Institute for Health Policy

Pharmaceutical Pricing: Lessons from Abroad

PREPARED BY THE KAISER PERMANENTE INSTITUTE FOR HEALTH POLICY



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The U.S. Compared to Three other Nations on Pharmaceutical Spending

The high price of pharmaceuticals in the United States is not a new problem, but the national dialogue on this issue has been reinvigorated as spending on drugs—particularly specialty drugs, such as breakthrough Hepatitis C treatments

Sovaldi and Harvoni—has substantially increased. Overall, the United States spends more on pharmaceuticals than any other country in the world: \$1,010 per capita, representing 12 percent of total health spending.¹ 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 2020.²

COUNTRY PROFILES 2012				
Country	Australia	Germany	United Kingdom	United States
Population (millions)	22.724	80.426	63.696	313.914
GDP (trillion USD)	\$1.04	\$3.54	\$2.45	\$16.77
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
Out-of-pocket health care spending per capita (USD)	\$731	\$627	\$297	\$1,045
Life expectancy (years)	82	80	81	79

Source: OECD Health Statistics 2014. http://www.oecd.org/els/health-systems/health-data.htm

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Unlike many countries, the United States does not have broad policies to negotiate or control pharmaceutical prices. Although the Veterans Health Administration and the Medicaid program limit the prices companies can charge for drugs via statutory discounts, private health insurers individually negotiate prices with manufacturers, and the federal government is legally barred from any type of price negotiation in Medicare (only private entities administering Part D plans are allowed to negotiate.)³

Several attempts have been made over the past few decades to establish pricing policies without success. For example, President Clinton's *Health Security Act* of the early 1990s would have established a federal advisory council to evaluate the "reasonableness" of new drug prices and given the Secretary of Health and Human Services the ability to deny Medicare coverage for drugs deemed to be overpriced.⁴ The pharmaceutical industry and some members of the Congress fiercely opposed such a council, and it ultimately failed with the Act itself. In 2003, Democrats attempted to include provisions in the *Medicare Prescription Drug and Modernization Act* that would have allowed importation of drugs from abroad and given the federal government power to

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negotiate prices for drugs purchased under Medicare Part D. Neither provision was included in the final law, although several bills since then have sought to give the government authority to negotiate or to require discounts for low-income beneficiaries.⁵ President Obama's FY 2016 budget proposal recommends that the federal government be allowed to negotiate drug prices in the Part D.

Despite these unsuccessful attempts, many stakeholders remain committed to addressing the high price of pharmaceuticals in the United States. Indeed, there is renewed focus on how the government can—and whether it should—intervene in a market that seems to have spun out of control with the pricing of the latest specialty drugs. Moreover, many believe the government—which is itself a purchaser of pharmaceuticals—has an ethical imperative to act if it is to be a good steward of taxpayer dollars. As proposals are considered in the United States, case studies from other similarly situated countries can be informative. In this brief, we outline pharmaceutical pricing policies in three countries: Australia, Germany and the United Kingdom. We conclude by reviewing the evidence on the impact of price regulation on innovation and outlining key questions that should be raised as proposals are debated.



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AUSTRALIA

The Australian health care system

Australia's mandatory national public health insurance program, Medicare, provides coverage for all citizens and permanent residents, as well as people from countries with which Australia has reciprocal relationships. Private health insurance for non-covered services and

out-of-pocket cost sharing is also available. As of June 2014, about 50 percent of the population had private health insurance. The federal government is primarily a funder of health services; only to a lesser degree does it provide services. In addition to Medicare, the federal government pays for pharmaceutical benefits, and in conjunction with states and territories, funds public hospitals and population health programs. The federal government also has a strong regulatory function over medical services (public and private), pharmaceuticals, private health insurance, as well as government-subsidized residential care facilities.

