Peter Bach has another crazy idea.

Bach, the director for the center for health policy and outcomes at Memorial Sloan Kettering Cancer Center, thinks that biosimilars, the would-be cheaper alternatives to the biologic drugs that are among the industry’s most expensive, are a lost cause.
The government has been developing policies to foster a biosimilars market, one that would work like the generics market and ultimately drive down the price of versions of drugs like Epogen, Avastin, and Humira. But Bach and his frequent co-author, Mark Trusheim of the MIT Sloan School of Management, argue in two new blog posts in Health Affairs that it’s time to abandon that approach. Instead the government should simply start regulating the prices of those medicines after their patents expire. The current system exists, they argue, only because lawmakers are unwilling to embrace the obvious. Doing so, they argue, could save $250 billion over 10 years.

“The constraint we think is being unduly imposed is that we have to use a competitive market to get price decline,” Bach said in a recent interview. “The right standard should be what is the best and most effective way to get a price decline while ensuring supply?”

The idea is a radical one that upends U.S. ideas about how the government interacts with pharmaceutical companies. Under the current system, cheap generic versions of medicines can be substituted for brand name medications after a drug’s patents expire. Relatively simple tests can tell that a generic is chemically identical to the original drug and behaves similarly in the body, and competition drives the prices of generics down close to the cost of manufacturing.

But biologic medicines, which are proteins grown in cells, not chemicals made in factories, are different, everyone agrees. Bach and Trusheim point out that a biologic medicine can be composed of more than 100,000 atoms, compared to fewer than 100 for a traditional medicine — what drug industry insiders call “a small molecule.” Biologics, they argue, are a natural monopoly, like an electric utility. Just as multiple companies are not going to build power lines to your house, they argue, it’s not reasonable to expect multiple companies to make cheaper versions of your psoriasis treatment.

Other experts contacted by STAT said that while parts of Bach and Trusheim’s argument might ring true, it is too early to abandon a competitive system that is just beginning to take shape.

“I’m not ready to throw in the towel,” said Dr. Scott Gottlieb, until recently the commissioner of the Food and Drug Administration. “Because, remember, once you throw in the towel, you basically end the whole model. I think this is going to be a very competitive and viable market. I think it’s going to take time to take shape.”

Gottlieb likened the process to what happened with the development of the generics market.

“It took time for that market to take shape as well. This is going to be no different. I think people need to have patience and to have reasonable expectations,” he said.

Bach and Trusheim, though, argue that the current drug pricing market deserves anything but patience. And their previous crazy ideas have had an impact.
Bach began working in cancer epidemiology in the mid-1990s because, he said, he was not smart enough to be one of the people developing new treatments. “I think the resources of our society and the smarts I happen to get through luck should be devoted to helping people,” he said in the interview. The question, for him, was how to get treatments that already existed to people. His first paper as a first author, which appeared in the New England Journal of Medicine, showed that African-Americans with lung cancer were dying sooner than whites because they were not receiving surgery soon enough. “Lung cancer surgery,” he said. “Essentially an ancient approach.”

In 2005 he got what he calls “the opportunity of a lifetime.” Mark McClellan, who had initially run the FDA under George W. Bush, was being tapped to take over the Centers for Medicare and Medicaid Services, and wanted Bach to join him at the agency. Bach accepted and took a leave from Memorial Sloan Kettering.

During his 22 months at CMS, his thinking about cancer drug prices changed. His first project involved working on the movement between paying for chemotherapy drugs based on their average wholesale price, which can be inflated, to their average selling price. But the more he got into the details of drug pricing, the more bothered he became. “Wait a minute, this system is designed to be inflationary,” he remembered thinking. When he returned to Memorial, he was obsessed with understanding why.

In 2009, he published a paper in the New England Journal titled “Limits on Medicare’s ability to control rising spending on cancer drugs.” In its first paragraph, it noted that 15 years before, only a single cancer medicine, Taxol, cost more than $2,500 a month. At that time, cancer drugs with $10,000-a-month prices were becoming routine. He has continued to use that chart in every talk he has given, updated as costs have continued to skyrocket.

But he really got the drug industry’s attention in 2012. He helped Leonard Saltz, the head of Memorial Sloan Kettering’s pharmacy committee, decide not to use Zaltrap, a colon cancer drug sold by Sanofi and Regeneron, because it was too expensive. At $11,000 a month, it cost twice as much as Roche’s Avastin with no additional benefits. The decision led to a New York Times op-ed and, later, an appearance on “60 Minutes.” The drug makers backed down, cutting the price of Zaltrap in half.

At the same time as he was becoming increasingly prominent, Bach faced personal tragedy. In 2009, his wife Ruth was diagnosed with breast cancer. He initially wrote about her illness in a series of stories for The New York Times in 2011. After he wrote those articles, Ruth relapsed. She died the next year. He wrote about the experience of losing her in New York Magazine, in 2014.

Those experiences shook him to his core. But did they affect his views on drug pricing at all?
“No. No they don’t,” Bach said. He continued: “I don’t ascribe evil motives to the industry, and I’m surrounded by many people you know, who are wonderful, serious scientists trying to make progress. No, she got great care, we’re in the 1% of society, and I’m a doctor at a very fine institution where, if anything, we even got special treatment.”

His concerns come from “a very different place,” he said. “I became a doctor to try and help people.” Researching drug prices, he said, is a way to do that.

