

Commentary

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Thank God for Big Pharma

by James B. Meigs

ON MARCH 15, 2020, JOE BIDEN AND BERNIE SANDERS APPEARED IN A CNN debate. The timing was ominous. COVID-19 had begun its exponential explosion in the United States. New York and other cities were locking down and hospitals were bracing for the inevitable deluge. CNN's Jake Tapper asked Senator Sanders, "If you were president right now, what would you do to make sure every sick American is able to get treatment?"

Sanders quickly zeroed in on what he believed was the core problem. "We have a bunch of crooks who are running the pharmaceutical industry," he thundered. "Right now, in the midst of this epidemic, you got people...saying, 'Oh, wow, what an opportunity to make a fortune!'" As president, Sanders vowed, he wouldn't let that happen. "The drug companies will not rip us off!"



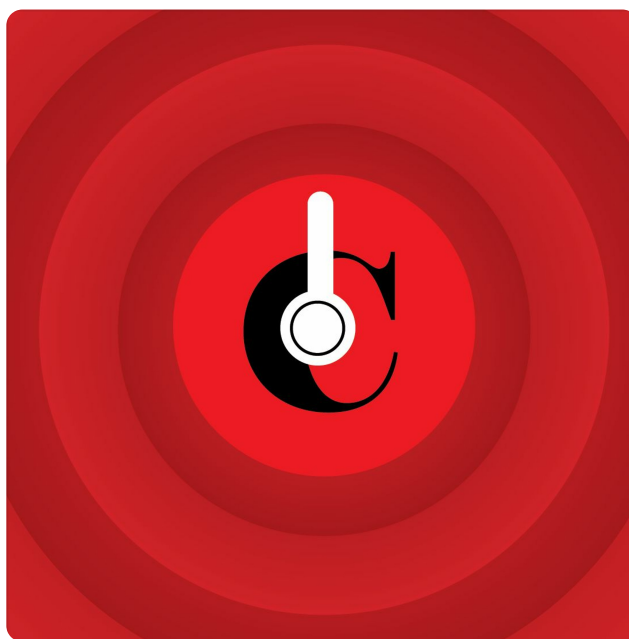
In *The Telling*, Mark Gerson gives a masterful overview of the principles underlying the Seder. For anyone looking to explore purpose in a modern world, and anyone looking to add lively discussion to your net observance of Pesach, this book is for you.

-Gordon Robertson
CEO, The Christian Broadcasting Network



His position was hardly out of the mainstream. In a 2019 Gallup poll that measured attitudes toward major industries, the pharmaceutical industry ranked dead last, with 58 percent of respondents holding a negative view. Even Republicans, who usually at least pay lip service to free enterprise, often rail against the industry. Ever alert to populist antipathies, Donald Trump made a habit of slamming Big Pharma in his rallies and on social media. So, as coronavirus fears ramped up in early 2020, it was only natural for both parties to renew their attacks on this most widely loathed branch of the health-care establishment.

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But while Biden and Sanders debated in Washington, scientists and executives at Moderna, Inc. were preparing as if for war. The 10-year-old biotech firm, located in Cambridge, Massachusetts, was a small but ambitious player in an industry dominated by giants such as Johnson & Johnson, Merck, and Pfizer. In its short life, the company had raised \$1.6 billion in venture capital before going public in 2018. Investors believed that Moderna's core technology—a method of inserting bits of synthetic RNA (DNA's fragile sister) into human cells—could revolutionize the treatment of cancer and other diseases. But the company had yet to bring a single drug to market—or even to prove that its “messenger RNA,” or mRNA, technique was safe.


In January 2020, when news broke that a mysterious coronavirus was circulating in China, Moderna's scientists quickly realized that a vaccine against the new disease might be a perfect application for their process. On a Saturday—January 11, 2020—a heroic Chinese researcher made the new virus's genetic sequence public. Moderna's technicians took that data and then worked through the weekend engineering a vaccine using their mRNA technique. By Monday, they were finished. “This is not a complicated virus,” Moderna's French-born CEO, Stéphane Bancel, later told the *New York Times*.