Medicare covers a comprehensive package of services with no cost sharing for inpatient care in public hospital, optometry, and allied health if referred by a doctor. Physicians may choose to charge copays at their discretion but do not for the vast majority of primary care and diagnostic services. Cost sharing (including deductibles) is more prominent for surgical procedures and pharmaceuticals. According to the 2014 *Commonwealth Fund International Profile of Health Care Systems*, direct out-of-pocket payments accounted for almost 18 percent of total health care spending in 2012-13, of which 40 percent was spent on drugs.⁶

Two main government agencies oversee the health and health care needs of the population – the Council of Australian Governments' Health Ministers Conference and the Department of Health. Other entities include the National Health and Medical Research Council, which produces clinical guidelines. The Therapeutic Goods Administration (TGA) in the Department of Health is responsible for ensuring that therapeutic goods (over the counter and prescription medications, vaccinations, and blood products) are safe. The TGA conducts technology assessments and classifies drugs based on risk, quality, safety, and efficacy. Once approved and available for supply, the TGA conducts post-marketing surveillance activities.

How drug costs are contained

Australia operates a national purchasing scheme called the Pharmaceutical Benefits Scheme (PBS) that has been in operation since the late 1940s and is part of

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the government's broader National Medicines Policy. Approved pharmaceuticals are made available for sale via the PBS. Once listed, drugs may be prescribed and supplied at the fixed price set by the PBS.⁷

This copayment for drugs is the same regardless of the price of the drug (if the price of the drug is less than the copayment, no benefit is paid). The list of covered drugs is on-line and updated monthly. The PBS operates as a monopsony with the government able to bring significant market pressure into pricing negotiations because it is willing not to cover certain drugs. The result is prices that are relatively low by U.S. standards. In the literature, Australia is described as having a "mature generic pharmaceuticals market". Other explanations include the publication of agreed-upon prices by health insurance funds with their providers (private hospitals and doctors).

Considerations

Australia has historically boasted low pharmaceutical costs and prices. Currently, there is a lively public debate as to whether or not the government is getting the "maximum" advantage from its monopsony leverage, with concerns expressed about alleged "sweetheart deals" being brokered with the pharmaceutical industry both in relation to pricing and "evergreening" of patents to keep powerful (American) interests happy. Some Australian observers continue to express concerns over concessions made in the Australia-United States Free Trade Agreement (AUSFTA), which includes provisions that may negatively impact the PBS' ability to ensure equitable and affordable access to medications. For example, the agreement includes: strong emphasis on rewarding and enhancing the rights of manufacturers of "innovative" new drugs; intellectual property provisions that cause delayed entry of cost-effective generics; transparency provisions that allow U.S. pharmaceutical applicants to request an independent review of a PBS decision, an option that is not available to consumer or public health organizations; the ability for pharmaceutical companies to disseminate drug information on web sites frequently used by Australian patients, circumventing Australia's laws against direct-to-consumer advertising.^{8,9}

As the pharmaceutical market becomes more global, and with rising health expenditures, there is a strong case for efficient pricing of pharmaceuticals. As such, Australia has chosen to focus on providing what some may argue is a reduced set of therapeutically important drugs for its population, along with timely access to medications that the population needs, and at a cost that individuals can afford. However, the quality of the drugs—which meet national regulatory requirements and World Health Organization standards—is not being questioned.







GERMANY

The German health care system

Germany has a statutory health insurance system (SHI) in place and coverage is universal for all legal residents. The system comprises 124 competing, statutory insurers or "sickness funds" that operate like private companies and bear risk for their insured populations. Germans

also have an option to purchase private health insurance (PHI) in addition to or in place of SHI. About 86 percent of the population receives primary coverage through SHI and 11 percent through PHI. SHIs are funded by mandatory contributions of 15.5 percent of gross wages (divided equally between employers and employees) up to a pre-determined amount of U.S. \$62,020 annually. A small share is paid by general revenues. SHIs may charge an additional premium if they deem their revenue from contributions insufficient.

