the price would eventually rise again and we would be back to the same situation.”

There was a strong debate during the conference about feasibility and all the issues that needed to be dealt with to make it happen, such as raw materials availability and disruptions upstream. They talked it through and at the end of the conference, the manufacturing experts said they could make the drugs – the rest was the hard part. Everyone vowed to keep the secret. A group formed, which later became known as the Drug Selection Advisory Committee (DSAC), which would have an overview of which drugs that this new entity, which would eventually be called Civica, would produce. Another invitee to the conference was Martin VanTrieste, a veteran of the pharmaceutical industry who had worked at leading pharma companies including Abbott Labs, Bayer Healthcare, and Amgen, the world's largest biotech company. VanTrieste explained his involvement:

“One day a call from area code 801 appeared. Usually, I don't take calls from people I don't know but for some reason I answered it. It was Dan Liljenquist. He had me on the phone for 90 minutes trying to convince me about his crazy idea. Then invited me to the conference. I thought it would be a couple of days' vacation for my wife and I. At the end of the conference, I went over to Dan, thanked him and said, 'Running a pharma company is really hard and really complex, and I know running a

hospital is really hard and really complex, but they're different. So, don't put a bunch of hospital executives in charge of running a pharma company, because you'll fail.' "

VanTrieste returned to Florida and, two days later, Liljenquist visited him to discuss what it would take to make it happen in terms of talent and money. Then, in VanTrieste's words, "Dan disappeared." Liljenquist turned his attention to bringing people together to work out just how they could make the crazy idea they named "Project Rx" happen.

To stress-test the idea, a small group of people, including Liljenquist, VanTrieste, Dredge and others, met with Don Berwick, President of the Institute for Healthcare Improvement and former CMS Administrator, and Professor Clayton Christensen of Harvard University, a renowned business expert. Christensen, who was recovering from a stroke, would later tell Liljenquist that he had prayed his whole life that his writing "would inspire an idea like Civica."

Realising Project Rx

In May 2018, the New York Times interviewed Liljenquist about the generic drug problem:

"We had no idea how pent-up the frustration was. Within three weeks, there were 2,000 news articles published and millions of social media impressions. After that I spent all day, every day for about three months in 30-minute meetings talking to 120 health systems across the U.S. and to the press and then organising the market."

Liljenquist, Dredge and others investigated and planned how a non-profit could be created as the country's first large-scale, generic drug manufacturer. Even with multiple engaged stakeholders from the original conference, VanTrieste, who was supporting with expert advice, recalls that nothing was moving forward because the "20,000 lawyers behind the scenes were arguing about 'the' or 'and' as they tried to put bylaws and covenants and contracts together." And it wasn't just the lawyers that had different views, one health system saw it as a very large potential diversified revenue opportunity rather than a non-profit play, and the CFO of this healthcare system called Liljenquist:

"He said, 'Dan, we've never seen anything like this. We're going to make a fortune.' I replied, 'No, we're not, because we're a non-profit.' He then said, 'No, it's really simple. What you do is you create a non-profit to start with but you make it a simple majority vote to convert it to a for-profit later and we'll have moved the market.' I responded that we will make it a unanimous vote and that I want to bring three foundations on board so becoming a for-profit can never happen."

Liljenquist went to look for three philanthropic foundations. He called his friend, billionaire John Arnold, explaining that he knew his foundation would not buy drugs but their participation would keep Project Rx "honest."

Arnold agreed and, in the three weeks before the launch of Civica Rx, together they identified two other foundations to join them; each would contribute \$10 million. One of the foundations was the Gary & Mary West Foundation, run by Shelley Lyford. She described why they came on board:

“Gary and Mary started their company in their garage and built it into a billion-dollar enterprise. They want to solve big societal problems and I brought the Civica idea to them as they are interested in lowering the cost of drugs. My founder said to me, ‘I want a good fight with pharma. We’re all good capitalists and want everyone to make money but the amount of profit is obscene and it’s at the cost of cancer patients, seniors, and the destitute, who cannot afford their drugs. It’s inappropriate for us, as the richest country in the world, to be living like this.’ ”

Lyford became the Vice Chair of Civica’s board. In her words, her role was to be “a little bit of a watchdog, making sure we are fulfilling our philanthropic mission. While we want to make sure we are fulfilling contracts and having a steady supply chain and remaining low-cost, in the end it is about patients having access to low-cost drugs.” Lyford noted that when she and the other foundations joined Civica there was a feeling of ‘what are they doing here?’ from some of the other members. It wasn’t adversarial, just new, and the focus soon switched to jointly solving the problem and the additional \$30 million investment the foundations brought with them was a critical catalyst to help accomplish what lied ahead.

