

Pharmaceutical Pricing: Lessons from Abroad

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IN BRIEF **What's the issue?** Pharmaceutical prices in the United States are extraordinarily high and have contributed to an unsustainable level of spending on drugs. The U.S. spends more on pharmaceuticals than any other developed nation in the world: \$1,010 per capita, representing 12 percent of total health spending. Spending on specialty drugs—which accounts for a disproportionate share of the total—is high and expected to grow, from \$87 billion in 2012 to \$400 billion by 2020. Unlike many countries, the United States does not have broad policies or regulations to negotiate or control pharmaceutical prices, which many believe has led to sky-rocketing prices.

What has the U.S. done to regulate prices? The Veterans Health Administration and the Medicaid program receive statutory drug discounts, but private health insurers must individually negotiate prices with manufacturers, and the federal government is legally barred from any type of price negotiation in Medicare. In the past, federal policy approaches to rein in prices have not been successful. Notable examples include the attempted establishment of a federal advisory council to evaluate the “reasonableness” of new drug prices, which failed with President Clinton’s *Health Security Act*, and provisions to import drugs from abroad and give the federal government power to negotiate prices for drugs purchased under Medicare Part D, which was not included in the final version of the *Medicare Prescription Drug and Modernization Act*.

What have other countries done to regulate prices? Other countries employ a variety of tactics to control or negotiate pharmaceutical prices. For example, the Australian government directly negotiates prices with manufacturers via the Pharmaceutical Benefits Scheme. The United Kingdom negotiates maximum profit margins and growth in prices in the Pharmaceutical Price Regulation Scheme. And Germany establishes reference prices for entire groups of therapeutically-similar drugs. See table on page 2 for additional details.

What would happen if the U.S. adopted policies similar to those abroad? If the U.S. adopted policies similar to those abroad, pharmaceutical spending would likely go down. However, critics say these policies would also stifle innovation. Research shows that pricing policies can have an impact on research and development spending. But the real policy question that should be evaluated is whether reduced R&D spending stifles the development of medicines that have a true net benefit to society. Pharmaceutical companies tend to invest in drugs that are profitable, but what is profitable is not always the most beneficial to society. Policymakers must ensure companies have incentives to manufacture drugs that have an overall value that is clearly correlated to the price of the drug.

What are the next steps towards implementing pharmaceutical price policies? Policymakers must be open about the consequences of pricing policies and make an honest effort to determine what tradeoffs society is willing to make. In addition to thinking about the effect of policies on innovation, they must ask: What effect would these policies have on the domestic and global economies? How would public opinion influence the debate? To what extent does the structure of our current health care system lend itself to robust pharmaceutical price regulation? Should we focus on making market more competitive, rather than introducing price regulations? Although these are challenging questions to address, the urgency of the pharmaceutical pricing dilemma necessitates action.

COUNTRY PROFILES

Country	Australia	Germany	United Kingdom	United States
Percentage of GDP spent on health care	9.1%	11.30%	9.3%	16.9%
Health care spending per capita (USD)	\$3,997	\$4,811	\$3,289	\$8,745
Pharmaceutical spending per capita (USD)	\$588	\$668	\$367 (2008)	\$1,010
Health care system	<p>Universal public health insurance program (Medicare). Private health insurance for non-covered services and out-of-pocket costs also available. Approximately 50% of population has purchased private health insurance.</p> <p>Federal government primarily funds services and to a lesser degree provides care. Comprehensive package of services, including pharmaceutical benefits.</p>	<p>Mandatory, statutory health insurance system (SHI) which is comprised of competing, non-governmental insurers of "sickness funds." Eleven percent of the population buys full-coverage private insurance. Employer and employee contribute equally to sickness funds. Benefits package is comprehensive across all levels. Government has very little role in direct financing or delivery of health care.</p>	<p>Universal, publicly funded health insurance. Health care services are provided free of charge to UK citizens, with the exception of prescriptions, dental care and eye care, which are subject to co-payments in England (although co-payments can be waived or reduced for low-income and other vulnerable patients.) About 8% of population has private insurance to get speedier access to services and get elective procedures.</p>	<p>Private insurance covers 56% of population. Offered by employers or purchased individually through exchanges, with subsidies available to lower income enrollees. Seniors and some disabled persons covered by Medicare. Veterans covered by Veterans Health Administration. Some low-income groups covered by Medicaid. Coverage is mandated for most people (~13% remain uninsured.) Benefit designs (incl. premiums, coinsurance and copays) vary between plans.</p>
Cost containment policies	<p>The government has near monopsony on purchasing patented medicines, which combined with strict prescribing requirements, allows for a high level of control in pharmaceutical pricing.</p> <p>New drugs have to meet cost-effectiveness criteria and negotiated pricing to be included on formulary for publicly subsidized medicines.</p>	<p>All drugs, patented and generic, are placed into groups with a reference price serving as a maximum level for reimbursement. If drug is deemed to have added benefit by the Institute for Quality and Efficiency, then price negotiations ensue between manufacturer and Federal Association of Sickness Funds. Physicians are financially liable if they exceed "regular" volumes for their patient mix above the prescription cap</p>	<p>Main policy is the Pharmaceutical Price Regulation Scheme (PPRS), a voluntary agreement between the government and industry which sets maximum profit margins and annual growth rates in prices. Drugs not covered by the PPRS are subject to the statutory scheme, which mandates 15% discount on list prices. UK uses drug formularies—largely based on assessments from the National Institute for Health and Clinical Excellence—and incentives for prescribing generics.</p>	<p>Medicaid and the Veterans Health Administration have statutory drug discounts. Federal government legally barred from negotiating prices in Medicare (only private Part D administrators can negotiate.) Private health insurers and other drug purchasers individually negotiate prices. Health plans use patient cost-sharing, formularies, preauthorization, "fail first" policies, and drug tiers to help control costs.</p>
Considerations	<p>The practice of revealing the proposed price of a competitor drug (following expiry of a patent) provides opportunities for cost containment and competition. Is this level of transparency achievable in other countries?</p>	<p>Use of comparative effectiveness analyses integrates value into the price equation, and sends a signal to encourage innovations that benefit patients. Is it possible for the US to employ a value-based approach to drug pricing?</p>	<p>The UK attempted to include value-based purchasing in the 2014 PPRS, but industry blocked it in favor of using maximum annual price growth percentages. Does this mean that value-based pricing can only be achieved in absence of other robust policies?</p>	<p>Previous efforts to establish price regulations have failed. Fierce opposition to advisory councils, drug importation and ability for federal government to negotiate prices. Even if pricing regulations are established, may not make a huge impact given fragmented system of care.</p>

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