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ISSUE BRIEF

The Rise—and Potential Fall—of America's Drug Industry: How to Avoid the Road to Serfdom

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Contents

Executive Summary 4
Free Market, Bold Science: How America Came to Dominate the Drug Industry 5
The Inflation Reduction Act Is Already Deterring Research Investment 6
Shuttered Pipelines and Discontinued Drugs 7
The “Pill Penalty” and Abandoned Research 7
Most Favored Nation Pricing: The Next Blow to U.S. Drug Innovation? 8
Europe’s Cautionary Tale: From Industry Leader to Laggard 8
Europe’s Descent: It’s a Long Way Down 9
The Path Forward 10
Endnotes 11
About the Authors 17
About PRI 18

Executive Summary

"The Rise—and Potential Fall—of America's Drug Industry" issues a timely and urgent warning: government-imposed price controls threaten the United States' status as the world leader in biopharmaceutical innovation.

For over four decades, pro-innovation policies like the Bayh-Dole and Hatch-Waxman Acts, along with the competitive framework of Medicare's Part D prescription drug benefit, have enabled the United States to outpace the rest of the world in drug development and patient access. The U.S. market-oriented biopharmaceutical ecosystem has produced life-saving breakthroughs for hepatitis C, HIV, cancer prevention, rare genetic diseases, and more.

But price controls established by the 2022 Inflation Reduction Act—starting with 10 drugs dispensed through Medicare's Part D prescription drug benefit that take effect in January 2026—are discouraging investment and prompting drugmakers to cancel dozens of research and drug-development programs. Venture capital funding is drying up, and early-stage biotech pipelines are shrinking. Additional price controls in the form of "Most Favored Nation" policies, which would peg U.S. drug prices to those set by governments abroad, could further devastate domestic innovation.

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Europe's own descent from pharmaceutical leader to laggard offers a cautionary tale. The continent's aggressive price-control policies resulted in fewer drug launches, diminished clinical trial activity, and longer waits for patients to gain access to novel therapies. The United States risks repeating these mistakes.

Policymakers must preserve the market-oriented principles that reward risk and incentivize innovation. Failing to do so will place America on a path of irreversible decline—one with devastating consequences for patients and public health.

"One need not be a prophet to be aware of impending dangers."—Friedrich Hayek

Eighty-one years after Friedrich Hayek penned *The Road to Serfdom*, his warning against centralized economic planning remains all too relevant. Hayek cautioned that even well-intentioned state interference in markets inevitably paves the way to socialism and ultimately, decline.

Nowhere is that warning more urgent than in the American healthcare system. For decades, the United States has led the world in biopharmaceutical innovation—thanks to a supportive policy environment and a market-based system that rewards risk-taking and scientific discovery.

But America's pharmaceutical industry now stands at a dangerous crossroads. The Inflation Reduction Act's price controls on prescription drugs dispensed through Medicare won't take effect until January 1, 2026. Yet they've

already forced biotech companies to pull the plug on dozens of promising research programs. And members of both major parties are calling for even more stringent and widespread European-style price controls.

We don't need prophecy to know where this road leads. We only need to look across the Atlantic. Price controls have gutted Europe's once world-leading pharmaceutical industry, delayed access to cutting-edge treatments, and driven investment elsewhere.

If we abandon the market principles that are foundational to the biotech industry's success, we will follow Europe down a path of stagnation. The question is not whether the consequences will come but how soon they'll arrive and how painful they will be.

Free Market, Bold Science: How America Came to Dominate the Drug Industry

In recent decades, the United States has become the global epicenter of the pharmaceutical industry, outpacing Europe in new drug launches, research investment, and access to cutting-edge treatments. This transformation was not accidental. It was policy-driven.

America's pharmaceutical dominance was propelled by a series of legislative and regulatory reforms in the 1980s and 1990s. Rather than a top-down industrial policy, the United States embraced market-oriented principles that created powerful incentives for private investment in drug development.

> "Price controls have gutted Europe's once world-leading pharmaceutical industry, delayed access to cutting-edge treatments, and driven investment elsewhere.