Government has little to no role in the direct financing or delivery of health care, with most regulation delegated to self-governing associations of SHIs, and to provider associations. SHI-contracted physicians may not charge above the fee schedule for core comprehensive SHI benefits but patients may pay out-of-pocket to receive some other services. In addition, adults' cost sharing is capped at 2 percent of household income (1 percent for people designated as chronically ill), and children under eighteen years of age are exempt from cost sharing. Most out-of-pocket spending is for psychotherapy, vision aids, medical aids, and pharmaceuticals, dental care, and elective services. Prescription drugs are dispensed at no cost; a typical copayment for an outpatient prescription is U.S. \$6.50.

A distinct feature of the German health care system is its key governance entity, the Federal Joint Committee (GBA). The GBA, formed by representatives from self-governing associations of payers and providers as well as patient delegates, has far-reaching regulatory power to determine the covered services in both SHI and PHI and sets quality measures for providers. GBA commissions the Institute for Quality and Efficiency in Health Care (IQWiG) to evaluate the effective-ness of new drugs and therapies against existing treatments. Coverage decisions are determined by evidence from the IQWiG's Health Technology Assessments (HTA) and reviews of comparative-effectiveness. Some purchasing powers have been granted directly to the SHIs. For example, they may contract with select providers in an integrated care contract or negotiate rebates with pharmaceutical companies.

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How drug costs are contained

Prior to the Pharmaceutical Market Restructuring Act of 2011 (AMNOG), pharmaceutical manufacturers were free to set prices for new medicines brought to the market. Germany had been a leader in the use of generic drugs, but pharmaceutical manufacturers began putting new products on the market to recover revenues lost to generics. As providers prescribed newer and more expensive drugs, legislation was enacted to transform the way in which new drugs were valued and priced, with an overall goal of cost containment. Today, new drugs that do not show added therapeutic benefits are placed into groups with a reference price that caps reimbursement. Once a drug enters the market, manufacturers set the price, valid for one year. If, based on the assessment conducted by the IQWiG, the GBA determines there is no added benefit, then the price is set equal to the cost of the comparator (usually the current therapy). The burden of proof rests with pharmaceutical companies to produce evidence that supports claims of added clinical benefit. If there is added benefit, the new price, valid after one year of market entry, is negotiated between the manufacturer and the Federal Association of SHIs and applied for all patients.

While the AMNOG exempts orphan drugs¹⁰ from this benefit assessment process, the cap has resulted in less spending on medicines that are no more effective than current treatments, while spawning innovation among drug companies to invest in those drugs that improve individual and population health. According to the Commonwealth Fund, "while the pharmaceutical marketing restructuring legislation primarily targets new medicines, it has also paved the way to expand assessments to pharmaceuticals already on the market, medical devices, and medical treatments and interventions in general."¹¹

Considerations

The process of determining additional benefit is complex and extremely laborious for all stakeholders, and engenders feasibility challenges from drug manufacturers, providers, payers, and policymakers alike. In response, some pharmaceutical companies are bringing new drugs to market outside of Germany in order to avoid the clinical assessment of additional benefits.

Still, Germany approves new drugs at a higher rate than many other European countries, with 64 percent of drugs determined to have some added benefit. The jury is still out as to whether these tactics will identify true innovations and lead to fair pricing. However, early clinical benefit assessment and value-based pricing seems to align with where U.S. payment reforms are headed, and as such offers U.S. decision makers something to consider.

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UNITED KINGDOM

The UK health care system

The National Health Service (NHS) is the United Kingdom's universal health care system and has been in place since 1948. Although the NHS is often referred to as a single entity, each nation in the United Kingdom—England, Scotland, Wales and Northern Ireland—operates its own system. The NHS

is almost entirely publicly funded through taxation. In England, 80 percent of NHS funding comes from taxes, 12 percent comes from national insurance and the remaining 8 percent comes from other sources.

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 copayments for these services can be waived or reduced for low-income and other vulnerable patients.) Most UK citizens receive care through the NHS, although capacity issues within the system and demand for elective procedures has supported a private insurance industry that covers about 8 percent of the population.

How drug costs are contained

The United Kingdom employs several policy levers to control pharmaceutical costs: the Pharmaceutical Price Regulation Scheme (PPRS), the statutory scheme, formularies, prescribing budgets, and incentives for prescribing generics.