**"It's inappropriate for us, as the richest country
in the world, to be living like this."**

As Lyford explained, everyone’s motivation was to get the documents signed and get going. With new organisations becoming involved with this broader group, meetings became more formalised. Weekly strategy calls were scheduled as well as multiple all-day sessions; the latter were attended by a small group of key stakeholders working face-to-face. Often there were differences in opinion. Each organisation had to be willing to give up any potential first-mover advantage, special deals or strategic windfalls and individual purchasing advantages, as these went against the collective approach. Lyford recalled:

“We were all working on the agreement. Then the night before we went public with the announcement, the gloves came off and everyone was like, ‘Oh, this is what I need. We must put this in the document, we must put that in ...’ It was kind of crazy at the end. People were up until 3 a.m. redlining the documents and trying to get things done. Dan was brilliant taking charge and saying, ‘This is how we’re doing it. Intermountain isn’t going to get that, West Foundation, you’re not going to get this, this you can get. His leadership in the last 12 hours was incredible to get the final document over the line and get everyone to agree.”

Dredge would later call this a “triumph of the good of the collective over any one individual or organisation.”

Four tenets were agreed to for the business model:

- Nobody would own the company.
- Everyone would be charged the same low price and there would be no special deals.
- The company would go big and go long from the very beginning.
- The purchasers of the products also became the funders of the company.

In September 2018, Civica Rx was launched, the name being rooted in the importance of a civic responsibility to all citizens. Initial governing members included seven health systems—Catholic Health Initiatives (now CommonSpirit), HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence, SSM Health, and Trinity Health—and three philanthropic foundations—Laura and John Arnold Foundation, Peterson Center on Healthcare, and the Gary and Mary West Foundation. The focus was to produce a first batch of 14 agreed-upon generic drugs.

Civica Rx's name is rooted in the importance of a civic responsibility to all citizens.

An Innovative Business Model Built on Collaboration

Civica launched as a national-scale enterprise with more than 500 hospitals participating from its very first day of operation. The business model was very specific to safeguard the four tenets that had been agreed upon. See **Exhibit 2** for Civica’s Generic Drug Supply compared to a typical supply.

Nobody Would Own the Company

Civica Rx was set up as a non-stock, non-profit manufacturer of generic drugs with a 501(c)(4) social welfare organisation classification. There were no equity holders, stock options or dividends; and should the company be wound up, any proceeds would go to charity. The representatives of the philanthropic foundations would sit on the board of directors and the executives would be “stewards” rather than owners. As Civica grew through more entities joining, it would enjoy scale benefits but not equity dilution.

Everyone Would Be Charged the Same Price and There Would Be No Special Deals

Every entity that joined Civica would enjoy the same terms and prices as the existing members. In fact, the more scale Civica Rx could achieve, the better it was for all members as a larger volume of orders reduced the cost and thus the price would also reduce equally for everyone. Ensuring the same terms were offered at all times was key to ensuring collaboration. Through this concept of equal and low-cost pricing, Civica was considered a Health Care Utility¹⁴ – ensuring a high-quality service was accessible to all at the same price. Many of the hospitals that signed up for Civica already enjoyed individual purchasing advantages. They knowingly and voluntarily chose to give up

these advantages in the short term for long-term strategic advantages that would benefit the system and society.



Vancomycin was the first medicine produced by Civica Rx.

Participating members of Civica were guaranteed access to the products at the same price as founding members. But founding members of Civica could sit on the drug selection committee and thus could decide what drugs were produced.

It wasn't always straightforward, however. One large hospital system offered to leverage their network to promote Civica but in return wanted to take a small cut related to the network growth. The offer was declined by the team – preferring an "all for one and one for all" dynamic.

