

# The Unintended Consequences *of Price Negotiations*

As one of the most research and development (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.

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

---

In the three years since the passage of the Inflation Reduction Act (IRA), the healthcare system has already 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 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.

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 costs are high and patient burdens are significant.

Supported by a  
framework that encourages  
*innovation and competition,*

the pharmaceutical industry  
has developed

**>390** medicines to  
treat diseases

such as cancer, cardiovascular  
diseases, and diabetes

**in the *last 5 years* alone.**

# Downstream Effects of IRA Price Controls

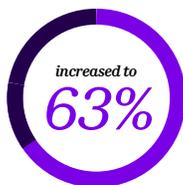
While much has been said about the IRA's effect on innovation in medicine, federal price controls have ripple effects beyond Medicare and the drugs selected for government price setting. Price controls also affect whole classes of medicines and patients' access under public and private health plans.

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.

In addition, insurers offering Part D plans in 2026 are [increasingly moving toward](#) requiring coinsurance or prior authorization on medicines — resulting in access and affordability challenges.

In 2026,

The average share of all covered drugs with coinsurance



among Medicare Advantage drug plans,

while insurers offering Part D plans now apply prior authorization



of covered brand drugs.

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 post-approval research for additional indications for a drug candidate. Multiple indication drugs deliver broader therapeutic impact by improving patient outcomes across multiple conditions.
- **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.*

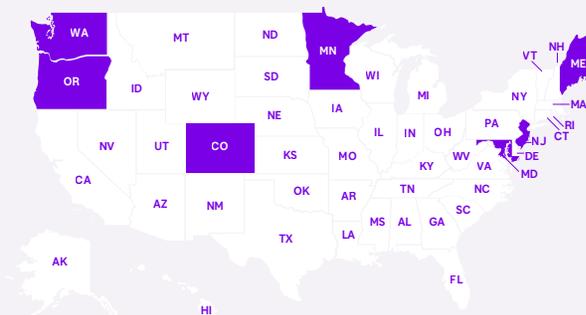
Just like the IRA, PDABs have unintended consequences for patient access and continued drug innovation. We share the concern of numerous patient and provider groups who have warned that government price setting could limit access to critical medicines by inserting a state’s determination of what is affordable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

At the federal level, Congress recognized how government price setting can harm continued innovation for drugs that treat rare diseases or conditions. Subsequently, Congress has exempted orphan drugs from IRA price controls. Similarly, state PDABs should exempt drugs that treat any rare disease or conditions to foster a landscape that encourages continued development and innovation for patients.

## 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.*



● States with PDABs    ○ States without PDABs