Developing a potential vaccine based on genetic data is one thing. Proving that it is effective and safe and then manufacturing and distributing it on a massive scale—those are challenges of different order. Fortunately, the Trump administration's Operation Warp Speed stepped in to provide the resources Moderna didn't have: \$1 billion to support the production and testing of the vaccine and another \$1.5 billion to pay for 100 million doses. Though the Warp Speed program wasn't officially announced until April, in March—as Sanders was denouncing Big Pharma “crooks” from the CNN podium—Moderna was already ramping up a huge manufacturing operation to produce its exquisitely delicate vaccine. It needed to expand its workforce by 50 percent virtually overnight. Perhaps hardest of all, the company had to conduct the clinical trials that would confirm its vaccine's safety and efficacy. Normally, these steps take two to five years. Sometimes, researchers work for decades without ever producing a viable vaccine.

Moderna would get the job done in 10 months.

At the same time, some of the biggest players in the pharmaceutical industry were racing to get their own vaccines into the testing pipeline. Pfizer, working with the German firm BioNTech, also had an mRNA vaccine in development. Johnson & Johnson, AstraZeneca, Novavax, Sanofi, and GlaxoSmithKline were working on different approaches. No one knew which of these vaccines would get to the finish line first. It seemed likely that some—perhaps most—of the candidates wouldn't survive the testing gauntlet. Such high-visibility failures could cost these companies billions and damage their reputations for years. In general, developing a vaccine for a new disease is a surprisingly risky investment for any drug company. Competitors might beat you to market, making your product an also-ran. Or, as happened in the cases of SARS and Zika, the disease might subside quickly, making it impossible to test the vaccine's efficacy. Even successful vaccines aren't usually big moneymakers. Unlike drugs for chronic conditions, most vaccines need to be administered, at most, only a few times in a patient's life. That doesn't add up to a lot of billing cycles.


Under normal conditions, steely-eyed investors shoulder most of the financial risks of drug development. And companies usually wait until they think a drug or vaccine is likely to get FDA approval before building out the necessary manufacturing facilities. But these weren't normal conditions. By offering up-front money to the drug makers who needed it and placing advance orders for hundreds of millions of doses, Operation Warp Speed helped share the risks. Drugmakers expanded facilities and started cranking out tens of millions of doses even as their vaccines were still in the testing phase.

When Bancel left a much larger firm to become CEO of Moderna in 2011, he had warned his wife that the company's mRNA technique had only a 5 percent chance of yielding successful products. But if it worked, it would "change the course of medicine." The company attracted serious investment, but it also faced devastating backs. Several promising treatments failed in early phases. In 2016, the journal *Nature* slammed Moderna, comparing it to the scandal-plagued blood-testing

start-up Theranos. Bancel knew that failing to deliver a viable COVID-19 vaccine might be a nail in his company's coffin. Results from the vaccine's all-important Phase III clinical trial were due in mid-November. As he later recounted to the *New York Times*, Bancel anxiously retreated to his home office and waited for the results. They were stunning: The vaccine was 94.5 percent effective in preventing infection.¹ And the handful of infections that did occur were all mild. The audacious biotech company had not only proved that its technique was workable and safe, it had developed a vaccine with the potential to save millions of lives. Bancel burst out of his office to tell his wife and two teenage children. "The four of us were crying," he said.


Early in the pandemic, the FDA said it would accept a vaccine that was only 50 percent effective. And many experts thought such a vaccine would take a minimum of two years to develop. Instead, the Moderna and Pfizer vaccines both gained approval before the year was out. In other words, the U.S. had vaccines "ready at half the time the most optimistic timeline projected, with twice the efficacy hoped for," noted Zeynep Tufekci, one of the smartest pandemic-policy analysts. Other companies were close behind with their own vaccines. "This will go down in history as one of science and medical research's greatest achievements," the acclaimed medical researcher Eric Topol wrote at the time. "Perhaps the most impressive."

By April 2021, the U.S. was administering more than 3 million shots a day; more than half the country's adult population had received at least one dose. By May, the biggest hurdle wasn't the supply of vaccines but the reluctance of some segments of the population to get vaccinated. Nonetheless, deaths and hospitalizations plummeted. People began returning to offices, restaurants, and places of worship. They were taking off their masks and hugging their friends and relatives again (overcautious admonitions from public-health officials notwithstanding). America was coming back to life. Big Pharma had delivered.

ould it be asking too much to expect Americans to pause briefly at this moment and say, "Thanks!"?

