

Free COVID-19 Vaccines and Treatments Are Here: Why America's Families Keep Paying

When asked who owns the patent for the polio vaccine, Jonas Salk, the developer of the first successful polio vaccine, chuckled and responded, "The people, I would say. There is no patent... Could you patent the sun?"¹ Salk and Albert Sabin, who later developed the oral polio vaccine, both elected not to patent or profit from the vaccine, forgoing an estimated \$7 billion and saving millions of people around the world from paralysis and death.²

The COVID-19 pandemic provides a stark reminder that if any of us are sick, we are all at risk. Hundreds of thousands of Americans have died — family, friends, and neighbors. Millions have lost their jobs, and millions more are at substantially greater risk because they perform essential services, like providing health care; preparing, picking, and packing the food we eat; transporting us; and manufacturing our goods.³ Their risk is our risk — both in public health and in the economic vitality of our communities. Because we are all in this together, Americans have taken on the financial risk of investing billions of dollars in development and production of COVID-19 tests, treatments, and vaccines. Through the government-funded Biomedical Advanced Research and Development Authority (BARDA) alone, Americans have invested over \$15 billion⁴ — building on years of financing basic science through the National Institutes of Health (NIH) and the Defense Advanced Research Projects Agency (DARPA) to make COVID-19 biomedical innovations possible.⁵ The results of these investments in development and production are vaccines and treatments promising to stem the tide of tragic death

and serious illness at an astonishing pace and providing a path back to "normal."

The creation and dissemination of the COVID-19 vaccines and treatments are wonderful advances from a public health perspective. They also have resulted in a windfall financial gain for pharmaceutical companies and their shareholders. Moderna and Pfizer stock prices are surging, and CEOs have drawn scrutiny for selling large portions of stock when positive news about their coronavirus vaccines drove up share value.⁶ Moderna stock (funded entirely by taxpayers and modest charitable investment) reached almost \$190 per share with \$18.4 billion in procurement agreements for 2021. Fellow pharmaceutical giants are cashing in. AstraZeneca made \$1 billion by selling Moderna shares, and Merck reported a fourth-quarter gain as a result of divesting its stake in Moderna.⁷ Even Warren Buffet dumped stocks in Apple and big banks to invest in the promise of vaccines and other pharmaceutical industry payoffs.⁸ Pfizer is on track to reach \$15 billion in sales from its vaccine this year, and the company CEO alone collected \$21 million in 2020.⁹

Johnson & Johnson is projected to generate \$2.4 billion in additional revenue this year. Eli Lilly, Regeneron, and Gilead forecast 2021 COVID-19 therapeutics sales to be between \$1 billion and \$3 billion.^{10,11} All told, **Wall Street forecasts \$38.5 billion in sales for the top five COVID-19 therapeutics in 2021**, on the heels of **generating \$4.23 billion last year**.¹² And it's only looking up. Once we are back to our new "normal," companies also plan a return to "normal" pricing approaches which could result in dramatic price increases per shot. Coupled with the expectation of yearly booster shots, manufacturers anticipate a thriving market, much like the several billion dollar per year flu shot market.^{13,14}

While returns are strong via the stock market, almost half of Americans do not own stock and do not benefit from stock market windfalls.¹⁵ The news is replete with stories of financial risks borne by the industry, but we rarely hear about the massive financial burden taken on by taxpayers and payments made to secure these life-saving therapeutics. The public's investment is sizable and very real. For example, **across all COVID-19 vaccine development, government and charitable investments account for almost 43% of dollars invested**, including 100% of the Moderna vaccine.¹⁶ Instead of expecting returns, most Americans are tightening their belts.

