

A Rare American Plant for a Key Drug

● USAntibiotics risks closure without federal contracts for amoxicillin, the nation's most popular antibiotic

A manufacturing plant nestled in the Appalachian Mountains in the town of Bristol, Tennessee, was built in the 1970s and used to make enough amoxicillin to treat the entire country's strep throat as well as ear and other infections. At its heyday, it employed more than 500 workers and pumped out billions of pills of the most-prescribed antibiotic each year.

But by late July, only 62 people were working at USAntibiotics LLC. Some of the plant's equipment sat dormant, plastic draped over the machinery, and the once-bustling cafeteria was closed. Over the summer, the plant was making a mere 3% of America's amoxicillin supply. Yet Rick Jackson, chief executive officer of Jackson Healthcare, which bought the facility two years ago for \$8.7 million, says it could instead be filling a desperate need.

For the first time in decades, liquid amoxicillin—a go-to treatment for children's infections—has been in short supply in the US for almost a year. It's one of hundreds of commonly used drugs, including cancer treatments and attention-deficit/hyperactivity disorder meds, that Americans can't reliably get their hands on. Various factors are driving shortages, but a relatively simple one has sent parents frantically scouring pharmacies for antibiotics: Generic drugs, such as amoxicillin, aren't profitable enough.

Over the past decade, prices for generic drugs have plummeted. Because generics are essentially commodities, with cost the only real differentiating factor, there's been a race to the bottom on pricing. In 2015 pharmacies spent about \$11.6 billion on generic drugs for people on Medicaid. In 2023 those very same medicines would cost \$5.4 billion, adjusted for inflation, according to the consulting



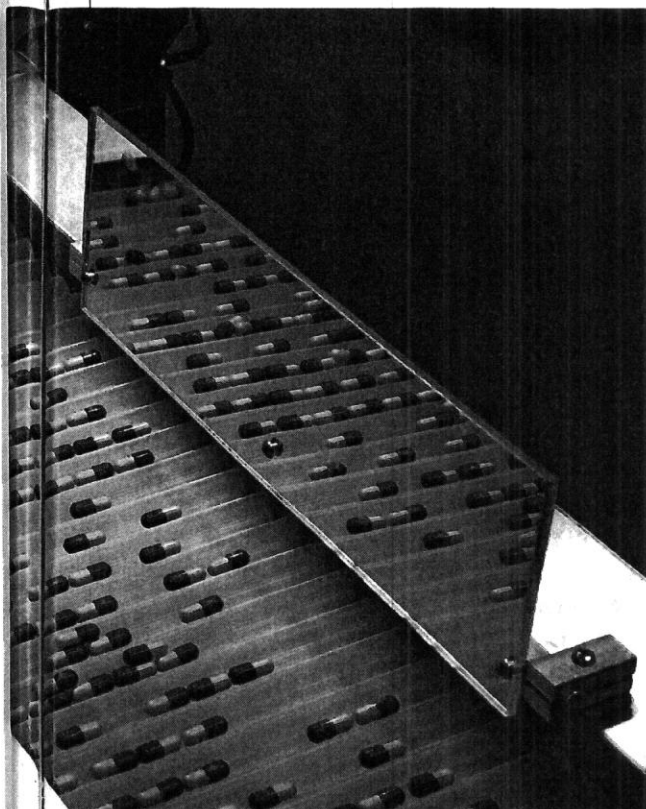
company 3 Axis Advisors. Americans might not be aware of this price drop because the price they pay is determined by opaque negotiations between drug-makers, insurance companies and middlemen.

This year, two American generic drug companies have filed for bankruptcy. Tel Aviv-based Teva Pharmaceutical Industries Ltd. announced plans in May to stop producing some products that aren't making much money. When the Tennessee plant's previous owner filed for bankruptcy in 2020, it was the last domestic manufacturer of amoxicillin.

Jackson's current operation isn't immune to these forces. "We're losing a lot of money," he says.

His survival plan: persuading the US government to buy his antibiotics. He wants a contract for \$30 million a year for the next three to five years for amoxicillin. That would help him stay in business and keep running the plant—and give him the ability to produce more in the event of a shortage. "If an emergency happened, we have that capacity, and we can ramp up immediately," he says.

