

Disrupting the Drug Market with Martin VanTrieste – Hospitals In Focus Transcript

- Chip Khan: [00:11](#) Hello, this is Chip Khan and welcome back to Hospitals in Focus. Our topic today is an important one, making sure generic drugs are affordable and accessible to patients. We are speaking with Martin van Triaste, president and CEO of Civica Rx, a new nonprofit company developed by large health systems that is really shaking up the drug market. Thanks for joining us today, Martin.
- Martin: [00:37](#) Well, thank you for having me today. I appreciate the opportunity.
- Chip Khan: [00:40](#) Martin, let's start with the basics, what is Civica Rx?
- Martin: [00:44](#) Civica is a generic drug company that's newly formed. It created a very disruptive, transformative model to solve drug shortages and look at predatory pricing of generic drugs. We were founded, as you noted, by several prestigious large health systems who struggle every day with drug shortages, and so the mission of Civica is to do what's in the right interest of patients. Then that means to make sure there's quality products available when patients needed to be treated at affordable prices.
- Chip Khan: [01:17](#) Martin, it's hard to believe that you've taken such a program and developed it from scratch, what is the path that you've taken to get to this position leading this important project?
- Martin: [01:29](#) You know, I'm a pharmacist by training and right after I left pharmacy school I went into the pharmaceutical industry and I've been in research and development, manufacturing and quality, and I've always had this yearning to serve patients. So when I was approached about the idea of Civica, I thought it was a very interesting idea and had a lot of possibilities to be successful and it would solve a pretty big problem out there. But I came on just to advise the individuals who are trying to put Civica together, 'cause I had retired from my previous job and I loved retirement and I was just giving them free advice about from a pharmaceutical perspective how to be successful, how to do it the right way.
- Martin: [02:22](#) And over time a gentleman by the name of Dan Lilliquest whose really the idea king of Civica, kept approaching me and saying, "We need a CEO." And I said, "Well, I'll go find one for you and I'll hire one." And eventually he said, "No, no, no. We want you to be our CEO." And I'd have to say I was a very reluctant leader before I started. As I said I enjoyed retirement, my wife enjoyed the traveling and the things we were doing together. And but over time, Dan was a very persuasive man and convinced me

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that the organization needed someone like me with my passion and with my skillset. And so I decided to take the role.

- Chip Khan: [03:08](#) Well, Martin, we are glad that you decided to come back and that you're in the saddle again in such an important project for patients. Before we start with what Civica RX is doing with the plan is, let's go broad for a moment and could you define for hospital patients what the problems are that Civica RX was designed to respond to in terms of drugs, drug costs, drugs, availability. I know from research that the Federation of American hospitals and the American hospital associations' done that generic drugs and those drugs that are the old pre FDA drugs, their costs have skyrocketed over the last few years, thousands of percent in some cases. So to me the need for Civica RX or some thing like it, you know, cried out just from the data we looked at. But can you give us a sense for the scope of the issue?
- Martin: [04:14](#) Yeah, I think I break the situation into two distinct areas. One is what's causing drug shortages, and what's causing these very high prices that you mentioned about where things are going up thousands of percent? First I'll talk about drug shortages. So drug shortages really have a negative effect on patient outcomes and patients are actually harmed. Either their treatments get delayed, even counseled or they have to find alternative therapies to treat a patient. And sometimes those alternative therapies are not as effective as the one that was originally prescribed. And the whole process about drug shortages is [inaudible 00:05:04] as a result of the opposite of what's causing the high prices. These very old sterile injectable drugs that are very hard to make, they require lots of capital, that have strict regulations that oversee their production and have very strong enforcement by the FDA, have started to get into a situation where the economic model has been broken.
- Martin: [05:28](#) The prices of those drugs have gotten so low, I call it the race to the bottom, where manufacturers are chasing the lowest possible price so they can get as much volume as they can have to make the product efficiently. At the end of the day, what happens though, is many people and investors leave the business and go on to something else, leaving one or two suppliers left in the marketplace. Who have moved their supply chains to places like China, India, Vietnam, Burma, et Cetera. So you have a very long supply chain, it's very complex and it's very fragile. And so if one manufacturer has a problem in their supply chain, it immediately causes a drug shortage and there's no other manufacturers with the capacity to fill that void. And

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so you have an immediate drug shortage and it lasts for about a year until people can recover. Government has done a study that says the number one predictor of a future drug shortage is has the drug been on shortage before?