The Company Decided to Go Big and Go Long From the Very Beginning

Civica introduced a take-or-pay purchasing agreement they called a minimum viable volume contract (MVV). Members agreed to buy approximately 50% of their expected Civica-produced generic drug volume from Civica for a minimum of five years, with the remainder purchased from existing manufacturers.

"Do what's in the best interest of patients."

The Civica Rx mantra

Without the MVV, Civica would start life in a precarious position. The MVV resolved two issues:

1. **Demand Stability** – Civica would be able to produce the critical hospital-based drugs that were often in short supply with guaranteed demand, thus facing off against any predatory price-reductions by competitors.
2. **Supply Stability** – The MVVs allowed Civica to partner with existing contract manufacturers (CMOs) who already held the Abbreviated New Drug Applications (ANDAs) required to produce generic drugs issued by the U.S. Food and Drug Administration (FDA).

This second point was particularly important to the rapid scaling, because at first the Civica team believed they would have to develop their own ANDAs, adding millions to development costs and years to drug production. As they studied the market, the team learned that this wasn't true and they could identify companies who already held an ANDA from the FDA but weren't actively selling it due to nearly impenetrable market conditions. Civica was able to approach these companies (with underutilised or dormant ANDAs) and, having the MVVs as long-term guaranteed contracts, Civica could offer them entry into the U.S. market. Given that many of these CMOs were too small to take on the existing Big Pharma giants, it was an attractive offer to have guaranteed supply for five years. Another aspect that made it attractive to the manufacturers was that Civica paid them on delivery,

improving their cashflow. This was much faster than the typical timeframe where a manufacturer sent product to a wholesaler and was only paid once the product was sold, which could be six months later.

MVVs also enabled Civica to ensure six months' inventory for each product, allowing the company to become agile in the face of demand surges or production problems. During the COVID-19 pandemic, this aspect played a role in ensuring hospitals could continue to receive supplies during an external shock.

The Purchasers of the Products Would Become the Funders of the Company

Civica raised financing directly from its customers and the philanthropic foundations who believed in its mission rather than banks or venture capitalists. This aspect was a critical element in the business model, enabling Civica to focus on achieving the lowest sustainable cost for which it could deliver products to the market, rather than achieving the highest possible return for funders by leveraging the market's willingness to pay high prices. To do this at launch, the company raised \$100 million in membership donations and low-interest, long-term debt directly from hospitals and foundations.¹⁵

Operating Civica Rx

Liljenquist and the other stakeholders did not have the deep pharma operational expertise required to run Civica by themselves once it was launched. As they worked through the fine print, Liljenquist asked VanTrieste to hire a team to run the non-profit. VanTrieste recalled:

“I hired a team of seven people to work in the company and presented three candidates for CEO. They started interviewing and then said, ‘We think we need to do a national search.’ I said, ‘You’re making progress and you’re going to launch the company and the team is going to be asking who is the boss? – just pick one of the three.’ A few days later, Dan called and said, ‘We’ve got the answer, we want you to be the CEO.’ I responded, ‘Which part of “Martin loves retirement” don’t you understand?’ He called the next day, I said ‘no’ – he called again, and again, and again; this went on for two weeks.”

In the end, VanTrieste's wife convinced him to take the role because he was passionate about it and knew how to do it. VanTrieste called Liljenquist, saying he would accept the role if the board would agree to three key conditions: (i) VanTrieste would be on the board of directors so there would not be any "second-guessing" of agendas and strategy, (ii) VanTrieste would not take a salary, and (iii) he would take the role for six months. The board agreed to all the conditions. There was only one condition that was broken; VanTrieste of his own volition was still the CEO 3.5 years later.

The newly formed Civica team created what they referred to as "an amazing mantra" for the company – *Do what's in the best interest of patients*. Everything they did would be driven by that. There was little to no bureaucracy at Civica, just enough to get things done effectively and efficiently and recorded. Decisions also followed a unique process, guided by the concept of what was best for the patient. VanTrieste explains:

“There is a decision-maker for an issue but all of us are invested in the decision. Everyone provides input and once a decision is made we all support it like it’s our own. One example was a decision that had to be made that was potentially better for the health systems but worse for the company. The person responsible agonised over it for three days and kept asking me what to do, but I said it was her decision to make and we would support. She finally made the decision and we supported her and each other over it.”



Civica Rx board members and management tour the Civica Rx manufacturing facility in Petersburg, Va.

