The Myth of the Free Market for Pharmaceuticals

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Critics of U.S. policy aiming to reduce spending on prescription drugs claim that the government is wrongfully interfering with a "free" market. A recent comment from Merck about the 2022 Inflation Reduction Act (IRA) exemplifies industry complaints: "Congress has long been committed to a free-market approach based on market-driven prices. . . . Last summer, however, Congress charted a radical new course."[1] But the modern U.S. pharmaceutical market is not what Adam Smith would have considered "free."

In free markets, consumers are assumed to be fully informed, and it is assumed that they choose products on the basis of their discernable benefits and costs; sellers can freely enter markets and make products similar or identical to others; and prices, set by firms seeking to maximize profits, are competitive with those of other sellers and unmodified by government intervention (see table). The U.S. pharmaceutical market strays from all these features.

The government grants firms patents establishing a drug's monopoly period when no alternative versions can be sold. No drug can be sold without meeting standards for manufacturing quality, safety, and efficacy and attesting to these features on its label, which curtails competition. Although a drug's active-ingredient patents last 20 years, firms commonly obtain additional exclusivity rights, potentially extending monopolies to 35 years.[2]

Consumers are not well informed: patients rely on doctors to recommend drugs and on insurers to determine access. Though doctors are educated to understand a drug's clinical properties, they're often unaware of the costs and therefore rarely assess drugs' economic value to patients when prescribing. Unlike policies in most countries, U.S. policy permits firms to advertise drugs, but ads need not discuss price — and are often misleading.

Most consumers are insured,

Free-Market Features According to Economic Principles versus the U.S. Market for Pharmaceuticals.

Variable	Free-Market Feature	U.S. Pharmaceutical Market
Consumer behavior	Patients are fully informed purchasers who can easily discern a product's benefits and costs.	Patients are not fully informed. Doctors and patients may be influenced by advertising, detailing, and insurance policies. Insured patients are not as price responsive as uninsured patients. Doctors, pharmacy benefit managers, and health plans may profit from patients using higher-priced drugs.
Producer behavior	New firms can freely enter the market and produce products similar to those offered by other firms.	Government patents and market-exclusivity rights are granted to firms, restraining market entry and competition. Government rules restrain market entry of drugs on the basis of manufacturing quality, safety, and efficacy. Labels must accurately reflect drug ingredients and clinical benefits.
Prices	Prices are set by competing firms selling related products, unfettered by government intervention.	Firms selling brand-name drugs have government-granted patent and market-exclusivity rights, which provide them monopoly pricing power. Government policies underwrite costs of new drug discovery and development. Government policies require firms selling drugs to provide discounts and rebates to selected purchasers or withdraw from public insurance coverage.

and insurance is publicly subsidized. Firms can therefore charge high prices: if a drug is worth $100 to patients who pay only 20% of the price, the firm can charge up to $500 without having patients balk. Doctors may be financially rewarded for using more expensive drugs even when less expensive drugs are equally effective: doctors may be paid an administrative fee, based on a drug's cost, for delivering it, and pharmacy benefit managers and insurers may receive payments for providing favorable access to expensive drugs.

The net effect of these deviations from the free-market ideal is that prices are high, compromising affordability. The United States is the largest market for drugs and pays the highest prices in the world. Some firms increase prices greatly for years after launch.[2] The United States thus favors producers over consumers by allowing the industry to take more than its share of drugs' economic value.

Policy has promoted affordability by expediting the availability of generic drugs that are of the same quality, safety, and efficacy as brand-name drugs and produced by competitive firms. The Drug Price Competition and Patent Term Restoration Act of 1984 amended regulations on patents and exclusivity to facilitate the sale of generic drugs while ensuring that brand-name drugs had adequate time to recoup their investment. These amendments have resulted in a robust generics market. In 2010, the Biologics Price Competition and Innovation Act established an abbreviated pathway for biosimilar approval to encourage biologics competition.

Policy has also expanded insurance coverage to reduce consumers' costs. The Medicare Modernization Act in 2003 established Medicare coverage for drugs dispensed by pharmacies. The Affordable Care Act (ACA) in 2010 extended insurance access to millions of previously uninsured patients. Both policies reduced out-of-pocket costs among newly insured people. Industry profits grew thanks to increased drug sales.