Taxpayer Purchases of COVID-19 Treatments and Vaccines

The Food and Drug Administration has granted emergency use authorizations (EUAs) to the three vaccines developed by Pfizer/BioNTech, Moderna, and Johnson & Johnson, and the United States government has purchased 600 million doses of vaccine from Pfizer-BioNTech and Moderna and 100 million from Johnson & Johnson, totaling more than \$10 billion.¹⁷ Therapeutics for both inpatient and outpatient use are being delivered. For example, Regeneron agreed to supply the United States with 1.25 million doses of its antibody cocktail treatment for people with mild to moderate COVID-19 symptoms by summer 2021 for over \$2.6 billion on top of a \$633 million BARDA investment. The U.S. agreed to an initial purchase of \$210 million for 100,000 courses of Eli Lilly's combination monoclonal antibody treatment (bamlanivimab-etesevimab) and flexibility to purchase up to 1.2 million doses through November 2021.¹⁸ At the current rate of \$2,100 per course, taxpayer investment would reach \$2.5 billion if the U.S. purchased all 1.2 million doses. This follows a \$1.8 billion agreement with the federal government for bamlanivimab doses.¹⁹ And taxpayers purchased more than 500,000 courses of Gilead's remdesivir (for treating severe symptoms in hospitalized patients) at the well-known \$2,340 to \$3,120 price per course after a \$99 million taxpayer investment in the drug.²⁰

And, anticipating that they may have to pay twice, Americans have expressed overwhelming support across party lines for legislation that would cap the price on any COVID-19 vaccine or treatment developed with federal funding.²¹ The pandemic has made the issue of high prescription drug costs even more important, especially among Black, Latinx, and younger voters. Moreover, despite reports that public opinion about drug companies is improving,²² most voters point to unreasonable prices as the culprit for high drug costs.²³ This message familiar and unrelenting. Poll after poll, including a poll conducted by Families USA post-vaccine deployment, has shown that nearly 9 in 10 voters say it is important that Congress and the president take action to lower prescription drug prices and health care costs this year.^{24,25,26} Employers are equally concerned, with 9 in 10 employers reporting drug prices are among the greatest threats to affordability of health coverage for their employees.²⁷

Though the pharmaceutical industry frequently tells the public that they are in it with us, it doesn't seem like we are all in this together. At the same time that people are rationing medicines and making impossible trade-offs to keep a roof over their heads and food on the table, the pharmaceutical industry is doubling down to maximize profits because it can. Drug prices increase unabated, many of them arbitrary and unjustified. For the month of January 2021, a record-setting 900 drugs saw price increases²⁸ averaging 4.6%, on trend with pre-pandemic years.²⁹ According to a [study by the Institute for Clinical and Economic Review \(ICER\)](#),

of the 10 drugs with the largest sales revenue (2018-2019), seven showed no additional clinical benefit but reaped \$1.2 billion in increased spending in the United States in just one year.

Prices have also increased for drugs directly related to COVID-19 risk and treatment, according to a report by Patients for Affordable Drugs.

Of the drugs with price increases in the first half of 2020, 75% impact COVID-19 risk, treatment, and recovery.³⁰ They also found that the price of common sedatives needed for patients in intensive care increased between 10 and 60% while they were in shortage. Prices for blood thinners to address clots and prevent strokes were subject to price increases, and a branded version of prednisone (a common steroid needed to treat the most severe cases of acute respiratory distress) experienced a price increase of 4.6%.³¹

Even dexamethasone — a key therapeutic now considered a standard of care for COVID-19 and hailed for being inexpensive and accessible — **increased in price by 137% in recent months, from \$0.59 to \$1.39 per unit, all while it sits on the Food and Drug Administration (FDA) shortage list.**^{32,33}

Sadly, this type of opportunistic behavior is not new. **High launch prices of novel hepatitis C treatments established a new pricing regime of orphan drug pricing for a high-volume drug, and in the midst of the opioid crisis, the price of a dose of lifesaving naloxone rose from \$1 to \$150 for a two-pack of nasal spray and a stunning \$4,500 for an auto-injected version.**^{34,35}

Drugs Cost U.S. Taxpayers More, and It Is NOT Due to Research and Development (R&D) Investment and Innovation