VanTrieste wanted to create a strong culture where “team” was at its heart. To achieve this focus, he created a compensation structure for the executive team where each one earned exactly the same amount. Bonuses were also the same. As the company grew, a training program called *The Civica Way* was developed with modules that everyone took. For example, *Know Civica* was about background and history, *Know My Team* and *Know My Job*, helped new hires understand what they were meant to be doing and why. The training was developed by junior employees who had “train-the-trainer” experience. They

continued to evolve and develop the training program. Debbi Ford, Civica’s Chief Communications & Public Affairs Officer, explained the unique culture:

“The culture early on was everyone was 100% solid behind the idea, willing to go above and beyond to advance it. And that really has stayed the same, even as we’ve grown. I think a big part of that is even though we are not all in the same location, because remote working was part of the design for some of us early on pre-pandemic, we made a real effort to stay in touch as a team, and have weekly all-team discussions that continue today with almost a hundred people. We’re bringing new people on board and assimilating them starts right away through The Civica Way. That’s helped maintain that level of engagement that was there so early on.

“Additionally, we have strong leadership who have ‘been there, done that,’ and they know the importance of keeping their teams engaged and involved. Our leadership team is very transparent and probably would make some other companies feel uncomfortable with the level of information that’s shared in an all-team huddle. It’s not that there’s anything to hide, but we’ve hired people who can handle challenges, whatever that may be on any given day. It’s essentially our philosophy that, wherever possible, they’ll be better informed and better able to do their job with context. So, context is key.”

In addition to core management team running the day-to-day operations to produce and distribute the medicines, another critical body of Civica was the Drug Selection Advisory Committee (DSAC). It included representatives from the founding hospital systems, pharmacists, and supply-chain professionals. The first meeting had 60 people in the room, including 10 from VanTrieste’s team. He described:

“I thought it was going to be two hours of a food fight and they would give me a thousand drugs to work on. I told them we could only produce 10 drugs in the first year. There was a lot of sausage-making in the beginning but, by the end, they asked if it was possible to produce 14 drugs because they had consensus around them and they caused the most pain when they weren’t available.”

