

U.S.-Made Meds Rely on Drugmaker Braving Scattershot Policies

By Jacquie Lee

June 5, 2020, 11:58 AM

- Phlow sees itself as 'catalyst' to increase U.S. manufacturing
 - Drug consultants, researchers say other drugmakers have failed
-

The global drug markets shocked by the coronavirus are giving generic drugmaker Phlow a chance to return more manufacturing to the U.S. But millions of dollars in government support won't be enough unless the company learns from other drugmakers' past mistakes.

The reliance on foreign drugmakers has long been deemed a national security risk, but the U.S. has been scattered in its efforts to lure more domestic manufacturing. Past efforts failed when an immediate threat passed and funding dried up or when companies propped up with federal dollars couldn't secure other buyers.

"The chance of success on their own without policy put in place is fragile," Nigel Smart, president of Smart Pharmaceutical Consulting in Pennsylvania, said. He was one of the consultants on a federal project to produce an anthrax vaccine after 9/11. "As a country, we have a great record of throwing money at things, but then we lose interest very quickly if we think the threat has gone away," Smart said.

The Biomedical Advanced Research and Development Authority within the federal health department awarded Phlow \$354 million last month to make essential Covid-19 drugs and build new U.S.-based plants for "essential" medicines and pharmaceutical ingredients.

Phlow can succeed where others have failed by using its partners to find buyers for its products, CEO Eric Edwards said in an interview. Those companies will help Phlow build drug plants quickly that use newer technology to make production faster and cheaper, he said.

"We recognize it takes a team to make a massive change in the pharmaceutical industry," Edwards said. His plan is to make Phlow and its partners "a catalyst for others to follow because we believe there is an enormous amount that needs to be done to reestablish our domestic base here."

Sustained Funding Crucial

Phlow will have to cover the huge cost of building and sustaining new drug facilities that will be outfitted with unique, state-of-the-art technology. Phlow's production set-up was developed by its partners at the Medicines for All Institute based at the Virginia Commonwealth University, Edwards said.

The novel process should save the company money by making production seamless and eliminating the chances for mistakes. But that sort of investment is expensive and historically has been too difficult for generic drugmakers that live on slim profit margins.

Smart anticipates a project like Phlow's would take at least \$500 million to \$600 million to get off the ground. It will take "billions to get it sustainable," he said.

Edwards acknowledged the \$354 million won't cover the entire cost of building new facilities, but he said Phlow is supplementing its federal contract using private funds. Phlow's partnership with AMPAC Fine Chemicals, a drug ingredient producer, gives the company access to buildings and equipment such that Phlow won't have to build all its plants all from scratch. He declined to give an estimate of the total anticipated cost.

Sustained funding is especially important because a huge amount of capital is needed to build new plants, Smart said.

That's an area where the government has fallen short in the past, according to Rena Conti, a professor and associate research director for the Institute for Health System Innovation and Policy at Boston University.

"Inconsistency in committed funding from BARDA has been a problem for getting other types of drug development and vaccine development off the ground," Conti said. The additional \$458 million the government has tentatively offered Phlow down the line could dry up.

That's what happened to Sanofi's Zika vaccine. The federal government offered the drugmaker \$43 million in 2016 to help develop a vaccine to fight the virus after a 2015 outbreak spread across the Americas, Africa, and other regions. In August 2017, BARDA told Sanofi it was cutting back funding for the vaccine because the government had shifted its priorities.

Congress opted to not renew the one-year supplemental appropriations it gave BARDA during the Zika outbreak "when the immediate public health threat appeared to wane," a Department for Health and Human Services spokesman said.

BARDA isn't given funds each year to support emerging infectious disease and relies on supplemental funding during a public health crises, the spokesman said.

A Hunt for Buyers

Failing to establish a solid demand for its products is what drove another BARDA recipient, Achaogen, to declare bankruptcy last year. The government poured over \$100 million into the antibiotics company, but it couldn't sell enough of its products and went belly up.

Phlow plans to sell some of its products to the roughly 1,300 hospitals within the network of its nonprofit partner Civica Rx, Edwards said.

It doesn't appear the government will sustain Phlow by buying its products once the project is up and running. Edwards says the government "has committed to long term sustainability of the plan."

An HHS spokesperson said the agency is "committed to success" but anticipates Phlow will succeed in the long run "without direct federal support."

That means securing buyers outside the government is crucial to the company's survival.

The Trump administration is considering an executive order that would require certain essential drugs to be made in the U.S. Such a policy would benefit a company like Phlow and could bring it more customers, but that plan isn't final yet and it's unclear if it'll ever come to fruition.

Bolstering U.S. drug production is challenging any efforts to that end are step in the right direction, Smart said. "Many of us in the industry haven't been happy for awhile that so much of it is outsourced."

"But now we see economics isn't the only risk factor" he said. "Public health can be severely impacted if we don't have the supply of these drugs. And when you can't get them, that's a ridiculous situation."

To contact the reporter on this story: Jacquie Lee in Washington at jlee1@bloomberglaw.com

To contact the editors responsible for this story: Fawn Johnson at fjohnson@bloomberglaw.com; Andrew Childers at achilders@bloomberglaw.com