Government support for domestic drug manufacturing has become increasingly popular as countries struggle to keep critical medicines in stock. Shortages of masks, oxygen and other medical gear earlier in the pandemic alerted nations to the vulnerabilities of relying on a global supply chain. Some, including the US, talked of subsidizing some generic drug and medical supply manufacturing to help fill gaps and make sure new ones didn't pop up.



Austria committed €50 million (\$53 million) to buoy local antibiotics operations. France put €160 million toward local drug production, including antibiotics.

The US Department of Health and Human Services in 2020 gave \$354 million to Virginia drug-makers Phlow Corp. and Civica Inc. to build out domestic manufacturing of drugs at risk of shortage. And in 2021, Phlow got an additional \$87 million. The company says it's using the money to manufacture ingredients for some drugs; Civica used its funding to build a factory. Civica asked the government for more money for another facility for antibiotics, but HHS said it didn't have the funds, says Allan Coukell, Civica's senior vice president for public policy.

HHS's Administration for Strategic Preparedness and Response, which manages emergencies such as pandemics, has a division that spent billions on domestic manufacturing of Covid-related materials, with funding Congress appropriated for that purpose. But that division doesn't have money for initiatives that are unrelated to the pandemic. "With annual funding, this office looks forward to further strengthening the domestic supply chain in partnership with the Food and Drug Administration to decrease future shortages," a spokesperson says. The department did not respond to requests for comment on Civica's plan.

"Subsidy" can be a dirty word in the US, but much of American business relies on government assistance. Elon Musk has said the federal

government should "delete them all," even as his Tesla Inc. business is expected to receive billions of dollars in tax credits. And Jackson himself hesitates to use the word. But in its battle with China for economic supremacy, the Biden administration has poured big money into US industry: \$53 billion for semiconductors and \$2.8 billion for electric-vehicle batteries.

There's a case to be made that having enough lifesaving drugs should be as much of a priority as funding batteries for EVs. It's not only that patients can't get the medicines they need to stay healthy. Swapping one antibiotic for another risks creating mutated bugs that are resistant to treatment. And when one drug runs out, doctors scramble for alternatives, which can lead to knock-on shortages.

There's a geopolitical angle, too. India makes many of America's pharmaceuticals using ingredients that often come from China. China even used its drugmaking dominance as leverage during trade negotiations in 2018, according to Nick Ayers, former chief of staff to Vice President Mike Pence.

America's vulnerability helped solidify Jackson's interest in the plant. His interest was piqued when he learned the last potential source of amoxicillin in the US was for sale. Soon after he happened to be on a call with Ayers, whom he knew through the Atlanta business community, and learned that high-level government officials were concerned with America's dependence on China for drugs.

Within weeks, Jackson put in a bid and won. Now a red, white and blue sign that resembles an American flag welcomes visitors to the "only plant in North America proudly manufacturing amoxicillin." (A lawyer for another drugmaker in New York says that company also makes some amoxicillin.)

"We need to have independence on any crucial drug," Jackson says. "I think it's a national security problem, I really do."

Multiple committees in Washington are discussing the issue, and lawmakers recently introduced a bill that would subsidize domestic drug manufacturing, but nothing has been passed into law.

Politics might be driving the dearth of public investment, says Thomas Bollyky, director of the global health program at the Council on Foreign Relations. Domestic manufacturing could lead to higher prices and increased health-care costs, a politically unpopular proposition. Few people think the drug industry needs or deserves free money, even though leaving generic drug makers to navigate the market means not having antibiotics to treat their kids' strep throat.

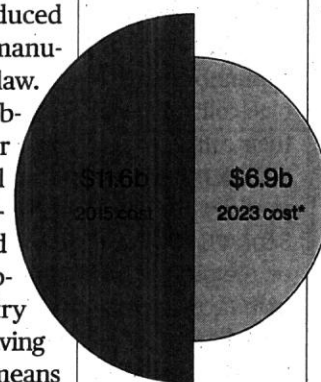
Most of the raw materials for amoxicillin—60% of the active ingredient and 90% of a necessary ►

◀ Amoxicillin production at the USAntibiotics plant in Bristol, Tennessee



● Jackson

▼ What the same generic drugs pharmacies bought in 2015 for Medicaid patients would cost today



◀ precursor chemical—are made in China, says Ian Ball, global head of anti-infectives for Sandoz, Novartis AG's generics business. Even USAntibiotics isn't self-reliant. It imports its pharmaceutical ingredients from Europe, creating its own vulnerability.