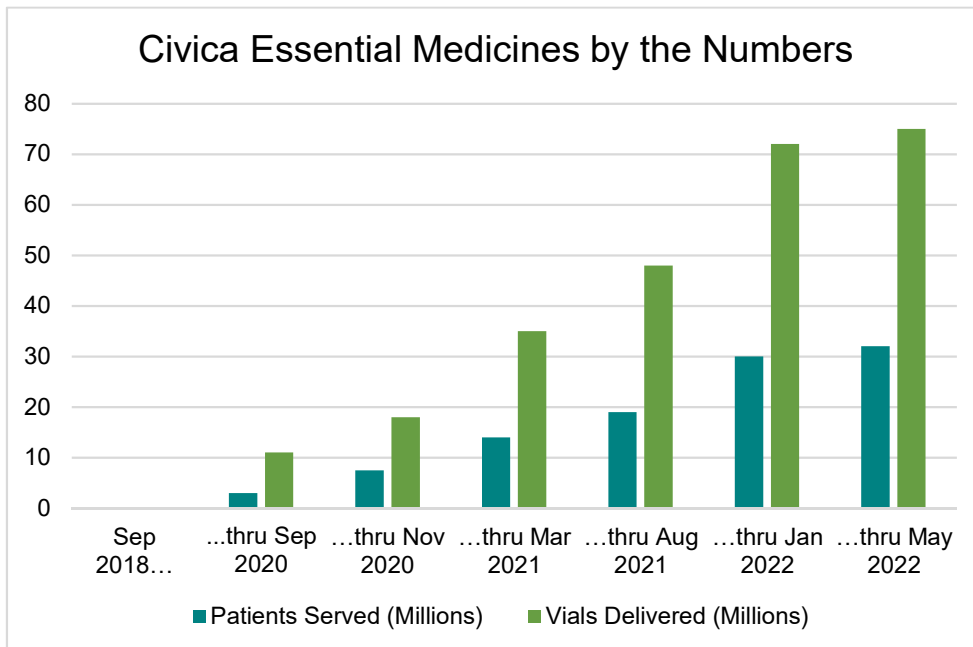
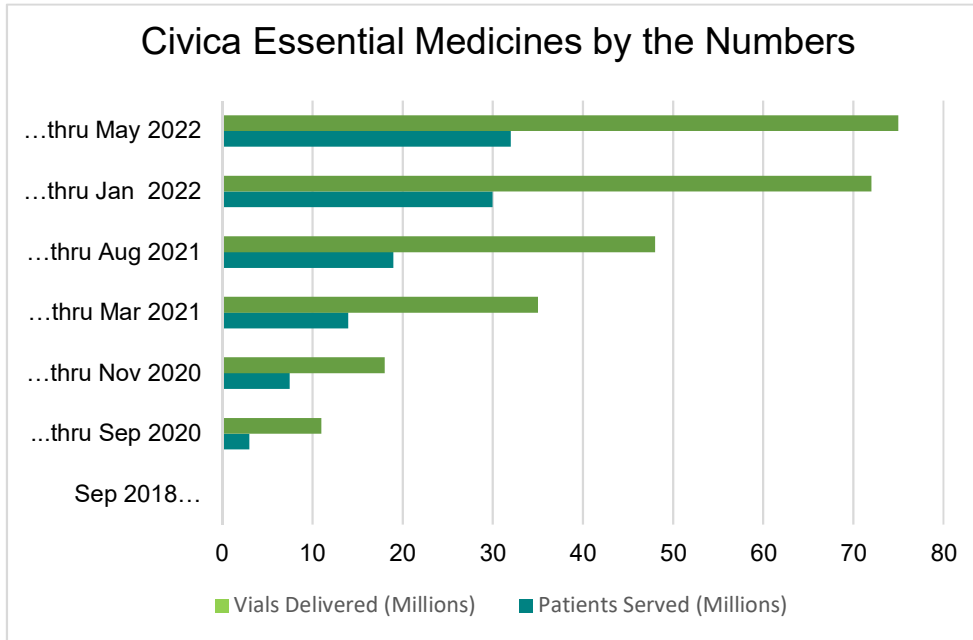
The group had agreed on core criteria for quickly being able to get to a consensus. These were: availability, affecting the greatest number of patients, and if the drugs currently suffered from predatory pricing. There were four buckets of priority drugs, with the 14 they agreed on being the priority in bucket one. Once the drugs had been identified and agreed on, the Civica team went and negotiated with vendors – sometimes they were unable to source products immediately and they had to pivot and change plans.

As Kharbat explained, the DSAC had its disagreements:

“We might agree on a certain product being necessary but one member system might say ‘it comes in 2-ml vials’ while another might say, ‘no it comes in 10-ml bottles; we want to use that.’ And then someone else says, ‘We can’t make both; you have to agree to a size and everyone has to use it.’ Or someone says, ‘This drug comes in a vial,’ and someone else says. ‘We want a prefilled syringe as our nurses prefer that.’ We had to make these hard compromise decisions, which were not easy.”

With the mission guiding everything, the DSAC agreed to make the compromises it did, never leaving the meeting room without consensus. This worked for the first four buckets; however, when these were completed, it became harder for the DSAC to reach consensus as they were switching to specialty products that not all the hospital systems used. Paediatric hospitals, for examples, need child-appropriate drugs that were not universal.

In April 2019, Civica opened its headquarters in Lehi, Utah, and in May announced it had picked Copenhagen-based, Xellia, to produce its first two antibiotics, vancomycin and daptomycin, available from Q3 2019. Civica committed to purchase these drugs from Xellia for five years. Leveraging technology for better demand forecasting, the company teamed up with Vizient to use analytics and data into purchasing patterns and provider needs. The rest of the year was equally busy, signing a five-year agreement with Hikma Pharmaceuticals for 14 sterile injectable medications and with Exela Pharma Sciences for sodium bicarbonate injections used in emergency care.



“They were two antibiotics – Vancomycin and Daptomycin – it was a really exciting time for us. It was really happening. Our communications team worked with local TV stations and reporters when the products arrived. It was amazing to see the product with Civica printed on the bottle, vial, and box. It made the news.”

