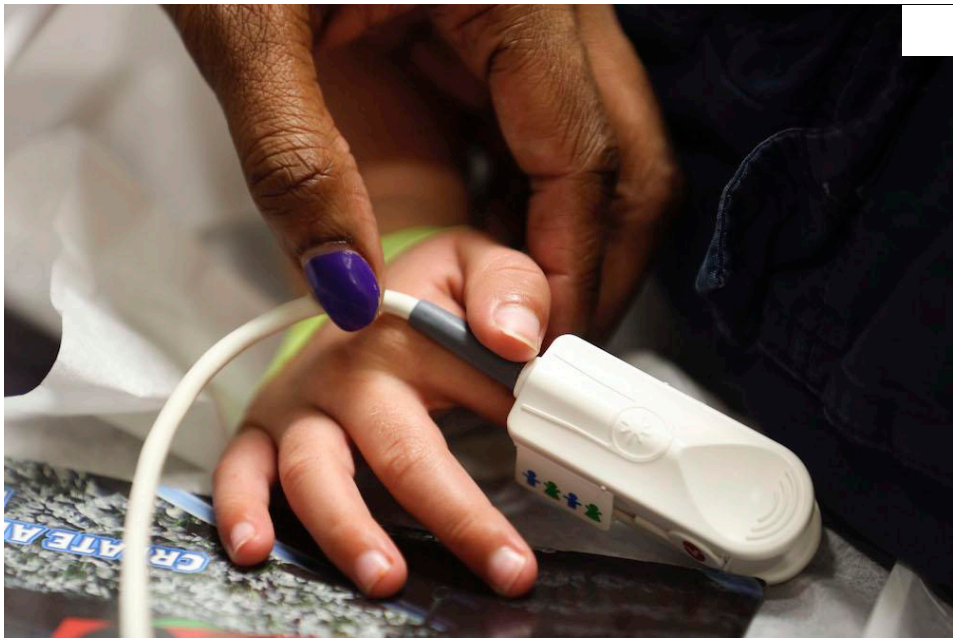
How the Drug Industry Sacrifices Children With Cancer

The outrageous, contrived shortage of one of the most widely used generic cancer drugs, vincristine, reflects multiple policy failures.

BY ROBERT KUTTNER OCTOBER 18, 2019



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A nurse holds a young leukemia patient's hand during an exam at Johns Hopkins All Children's Hospital in St. Petersburg, Florida, 2015.

Lately, there has been a spate of articles about the shortage of a vital drug used to treat childhood leukemia and other cancers that occur in children. The shortage of vincristine is so severe that some hospitals are on the verge of rationing the drug—having to make a Sophie's Choice of which children will live and which ones will die.

The stories have focused on the humanitarian aspect, but have mostly missed the underlying question of why there have been increasing shortages of such drugs at all, as well as many others. The answer is the increasing concentration and political power of the drug industry, the political refusal of regulators to address it, and the multiple policy failures that have resulted.

Vincristine is a well-established drug. The introduction of chemotherapy agents like vincristine turned childhood cancers from a death sentence to a category of cancer with a high cure rate.

It was first developed in 1961, and has long been a generic. That means it should be cheap and plentiful, like aspirin. Indeed, the average price of vincristine in the developing world, where it is on the World Health Organization's list of essential medicines, is $1.80 a dose, compared to $42.60 per dose in the U.S.

But the failure of the antitrust authorities to prevent the increasing concentration of the drug industry has left that industry with fewer and fewer makers of generics.

Many generic producers have been bought up by the big, high-profit drug-makers affiliated with PhRMA, who then use their market power to raise the price of generics that should be cheap. There is even a relatively new, totally artificial category of drug with the contradictory name, "branded generics."