Martin: [06:37](#) So these drugs go through cycles of on shortage off shortage, back on shortage. And so it's all related to this broken economic model that we can discuss later. On the other hand, as you mentioned, these Desi drugs or grandfather products that came out before in 1963 that did not have a new drug application file with the government, are seeing the other effect and what's happening there is the FDA with all good intentions, implement that regulations to try to get people to file a new drug application and then abbreviated new drug applications. So what they did, they said anybody who files a new drug application for a Desi drug, we will review it. And if we grant approval of that new drug application, everybody else on the market will have to withdrawal their product until they get an abbreviated new drug application approved.

Martin: [07:38](#) So what has happened is people have filed and received approval for a new drug application, FDA has made people remove the other products from the market. And in that interim, before the datasets assembled and a manufacturer can file for an abbreviated new drug application, you've created a monopoly for one supplier to be producing a product that used to have many. And of course in a monopoly situation it is very likely that prices will go up significantly. And then the company who has raised their price significantly enjoys the revenue that's been generated during that small period of exclusivity. And then they start to do things to create an artificial monopoly to extend that high price, such as getting exclusive contracts with all of the active pharmaceutical ingredient manufacturers in the world. Thus making it very hard for anybody else to get an abbreviated new drug application, a dataset put together and proved.

Chip Khan: [08:41](#) Gosh, I guess the old saw, you know, nothing is simple in healthcare really is relevant to the issue here. How do you see hospitals beginning to assure the continuous supply that's been undermined by the factors you've outlined and what's the plan for Civica Rx?

Martin: [09:07](#) So, I mean, I think what happened was, you know, the pain became so intense within the health systems and within hospitals related to drug shortages, not only did they see their patients suffering every day, they were experiencing so much

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financial instability related to drug shortages. So if a drug goes on shortage, the first thing the hospital does is try to buy product, either the product that's on shortage or an alternate. And then there are people out there that try to take advantage of those situations. And so it's been estimated that health systems in America spend an extra \$400 million a year at just finding alternative therapies. And then they spend another \$200 million a year in any efficiencies, where healthcare providers rather than be treating, patients are trying to figure out what is the alternative therapy path, what is the new regiment we have to use, where can I find these products that are on shortage?

Martin: [10:14](#) And so there's immense financial instability that happens in a hospital when a shortage occurs. So the pain that they were experiencing because of watching their patients suffer and the financial instability institutions got so great, and people had been promising them we're going to fix it, we're going to fix it and no one has, that they decided to take the ball into their own hands and create Civica. Now, what Civica is doing is what we call a very disruptive and transformative model and there are really like eight key points of what we're doing that's disruptive to the industry.

Martin: [10:53](#) First, we are non for profit. There are no stockholders in the company, there are no equity investors. We do not have to worry about raising our stock price and giving a return to a shareholder or providing an interest payment to an equity investor. We can keep the price as low as possible and provide any excess revenue into developing the next new drug. We are very transparent at Civica. So our business model is very transparent and our pricing is very transparent. And the reason we want to be transparent is we think one, transparency leads to other people following the model. And what I mean by that is if we show that we can solve drug shortages and maintain good pricing, maybe other players in the marketplace will copy what we're doing. So that's the one reason we're transparent.

Martin: [11:48](#) The second reason is, we want our members to know where the product's coming from, by city, state and country. That way if they hear of something like an explosion in China, and they know that that plant was in that city that had that major explosion, they can try to prepare for a potential drug shortage. And on price, we charge one transparent price, no rebates, no fees to the middlemen and that one transparent price is the same for all members. The smallest community hospital of ten beds in the middle of Wyoming, and the largest health system in America all pay that one same transparent price.