In October 2019, just a few months after signing with Xellia, the first drugs were delivered. Kharbat remembered when they arrived (see <https://civicarx.org/timeline-2019/#aug-2019>):

Big Pharma Fights Back

As soon as Civica Rx was announced, the drug manufacturers started taking action and reduced prices. Having already worked through this possibility, the Civica team was able to manufacture the drugs it had prioritised because the hospital systems had committed to purchasing 50% of their need from Civica.

Everyone involved in Civica saw this as a good thing. Kharbat explained:

“One of the effects of Civica on the market is (a) we’re not seeing pricing volatility with these products like we did before, and (b) the supply is improving. As a matter of fact, because some of these companies are trying to compete with Civica, they’re dropping their prices below the pre-Civica entry point. Carter Dredge frequently reminds us that the success of Civica is not measured by market share but by market effect. This results in benefits to the broader market well beyond just the Civica members.”



The Civica manufacturing facility in Petersburg, Va.

This meant that Civica’s entry into the market didn’t just improve affordability for Civica-produced drugs, but also on other similar generic drugs produced by non-Civica manufacturers due to increased competition—and that was good news for many different groups, including patients.

Building for the Future

Civica’s success attracted attention. In 2019, the U.S. government approached VanTrieste asking if he would be interested in the government giving Civica \$100 million to build a manufacturing facility in the U.S. The caveat was that, in the case of an emergency, production would switch to whatever the government needed. VanTrieste described:

“Civica is hard to hate. The Democrats like us because we’re providing low-cost drugs and the Republicans like us because we’re a private solution and not one where the government has to get involved. We were going to build a plant anyway that would cost \$140 million, so we entered into negotiations with the government but they make you jump through hoops and you don’t hear back for months. Then the pandemic hit and the conversation was no longer ‘Wait,’ but ‘Here’s the money; how fast can you get it done?’ ”

In January 2021, Civica signed a contract to develop and manufacture its own drugs in a 120,000-square-foot sterile injectable manufacturing facility in Virginia in partnership with Phlow Corp., a public benefit pharma manufacturer. The world-class, state-of-the-art, plant would create more than 180 jobs.

Civica continued to expand. By the close of 2021, it included more than 1,500 hospitals, 55-plus hospital systems, covering 225,000 licensed beds (1/3 of the U.S. inpatient hospital beds) and produced more than 50 generic drugs. During the first few years, an average of 40-50 hospitals had joined Civica each month since Civica's launch. Civica Rx also supplied generic drugs to the U.S. Department of Veterans Affairs and the US Department of Defense, as well as contributing millions of medication vials to the U.S. Strategic National Stockpile. Within 2.5 years of supplying more than 50 essential medicines, Civica had produced more than 40 million vials treating approximately 16 million patients at an aggregate price that was 30 percent less than before the company had existed.

Liljenquist reflected:

“I have people say, ‘How much money have you made off of this?’ I answer, ‘Zero. I’m a volunteer but I’m going to have to live through the next 40 years of this country, and I don’t want it to burn down.’ I can’t solve every problem, but I can solve this. We’ve looked to government far, far too much to solve some of these problems. I’ve served in government. They have very blunt tools. With the right ethos and the right backing, you can systemically change the game. That’s what we’re working to do. And when I think about that moment on the treadmill when I could see Civica, I could see what it could be – it was a flash of pure inspiration. And now it’s just fun to see it happening, actually living it, and far beyond what I thought it would do. And we’re just getting started. We’re a young company; we’re growing like crazy.”

The Civica team, its board and members had created an agile enterprise that would continue to expand. They focused on improvements and innovation and strengthening the pro-social mission. The new company is a disruptive force in the generic drugs market in the U.S. and the disruption had been a collaborative effort of the member systems, not the result of a venture-backed new entrant.¹⁶ Civica had managed to make this innovative business model work for products.

However, several open questions remained about other possibilities. Could the model be replicated in other healthcare contexts? Which products or services are appropriate and how could they be serviced through utilizing a Health Care Utility Model like Civica Rx?

Exhibits

Exhibit 1: Biographies of Dan Liljenquist & Martin VanTrieste

Daniel R. Liljenquist



Dan Liljenquist is the lead architect and Board Chair of Civica Rx, a new nonprofit generic drug company established to reduce chronic generic drug shortages and price gouging, which have negatively impacted patient care for over a decade. Dan's commentary on generic drug market issues was published in the *New England Journal of Medicine* (*Addressing Generic Drug Market Failures—The Case for Establishing a Nonprofit Manufacturer*) and informed Civica Rx's mission to ensure that essential generic medications are available and affordable to everyone.