The 1980 Bayh-Dole Act was one catalyst.[1] For the first time, it allowed universities and other institutions conducting federally funded research to retain ownership of their inventions. Discoveries made in academic labs could now be patented and licensed to private companies for development and commercialization. Since its passage, over 200 drugs and vaccines have been developed thanks to these public-private partnerships.[2]

The 1984 Hatch-Waxman Act reinforced these incentives by creating a more predictable regulatory environment and stronger incentives for pharmaceutical development.[3] It extended patents for brand-name drugs to compensate for regulatory delays and established an abbreviated approval process for generic drugs.

As the biotech industry grew, and investment poured into the United States, policymakers in both parties rejected attempts to install price controls. In 1995, the Clinton administration repealed a "reasonable pricing" clause that had previously been inserted into the contracts for a type of research partnership between the National Institutes of Health and private companies, citing its chilling effect on private investment.[4] Congress later rejected legislative efforts to reintroduce and codify those reasonable pricing clauses—a sign of bipartisan consensus around the principle that the best way to drive innovation was to empower private researchers.[5]

In 2003, Congress passed the Medicare Modernization Act to create Medicare Part D, the first federal prescription drug benefit program for seniors.[6] The law codified the principle of market competition into federal drug policy. At its core, the program was built on competition and choice.

Instead of a government-dictated formulary, or list of covered drugs, the program established a decentralized marketplace where private insurers negotiate directly with drug manufacturers in order to design their own benefit packages and compete for enrollees.[7] The law's non-interference clause prohibited the federal government from setting prices, ensuring that commercial dynamics, not bureaucracy, would rule the market.[8]

Over its first two decades, Medicare Part D proved resilient and cost-efficient. Spending on the program has historically come in below the Congressional Budget Office's initial projections.[9]

In 2023, average monthly premiums for standalone prescription drug plans remained under $40[10], even as utilization rose and new therapies entered the market. Generic utilization exceeds 90%.[11] Surveys consistently show high beneficiary satisfaction.[12]

Part D greatly expanded the number of seniors with prescription drug coverage—thus triggering a "significant increase"[13] in pharmaceutical spending on research and development of treatments that serve the Medicare-age population. And a bigger potential market has spurred investments that have yielded significant advances in pharmaceutical innovation.[14]

The U.S. biotech industry now accounts for 55%[15] of global biopharmaceutical research and development spending and up to two-thirds[16] of all new drug launches globally. Most new drugs[17] launch first in the United States. This country is also the default site[18] for early- and late-stage trials, particularly in advanced treatments such as gene therapy.[19]

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These are not just empty statistics. They represent millions of lives transformed and saved.

Hepatitis C, once among the deadliest[20] infectious diseases in the United States, is now curable[21] in eight to 12 weeks thanks to direct-acting antivirals.[22] New antivirals have transformed[23] HIV from a death sentence into a manageable chronic condition with near-normal life expectancy.[24] Revolutionary CRISPR gene editing technology[25] allows Americans with sickle cell disease to produce healthy red blood cells. Cervical cancer deaths among young women fell 62%[26] following the introduction of Gardasil, the vaccine[27] that prevents the human papillomavirus that greatly increases the risk of cervical cancer and infertility.

But future medical breakthroughs like these are now at risk because of the unprecedented and drastic government interference into our market-oriented healthcare system.

The Inflation Reduction Act Is Already Deterring Research Investment

The Inflation Reduction Act of 2022[28] established direct government control over the pricing of prescription drugs, for the first time in Medicare's history. This move fundamentally departs from the market-oriented framework that has defined Medicare Part D since its inception.

The IRA empowers the U.S. Department of Health and Human Services to negotiate—or more accurately, to impose—drug prices through the "Medicare Drug Price Negotiation Program."[29]

Each year, the Centers for Medicare and Medicaid Services will select a growing number of drugs for price-setting. In 2023[30], CMS selected 10 dispensed through Part D; the price controls will take effect January 1, 2026. In 2025[31], it chose 15 additional Part D drugs for price-setting, with the prices taking effect in 2027. In 2026[32], Medicare will select another 15 drugs across Medicare Parts B and D for negotiation, with prices taking effect in 2028. And in 2027 and each subsequent year, Medicare will select 20 drugs across Parts B and D for the program, with prices taking effect two years later.

