Health Policy Solutions
Protecting Innovation

The Unintended Consequences of Price Negotiation

As one of the most R&D-intensive domestic industries, the U.S. pharmaceutical industry is the engine for scientific breakthroughs that change the way we treat and prevent diseases. Supported by a framework that encourages innovation and competition, the pharmaceutical industry has developed over 470 medicines to treat diseases such as cancer, cardiovascular diseases, and diabetes in the last 10 years alone.

Sanofi supports policy solutions that preserve drug discovery and development while ensuring broad and affordable patient access to life-changing medicines.

In the two years since the passage of the Inflation Reduction Act (IRA), the health care system has seen early, negative impacts on innovation and science from the IRA's Medicare Drug Price Negotiation Program.

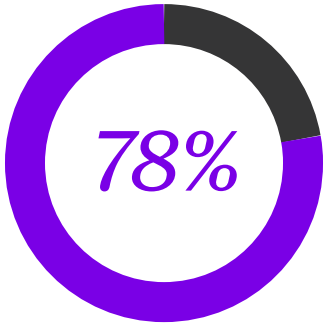
The IRA's "negotiation" process, as written, is essentially government price setting, which will artificially influence research and development (R&D) investment decisions. The pre-price control window limits a company's runway to conduct clinical trials for regulatory approval in different indications that target multiple disease areas. This could lead to as many as 139 fewer drugs developed over the next decade alone.

If the IRA continues down this path and curtails U.S. innovation in medicines, the lack of novel treatments could lead to higher medical costs and increased hospital stays – areas of the system where both costs are high and patient burdens significant.

Downstream Effects of IRA Price Controls

While much has been said about the IRA's effect on innovation in medicine, federal price controls have ripple effects beyond just the drugs selected for government price setting and beyond Medicare. Price controls also affect whole classes of medicines, patients' access to both public and private health plans, and the development of future innovative therapies.

Some of those ripple effects may impact seniors' access to certain medicines. One report found that 3.5 million seniors needing medicines with IRA's price controls could actually experience increased out-of-pocket costs because of their slower progression toward meeting their maximum out-of-pocket limit with copays. According to a recent survey of payors:



of insurers plan to **decrease the number of therapeutic options** in classes with medicines selected for government price setting.

Without changes, **the IRA's price controls will place a thumb on the scale of science** in ways that will significantly limit research, **and too many seniors will continue to struggle to afford the out-of-pocket costs of their medicines**. Sanofi supports changes to the IRA's drug pricing policies to minimize the harms to innovation and make the system work better for patients, including:

Modifying the current law's unscientific and arbitrary distinction between small molecule drugs and biologics, which discourages the development of medicines that typically come in pill or capsule form (i.e., the "pill penalty"). Small molecule drugs, which are often preferred by patients, have government price controls imposed four years earlier than other forms of prescription drugs.

Reducing the disincentives that constrain investment in multiple indications for a drug candidate. For example, the IRA exempts orphan medications for one disease. This exemption should be expanded to orphan drugs that treat more than one rare disease.

Accounting for value as it relates to both patients and the healthcare system. For example, value should reflect the ability to lead a productive life mostly free of disease, the impact of side effects, the cost of physician monitoring, and other clinical outcomes valued by patients and their families.

Monitoring formulary decisions by health plans to protect patient access to new medicines through frequent, adequate updates of plan oversight. Medicare should offer patients and their providers an array of clinical choices so that the best and most appropriate innovations are available to treat patients needing such advances.

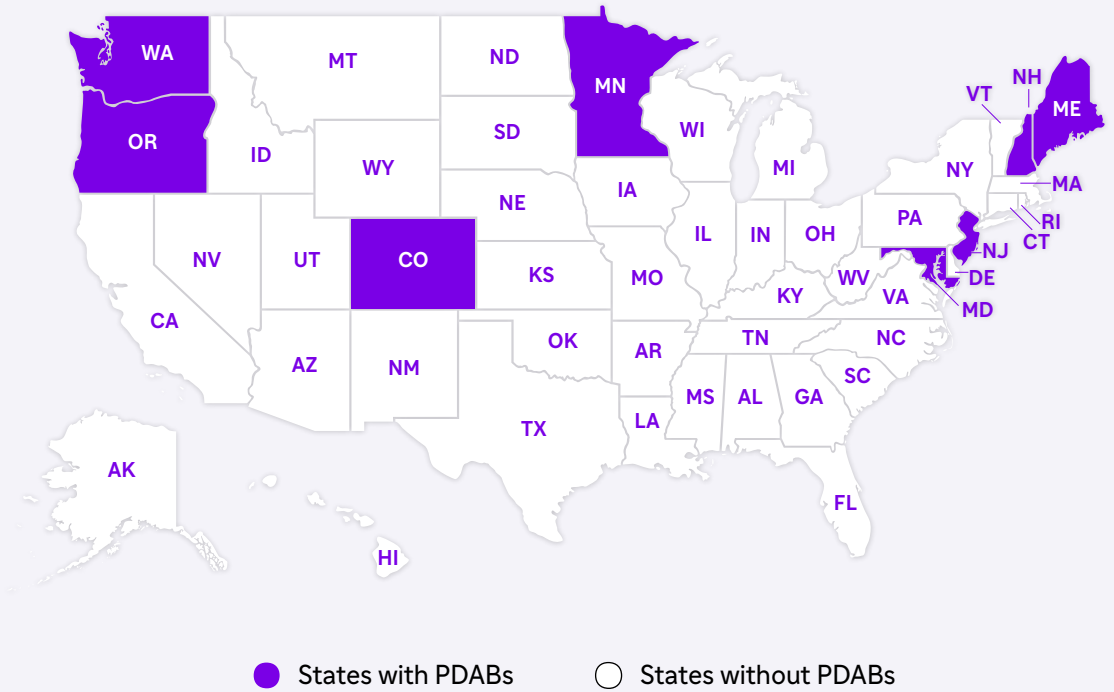
What are Prescription Drug Affordability Boards?

Often pushed by the special interests of healthcare insurers, state governments have begun to adopt price control measures by establishing politically appointed panels, or prescription drug affordability boards (PDABs), to assess the prices of medicines in their state.

While each state's PDAB varies in operation and level of legal authority, some are authorized to arbitrarily establish "upper payment limits" on drugs that the panel determines are "unaffordable." **No state PDAB, however, lowers out-of-pocket costs for patients or requires insurers and pharmacy benefit managers (PBMs) to directly share potential savings with patients**.

Just like the IRA, PDABs have unintended consequences for patient access and continued drug innovation. We share the concern of numerous patient and provider groups who have warned that government price setting could limit access to critical medicines by inserting a state's determination of what is affordable between patients and their prescribers. Government price setting also reduces the ability of the pharmaceutical industry to continue investing in innovation for new therapies.

Where are PDABs in the U.S.?



State-level prescription drug affordability boards have been authorized in more than a dozen states, though just a handful have begun operations. Many more states are expected to consider similar boards in this year's legislative session.

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