SADLY, YES. Anyone who thinks the public, the media, or our political leaders might show a smidgeon of appreciation for these lifesaving vaccines hasn't followed the history of the pharmaceutical industry. It seems the more lives the drug companies save, the more people revile them. Yes, yes, I know—the opioid crisis; high drug prices; that slimy “pharma bro” Martin Shkreli—we'll get to all that. But first, let's focus on our current situation. The U.S. is emerging from pandemic hell while much of the rest of the world struggles with recurring waves of infection. Shouldn't we take a minute to study how we achieved this miracle and to think about policies that might help us do even better next time?

“This is not the time for profiteering,” Bernie Sanders said at that March 2020 debate. But profiteering—or, to put it more politely, the hope of earning a healthy return on investment—was an indispensable ingredient in the vaccine triumph. It wasn't the only ingredient. The people who choose to work in pharmaceuticals don't do it solely with the expectation of getting filthy rich. (Surely, investment banking, a job in the digital economy—or perhaps a career in politics—would be easier paths to that goal.) Most of them genuinely care about alleviating human suffering. Nor was the vaccine breakthrough purely a free-market triumph; the federal government provided both crucial investment and logistical support. Operation Warp Speed was a staggering example of how public-private partnerships can combine the power of government with the resourcefulness of private industry. But none of it would have happened without those greedy investors who, year after year, poured billions into companies like Moderna, risking massive losses in the long-shot hope of spectacular returns.

One is tempted to thank God that no one listened to Bernie Sanders. But that would be premature. Although Sanders didn't win the Democratic nomination, his progressive brand of politics is growing ever more dominant in the Democratic Party. And, despite Biden's campaign image as a benign centrist, as president he  shown little willingness to restrain the radical flank of his coalition. In fact, many of his administration's proposals come straight out of the progressive

playbook. In early May, the White House announced that it will rescind intellectual-property protections for COVID-19 vaccines. Various progressive groups, along with the World Trade Organization, had been pushing for such a move for weeks. The activists aren't just demanding that the pharma companies give up their patents. They also want to force them to perform a "technology transfer," teaching manufacturers in India and elsewhere their proprietary methods for creating the breakthrough vaccines.

The news was a blow to vaccine makers. Obviously such a move would strip these companies of some of the profits they'd counted on in return for developing successful vaccines. Worse, if tech-transfer rules are enforced, it will also undermine their ability to make money on future breakthroughs. For example, Moderna spent a decade developing methods to handle those fragile strands of mRNA. If some of those methods are revealed to competitors around the world, the company will have less market advantage when it comes to developing future products. The message to investors is clear: Don't invest in companies trying to save lives. If they succeed, the government might throw away their patents.

Ironically, the Biden administration's move probably won't do much to increase global vaccine supply. The technology involved in producing mRNA vaccines is extremely finicky and complex. It could take many months, possibly years, for overseas producers to get up to speed. And before that process even starts, all negotiations on the issue have to go through the WTO, a notoriously slow-moving organization. Economics writer James Surowiecki suggests a better plan: The U.S. government (and those of other wealthy nations) should simply pay the drugmakers to ramp up production, license their technology where feasible, and send billions of doses wherever they're needed. "I guarantee they will find a way to do it," he wrote on Twitter. But paying pharma companies to make more vaccines would offend the sensibilities of Biden's progressive flank. White House insiders told the *New York Times*, "It is bad politics for the president to side with pharmaceutical executives." So Team Biden took the easier path: blowing up the business model for making vaccines and stripping pharma investors of their returns. While it was Sanders who said he'd make sure no drug companies "make a

fortune” during the pandemic, it is Biden who is making good on the promise. As so often happens when progressives make policy, their zeal to punish their enemies takes precedence over their desire to achieve actual results.

Meanwhile, in Congress, Sanders and his progressive colleagues in the Senate and the House have their own plan to cut Big Pharma down to size. They have introduced three bills intended to force down drug prices and strip drug companies of their patents if they don’t play ball. In the business of saving lives, no good deed goes unpunished.

Normally, conservative lawmakers push back when Democrats try to hog-tie an industry with excessive regulations. But Big Pharma can no longer count on support from Republicans. “Pfizer & others should be ashamed that they have raised drug prices for no reason,” Trump tweeted in 2018. It was one of his many swipes at the industry. His administration made several abortive attempts to control drug prices under Medicare Part B. Senate Republicans Josh Hawley and Rick Scott proposed their own price-control plan in 2019, though it never came up for a vote. If congressional Democrats prioritize sweeping pharma regulations under the current administration, will Republicans even push back? Don’t count on it.

