

To: The Honorable Joseph Biden
President of the United States

The Honorable Xavier Becerra
Secretary of Health and Human Services

The Honorable Nancy Pelosi
Speaker

The Honorable Kevin McCarthy
House Republican Leader

The Honorable Chuck Schumer
Senate Majority Leader

The Honorable Mitch McConnell
Senate Republican Leader

Dear President Biden, Secretary Becerra, Speaker Pelosi, Majority Leader Schumer, Leader McCarthy, Leader McConnell, America's Lawmakers, Patient Advocates, and Fellow Americans:

We lead, fund, and count on the many small biotechnology companies that develop medicines for diseases* that lack sufficient treatments and cause considerable suffering. The companies led by the executives among us employ 23,250 people in the US and collectively invest over \$17.7 billion/year in search of breakthroughs. We are currently testing 407 new and potentially life changing drug candidates in clinical trials, some of which build upon foundational NIH-funded research led by the academic researchers among us. The investors among us work at firms managing over \$185 billion of life science-focused capital that comes primarily from pension funds, families, universities, non-profits, and others who invest in drug development. Many of us are also patients and patient advocates, with loved ones who suffer from difficult diseases in need of better treatment options. We have dedicated ourselves to that effort.

Collectively we come together to defeat disease. Each drug in development is a complex, time consuming, and expensive scientific and medical undertaking. Most of the time we lose the battle. But we persist because the few projects that succeed will forever improve human health.

Our industry invests over \$160 billion in R&D each year. In the past decade it has created vaccines and treatments for Covid-19, treatments for cystic fibrosis and sickle cell disease, and cures for several cancers and hepatitis C. These successes are just a few examples of the many significant advances we are driving. Our efforts are reducing the burden and threat of diseases across the USA and around the globe.

It has become clear that we must also help our lawmakers understand the basic economic framework that inspires companies and investors to take the financial risk required to create new medicines. Called to action by the justifiable outrage of patients who cannot afford their out-of-pocket costs, some lawmakers have misdiagnosed the problem. They believe drug companies charge too much for their products. In response, they are proposing to enact laws that not only fall short of making drugs affordable to all patients but also defund our efforts to create better ones.

The Right Goal

To be clear, we are concerned about the high and rising out-of-pocket costs that have made our medicines increasingly unaffordable to many patients. We, too, call for a solution to affordability. We don't invent drugs to have them placed out of the reach of people who need them.

Insurance makes it possible for Americans to afford today's medicines and collectively invest in tomorrow's, as is captured in [this short video](#). To solve the problem of affordability for patients, we must lower the amount that insurance plans can make patients pay out-of-pocket, redefining proper insurance by law, just as policymakers have appropriately outlawed discrimination on the basis of pre-existing conditions.

The Wrong Policy

Instead, Congress is considering allowing the government to dictate the price that a company may charge for a novel drug with the threat of ruining the company financially with a 95% tax should the company refuse to accept the government's price.

Such draconian measures would immediately halt private funding of drug discovery and development. As an industry, we would no longer be able to infer what insurance plans might value and pay tomorrow from what they value and pay today, which is the premise of a market economy. Unpredictable government-dictated prices would supplant the current market-based framework that inspires biomedical R&D investment.

The investors among us would have to shift our investments toward areas still governed by markets, such as technology and consumer goods. Those companies with drug candidates in development would fail to raise more capital, making it pointless for them to spend existing dollars on ongoing research. The loss of hundreds of thousands of well-paying jobs would be swift, though it may take longer for the public to sense the loss of future treatments and cures.

Some may think NIH funding will be sufficient to fund continued R&D. The NIH is a crucial funder of the basic research that provides the ideas for what kinds of drugs might be possible.

Translating those ideas into actual medicines is almost entirely driven by the private sector and makes all that basic research worth funding in the first place. Some of us signing this letter are NIH funded academic researchers whose discoveries have had significant patient impact, and we affirm that the private sector has been and will continue to be essential for turning our ideas into medicines. The NIH and industry are parts [of one whole ecosystem](#), not a replacement for one another.

What's in a Word?

Successful negotiations result in market-based prices based on competing alternatives – this negotiation already takes place between drug manufacturers and insurance companies, resulting in an average 50% reduction from drugs' list prices to their net prices.

True negotiation requires that both parties can walk away from the table. True negotiation is acceptable to all of us and spurs us to compete. True negotiation means that even if we don't get to the market first, our second and third place drugs can still secure some market share by competing on price.

The proposed introduction of a 95% tax penalty would allow The Center for Medicare and Medicaid Services (CMS) to simply dictate any drug's price. This is not true negotiation.

As proposed, the government would be able to keep a company from walking away from an unacceptably low price. This gives the American public the impression that they can have any drug that's been invented for any price, however low. Overlooked in that bargain is that investors and companies will stop investing in new programs, and we'll give up the medicines that haven't been invented yet.

Congress may not intend to dictate the price for every drug. But dictating the price of drugs covered by Medicare would defund R&D for diseases of aging, including Alzheimer's, osteoporosis, and cancer. Dictating prices for medicines priced above a certain threshold would defund R&D for rare diseases. Dictating prices for medicines that generate the most total revenue would defund R&D for our most difficult diseases, since those are the ones that require greater expected revenues to incentivize substantial R&D investment.