Jackson's plant got some help from the government. The FDA expedited its review of one of the manufacturer's raw materials suppliers during the height of the amoxicillin shortages in December, says Patrick Cashman, president of USAntibiotics.

But that same month, when Cashman got on a call with HHS Secretary Xavier Becerra, he had less success. Cashman told federal officials he could ramp up manufacturing even more, if the US government would commit to buying the drugs.

USAntibiotics hasn't heard back. "That's been crickets since then," Jackson says. (HHS didn't respond to requests for comment.)

Jackson says he'll keep the plant open until he hears a firm "no" from the government. But he's not going to support it forever: "It's just not good stewardship to lose that kind of money." —*Ike Swetlitz*

THE BOTTOM LINE The pandemic exposed the vulnerability of global supply chains for some medical goods. But it's a hard sell to win government subsidies for drugmakers to guarantee supplies.

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Biden and Trump Vie For the Union Vote

● Political rivals woo organized labor support for their 2024 presidential bids

As the strike by union autoworkers threatens the economy in the battleground state of Michigan, visits by President Joe Biden and former President Donald Trump to Detroit the last week of September gave both men a chance to appeal to blue-collar America. Whether union members heed their calls remains to be seen.

Biden, who calls himself the most pro-union president in history, traveled to Wayne County on Sept. 26 to join United Auto Workers members on the picket line. Trump, the leading Republican in the 2024 race, was to host an event near Detroit the following evening, which his campaign says will include autoworkers and other union members.

The candidates are trying to show their support for laborers after the UAW expanded a strike on Sept. 22 against Detroit's Big Three automakers to

38 additional facilities, adding to the three plants it initially targeted on Sept. 15.

In his remarks, Biden pointed to his pro-union stances and defended his green energy agenda. Trump's advisers said he was to argue that Biden's support for electric-vehicle production will send jobs to China and that his trade policies, along with a jump in inflation, have devastated workers.

Michigan voters—and the union workers among them—are expected to be critical in the 2024 race based on prior elections: Biden won 62% of the state's union household vote in 2020, topping Trump's 37%, and won Michigan by more than 154,000 votes. But in 2016, Trump won the state by only 10,704 votes, with exit polls showing he received 40% of the union vote, compared with Hillary Clinton's 53%.

Bernie Porn, the president of Michigan polling company Epic-MRA, says Biden's support among union members has fallen as Trump's has risen in recent months. Trump led Biden 46% to 43% among union members in an August survey, after Biden led Trump 51% to 42% in June.

Porn attributes that shift to Trump's comments criticizing electric vehicles and Biden's support for them as part of his clean energy agenda. Workers in plants geared toward internal combustion engines are hearing from Trump that all EVs will be built in China and the UAW will be "wiped out." That claim is extreme, and Biden can ease workers' concerns, Porn says, adding, "If he can address that, he should be able to get those voters back. But right now, the only message they're hearing about electric vehicles is addressing their fear and trying to play on their fears about union members losing their jobs in the future."

Trump is trying to re-create his 2016 appeal to blue-collar workers in states such as Michigan, Ohio and Pennsylvania and drive a wedge between a UAW leadership that historically has backed Democrats and rank-and-file members, many of whom support Republicans, says Saul Anuzis, a former chairman of the Michigan GOP.

But UAW President Shawn Fain has overwhelming support among striking workers of all political stripes, and Trump won't divide the leadership and membership, said Nick Kottalis, chairman of UAW Local 600's Dearborn Truck Plant unit, on Sept. 24 outside the Local 900 hall in Wayne. Striking workers were chanting, "No justice, no peace." —*Mark Niquette, with Gabrielle Coppola and Josh Eidelson*

THE BOTTOM LINE With both major US political parties facing a closely divided electorate, their leading candidates are wooing UAW voters worried about inflation and EVs eliminating auto jobs.

● Number of auto plants being struck by the UAW, including those of GM, Ford and Stellantis

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