Even though the negotiated prices for the first 10 drugs have not yet gone into effect, early indicators suggest that the IRA is already altering research incentives and distorting investment flows.

Shuttered Pipelines and Discontinued Drugs

Since the IRA passed, drugmakers have closed 51 research programs and discontinued 26 drugs[33], according to a database run by Incubate, a coalition of early-stage life sciences investors.

Alnylam Pharmaceuticals[34] halted development of an expanded indication for its drug Amvuttra. Novartis[35] stopped research for several early-stage cancer drugs. Genentech[36] has considered delaying a treatment for ovarian cancer. Each company cited the financial disincentives in the IRA as a motivating factor.

> "Each year, the Centers for Medicare and Medicaid Services will select a growing number of drugs for price-setting.

While early effects are concerning, the true impact of the IRA will play out over decades, with fewer new drugs reaching patients. Research from University of Chicago economists Tomas J. Philipson and Troy Durie suggests price controls could lead to an 18.5% decrease in spending on research and development—equivalent to roughly $663 billion—and 135 fewer new drug approvals by 2039.[37]

Older Americans could be most vulnerable. A study from Vital Transformation, a consultancy, found that since the IRA passed, there is evidence of a decrease in new treatments developed for seniors.[38]

The "Pill Penalty" and Abandoned Research

The IRA's price controls are particularly aggressive for small-molecule drugs[39], which are typically chemically synthesized oral medications taken at home. Under the IRA, small molecules become eligible for price controls just nine years[40] after FDA approval, compared to 13 years[41] for "biologic" drugs that are grown from living cell cultures and typically injected or infused at doctor's offices, clinics, and hospitals.

In response, many drugmakers are scaling back or discontinuing[42] their small-molecule programs. This "pill penalty" discourages the development of orally-administered drugs, which have different strengths and

weaknesses compared to biologics. Due to these differences, small-molecule drugs have advantages for treating certain conditions, such as dementia. These patients bear a disproportionate harm from the pill penalty.

Recent analyses underscore this trend. Late-stage clinical trial activity for small-molecule drugs has declined by 47%[43] since the IRA passed in 2022, as sponsors divert funding to biologics and other protected platforms. Early-stage funding for small-molecule drugs has dropped 70%[44] since the IRA was introduced. VC funding for U.S. biotech startups declined 20% in the first quarter of 2025[45], continuing two consecutive years[46] of declines in investment.

> “Late-stage clinical trial activity for small-molecule drugs has declined by 47% since the Inflation Reduction Act passed, as sponsors divert funding to biologics and other protected platforms.

Drugs for rare diseases, 95%[47] of which have no treatment, are also in danger. A study by the National Pharmaceutical Council found that second indications for rare disease drugs have dropped by 48%[48] since the IRA passed.

Despite these warning signs, the government is considering even more stringent price controls that would make the IRA's consequences seem mild by comparison.

Most Favored Nation Pricing: The Next Blow to U.S. Drug Innovation?

President Trump issued an executive order[49] on May 12 calling for “Most Favored Nation” drug pricing. The MFN model—first proposed by the Trump administration in 2020[50]—would tie American drug prices to the lowest price offered in other comparable developed countries like Germany, France, and Canada.

The proposal seeks to address the real problem of foreign countries freeloading off American investments in research and development.

But instead of ending the freeloading, an MFN model would reward it. It would let the same foreign bureaucrats who have already destroyed their own biotech industries with price controls impose the same damage here.

Europe's Cautionary Tale: From Industry Leader to Laggard

In the three decades following World War II, European firms dominated[51] global pharmaceutical development. By the 1970s, European firms were producing more than twice as many[52] new drug treatments as their U.S. counterparts, while continuing to outspend[53] them on research and development. Of the 692 new medicines launched between 1961 and 1970, over half[54] came from just three countries: the United Kingdom, Switzerland, and France.

