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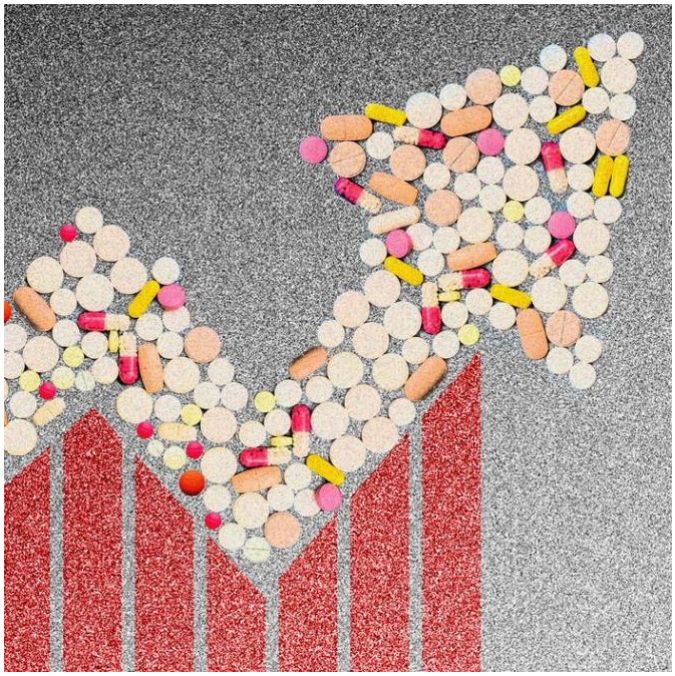

This Is How Big Pharma Wins

Two years into the pandemic, the industry has evaded reforms a supermajority of voters want.

By Alexander Zaitchik

Photo-Illustration: Intelligencer; Photo: Getty Images

On September 19, 2019, House Speaker Nancy Pelosi introduced the Elijah Cummings Lower Drug Costs Now Act. The bill, known as H.R. 3, was a shot across the bow of an industry accustomed to congressional docility and deference. If passed into law, H.R. 3 would allow the federal government to

negotiate drug prices on behalf of Medicare, a right assumed by the governments of every other major economy. The bill reflected an intra-party compromise and disappointed progressive Democrats who had pushed for deeper reforms. But H.R. 3 was no trifle. It put a hard cap on insulin prices and allowed Health and Human Services to negotiate prices on "at least" 50 of the 250 most expensive Medicare drugs.

To call the bill popular would be understatement. Polls showed support ranging from 80 to an eye-popping 90-plus percent, a bipartisan firewall without analogue in American politics. These numbers reconfirmed the existence of a decades-old supermajority committed to the proposition that government has a right and a duty to prevent drug companies from price-gouging the American people. This consensus resembles a lone building standing after an earthquake, uniquely impervious to the polarization that has fractured so many points of former agreement. In 2022, while Pharma profits soar, a quarter of Americans struggle to pay for their prescription medicines; one in three ration them as a result.

My Week In *New York*
A week-in-review newsletter from the people who make New York *Magazine*.
Despite Donald Trump's campaign promise to rein in drug companies that he said were "getting away with murder," he and every other Republican was silent when H.R. 3 was delivered stillborn into Mitch McConnell's Senate in November of 2019. Two years later, when Joe Biden released the massive social-spending and climate-change bill dubbed Build Back Better, H.R. 3's reforms were nowhere to be found within its 2,135 pages. This shocked and alarmed Democrats, who understood the risks of inaction went beyond the next election to the party's very legitimacy. "People can't understand why we haven't brought up important legislation that 80 percent of the American people support," noted Bernie Sanders at the time. "This has got to get done because seniors have expected it," Oregon's Ron Wyden urged the White House.

In response to the outcry, the Biden administration added drug-pricing reforms to the bill in early November. But they were a wan and watery version of H.R. 3.
The compromise version of the original bill — which had itself been a compromise — limited the government to negotiating "up to ten drugs" beginning in 2025, expanding to a maximum of 20 by 2028. The only drugs eligible for negotiation, meanwhile, were products that had already enjoyed nine to 12 years of market exclusivity, i.e., monopoly pricing, and were on the downward slide to facing generic competition anyway. Unlike the original H.R. 3, the new version did not make the negotiated prices available on the commercial market to benefit those without government insurance. (A $35 across-the-board cap on insulin was the exception.) Instead, the bill proposed a targeted corporate tax to limit commercial price hikes to the rate of inflation. But without the power to cap launch prices, the reform simply invites drug companies to raise their price floors.