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- Martin: [12:31](#) We have set up a system where we enter into longterm guaranteed contracts. We'd go to our manufacturers and we say, "Over the next five, seven or ten years, we're going to buy so much product from you a year at such and such a cost." And by doing that we've limited it uncertainty from the manufacturing network. They now know how much they need to make every year for the next five, seven or ten years. They know what their revenues are going to be and they know what their margins are going to be and they feel that by having that certainty, they're willing now to invest in more capacity, invest in keeping their facilities updated, invest in people, invest in bringing their supply chain closer to home. And so that is providing certainty to manufacturers and financial predictability to the hospitals. We are creating a system where everybody should feel like they win at the end of the day.
- Martin: [13:37](#) Our disruption also requires us have redundant manufacturing. We will not just depend on one manufacturing location to make any of our products. We'll make them in multiple locations. And the reason we want to do that is if any manufacturer has a problem, there's always another manufacturer that can step up and fill the void. We will keep a strategic stockpile of all of these product, we call it sometimes safety stock. So we'll keep about six months of inventory in a strategic stockpile as a buffer when our shortages in the marketplace.
- Martin: [14:14](#) And so all of that together and our very pro competitive view of the world and our approach to this, 'cause we don't want to be the only manufacturer of these drugs. We want to have many companies manufacturing. So we encourage that by only giving away, and only accepting 50%, one half of the volume of any particular product from any health system. And that way we give the other half to competitors in the marketplace. We believe the more people making the product, you get the best quality, the most reliable supply chain, and the most affordable prices. So it's a very disruptive model that we're applying. It's not been tried in the industry in any large extent, and we're being transparent about it so other people can copy it.
- Chip Khan: [15:03](#) Wow, that's a really impressive program you've outlined. Can you give us some examples of what Civica Rx has accomplished already, directly addressing either particular drug production or shortages? What have you done so far?
- Martin: [15:21](#) So we're less than a year old. The company was founded on September 6th, 2018, and we're less than a year old. And I have to say, after 35 years of being in the pharmaceutical industry

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and working on some very exciting fast paced projects, I've never seen anything move as fast as what we're doing at Civica. And I think that comes for two reasons. One, the problem's real and it's significant and people want to solve it. And so all of those together I think allow us to move very fast. So I think our accomplishments that are really important is one, we've hired a world class leadership team consisting of pharmaceutical and hospital professionals.

Martin: [16:05](#) We have created an entire quality and manufacturing system that will guide us to manufacture and oversee the products that we make. We have already established ourselves with two products, that's Vancomycin and Daptomycin, and they are very important antibiotics used in hospitals on a routine basis. We have many suppliers in our pipeline that want to continue to supply us with new products that we haven't launched yet. And then finally we're in the process of building a buying a manufacturing facility, so very exciting times at Civica. We now have over 900 hospitals that are members of Civica, consisting of 200000 licensed hospital beds, which represents about one third of the hospitals in the country. So great demand for the products that we're going to produce and be part of the company both from a hospital perspective and a supplier perspective.

Chip Khan: [17:09](#) You know, the program you're describing is so impressive because clearly as you said in your intro, the hospital systems, the healthcare systems, have decided to take this on themselves. But there is consideration right now in Congress of new policies regarding generics and biosimilars. There also is, you know, some energy I think at FDA to try to find some solutions to some of the issues that have been raised that that you've cited today. Can you give us a sense for the kind of policy, either from Congress or from the government itself that you think would facilitate or help alleviate the reasons that Civica RX was formed and maybe make Civica RX in its processes more powerful in terms of meeting the needs of the depth of the problem that you have defined?