Drug companies often tout investment in R&D as the primary driver of prices and blame increasing pressure for price concessions sought by payer and purchasers for price increases. To be sure, market distortions include opaque supply chain price concession, but list prices for drugs without competition and routine price increases for already high-cost drugs have a singular impact. Several studies show that rebates have risen, but prices rose faster. For example, a recent analysis of Medicare data over a 12-year period (2006-2017) showed that the unit price of brand-name drugs rose over 300% after rebates.³⁶ All the while, generic prices without rebates didn't move, widening the price gap over the 12 year period by over 400%.³⁷ A [bipartisan study of insulin price increases conducted by the U.S. Senate Finance Committee](#) showed that between 2014 and 2018, manufacturers' R&D investments in those drugs were dwarfed by sales and marketing expenses and reflect a fraction of the revenue generated during the same period. They also found that insulin manufacturers "aggressively raised the list price of their insulin products absent significant advances in the efficacy of the drugs." Similarly, the ICER study of unsupported price increases showed that for half of the drugs evaluated, net price (which reflects any rebates and discounts for payers or purchasers) increased significantly more than list price, costing the U.S. health system \$1.2 billion for no benefit to consumers.

All of this occurs while taxpayers bear the brunt of investment. A full treatment of the R&D argument is beyond the scope of this paper, but recent reports provide substantial evidence against its merit (see reports by [Patients for Affordable Drugs; Ekaterina Cleary, Matthew Jackson, and Fred Ledly](#); and [Sean Dickson and Jeromie Ballreich](#)). Three compelling findings lay the argument to rest. Cleary, Jackson, and Ledly found that U.S. taxpayer dollars funded every single new drug developed from 2010 to 2019, totaling more than \$230 billion.³⁸ A U.S. Government Accountability Office (GAO) study found that large pharmaceutical companies are less engaged in basic research and rely on academic institutions with government grants instead.³⁹ The same study also found that fewer competitors and increased consolidation are correlated with higher prices, which negatively impacts innovation. Finally, Dickson and Ballreich concluded that **brand-name drug manufacturers would still be the most profitable industry sector** — and would be able to keep their research investments at the same rate — **even if they were to lower their sales by \$1 trillion.**⁴⁰

At the end of the day, America's families are paying, and it doesn't seem like we are all in this together. Multinational drug companies and their investors aren't in it with us, and the system is working against us. In fact, brand-name prescription drugs cost America's families significantly more than almost all other families across the globe.

According to a RAND report (on 2018 data), **drug prices in the United States are 256% higher than those in 32 other countries included in the study. For brand-name drugs, the figure rises to 344%** (and to 400% for the top 60 drugs by sales) — almost 300% more than in Canada and well over 350% more than in Mexico.⁴¹

These high prices and unrelenting price increases are due to a broken and distorted market that results in unaffordable medicines for America’s families. The current policies protecting the pharmaceutical industry not only allow for indefinite monopolies, but also distort the market to bar entry of competitors including generics and biosimilars and eliminating checks on prices. Americans are asking for change; public support for lower drug prices is consistently overwhelming, with 9 out of 10 of voters asking the federal government to negotiate reasonable drug prices.⁴² America’s families need elected officials to live up to campaign promises and be in the fight with them.

Policy Loopholes

The market distortions that have led to this situation are only possible due to loopholes in our existing regulatory and legislative infrastructure. Congress has granted government-sanctioned monopolies to brand-name drugs through patent and market exclusivity laws, thwarting necessary competition. Drugmakers

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have systematically abused these patent and market exclusivity rules to quell product competition for decades. For example, AbbVie has nearly 250 patent applications around a single product — Humira — with the aim of extending the company’s monopoly and delaying competition for 39 years at an estimated cost of \$14.4 billion to American taxpayers.⁴³ The company is deploying the same approach with its cancer drug, Imbruvica, with 165 patents filed and half granted already.⁴⁴ This is common practice. The makers of the top 12 best-selling drugs in the United States have filed, on average, 125 patents per drug, resulting in an average 38 years of blocked competition, far in excess of the exclusivity envisioned under federal law.⁴⁵ Instead of investing in real innovation, drugmakers prioritize minor tweaks to existing drugs to maximize profits and appease shareholders, which is why more than 75% of new patents are for existing drugs.

When patents on blockbuster drugs are close to expiration, brand-name manufacturers either increase prices on their remaining products to maintain and expand high revenues, develop authorized generics (generic versions of their own brand drug) to stifle generic competition, or buy off generic competitors through “pay-for-delay” arrangements that create a bottleneck for a healthy generics market — all tactics that extend singular market share and grossly inflated prices. All of which are tactics that trickle down and result in higher prices and unaffordability for consumers.