All told, the reforms belatedly added to Build Back Better would reduce government drug spending by roughly $80 billion over a decade. The biggest "savings" will be had not by limiting prices but by rescinding a Trump-era law that was never implemented. By contrast, the Congressional Budget Office estimated the original H.R. 3 would have

reduced government drug spending by $500 billion, enough to pay for expanded dental, hearing, and vision coverage for more than 60 million people on Medicare.

The drug-pricing reforms in Build Back Better are "a sorry precedent," said Representative Lloyd Doggett of Texas, who has been working on Pharma reform since he entered Congress in 1996. "It once again yields right of way to Big Pharma to engage in price-gouging. The simple act of permitting negotiation on a few obscure drugs may be novel under Medicare, but without an explicit requirement to negotiate, and authority to address a broad range of abusively priced drugs that most consumers rely on, the provisions would accomplish little."

As weak as the compromise reforms are, they must be measured against the all too familiar alternative of nothing at all. The fate of Build Back Better (or some version of it) remains in the fickle hands of Joe Manchin and Kyrsten Sinema, and the clock is ticking on a likely GOP reclamation of the Senate. "Build Back Better is a pale shadow of H.R. 3, but it would be a foot in the door," said Steve Knievel, director of Public Citizen's Access to Medicines program. "It puts a system in place to expand the scope of negotiated drugs, even if it leaves the government's hands unduly tied."

Chris Jennings, a veteran of Democratic drug- and health-policy fights who advised the Clinton and Obama administrations, agrees. "For a bill like this to make it this far is unprecedented," he said. "The reforms will lower costs for Medicare and for millions of people. It sets a precedent for more aggressive action. To say it isn't meaningful creates a disincentive to action that rewards Pharma."

And yet. In using its influence to manage two rounds of intra-party conflict and compromise, Big Pharma has done it again. Whether the reforms pass as part of Build Back Better or become law as a stand-alone bill, the industry will have added to its highlight reel of impossible escapes from attempts to place meaningful limits on its monopoly power. How do the drug companies do it? How have they been doing it for as long as anybody alive can remember?

The pharmaceutical industry lives in a state of permanent emergency. No victory is ever secure, no policy seedling too small not to be treated as a full-blown existential threat. The original H.R. 3 was no seedling, but Pharma announced its opposition with a familiar sounding of doom. At a press conference held in November 2019, Stephen Ubl, the CEO of PhRma, the drug trade association, warned that the proposed law would plunge medical science into a "nuclear winter."

The industry continues to pound on this analogy, using the pandemic to illustrate its merits. After the rollout of the first COVID-19 vaccines, the industry launched a campaign, "Don't Take Us for Granted," arguing that pricing and patent reform would leave humanity helpless in the face of future pandemics. Not because of the industry's sudden penury, but as result of Pharma taking its ball and going home. It made this clear in March of 2020, when a group of House Democrats sought to attach modest conditions to the first $8 billion tranche of coronavirus-research subsidies, only to be flung aside like so many Lilliputians by the Pharma and biotech lobby machines.

Industry would not participate in emergency pandemic research, said Ubl, "if collaboration with the government even in a limited way results in a loss of intellectual property or the government setting the price."

That the vaccines emerged from decades of publicly funded research in academic labs didn't stop Moderna and Pfizer from claiming them as their own achievements. As a U.S. official involved in the Trump administration's vaccine program, Warp Speed, told the *Financial Times*, the corporate branding of mRNA vaccines is "the biggest marketing coup in the history of American pharmaceuticals."

This coup helps explain the reputational bounce Pharma enjoyed during the vaccine rollout. A March 2021 Data for Progress poll found that, for the first time, 56 percent of Americans viewed the industry positively — twice the number of the last pre-pandemic polls. To industry's chagrin, however, support for H.R. 3 did not crumble. It did not even move. No matter how much it strutted like Atlas, or threatened to sit out future pandemics, the needle of public opinion refused to budge on government price negotiations.