This dominance persisted into the 1980s and early 1990s. Between 1985 and 1989[55], Western European companies developed 129 new drugs, compared to just 77 from American firms. In 1990, Europe commanded 49%[56] of global pharmaceutical research and development spending; the United States accounted for just 33%.[57]

Europe did not just develop the most drugs. It was also the destination of choice for companies looking to debut new treatments. Between 1993 and 1997, 81[58] new medicines were launched first in Europe, compared with just 48[59] in the United States.

But this leadership did not last. As the United States increasingly leveraged the power of market competition, private capital, and entrepreneurial risk-taking, European governments gave in to populist price controls. European countries capped[60] annual list-price growth, implemented[61] profit caps, contracted[62] the supply of drugs, and excluded[63] certain drugs from reimbursement lists. Internal reference pricing[64] soon followed in many European countries. This drug pricing model sets static prices among groups of similar drugs.

These policies culminated in Europe's adoption of international reference pricing[65], which pegged drug prices to the lowest prices in a basket of countries and undermined the reward for medical breakthroughs.

By the early 2000s, the United States had vaulted to the top of the pharmaceutical ladder. Between 1998 and 2002, 85[66] new medicines launched first in the United States; just 44[67] debuted in Europe.

Europe's Descent: It's a Long Way Down

Today, fewer than one in five[68] clinical trials are conducted in Europe. Europe lost its status as the default launch market[69] for new therapies. More than two-thirds[70] of sales from new drug launches occur in the United States, compared to just 15.8%[71] for the five largest EU countries. European patients wait an average of 19 months[72] for access to new drugs. Americans, by contrast, often gain access immediately.

> "Between 1998 and 2002, 85 new medicines launched first in the United States; just 44 debuted in Europe.

The story is similar in Canada, which levies price controls on prescription drugs just as Europe does. Shortages—or a lack of access altogether—are the inevitable result.

According to the Canadian Pharmacists Association[73], "At any given time, there are between 1,500 and 2,000 active drug shortages in Canada."

Research from the RAND Corporation[74] found that just 28% of the 287 drugs launched between 2018 and 2022 across 27 OECD countries were available in Canada at the end of 2022. Patients in Europe had it only slightly better: 43% were available in the United Kingdom and 52% in Germany.

Just under three-quarters[75] of those drugs were available to patients in the United States.

Shifts like these have consequences that are not just clinical but economic, too. Massachusetts[76] alone now attracts more venture-backed biotech investment than the entire European Union.[77]

Europe's long fall from grace is the result of political, not scientific, missteps. Now, as Washington weighs MFN benchmarks and aggressive expansion of the IRA, it flirts with repeating that cycle—this time on American soil. The risk is real. A 2010 study[78] by the University of Connecticut and the University of North Carolina found that European price-setting policies led European drug companies to forgo 46 potential new medicines between

1986 and 2004. Had the United States implemented similar policies during the same period, the researchers estimated a loss of 117 new drugs.

Europe's history offers a simple lesson to American lawmakers—innovators respond to incentives. Price controls might trim spending in the short term. But they destroy the systems that produce new medicines—and allow patients to live longer, healthier lives.

The Path Forward

The American life sciences ecosystem is a product of market principles, where risk is rewarded, competition fuels discovery, and innovation thrives in the absence of price mandates. The Inflation Reduction Act and the resurrection of Most Favored Nation pricing signal a fundamental departure from this model. Together, they mark a pivot toward centralized control, bureaucratic price-setting, and diminished rewards for breakthrough science.

The consequences for American patients will be profound: fewer new therapies, longer waits for treatment, reduced global leadership, and a chilling of the entrepreneurial spirit that has delivered so many lifesaving medicines.

The choice facing our country is stark. We can only hope our leaders choose wisely. If they do not, America will be on the "Road to Serfdom"—and there will be no off ramp.

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