Pharmaceutical Price Regulation Scheme

The PPRS is a voluntary agreement between the Department of Health and the Association of the British Pharmaceutical Industry and has existed in some form since 1957. The PPRS covers all branded medicines supplied to the National Health Service. In the PPRS, pharmaceutical prices are not directly regulated, but companies are subject to maximum profit margins. The PPRS sets allowances for research and development, sales and marketing, manufacturing costs, general administrative costs, and maximum profit percentages. If a company exceeds the profit margins set by the PPRS, it has an opportunity to justify its profits and alter maximum margins based on innovation expenses, new drug launches, improved drug efficiency, investment in the UK industry and increased exports from the UK.¹²

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Until 2014, the PPRS also applied an across-the-board discount to list prices for drugs. The 2014 PPRS—in effect through 2018—replaced this discount with allowable annual growth rates for drug prices. For years 2014 and 2015, the allowable growth rate is 0 percent. For years 2016, 2017 and 2018, the growth rate is 1.8 percent, 1.8 percent and 1.9 percent respectively. If NHS spending exceeds the allowable growth rate in these years, companies must return the difference in the form of a cash rebate to the government. Importantly, overspending on new medicines (those introduced after January 1, 2014), centrally procured vaccines and medicines needed to prepare for national security reasons or pandemics will not be counted for rebate purposes.

The Statutory Scheme

Pharmaceutical companies that choose not to participate in the PPRS are subject to an alternative statutory scheme that imposes a discount of 15 percent on any product with a list price above £2.00 (\$3.06 USD) per fill. As of 2014, about 10 percent of branded medicines used by the NHS were covered by the statutory scheme¹³ Unlike the PPRS, no negotiations occur between government and industry, and the government has the ability to change the scheme at any time. Over the years, many attempts have been made to increase the discount, and the Department of Health is now considering proposals to raise the discount to 25 percent.¹⁴

Formularies

The NHS uses formularies to limit the availability of drugs to patients. To determine what is included, each nation consults Health Technology Assessment (HTA) entities that evaluate medicines and other technologies.¹⁵ The National Institute for Health and Clinical Excellence (NICE) is the primary HTA entity serving the UK, but Scotland, Wales and Northern Ireland involve additional groups in the assessment process.

NICE makes recommendations based on evidence, cost-effectiveness (primarily using quality-adjusted life years or QALYs, with a threshold of about £20,000-£30,000 (\$30,635-\$45,953 USD)/QALY for pharmaceuticals), and input from patient groups, health professionals, experts and other stakeholders.¹⁶ NHS England and NHS Wales are required to fund all drugs that NICE recommends for inclusion, and these are published in the British National Formulary and the Drug Tariff. Within these lists, there is the "Black List"—drugs that will not be reimbursed under any circumstance—and the Selected List, drugs that may only be reimbursed under some circumstances (for example, for specific diseases or patient groups.)¹⁷ Local health authorities—who are responsible for the provision of most planned hospital care, emergency care and some other services— and hospital trusts may use their own formularies, although they are not necessarily binding and are usually derived from the national formulary.

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Incentives for Prescribing Generics

About 83 percent of medicines prescribed in England are generics, a proportion higher than most other countries in Europe. Two factors contribute to the high use of generics: first, physicians are taught to prescribe by international non-proprietary name (INN), rather than brand name, in medical schools. Second, the UK uses drug budgets to control overall pharmaceutical spend and increase the use of generics. Local health authorities are free to develop policies and practices to encourage the use of generics, such as setting prescribing targets, giving physicians feedback on prescribing behavior, issuing guidelines, and providing financial rewards for prescribing generics.¹⁸

Considerations

The United Kingdom has been interested in pursuing some form of value-based purchasing to slow growth in pharmaceutical spending. The government originally intended to introduce value-based pricing in the 2014 PPRS, but industry successfully fought this proposal in favor of using maximum growth rates. The government is continuing its pursuit by looking into the use of "value-based assessments," which would add two additional factors to NICE cost-effectiveness evaluations: burden of illness and wider societal benefits. In addition, economists at the University of York have recently suggested that the cost-effectiveness threshold of new drugs be reduced from £30,000 (\$45,953)/QALY to £13,000 (\$19,913 USD)/QALY.