But if public opinion made laws, the government would have started negotiating prices years ago. The real question is whether the elected representatives of this obstinate supermajority would show similar resolve. The inside game, the one that really matters, still seemed to favor industry. The Biden White House is heavy with friends and alumni of drug majors and their lobbying firms. In Congress, unified Republican opposition and thin Democratic margins gave enormous power to industry-allied Democratic representatives like California's Scott Peters and Oregon's Kurt Shraeder. With zero room for error in the Senate, Sinema, Bob Menendez, and Chris Coons were in a position to whittle H.R. 3 down to its current form.

Even after the new bare-bones version was released last November, Pharma did not let up its attack. It continues to strategize with Republican senators to use the so-called Byrd rule — which governs the scope of reconciliation bills — to kill the two remaining commercial market reforms: the insulin co-pay cap and inflation-rate limits on price hikes. Outside of Washington, it has hired the president's own favorite media agency to bombard public support and punish vulnerable Democrats by filling local airwaves and editorial pages with its patented mix of disinformation and fear-mongering, now served with a pandemic twist.

And at every level of government, Pharma's endless river of money continues to flow, the widest, steadiest current of lobbying largesse the capitol has ever known. In the post–*Citizens United* era, it is impossible to say exactly how much drug money sloshes through the system. In 2021, the industry reported spending $124 million on a fleet of 846 lobbyists, roughly two for every member of Congress. Sixty-five percent were former government employees.

But these numbers only hint at the fullness of Pharma's influence.

Pharmaceutical manufacturers are part of a larger coalition that includes the insurance, medical-device, and hospital industries. At forums such as the Healthcare Leadership Council, this group coordinates how to leverage its collective resources and harmonize its public relations. Its combined resources flow downstream through dozens of lobbying firms, communications shops, and front groups that advance industry lines while providing a degree of credibility and plausible deniability.

"Pharma and the health-care industries are smart about using money to support organizations with 'white hat' reputations," says Wendell Potter, a former health-industry executive who now runs a number of reform initiatives. "If an organization is perceived on the Hill as being respected and thoughtful — the Mayo Clinic, the Chamber of Commerce — it carries more weight. But it's all about preserving the status quo. During the Obamacare fight, the industry hired the PR firm Porter & Novelli to lobby through the Federation of Independent Businesses. It cast the campaign as something organized by small business, but they were working hand in glove with the industries that run the Healthcare Leadership Council."

The funding and creation of front groups and astroturf "partnerships" is a ceaseless churn, with outfits activated and retired as needed. One of the latest is called the Partnership for America's Healthcare Future, an industry-funded group with state affiliates that parrot national messaging to defeat state-level reform initiatives. Last month, the group played a central role in outmaneuvering a Democratic supermajority to defeat a single-payer proposal in the California Assembly.

Coordination between Pharma and its health-care allies extends to what looks to outsiders like internecine conflict. Signs of discord, says Potter, are most often staged-managed ruses in an elaborate corporate Kabuki theater. "The finger-pointing among Pharma, insurers, and the hospital chains is done in concert to deflect attention and confuse the public and policy-makers," says Potter. "It feeds the idea of an intractable problem when America's Health Insurance Plans calls Pharma 'evil,' and vice-versa. It's a game they've been playing for a long time."

This is not to say Pharma is just one player among equals. As a lobbying force, Pharma is the ruthless elder statesman of the group. In the middle decades of the last century, it was the drug companies that spearheaded strategic partnerships with organized medicine, insurance, and university patent offices to protect and entrench its monopoly pricing power. Presiding over the fattest margins in the economy, Pharma has always had the most to lose, and it has evolved mandibles to devour any and all threats to its monopoly power.

"When I started working on energy in the mid-'70s, I thought the oil companies were adept at turning political dollars into strategic influence," says Cathy Hurwit, a health-care policy veteran who spent much of a four-decade career on the Hill as Illinois representative Jan Schakowsky's chief of staff. "But the drug companies are just amazing."