Without question, there are a number of areas where the U.S. system of developing and regulating drugs does need reform. But some of the things that bother Americans most about Big Pharma—high prices and industry consolidation—are themselves partly the *result* of layer after layer of health-care regulations. Smart proposals to unwind some of that complexity would be welcome. Not so welcome would be new rules that would squeeze out the profits from new drugs and vaccines, thereby cutting off the pipeline of private investment. “It is true that the American medical system is complex, and pricing is opaque and that can lead to abuses,” George Mason University economist Alex Tabarrok told me in an email. “But Americans are fortunate that it pays to invest in new drug research and development.”



For progressives, of course, that is precisely the problem: *It pays to invest in new drug research*. The idea that someone would make a profit off of curing a disease strikes them as immoral. In the progressive worldview, *intentions* always matter more than *outcomes*. If some of the people involved in drug development hope to get rich, it doesn't matter that their drugs save lives; any product that emerges from that corrupt system must be viewed as the fruit of a poisoned tree.

An academic critique of the pharma industry entitled “Thick as Thieves?”—written by a patient advocate and a business-ethics professor—makes this point explicitly. The industry’s “profound focus on self-interest places in question how much of what it does actually benefits society,” they write. Do you see the trap here? It’s not enough to *do* good; you must *be* good—you must save lives for entirely selfless reasons. (Former philosophy students may hear an echo of Kant’s unachievable “categorical imperative” here.)

This moral framework puts pharmaceutical companies in a bind: The more lives a company’s innovation might save, the more it is criticized for not giving it away for free. The drug company Burroughs Wellcome learned this the hard way over three decades ago. In 1987, just three years after HIV, the virus that causes AIDS, was identified, the company introduced AZT, the first effective treatment for the horrific disease. *Fortune* called that accomplishment “the pharmaceutical equivalent of an under-two-minute mile.” Like many breakthrough drugs, AZT was extremely expensive to produce, and it was initially approved for just a small number of patients. So Burroughs put what most people saw as an obscenely high price on it. The outrage was instantaneous. Over the next two years, the company was pilloried in the press and its leaders were called to defend themselves on Capitol Hill. AIDS activists slapped “AIDS Profiteer” stickers on other Burroughs products in drugstores and invaded the company’s headquarters with chainsaws. The Burroughs executives might have been pharmacological geniuses, but they were public-relations dunderheads.



Ever since, progressives have seized on every example of a Big Pharma “abuse”—whether fairly or not—as arguments to take down the industry as a whole. And too often, Big Pharma makes itself a Big Target. For example, it’s true that some companies, especially Purdue Pharma, were dangerously lax in the ways they promoted and distributed prescription opioids. Criticism is called for. But, as Jacob Sullum has documented in a series of articles at *Reason*, the popular notion that patients were routinely prescribed opioids for pain and then became hopeless addicts is largely a myth. Study after study has shown that illicit drugs such as heroin and fentanyl—and not prescribed pain meds—cause the vast majority of opioid deaths. That’s why it isn’t surprising that the opioid crisis has continued long after authorities radically curtailed access to prescription painkillers. (Indeed, today, many cancer patients and others have difficulty obtaining adequate pain medication.)

When firms dramatically hike prices on drugs that had previously been more affordable, they offer another occasion for outrage. Turing Pharmaceuticals founder Martin Shkreli became a household name by buying up the license to produce the anti-parasitic Daraprim, and then he boosted the price from \$13.50 to \$750 a dose. Shkreli was condemned by everyone from Sanders to Trump and then compounded the damage with his smirking responses to criticism. As one industry consultant put it to me, “Shkreli essentially wadded himself up into a softball for the press.” In reality, Turing was exploiting FDA rules that make it hard for new companies to win approval for their own generic versions of drugs that are no longer under patent. Since the market for Daraprim is fairly small, Shkreli knew it was unlikely that another drugmaker would want to go through the arduous approval process just to sell a generic version of the medication. Shkreli milked that near-monopoly power shamelessly, but he didn’t write the rules. It would have been useful for politicians and the press to explore ways to fix those perverse incentives. But they preferred to beat up on Shkreli—and on the pharma business as a whole. Again.