Martin: [18:13](#) Yeah, sure. One of the things I do a lot, I spend a lot of time in Washington DC, so I spend a lot of time with the regulators and I spend more time than I ever have in my life on Capitol Hill. And big piece of that is to educate everybody on what's happening in the marketplace, what's happening on the ground level in the hospitals, so they have a better understanding of any potential legislative or regulatory fixes that they are implementing. And I say that with the best of intentions, if you look at the entire

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ecosystem of the generic drug market, you have, you know the legislature, you have regulators, you have the pharmaceutical company, you have all the people in the middle, the middlemen. Then you have the health systems, the hospitals and healthcare providers. And if you look at drug shortages, every part of that ecosystem has done something with good intentions that have had unintended consequences.

Martin: [19:21](#) And so we talked about the FDA wanting more regulatory oversight of Desi drugs. And the unintended consequence of that was to create artificial monopolies in instances. But that's happened everywhere in the health system. Even healthcare providers, when they fear a drug shortage, the first thing everybody does is hoard product to buy as much inventory as possible. Logic, makes sense, You want to serve your patients, but when people hoard inventory, that's not necessary in the short term future, they're actually creating a situation that makes drug shortages worse, right? They're taking inventory not being used at this particular point in time out of the network. So a big piece of what I encourage the folks in Washington to do is really think through, it's a great idea, let's think about potential unintended consequences and let's design a system around that. So that's a big part of the equation.

Martin: [20:19](#) I think another piece that has to be thought of is how do you provide incentives for people to get back into this business of products where the pricing has gotten so low. It's basically a real low cost commodity and how do you then provide incentives for investors to invest money into this business. And I think that's a big important part where, you want them to invest but you don't want to have absorbenant prices and returns on their investments. How do you create those incentives to the regulatory or our legislative path. And that's why I spend a lot of time in Washington kind of dealing with, I've written a letter to the FDI when they were asking for public comments to[inaudible 00:21:05] about drug shortages and what they can do. And a big piece of that is to create what kind of regulatory incentives, not only can the FDA do but maybe the DEA, and other regulatory bodies to encourage manufacturing of these products.

Chip Khan: [21:22](#) You know, we've had some companies like Valiant that took advantage of the situation you described to when you define the problem at the beginning of our discussion, are you optimistic that the kind of policies and also the role in the marketplace of Civica Rx is going to bend that curve so that going forward in the future we're going to see more reasonable

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prices in this sort of, developing market or are we still going to go through a rocky period before we can see some light at the end of the tunnel in terms of continuously available, reasonably priced generics and pre FDA drugs?

- Martin: [22:10](#) Yeah, I think, I am an optimist. I do believe that by Civica being transparent and having a disruptive business model and proving that we can do this, we'll one, solve some of the problems ourselves. Of course, our 287 drugs on the drug shortage list today at the American Society of Health Systems Pharmacists. So clearly we're not going to be able to solve 287 drug shortages today. But by being transparent and using this disruptive model, I am optimistic that others will follow us. And there's lots of opportunity for collaboration and for other people to do what we're doing to solve these problems. You know, to me it, the other part of Civica that'll be nice is that we all should be a conscience in the marketplace, serve kind of a policeman. So and the next Valiant that comes along, they recognize that we can get in there and disrupt their business model if they don't act properly in the marketplace, maybe they'll think twice. However, I'm also very pragmatic individual and there were always be bad actors in the world and this industry is not immune to that.
- Chip Khan: [23:29](#) Thank you so much Martin, for joining us today. This has been just incredibly informative and of course we wish all the luck to you at Civica Rx, we appreciated the opportunity to learn about the business model that you're developing and a hope it is successful in bringing drugs to our patients continuously at reasonable prices. So with that, we'll conclude today and wish you the best, Martin.
- Martin: [24:00](#) Well thank you very much. And again, I appreciate the opportunity to speak to everyone today.
- Chip Khan: [24:05](#) Thanks so much.
- Chip Khan: [24:06](#) Thanks so much for listening and be sure to subscribe to Hospitals in Focus on Apple Podcasts or Google Play, or visit our website, FAH.org. It is so important that we get your feedback on our show, please rate us and give us a review. And if you like what you hear, tell a friend. Until next time, this is Chip Khan with hospitals in focus.