“First of all, they’re everywhere,” she continued. “And they spend as much as they need to to cultivate relationships. They’ll make donations to a rep, take them out for a wonderful dinner, and ask, ‘Will you do this?’ If the rep says no, there’s always next time. The rep will continue receiving checks, because it buys access. Most industries can’t afford to play this kind of long game.”

It is a long game of sharp sticks as well as honey-glazed carrots. Most members of Congress arrive in Washington without much specialized knowledge or strong feelings about drug-pricing or patent reform. The industry is legend for aggressively courting their allegiance upon arrival and making shows of force to steer them away from taking up the cause of Pharma reform.

“If a freshman Democrat so much as signs a letter related to drug prices, the lobby hammers them with phone calls and meeting requests, completely locking up the calendar,” says Alex Lawson, executive director of Social Security Works, a D.C. nonprofit that works on health care and prescription drugs. “The calls come in from ex-Democratic officials and staffers, so they have to take the meetings. They’re relentless until the target gets the message and decides, ‘It’s not worth taking on Pharma.’”

Whether first-termers get the memo or not, they can expect regular visits from families representing a growing list of industry-funded disease- and patient-advocacy groups. In the halls of Congress, industry money is likely to appear in the form of a stricken patient or family member unwittingly advancing industry-written scripts. Some of these groups are easily identified as astroturf organizations, but industry cash and messaging are also laundered through established national organizations with names like the Arthritis Foundation (Merck), Cancer United (Roche), and the American Diabetes Association (Eli Lilly). According to one recent study, 83 percent of all registered U.S. patient groups receive drug-industry funding.

“They’re going to wheel cancer kids into your office,” says Lawson. “And sitting next to them will be the $6,000 industry suit making sure the conversation doesn’t veer into pricing and affordability issues.”

“Before COVID, all of the patient disease groups would come to town pushing for NIH R&D money, and it’s very moving to spend time with these families who want to find cures for their children,” says Hurwit, the veteran health-care staffer. “They usually have a handler who’d step in and shut things down if I asked them about the cost of their drugs.”

The use of patient-advocacy groups is ingenious and profoundly cynical. Doggett, the Democratic representative from Texas, notes that it manipulates both officeholders and advocacy groups that become reliant on industry funding and lullabies.

“Disease-related advocacy groups are caught in a bind,” says Doggett. “Big Pharma is often the most ready resource for funds needed to help their members and advance their cause. But they are often compromised and misled by Big Pharma, which recognizes that the victims of dreaded diseases are the best advocates for protecting monopoly

profits. Too often, families sign onto mailers without realizing how they are being used. While I try to engage with constituents to cut through the misinformation, many of the lies still get through to colleagues. It is so difficult to question a family that has been convinced by industry that any meaningful reform will deny relief for a victim of a horrible disease."

Pharma is an industry with a thousand eyes, ever watchful for signs of danger and diligent about reminding dissenters that its watch tower is a panopticon. It is understood that any mention of pricing or patent reform in either caucus will be observed in real time and generate an immediate response. A well-known illustration of this occurred in September of 2016, when Democratic representative Mark Pocan of Wisconsin sent an email to Democrats seeking cosigners on a letter asking Barack Obama to support drug-pricing reform. The email was headed "Dear Colleague," a protocol signifying official correspondence reserved for members, committees, and officers of the House of Representatives. Within minutes of Pocan's email, Mike McKay of the Empire Group, a favored Pharma lobbying firm, sent a rejoinder to the recipient list under the subject line, "Urgent Request: Please Do Not Co-sign Rep. Pocan's letter to President Obama."

The lobbyist's riposte was notable more for its formal salutation than its speed: McKay addressed recipients with the same "Dear Colleagues" used by Pocan. "It was more than a breach with decorum," says Lawson. "It was a flex and a 'fuck you' meant to remind everyone that we (Pharma) get leaked internal letters immediately, and we will reply as if we are on equal footing with members of Congress."

Each of these levers of influence contributes to what Doggett calls Pharma's "stranglehold" on the government. "Tentacles that have long dominated the House Republican Caucus extend further into the Democratic Caucus," he says. "With a nominal majority, Pharmacrats can hold meaningful reform hostage, as in the shameful evisceration of the already modest H.R. 3 legislation."