“Pharma is the whipping boy for the whole medical establishment,” the industry consultant told me. The reason? “Drugs are the one component of healthcare where the prices are exposed to the consumer.” And, due to higher co-pays, “you have to reach into your own pocket to pay part of it.” Another factor—ironically—is the generally low prices consumers pay for drugs once their period of patent protection ends and they go generic (notwithstanding outliers like Daraprim). Because new drugs typically spend so many years in development, most are on the market for only a decade or so before their patents expire. “Suddenly a drug you’ve been taking for years drops dramatically in price,” he says. “People think, ‘Why wasn’t this \$8 all along? It must be some sort of scam.’”

When introducing a trio of bills aimed at forcing down drug prices in March 2021, Sanders said, “The greed of drug companies is out of control and the cost is human lives.” Now, it’s true that drug prices are confusing, and often alarmingly high, at least on paper. But the fault does not lie primarily with the drug companies. As Scott Gottlieb wrote in a piece published before he became FDA commissioner under Trump, “by the time a drug reaches your medicine cabinet, it passes through a long series of intermediaries who each take a cut of money.” The system, which grew up in response both to the regulatory environment and the needs of insurance companies, is too mind-numbing to describe in full. In a nutshell, it includes wholesalers and “pharmacy-benefit managers” (PBRs) who negotiate with the drug manufacturers on behalf of health plans. Drugmakers pay huge rebates to those PBRs, who pass much of that money on to the health plans, and, indirectly, to consumers. It’s a crazy-quilt system that gives pharma companies incentives to place the highest possible list prices on their drugs. They know that almost no one actually pays those prices. (Though, as always, people without insurance wind up getting the worst possible deal.) And Big Pharma critics get to rail against their cruelty and greed.



THE TRUTH IS, in most areas of human health, the pharmaceutical companies are not the problem; they are the solution. Yes, there are legitimate concerns about how Big Pharma sets prices. If companies are colluding to limit competition or prop up prices, for example, those cases should be investigated as antitrust violations. But the majority of complaints about the pharmaceutical business aren't just exaggerated; they get the issue entirely backwards. Activists who want to rein in the drug companies are attacking the part of our health-care system that works best. "New drugs are one of the best and cheapest ways to increase lifespan and improve life," Tabarrok told me.

The numbers are staggering. Deaths due to heart disease have been cut roughly in half since the 1950s, in large part thanks to cholesterol-lowering and other drugs. A 2019 study in the journal *International Health* looked at the impact of new drugs in reducing deaths from 66 diseases in 27 countries. The study measured the total number of "life-years" the population gained as a result of these new drug treatments (up to the age of 85). It found that if no new drugs had been introduced between 1981 and 2013, the number of life-years lost to these diseases would have been more than twice as high. It's true that many new drugs that target specific forms of cancer or rare diseases are fantastically expensive. Critics complain that some of the most expensive drugs extend life for only a few weeks or months. But those weeks and months add up. Look at how cancer survival rates have diverged between the U.K., where the National Health Service more strictly limits access to treatments deemed not cost-effective, and the U.S., where novel treatments are more available. One study found that, two years after diagnosis, 31 percent of U.S. lung-cancer patients were still alive, while only 19 percent of English patients were. (Of course, drug treatment may be only one of several factors contributing to that outcome.)

Medications for everyday chronic diseases are especially cost-effective. "It is a mistake to focus on the upfront individual cost of medications while ignoring the huge savings generated by preventing disease complications with early medical interventions," writes Larry Hausner, former CEO of the American Diabetes Association. Common drugs for hypertension and hyperglycemia can dramatically

delay or prevent the onset of diabetes, one of today's most debilitating and expensive diseases. "Preventing just 30 percent of pre-diabetics from contracting diabetes would save the health-care system \$74 billion," Hausner writes.

Critics of Big Pharma tend to look at our current medicine cabinet of treatments and conclude that those drugs could be delivered much more cheaply. They aren't wrong about this. If we voided existing patents and allowed anyone to manufacture these drugs, they could be produced at a fraction of today's prices. After all, it is the research, and not the chemicals that go into them, that makes new drugs so expensive. But anti-pharma activists rarely consider how society will then incentivize the *next* generation of medical innovation. New and better pharmacological tools are still sorely needed. For example, a study by the Alzheimer's Association estimates that a new drug that delayed the onset of Alzheimer's by five years would result in steadily growing savings in health-care expenditures. Within 25 years, those would amount to \$367 billion a year. Besides the dollars, such a drug's contribution to human happiness would, of course, be incalculable.