Until June of this year, there were just two manufacturers, Pfizer (a PhRMA company) and Teva, based in Israel. Then Teva decided to quit producing vincristine, evidently because it was not sufficiently profitable. Pfizer then became the sole producer. According to Dr. Sidney Wolfe, who founded the Public Citizen Health Research Group, in situations like this the dominant producer then keeps the supply relatively scarce in order to keep the price high, and sometimes cuts its strategy too close, creating shortages.

There's another factor as well that leads to the winnowing of generic manufacturers. Hospitals

acquire medications like vincristine through special firms called group purchasing organizations, or GPOs. Established around 1910 as co-op buying groups, GPOs sprang from the impulse that a coalition of many hospitals could bargain down prices by securing volume discounts.

That's not how it worked in practice. GPOs eventually merged into four large firms, which purchase 90 percent of all needed medicines for hospitals. They buy them on sole-source contracts; if a generic manufacturer doesn't secure one, they have almost no way to get into the hospitals. Many contracts include required "90-10" purchases; if a hospital purchases 1000 doses of vincristine one year, it would have to purchase 900 the next, or lose an administrative discount and pay a penalty. The effect is to entrench the dominant supplier, and make it impossible for competitors to survive.

That may have factored into Teva's business decision (GPO contracts are usually kept secret, so it's hard to know for sure). Even before then, minimal suppliers can lead to fragile supply chains, where any manufacturing delay causes a shortage. Since the hospitals have a locked-in supplier, they cannot seek out alternatives, even in an emergency situation.

GPOs pull huge fees out of the cost of the supplies, which accounts for the price rise. The kickbacks are a percentage of the total cost; if the price increases, GPOs get more money, and since they dictate which products get in to hospitals, the incentives to raise prices are obvious. Hospital administrators get "share-back" payments as well, keeping them happy even though they're overpaying. The whole thing is secured by a safe harbor provision, making kickbacks between medical

suppliers and GPO firms legal.

In addition to the capture of antitrust policy, the drug industry also persuaded Congress to revise the patent process, so that more drugs would stay on patent for longer terms, and drug companies could get new patents for drugs that were only trivial variations of existing ones.

Two other government players that should be directly engaged in preventing outrages such as the vincristine shortage have also totally dropped the ball. The Food and Drug Administration, which has effectively been a captive of the drug industry under both parties since the 1990s, has treated drug shortages as if they were some kind of naturally occurring calamity. The FDA has a whole department that monitors shortages and provides extensive information on shortages to hospitals and doctors, but does nothing to get at the root cause.

And Congress, which used to hold extensive oversight hearings on abuses in the drug industry under such public heroes as Representative L.H. Fountain in the House and Gaylord Nelson in the Senate, has essentially stopped doing its job. If there were such leaders today, there would be immediate oversight hearings, with executives of Pfizer and Teva—and FDA and FTC officials as the first witnesses.

Generics, by definition, are drugs whose patents have expired. So they tend not to be the kind of blockbuster profit centers that the industry craves. But while government, when it does its job, can regulate pricing abuses, it cannot compel private companies to produce a given drug.

So there are only two possible remedies: Either restore

significant competition to the drug industry, including reforming or abolishing GPOs, so that other generics are as cheap and common as aspirin. Or conclude that because generics are (or should be) low-profit items, profit motivated companies just can't do this properly—and have the government, or a group of non-profits sponsored by the government, manufacture them.

And—wouldn't you know it?—someone "has a plan" to do just that. Elizabeth Warren, of course.

The Prospect has written extensively about the drug industry's abusive pricing of drugs that are on patent. But that abuse also extends to generics—and even to lifesaving generics for kids suffering from cancer. These people simply have no shame.

Capitalism is so out of control that what once seemed radical now seems just common sense. Americans are beginning to connect these dots. And that helps explain Warren's slow and steady rise in the polls. Nothing less than a drastic set of remedies will get us back to what should be merely normal.

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ROBERT KUTTNER

Robert Kuttner is co-founder and co-editor of The American Prospect, and professor at Brandeis University's Heller School.

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