In the end, it is critical to understand when a system that is designed to incentivize innovation is so fundamentally broken, we not only pay abusive prices for old or low-value pharmaceuticals, but we also do not reap the benefits of possible new drugs. Stated differently, because the laws are so easily manipulated,

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we incentivize the pharmaceutical industry taking advantage of patent loopholes instead of incentivizing the creation of lifesaving drugs.

America's Families Need Relief: Congress Must Act

As we begin a new Congress under a new administration and with a newly confirmed secretary of Health and Human Services dedicated to tackling the high price of prescription drugs, voters are eager for relief this year. Addressing current market distortions to bring affordable drugs to America's families includes necessary follow-through on a robust legislative agenda. The following policies work to achieve sorely needed reform by correcting market distortions, closing legal loopholes, increasing transparency, and ensuring meaningful return on investment for taxpayers. All of these reforms translate to lower drug prices for consumers and a well-deserved return on multi-billion dollar investments. To achieve these goals, Congress and the administration should act to:

- » **Protect Medicare beneficiaries and allow the government to purchase and negotiate responsibly.**
- » **End patent abuses and drive competition.**
- » **Ensure fair prices for drugs developed using taxpayer dollars.**

Protect Medicare beneficiaries and allow the government to purchase responsibly

Allowing Medicare to negotiate drug prices, protect against egregious price increases, and reorient the system toward more responsible government purchasing will reduce the cost burden on seniors and address a broken market.

» **Allow Medicare to negotiate drug prices**

Congress should prioritize responsible government purchasing that aligns with that of all other developed countries and other parts of the U.S. government by allowing the Medicare program to negotiate the prices of drugs. Eliminating the restriction on Medicare's authority to negotiate drug prices will leverage government purchasing power to level the playing field and reduce costs for beneficiaries and taxpayers. The Veterans Health Administration (VHA) and the U.S. Department of Defense already negotiate directly with drug manufacturers. U.S. Health and Human Services is legally prohibited to do so resulting in Medicare paying 54% more for a unit of a drug than the VHA [according to the Government Accountability Office](#). There should also be an upper limit in negotiations by benchmarking the price of high-cost drugs to prices based on what other developed countries pay (such as included in H.R. 3 in the 116th Congress).

» **Protect Medicare beneficiaries from drug price increases above the rate of inflation**

Congress should impose a penalty to manufacturers in the form of a rebate rewarded to the federal government for drugs whose prices are increased at a rate faster than the rate of inflation, based on the Consumer Price Index for All Urban Consumers (CPI-U). The most recent data show that half of all drugs covered under Medicare Part B and Part D had a median price increase over three times the rate of inflation.⁴⁶ Of the drugs responsible for the highest total Part D spending (2019), all were brand-name drugs with increases as high as 19.7%, or 10 times the rate of inflation (for AbbVie's Imbruvica).⁴⁷

» **Medicare Part D should be restructured to cap out-of-pocket costs for beneficiaries and require drug manufacturers to pay a larger share of Medicare costs. Out-of-pocket costs should be based on net prices rather than list prices.**

» **Manufacturers should be required to reimburse Medicare for wasted portions of product.**

» **Medicare Part B incentives should be shifted to reimburse providers for uptake of lower-cost biosimilar products when available, require Part D plans to add FDA-approved generic and biosimilar drugs to formularies upon market entry, and encourage use of biosimilars before reference biologics when possible.**

» **Post-market safety and efficacy studies should be required to be submitted in a timely and transparent manner. The FDA should be empowered to impose penalties on manufacturers that fail to report.**

» **The federal government should create a federal/state purchasing pool to negotiate prices for Medicaid.**

Many of these key recommendations are the backbone of the House prescription drug package H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. This bill was passed by the House of Representatives in December 2019. This comprehensive bill addresses high drug prices by allowing the Medicare program the power to negotiate the prices of insulin and other expensive drugs. It also uses an international pricing index as a benchmark for drug pricing to bring reasonable prices paid by most other countries to families in America. It tackles price gouging by requiring drug manufacturers to pay back America's seniors if they raise drug prices higher than the rate of inflation. The Congressional Budget Office (CBO) has estimated that, if passed, this bill would save the Medicare program up to \$450 billion over 10 years.⁴⁸

End patent abuses and drive competition

Loopholes in current law allow drug manufacturers to abuse patent and market exclusivities and quell product competition. This results in less focus on real innovation and presents a barrier to cheaper generics and biosimilars from entering the market. Ending these abuses and practices will allow consumers to shop in a market with more competition and benefit from overall lower prices.