Our modern system of drug testing and regulation grew partly in reaction to the thalidomide tragedy of the early 1960s. That case involved a popular sedative developed in Germany, though never approved in the U.S. When doctors began prescribing it to treat morning sickness during pregnancy, a horrifying side effect emerged: a birth defect in which the baby's limbs failed to develop properly. The case produced global outrage and revealed that many clinical trials meant to test drug safety and efficacy were slipshod. In the U.S., the FDA moved to expand the clinical-trial process and tighten up standards for drug approval. (Germany, Britain, and other developed countries did the same.) All in all, that was a good thing. Over time, however, the approval process has grown into an obstacle course that can last years and cost upwards of \$1 billion to navigate—whether or not a drug is successful. Those lengthy trials also spin off detailed reports listing every possible side effect reported by participants. These might be significant, or they



might be completely unrelated to the drug being tested. Either way, they serve as road maps for legal firms that want to build class-action suits targeting drug companies.


Extended clinical trials and frequent legal challenges create what economists call “barriers to entry” for pharmaceutical entrepreneurs. Small companies find it much harder to navigate this swampy regulatory and legal terrain. Even big pharmaceutical players often seek greater clout and security through mergers and acquisitions. Which is how we wind up with global drug companies with names like GlaxoSmithKline. But big companies also have more to lose. David Taylor, a leading pharmacologist in Britain, writes, “More and more promising drug candidates are terminated early in the process, at the first sign of any potential problem.” Neither aspirin nor penicillin would have made it to the market under today’s industry drug-development regimes, he adds. This high failure rate can be devastating to the morale of pharmaceutical researchers. “It is not unusual for a medicinal chemist,” Taylor writes, “to have spent his/her whole career in the industry and to have never worked on a successful product.”

The inherent conservatism of drug regulators isn’t due to lack of professionalism or insufficient humanitarian concern. (“The people at the FDA really try to be good stewards,” the industry consultant told me.) But, as Milton Friedman pointed out decades ago, “the pressure on the FDA is always to be late in approval.” Here’s why: Imagine the agency is tasked with approving a new drug. It could accidentally certify the drug as safe and effective when it is actually dangerous or ineffective. In statistics, this is known as a Type I error. Or it could refuse to certify a drug that is, in fact, safe and beneficial—a Type II error. In the first case, the backlash tarnishes the FDA and endangers the careers of those who made the decision. But if the agency refuses to authorize a promising drug (or delays it for years), the damage happens off the public’s radar. It’s impossible to prove that particular patients would have survived if they’d gotten the drug in time. “When the FDA fails to approve a good drug,” economist Tabarrok writes, “people die, but the bodies are buried in an invisible graveyard.”

This is especially true in the case of very serious diseases. After all, questions of safety and efficacy aren't always black and white. A drug with potentially deadly side effects would be a wildly inappropriate treatment for, say, teenage acne. But those same risks might be willingly accepted by a patient with Stage 4 cancer. In a fascinating biostatistical analysis, three researchers (two of them associated with MIT and one with Pfizer) confirmed that the FDA's "current standards of drug approval are weighted more toward avoiding a Type I error than avoiding a Type II error." In cases of devastating illnesses such as pancreatic cancer, they found, the approval standards were too restrictive by an order of magnitude. Those researchers advocate that the FDA employ more nuanced statistical analyses that would allow it to weigh each drug's potential benefits more fairly.

Big Pharma critics complain that the industry churns out too many "me-too" drugs. *Stanford Medicine* magazine editor Rosanne Spector writes that drug companies "chemically rejigger an oldie but goodie, craft a new name, mount a massive advertising campaign and sell the retread as the latest innovative breakthrough." The argument goes that, if fewer such drugs were approved, overall drug prices would be lower. There are cases where a new drug, under a fresh patent, offers few advantages over an older, cheaper generic drug. But that is not an argument against new drugs. It is an argument against today's byzantine system of drug pricing. Too often, neither doctors nor consumers have clear incentives—or the right information—to choose less expensive alternatives. But limiting new drugs, even ones that are similar to existing drugs, doesn't solve that dilemma.

If you ask physicians, they prefer more options, not fewer. As the late analyst Peter Huber pointed out, "human biological diversity is much broader than regulators and researchers had assumed." Drugs designed for the average patient might not work for particular patients. In cancer and other fields, doctors have discovered that only rarely does a single drug serve as a silver bullet. But a combination of drugs tailored to the individual patient—a kind of silver shotgun blast—can often be effective. Of course, the FDA approval process isn't set up to test such

 combination therapies. Fortunately, the revolution in genetic testing, combined with big-data techniques, means we have entered the era of personalized medicine:

treatments micro-tailored to the individual patient. But designing such personalized drug cocktails requires having a vast range of drugs to choose from. As Tabarrok writes, we need to “give physicians a larger armory and let them decide which weapon is best for the task.”