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Although private firms bring new drugs to market, the government contributes to their creation by supporting the underlying basic science and providing grants and training to researchers who may go on to work in the industry. The science of drug discovery and development has become more complex, risky, and costly and more research and development is being undertaken, thanks to this government support. The Orphan Drug Act in 1993 provided financial incentives to attract industry interest in drugs for rare diseases, including expanded exclusivity periods and tax credits of up to 50% for research-and-development expenses. More than 50% of new drugs are now approved with orphan disease indications.[3] The Human Genome Project, the Cancer Moonshot, and the Cures Act underwrite private-firm costs, contributing to the development of precision medicine.

The IRA is the latest policy aimed at improving drugs' affordability for Medicare, its beneficiaries, and taxpayers. Previous policy changes have not done enough to reduce overall drug prices, as opposed to just the portion consumers pay — a mistake, in our view.

Seniors use most of the drugs that are sold, and though most of this use involves inexpensive generic drugs, Medicare pays much higher prices for brand-name drugs than do state Medicaid plans, other government purchasers, and international public payers.[2] High Medicare prices cause affordability challenges for beneficiaries who require treatment and for taxpayers. Medicare has had no role in establishing prices at a drug's launch. Unlike U.S. commercial insurers and payers in other countries, Medicare pays for drugs even when evidence suggests they have limited benefit or may not be cost-effective.

The IRA addresses some of these concerns. Perhaps most controversially, it gives Medicare authority to negotiate prices for some high-priced brand-name

drugs. Negotiations with participating firms for the first group of drugs began in 2023, and the negotiated prices go into effect in 2026. The first 10 drugs eligible for negotiation are taken by about 9 million beneficiaries for conditions such as blood clots, diabetes, cardiovascular disease, heart failure, and autoimmune diseases and accounted for $50.5 billion in Part D spending between June 2022 and May 2023.[4] They also accounted for $3.4 billion in out-of-pocket spending by beneficiaries in 2022. Medicare will select for negotiation additional drugs covered under Part D for 2027, up to 15 drugs covered under Part D or B for 2028, and up to 20 drugs covered under Part D or B each year after that.

Negotiation is intended to return some bargaining power to taxpayers so that Medicare pays prices for selected drugs with extended market-exclusivity periods that are closer to those one might pay in a better-functioning market. The forecasted reductions are 30 to 70% off current prices. The IRA's negotiation methods are like those used by the Veteran's Administration, the Department of Defense, state Medicaid agencies, and other countries to obtain affordable drug prices.

In targeting long-lived brand-name drugs accounting for high spending, the IRA aims for effects similar to those of policies promoting cost savings by means of generic or biosimilar competition. The initial drugs selected for negotiation reaped cumulative revenue after launch that far exceeded their development costs.[5] Some companies have already avoided negotiation by allowing generic and biosimilar competition to occur. The IRA also limits price increases for brand-name drugs to the rate of increase in the consumer price index, imposing on Medicare a restraint already operative in state Medicaid plans and some other countries.

The IRA leaves in place ample opportunities for firm profitability, maintaining incentives to invest in new drugs. It does not restrict launch prices and limits negotiation to drugs without significant competitors. It also caps out-of-pocket costs for high-priced products, including drugs for diabetes and cardiovascular disease, which will boost their sales; and it eliminates out-of-pocket costs for vaccines for adults. It exempts from negotiation drugs that are only approved to treat orphan diseases. And it doubles the research-and-development tax credit for small pharmaceutical companies and expands the conditions for its use.

The expected net effect of these reforms is slowed spending on drugs by Medicare and its beneficiaries, without substantial effects on firms' revenues or innovation incentives. Commercial insurers and employers may also benefit by incorporating negotiated drug prices into their policies.

The U.S. pharmaceutical market has always been a construct of government, not a free one. Government policy aims to establish rules that promote expanded access and improved affordability while supporting the development of new drugs that improve patient and population health. The IRA is the latest policy attempting to balance these goals. It will not be the last.

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