Dan is Senior Vice President and Chief Strategy Officer for Intermountain Healthcare, where he also oversees Intermountain's Enterprise Initiative and Market Intelligence & Planning Offices. Prior to joining Intermountain, Dan served in the Utah State Senate and was nationally recognized for his work on Medicaid and public-sector pension reforms. He is a former strategy consultant with Bain & Company, Inc. Dan received his JD from The University of Chicago Law School and his BA in Economics from Brigham Young University. Dan and his wife, Brooke, are the parents of six children and reside in Bountiful, Utah.

Martin VanTrieste



Martin VanTrieste is a former chief quality officer at Amgen who was recently named one of *Modern Healthcare's* 100 Most Influential People in Healthcare and a leader on *The Medicine Maker's Power List* of Industry Influencers. He brings over 35 years in the industry, with comprehensive experience in biopharmaceutical manufacturing, quality systems and related government regulations in the U.S. and around the world.

Under Martin's leadership, Civica has expanded its membership to include over 50 health systems and has more than 40 essential medications for hospitals, eleven of which are being used to treat COVID-19 patients. Most recently, Civica began providing its medicines to the U.S. Department of Veterans Affairs and the U.S. Department of Defense. During the peak of COVID-19 outbreaks in the U.S., Martin led efforts to deliver 2.1 million containers of Civica medicines to the country's Strategic National Stockpile. In addition to working with quality supplier partners, Martin and the Civica team are working to advance generic drug production in the U.S. and are in the design phase for Civica's future finished dosage generic manufacturing facility. The plant will be in Petersburg, Virginia and is part of a partnership with the U.S. Department of Health and Human Services and Phlow Corporation for end-to-end advanced manufacturing of essential medications.

Prior to joining Civica and Amgen before that, Mr. VanTrieste was with Bayer Healthcare's Biological Products Division as vice president of worldwide quality and Abbott Laboratories as the vice president of quality assurance for the Hospital Products Division.

Mr. VanTrieste is the founder of Rx-360, an international nonprofit organization that enhances patient safety by increasing security and quality in the biopharmaceutical supply chain. He has also served as the Chairman of the Parenteral Drug Association (PDA) Board of Directors. Mr. VanTrieste earned a Pharmacy degree from Temple University School of Pharmacy.

Exhibit 2: Civica’s Generic Drug Supply Chain Compared to a Typical Generic Drug Supply Chain

Typical Generic Drug Supply	Civica Rx Generic Drug Supply Chain
Often sources drug ingredients from lowest cost markets – especially China	Sources drug ingredients with quality and reliability as key objectives from predominantly U.S. and European suppliers – 93% of Civica’s Active Pharmaceutical Ingredients (API) are primary sources from countries other than China
Relies heavily on sterile injectable drug manufacturers from low-cost markets such as India and China	Relies mostly on sterile injectable drug manufacturers in the U.S. and Europe – 88% of Civica’s medicines are manufactured in the U.S., Canada, and Europe
Frequently relies on one or two manufacturers for drug ingredients and finished drugs	Ensures redundant manufacturing capabilities for drug ingredients and finished drugs
Little or no transparency in labelling regarding manufacturing location	Labelling includes manufacturer location
Operates with ‘just-in-time’ inventory, less than 30 days, for essential medications	Operates with several months of inventory of essential medications for its member hospitals
Prices for essential medications can fluctuate wildly from very low to extremely high	Prices are fair and stable with little fluctuation for member hospitals
Drug supply chain often disrupted due to shortages	Little or no disruption to drug supply chain due to shortages, including during COVID-19
To ensure patient care, hospitals hoard essential medications, leaving little or no inventory for others	Ample supply of essential medicines are guaranteed for member hospitals, so no need to hoard them to ensure proper patient care
Hospital staff scramble to find alternative medicines, taking time away from patients and adding to overall cost of care	No need for scrambling so patients receive optimal care with no additional costs incurred

Source: Civica documents, <https://civicarx.org/wp-content/uploads/2020/11/Highlights-Civica-Manufacturing-Approach-11.20.pdf>

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