HISTORICALLY, our drug-approval process has focused on delivering medicines that benefit the largest group of patients with the fewest possible risks. The progressives who want to overhaul our medical system believe that the range of future drug choices should be restricted even more, with low prices being the main goal. In contrast, a growing movement in health care calls for expanding options, and giving physicians and their patients more freedom to assess risks and benefits for themselves. “For more than 80 years, the FDA has infringed on the right of people to make their own lifesaving decisions,” writes surgeon Jeffrey Singer. I doubt many Americans would want to do away with the FDA’s entire testing regimen. But what if patients had the option of choosing medications that hadn’t yet received the FDA’s blessing but had been approved by similar regulatory agencies in a few other developed countries? That’s the idea behind the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act, twice proposed by Senators Ted Cruz and Mike Lee. In a world where medicine is more personalized, it makes sense to give doctors and their patients more options—and more control. Such a bill has no chance of moving forward in today’s Congress. But the concept should be championed, even if, for now, it is more thought experiment than policy.

Progressives have a bad habit of taking the benefits of free-market economies for granted. Cheap food, smartphones, housing, electric cars—they believe all of these things will remain abundant no matter how much we hobble the market system that produces them. In fact, they believe that if we rid the system of “excessive” profits—and remove those venal profiteers—all those good things will be even more affordable. They’ll be distributed more “equitably.”

Nowhere is this wishful thinking more prevalent than on the topic of health care. Big Pharma critics often argue that if the big companies were cut down to size, drug research would sail along much the same at universities and at federally funded research centers. They are partly right: nonprofit and federally funded research contributes a lot to biomedical progress. And the U.S. National Institutes of Health plays a big role in early drug development. (Moderna consulted with NIH when designing its vaccine.) Certainly, there's room for more private-public partnerships to develop treatments for very rare diseases and to address other challenges that the market overlooks. But for the drugs that are most likely to help most of us, the brutally expensive work of drug testing can happen only with massive private investment.

Though progressives might find the idea distasteful, the investors who pour billions into pharmacological research do more to save and improve lives than any top-down government program could. Even our miracle vaccines would not have arrived so quickly had investors not spent years gambling fortunes on longshots like Moderna's mRNA research. It was those years of tinkering and failing that allowed the company to refine its techniques. And then, when every day counted, Moderna was able to deliver a vaccine faster than any expert could have predicted. Now that it has been validated, the mRNA technique holds out realistic promise to create new treatments for cancer and other diseases. Not to mention faster and more flexible new vaccines for the possible pandemics to come.

"If I am stricken with a deadly disease," Tabarrok told me, "I sure hope that someone will profit from curing my disease!" Any regulatory scheme that sucks the profit out of drug innovation would slow the development of new drugs and vaccines to a trickle. Sure, university and government researchers would still come up with promising *candidates* for new drugs. But fewer companies would have the resources to turn those leads into products. They would sit on the shelf. Meanwhile victims of diseases such as cancer, diabetes, and Alzheimer's would never know about the drugs that might have helped their condition, the drugs that never made



through the pipeline.

That would be the ultimate Type II error—exactly the kind of error that was *avoided* in the miraculous innovations of the past year, from Moderna’s leap of faith to Operation Warp Speed to the accelerated vaccine approvals. We need to learn from that example and continue to chip away at the sclerotic ideas and regulatory policies that make drugs too expensive and their development and deployment too slow. Big Pharma has saved us from the pandemic. It could do so much more. But, between Biden in the White House and Bernie in the Senate, Big Pharma will likely be a lot less eager to go all-in next time we face a global health crisis. The precedent set by these threats to strip away hard-earned patents will never go away. Drug companies are now on warning that they’re better off sticking to inventing new meds for hair loss and erectile dysfunction. Trying to save lives only gets them in trouble.

¹ Just a week earlier, Pfizer had announced that *its* mRNA vaccine was both safe and extraordinarily effective.

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James B. Meigs is the former editor of *Popular Mechanics*, among other magazines, and a co-host of the *How Do We Fix It* podcast.