The odds that such "Pharmacrats" will increase their number in the party were improved last summer with the founding of a new Democratic PAC, Team Blue, launched by a group of moderates including Hakeem Jeffries, the likely successor to Nancy Pelosi. The stated purpose of the group is to protect moderate incumbents in safe districts from progressive primary challengers — what Team Blue's website calls "extremists and other outside forces." The young PAC was launched with maximum donations from lobbyists tied to AbbVie, Johnson & Johnson, Eli Lilly, UnitedHealth, and the Pharma-supported American Legislative Exchange Council.

The bulletproof popularity of price negotiations suggests Americans have long been wise to industry's claims about monopoly blood prices driving innovation. Everybody wants cures for cancer and Alzheimer's; few would support policies that undermined their prospects. The people are correct. Running the numbers on Pharma's claims shows just how light reform's injury to innovation would be.

In a new book, *Sickening: How Big Pharma Broke American Health Care and How We Can Repair It*, John Abramson demonstrates that a hypothetical bill that transferred $1 trillion in drug revenues to government coffers over a decade — call it H.R. 3 XXL — would still leave the pharmaceutical industry with the economy's highest rates of return on invested capital. This hit would also have minimal impact on the development of novel drugs with new therapeutic benefits.

"The CBO estimate of the Build Back Better impact on new drug development — ten drugs over three decades — is misleading, because no more than a quarter of newly approved drugs have been shown to provide heretofore unavailable benefits," says Abramson, a lecturer in the department of health-care policy at Harvard Medical School. "The number of new drugs providing truly new benefits that would be sacrificed to price negotiations over 30 years is between two and three. Hardly a 'nuclear winter' for drug innovation."

Why the industry produces so many drugs without new therapeutic benefits is the subject of a new report by the House Reform and Oversight Committee. Commissioned by the late representative Elijah Cummings in January 2019, the investigation uses drug-company strategy documents, executive communications, and board materials to reveal how much "innovation" factors into Pharma's pricing, patenting, and spending priorities, as opposed to executive compensation, stock-inflating buybacks, and marketing outlays.

Spoiler: Not much. Between 2012 and 2017, companies that manufacture the 20 most common Medicare Part D brand-name drugs instituted 250 price hikes at roughly ten times the rate of inflation. They then showered the profits on shareholders and executives, whose bonus structures "directly tied incentive compensation to drug-specific revenue targets."

In one of the report's many cases studies, Mark Alles, the former CEO of Celgene, received a $500,000 bonus as a consequence of his decision to crank the monopoly price on a cancer drug, Revlimid, which is little more than repurposed Thalidomide, a generic tranquilizer invented in the 1950s. In an internal presentation, Celgene executives attribute its "winning" of the Revlimid market to the U.S. government's inability to negotiate prices — which the executives describe in Pharma's funhouse lexicon as "free-market competition-based pricing for Medicare and commercial insurance."

Internal documents capture similar honesty among Pfizer's brass. In a 2016 presentation, executives assign the company's historic profitability not to the brilliance of its scientists or its commitment to innovation, but to its freedom to levy "price increases in the U.S. market."

"The industry's excessive prices and anticompetitive practices are not justified by the need for innovation," concludes the damning report. "They have been used to enrich company executives and shareholders."

The Oversight Committee investigation further exposes the depth of the fraud underlying the industry's most profitable monopolies. A large and growing number of scandalously priced drugs are not new treatments but expired monopoly products that have been modified slightly and rebranded for the purpose of securing second- and third-generation monopolies. The report's exposé of what the industry calls "drug life-cycle management," better known as evergreening, reveals a business model redolent of the pre-Enlightenment understanding of science as a process of endless rediscovery of ancient truths, not the creation of new knowledge.

"Seventy-eight percent of drugs being granted patents are old drugs," says Robin Feldman, the director of the Center for Innovation at the University of California Hastings Law School and the author of *Drugs, Money, & Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices*. "The evergreening games come in different baskets, but all utilize the power of the patent to make tweaks to existing products and extend the monopolies."