Dictating prices for drugs deemed less "valuable" to society sounds tempting, until one realizes that the math for estimating a drug's value is so nascent, imprecise, and controversial that it's easily biased to reflect the preferences of the practitioner. For example, a recent business plan competition demonstrated that [not a single project would be fundable](#) if future products could only be priced in accordance with the [over-simplified math](#) used in the UK and Canada. Furthermore, there is mounting evidence from health economics research that medicines offer greater societal value than is reflected by their prices.

Better Solutions

We already have a functioning mechanism to drive down drug prices: drugs go generic. Because drugs go generic, what America spends on drugs has remained at roughly 10% of healthcare spending for decades, yet we have so many more effective and safer medicines today than in the 1970s.

Hospitals, long-term care facilities, and medical procedures do not go generic; those costs have only been climbing. We can keep ourselves from having to rely as much on hospitals in the future by inventing better medicines, which will then go generic. Society saves money, and we all lead healthier lives.

Preserving market-based incentives for drug R&D is how we get the medicines to achieve this goal. Heart transplants were first performed in 1967 and climbed in price by over 2,000% to cost \$1.4 million today. The heart failure drug amiloride helps avert the need for transplants and was approved in 1967; today it costs 26 cents/pill. We haven't solved heart failure, but we're working on it. So, there's hope for the people who need better heart failure medicines, but that hope requires continued investment in R&D.

America, and specifically CMS, can still save on drugs without sacrificing future treatments, cures, and vaccines. Certain drugs do not go generic even after their patents have expired, and CMS could save money by solving that particular market failure. Doing so would not reduce R&D incentives. [Members of industry](#) and others have proposed [a specific, actionable framework](#) for how this could work.

Averting A Costly Error

It's true that replacing market-based pricing with non-market government-dictated prices will reduce healthcare spending in the short run (the Congressional Budget Office, which helps lawmakers determine what legislation may cost or save the government, uses a 10-year timeframe). But without new medicines, this policy will condemn America to spend far more on managing diseases in hospitals and long-term care facilities for decades to come.

The worst part is that it will take a long time to realize that we're not making progress like we used to. For example, antibiotic R&D has historically suffered from low investment incentives because the prices of antibiotics are so low. Today, we urgently need new antibiotics to combat the rise of resistant bacterial infections, but it will take years to remedy this gap in R&D even with proper incentives and funding. It's hard to appreciate what we don't have until we need it.

The advocates among us know this acutely, having worked with so many patients struggling to make it to the next breakthrough.

Where there are market failures, we should fix them. All drugs should go generic without undue delay. Americans should not suffer because their insurance burdens them with unaffordable out-of-pocket costs, whether they get their drugs through Medicare, their employer insurance, or on the public exchanges. Patients and policyholders should benefit from the savings insurers negotiate with drug companies, and drugs covered under Medicare Part B should be subject to the same competitive

market forces as those covered by Part D. Lawmakers should focus on these important, achievable, and bipartisan reforms for the benefit of all Americans.

In the meantime, the term “negotiation” must not be redefined to encompass the government dictating a price under threat of financial ruin. Were such a law to pass, capital would be immediately redirected away from biomedical R&D, with an immediate effect on biotechnology jobs and longer-term harm to patients and our national budget and security.

Some observers of the drug development ecosystem who propose different theories and models of how it works might contradict us. But the executives and investors among us write not as observers of biotech’s economic framework but as its actual elements and conductors; capital and incentives flow through our funds and our companies like electricity through a circuit. It is evident to us that replacing true negotiation with dictated prices would defund R&D, like flipping off a light switch.

Sincerely,

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*** Diseases that companies affiliated with signatories are working to prevent, treat, or cure:**

ADHD, ALS, Alzheimer's, Amyloid diseases, Anemia, ARDS, Autism, Autoimmune Disorders, Benign Prostatic Hyperplasia, Blindness, Breast Cancer, Chemotherapy Induced Peripheral Neuropathy and Chemotherapy Induced Cognitive Impairment, Chronic Hepatitis B, Chronic Lymphocytic Leukemia, Chronic Pain, Cognitive Injuries, Colorectal Cancer, Complement Disorders, COVID, Dementia, DM1, DMD, Enteric Hyperoxaluria, Fragile X syndrome, FSGS, FSHD, Gout, Heart Failure, Huntington's Diseases, Idiopathic Pulmonary Fibrosis, IgA nephropathy, Infectious Disease, Inflammatory Bowel Disease, Influenza, Long COVID, Lung Cancer, Lupus, Major Depressive Disorder, Melanoma, MLD, MPS2, Multiple Sclerosis, NASH, NMOSD, Non-Hodgkin Lymphoma, Obesity, Opioid Use Disorder, Osteoarthritis, Ovarian Cancer, Pancreatic Cancer, Parkinson's Disease, Parkinson's Psychosis, Pediatric Leukemias, Pediatric low grade glioma, PKU, Post-surgical Pain, Primary Biliary Cholangitis, Prostate Cancer, Pulmonary Arterial Hypertension, Rare Epilepsies, Renal Cancer, Retinal eye diseases, Rhetts Syndrome, Stroke, Type 1 Diabetes, Type 2 Diabetes, Uterine Cancer, and many other diseases.

***The appended signatures do not necessarily reflect the policy or position of any agency, organization, employer, or company with which the signatories are affiliated.*

CC: House Energy and Commerce Committee Chair Pallone and Ranking Member McMorris Rodgers
House Ways and Means Committee Chair Neal and Ranking Member Brady
Senate Finance Chair Wyden and Ranking Member Crapo
Senate Health, Education, Labor, and Pensions Chair Murray and Ranking Member Burr

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