

## **Coalition Letter to End IRA Prescription Drug Price Controls**

October 31, 2023

Dear Members of Congress,

When the Inflation Reduction Act was passed and signed into law a year ago, the legislation granted the federal government broad power to set and control the price of certain prescription drugs through a new Medicare price negotiation program run by the Department of Health and Human Services. Just last month, HHS and President Biden announced the first ten drugs chosen for price negotiation.

We first note that the IRA's price control regime is a solution in search of a problem. Legislators focused on drugs' list prices. But the actual net prices after all discounts and rebates have been relatively stable, and prescription drug inflation has been much lower than general inflation. Prescription drug expenditures are a lower percentage of overall health care expenditures in the U.S. than the average percentage in 11 developed countries.

Given the well-documented destructive history of price controls and the law's expansion of government power over our health-care system, we, the undersigned organizations, strongly urge you to repeal the prescription drug prices controls found within the Inflation Reduction Act.

Provisions found in Subtitle B (titled "Prescription Drug Pricing Reform") of the IRA, allow the federal government to dictate the price of certain common drugs and biologics and outlines repercussions for drug companies if their prices outpace consumer inflation.

More specifically, the IRA establishes a new drug price negotiation program run by HHS to negotiate directly with drug companies on the prices of their drugs and biologics. The law instructs the HHS secretary to select negotiation-eligible drugs based on which drugs and biologics had the highest share of spending through Medicare Part B and Medicare Part D the previous year. The law also designates the secretary as the sole arbiter of which single source drugs will be negotiation-eligible and specifies that there is no administrative or judicial route to dispute this selection.

Parts of the IRA also establish penalties for companies who refuse to negotiate or who intentionally or otherwise fail to comply with the prices determined by HHS. Under the law, if a drug company rejects negotiation or does not agree to the Medicare price mandated by HHS, it is subject to a confiscatory excise tax of up to 95 percent of all sales of the drug.

The price negotiation scheme and penalty regime put in place by the IRA are deeply troubling.

Because a particular drug's high Medicare spending (price times quantity) may be based on a drug's popularity, a drug may be subject to price controls solely for being effective and widely used even if it is priced reasonably. Hence, below market, lower prices may be set by the government, resulting in decreased supply of highly beneficial drugs. Under the IRA, manufacturers have no legal recourse to dispute which drugs are selected and what prices are set. They are effectively told to sell at the price set by HHS or not sell at all. This opens the door to arbitrary administrative actions and creates due process concerns.

Other parts of the IRA penalize manufacturers whose drug prices increase faster than the general consumer price index, by mandating a refund they must pay the Centers for Medicare & Medicaid Services. As written, these provisions penalize a company if their list price, not net price, outpaces inflation. That is problematic since list prices are almost always higher and increase faster than net prices. Therefore, many manufacturers will be subject to inflation price penalties even though their net prices and profits increase slower than the list price increases and are actually lower than the inflation rate.

CBO predicts these inflation price limits will elicit higher launch prices for new drugs. These higher list prices will result in higher out-of-pocket payments—normally based on list prices—for insured patients and higher prices for patients who lack drug coverage.

Permeating this whole portion of the IRA is the flawed notion that price controls are a good thing for consumers and patients. Time and time again, price controls have been shown to suppress innovation by distorting and interfering with supply and demand and other forces that make markets and capitalism work. Price controls on drugs lead to shortages in the short term and fewer innovative new drugs becoming available in the longer term. Fewer life-saving drugs forces higher expenditures on other forms of medical care and decreases overall health.

New drugs improve health by providing benefits that were not previously available at patent-protected prices for a limited period of time and at lower, generic prices for the long run. High initial prices for some specialty drugs are less a reflection of corporate greed than the direct result of the high costs of research, testing, development, and evaluation that goes into bringing new drugs to market. Most candidates never make it to clinical trials, and only about one in ten that start trials are approved. Drug prices also reflect the growing cost of regulatory compliance. Pharmaceutical companies must cover the costs of development failures and regulatory compliance for all their drugs in order to continue development of the innovative therapies that improve Americans' health.

Private innovation, not government, has brought us the life-saving and life-improving treatments used by millions of Americans each day. In the drug marketplace, price controls mean less

supply of these medicines, less innovation and creation of new medicines, and ultimately a sicker populace.

Health care provisions in the Inflation Reduction Act have put America one step closer to socialized medicine. If left in place, these provisions will make the American economy less competitive and leave America sicker. For these reasons, we urge you to repeal the prescription drug price controls in the IRA.

Short of repeal, Congress should perform rigorous oversight over implementation of the IRA and work to mitigate the harms from the new drug price controls put in place by the law.

Sincerely,

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