Last year, Feldman published a groundbreaking study of patent data documenting the industry shift toward evergreening as its preferred growth strategy. She found that the 12 top-selling prescription drugs enjoyed, on average, 38 years of patent protection, or nearly double the 20-year term stipulated by U.S. patent law. (Some of these drugs, such as Revlimid, were never novel enough to justify a patent and market exclusivity in the first place.) The most prolific evergreeners include the self-declared heroes of the pandemic. AstraZeneca, Pfizer, Gilead, and Johnson & Johnson have collectively super-extended monopolies on pricey treatments for a number of common diseases including diabetes and HIV. A study published this December in *Nature* magazine mapped the companies' new evergreening frontier: extending cancer drug monopolies by rebranding and reshuffling them as elements in "novel combination therapies." This is like a company with a monopoly on peanut butter blocking competition for half a century by adding a version that comes with a swirl of grape jelly.

By allowing drug companies to operate these schemes, says Feldman, the government is undermining policies to curtail drug spending and betraying the societal bargain the patent system is meant to serve.

"From a constitutional perspective, the goal of the patent system is to benefit society as a whole," she says. "Patents are time-limited grants to incentivize innovation of 'new and useful' medicines. And they are supposed to come to an end."

There are indications that public and political patience for these shenanigans is at a breaking point and that Pharma's grip on Washington is beginning to loosen. One of the first moderate Democrats that Team Blue targeted for support, New York's Carolyn Maloney, is also the person who picked up Elijah Cumming's mantle upon his death and saw through the hard-hitting Pharma investigation he started. She has evolved past her former positions in support of Pharma — and she's not alone.

Not long ago, the Congressional Black Caucus was considered friendly territory for the industry, with a corporate advisory board thick with drug companies that collectively

helped underwrite construction of the CBC Foundation building off Dupont Circle. But the ground within the caucus has shifted, as it has in the Hispanic Caucus. Positions once limited to the Progressive Caucus are moving toward the mainstream of the party. Major interest groups that once played ball with the industry have also hardened their positions. In 2003, the AARP was the only national consumer group to support the Medicare Modernization Act's ban on government price negotiations. The senior group now says it regrets the error.

Young representatives from New Jersey, long the closest thing to industry home turf, are showing signs of independence. Andy Kim, elected to New Jersey's Third District in 2018, co-sponsored a bill last summer to cap out-of-pocket prescription drug spending for 46 million Americans on Medicare. Within recent memory, this would have been unthinkable for an elected official representing New Jersey, where George Merck established an industry corridor to the halls of power.

No politician wants to be the subject of patient-group attack ads, but even that threat appears to be losing its old force. "That tactic hasn't gone away, but its power is eroding because people are seeing that it's not just new drugs being priced sky high — it's the drugs they've been taking for 30 years," says Hurwit. "It's dawning on the public that it's not an innovation thing, it's a profit thing."

This has provided the Democrats cover to cross the industry on the core reforms remaining from H.R. 3: insulin caps, inflation-plus rebates and tax penalties, and Medicare negotiating power. Not one Democrat is currently willing to go on record opposing Medicare negotiations on principle. They may privately oppose it, but for the first time, they are afraid to admit it publicly. On paper, the drug reforms have stronger party support than any other plank in the infrastructure bill. This includes the support of Joe Manchin, who favors stronger government negotiating powers than those proposed in the original H.R. 3.

"If you're going to negotiate, then negotiate," he said on West Virginia radio last month. "Don't start picking and choosing and playing games."

This is not just a Washington story. For years, grassroots groups across the country have been organizing, raising awareness, and educating the public to give substance and direction to their deepening anger. On insulin prices, arguably the economy's signature moral deformity, grassroots organizing was key in protecting the $35 cap in H.R. 3 and ensuring it survived the compromise. The same energy can be brought to bear on the cost of cancer drugs, HIV drugs, and the monopoly and patent rackets more generally.

"For decades, Pharma has exploited people's fear that they won't have medicines if industry profits are touched," says Hurwit. "But they're also afraid that if they get this disease, its going to cost them $200,000 to stay alive. When they learn the same drugs were funded by government money, they get real mad. The arguments Pharma has been making all these years suddenly don't hold water. There is a new political high ground."