- » **Patent abuses, such as “patent thickets,” “product hopping,” and “evergreening,” should be disallowed for brand-name drugs. These practices currently allow for the extension of the monopoly period for lifesaving treatments many years beyond original patent terms. The Federal Trade Commission (FTC) should be empowered to bring additional anti-competitive challenges against such abuses.**
- » **Tactics designed to keep generic drugs off the market, such as pay-for-delay deals, should be curbed.**
- » **Biologic exclusivity should be reduced from 12 years.**
- » **New chemical entity five-year market exclusivity should be granted only to products demonstrating a significant change to existing molecular structure.**
- » **FDA data and market exclusivities should be reformed both to reward innovation and to promote competition.**
- » **The abuse of the citizen petition process should be addressed, and manufacturers that abuse the process should be fined.**
- » **All patents relating to a drug should be placed in a publicly accessible database.**

Patients, pharmacists, and wholesalers should be allowed to import safe, affordable medicine from Canada and other major countries (such as in S. 97, the Affordable and Safe Prescription Drug Importation Act). All other developed countries enjoy significantly lower drug prices.

America’s families deserve the same through allowing for importation of safe and more affordable drugs.

Ensure fair prices for drugs developed using taxpayer dollars

Congress should pass protections for consumers and meaningful return on investment for taxpayers included in legislation introduced in the 116th and 117th Congress. Bills like the We Protect American Investment in Drugs Act (We PAID Act), the Pandemic Treatment Access and Affordability Act of 2021 (H.R. 597), the Taxpayer Research and Coronavirus Knowledge Act (TRACK Act), and the COVID-19 Emergency Manufacturing Act promote access and ensure fair prices for drugs and vaccines developed with taxpayer dollars.

The **We PAID Act** would establish an independent Drug Affordability and Access Committee to determine a reasonable price for drugs under consideration and require drug manufacturers to do the following: (a) provide drug price information (b) enter into licensing agreements for drugs developed with federal funding not to exceed a price determined by the committee one year after market entry, and (c) limit annual price increases to the rate of medical inflation.

The **Pandemic Treatment Access and Affordability Act of 2021 (H.R. 597)** would do the following: (a) ensure universal access to taxpayer-funded drugs and vaccines by prohibiting pharmaceutical companies from exclusive licensing and monopolizing the market, (b) require reasonable and affordable pricing of taxpayer-funded treatments and vaccines, (c) ensure transparent public reporting of total expenditures associated with treatments and vaccines for COVID-19 (including what percentages were derived from federal funding), and (d) prevent excessive pricing of drugs used to treat any disease that causes a public health emergency.

Families across the nation need and deserve a return on investment for the significant financial burden they have borne as a result of this pandemic and for decades prior.

The **Taxpayer Research and Coronavirus Knowledge (TRACK) Act** would create a single database of federal biomedical investment information for COVID-19.

The **COVID-19 Emergency Manufacturing Act** would increase public manufacturing of generic prescription drugs, lowering prices for consumers. The federal government would contract with private manufacturers to produce drugs critical for national security. The drugs prioritized for production would generally have a limited or nonexistent commercial market and would have the most impact on public health and the economy, putting consumer needs first. These products would be provided to federal, state, local, and indigenous entities at no cost.

By enacting these policy recommendations, the 117th Congress has the opportunity to live up to campaign promises and heed the urgent call for affordable medicines. Families across the nation need and deserve a return on investment for the significant financial burden they have borne as a result of this pandemic and for decades prior. Presently, 8 in 10 voters believe the system works for the benefit of insurance and drug companies and that Congress won't change the system to meet consumer need.⁴⁹ Families USA stands ready to work with policymakers to take on the challenge and to make it so we are all in this together.

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