In the spring of 2016 Bach was invited to a meeting in the Netherlands about imagining new ways of inventing and pricing drugs. That’s where he met Trusheim, a visiting scientist at MIT’s Sloan School and president of Co-Bio Consulting, which advises pharmaceutical companies. They were both badly jet-lagged; Bach recalled that they spent lots of time getting espresso together and talking about the pharmaceutical industry.

Trusheim, who had worked at Searle Pharmaceuticals, now part of Pfizer, said Bach came off as conservative compared to European experts who wanted the government to control prices and invent medicines itself. Kindred spirits, they immediately began talking about the news of the day: Sovaldi, the hepatitis C cure from Gilead. Initially, it cost $1,000 per pill, or $84,000 per treatment course.

That led to an idea that experts are now calling a “Netflix model” for buying drugs and that is having a big impact.

As Bach and Trusheim saw it, society pays for lots of incremental drugs. Solvadi, though, was a curative one, and the price blocked patients from getting it. What if, they reasoned, a purchasing coalition agrees to pay a fixed amount of money over several years for unlimited access to medication. In effect, this resembles a subscription-based agreement, just like Netflix.

Bach and Trusheim proposed the model to Louisiana officials.

Working with them, Louisiana became the first state in the U.S. to embrace the idea and signed a deal with Gilead in March. The amount of money needed to cover drug costs for state Medicaid beneficiaries and the Department of Corrections inmates would be equal to or less than what the state is currently spending to provide hepatitis C medicines to these populations. The state of Washington is also pursuing such a deal.

“This will make it possible for us to tackle the elimination of the disease on a broad scale,” Dr. Rebekah Gee, who heads the Louisiana Department of Health, said recently. “We hope other states will use this model. It just makes a lot of sense. Our spending has been constrained spend and, as a result, the access to the medicines have been limited.”

This wasn’t the craziest idea that Bach and Trusheim hatched, though. During a conference call
while Bach was driving home on a Friday, they joked that maybe it would be cheaper for the government to just buy Gilead. Though they knew the prospect was impossible, the math worked. They published it as an opinion piece in Forbes.\(^{19}\)

In their latest proposal, Bach and Trusheim (along with Preston Atteberry, a medical resident, and Jennifer Ohn, a data analyst in Bach’s group) try to make allowances for the realities of capitalism. For instance, they propose that if the government implemented their policy, it would spend $10 billion or more to make whole companies that had invested in the costly manufacturing capacity needed to produce biosimilar drugs. But they both agreed that the math on biosimilars didn’t work.

Unlike with generics, it is very difficult, if not impossible, to make a copy of a biologic that is completely interchangeable with a protein made by cells. “If the only social reason we went to biosimilars is to lower price, it just didn’t seem like a very safe or effective way to do that,” Trusheim said. “And in economics, we have other tools for these situations around what you do with a natural monopoly and that leads to price regulation.”

But experts who reviewed the idea largely saw it as an impossible dream. “I like this idea because it tries to solve a problem that I think is not going to be addressed by what we have today,” said Yaniv Heled, an associate professor of law and co-director of the Center for Intellectual Property Law at Georgia State University, who studies biologics and biosimilars regulation. “Anyone who is honest with themselves knows the current law will not result in price competition and price drops.” But, he said, Congress is unlikely ever to pass it.

Elaine Herrmann Blais, the Boston litigation leader at Goodwin Proctor LLP, said that every proposed solution to the biosimilars problem should be taken seriously. “But,” she added, “it’s just too soon to tell whether some version of this radical idea is in order and, in any event, an idea like this would require extensive consideration of patent issues, incentive to innovate, and the impact on the overall marketplace.”

Again, the politics. “You have to get Congress to pass a law that would say at the end of exclusivity the companies have to drop the price?” said Steven Horvitz, managing director of EMC Analytics Group, a pharmaceutical research firm. “Regulated is a highly charged word. To wish upon a star is a fun thing to do, but this is like peeing into the wind.”

It’s also widely agreed that biosimilars will never result in the same kinds of price decreases — at least 90% — as traditional generics. But can they accomplish 30%, or 50%? Some experts think they can, and that that’s enough.

Dan Mendelson, who founded the Avalere Health consulting firm, acknowledged: “You can differ on the actual size of the estimates, but the fact is we don’t have a functioning biosimilar market in this country, and this will cost the federal government tens of billions of dollars over time.”
But he also thought Bach and Trusheim’s solution is too extreme, even though, he acknowledges, this is how the government pays for missiles, tanks, and submarines. A simpler thing to try first: Change Medicare so biosimilars get precedence over branded drugs, encouraging doctors to switch patients and companies to enter the market and compete.

Gottlieb, the former FDA commissioner, went further. He argued that experience shows that when the government tries to set prices, it often overpays, and that this is exactly what happened in Medicare with cancer drugs. The best chance of a functioning market, he argued, is to find ways to encourage companies to create biosimilar medicines. The technical problems of how to do so will be solved over time.

Maybe. Bach said that his goal isn’t simply to propose policy change. But he wants readers to think about whether the constraints in the drug pricing system are actually real constraints. Some, he argued, are just ways of doing things that society has inherited, and that can be changed, without a direct affront to capitalism. Focus on what the actual policy objective is or should be, Bach argued. He said: “Let’s ask ourselves why we’re not doing this other than we don’t do things like that.”

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