CONCLUSION

Implementing pharmaceutical controls has helped countries rein in their health care spending. Critics of these policies and regulations, however, contend that they have also stifled innovation. In 2004, the U.S. Department of Commerce analyzed the effects of international pharmaceutical price controls in eight OECD (Organisation for Economic Co-operation and Development) countries, and estimated that spending on research and development was reduced by 11 to 16 percent annually due to lost revenue. The Department further asserted that deregulating foreign prices would increase the number of new molecular entities by three to four per year.¹⁹ Similarly, a literature review commissioned by the Institute of Medicine showed that implementation of price controls in the United States would lead to reduced investment in R&D.²⁰

There are some caveats to this research and to the notion that regulations can negatively impact R&D spending. First, studies may rely on R&D spending data reported by pharmaceutical companies, but there is evidence that companies overestimate the amount they actually spend. For example, a 2011 analysis by Light and Warburton found that median R&D costs for producing a new drug were about \$43 million, far from the \$802 million figure quoted by the pharma-

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ceutical industry.²¹ Second, research has revealed that pharmaceutical prices for some drugs (such as cancer drugs) are more closely tied to what the market will bear, rather than to the costs associated with development or to the value the drugs provide over existing therapies.²² In a similar vein, the Wall Street Journal recently reported that the list prices of two heart drugs—Nitropress and Isuprel—rose by 525 percent and 212 percent simply because the rights were purchased by a new manufacturer, who said their duty was to "maximize the value" for its shareholders.²³ Taken together, this suggests that a cut in prices can cut into profits, but it does not automatically mean that R&D budgets are affected.

That said, if we assume regulations can have some impact on overall R&D spending, 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. The pharmaceutical industry invests in drugs that will return the most profits, but outside of competitive markets, what is profitable to pharmaceutical companies may not always be what is most beneficial to society. And so we must ask: if price regulations were implemented in the United States, and R&D spending declined, how could we ensure that companies continued to invest in beneficial drugs?

Other questions that policymakers need to consider are:

- What impact would the loss of pharmaceutical revenue have on U.S. jobs and the overall economy? Pharmaceutical companies—like many companies in the United States—are increasingly relocating to countries with more favorable tax laws; could regulations speed up the exodus?
- What effect would policies have on the global market? Many argue that the United States is a victim of cost-shifting because price policies in other countries are so strong. While companies may have lower revenue in other markets, they are able to make up the difference by increasing domestic prices. If we implemented polices, how much would that impact global pharmaceutical revenues? Would other countries face greater pressure to pay more for drugs?
- How easily can the American public be swayed by anti-regulation arguments? Surveys show that public trust in pharmaceutical companies is relatively low, but could this change?²⁴ The public may not have an issue with policies that have a direct impact on pharmaceutical profits, but things like cost-effectiveness evaluations or value-based purchasing could be met with significant public criticism.
- To what extent does the structure of our current health care system lend itself to robust price regulation in pharmaceutical markets? Pricing policies in other countries may be successful in large part because their governments

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have strong purchasing power. The U.S. government does not enjoy the same power in our fragmented system of care.

• Is price regulation the only solution? Some argue that increasing market competition is a better approach than introducing drug pricing policies and regulations. A market-based approach could involve: increasing consumer price sensitivity (currently, consumers are shielded from the true cost of drugs due to limits on cost sharing and regulations on the use of formularies and benefit design), increasing price transparency (including costs of manufacturing and development), creating greater competition from generics (for example, by reducing patent terms), and reducing price discrimination (for example, by eliminating mandatory discounts in the Medicaid program, which would create a more level playing field among purchasers.)

No silver bullet exists to solve the pharmaceutical pricing dilemma. Any policy will have both positive and negative effects. And yet, taking no action because of the fear of negative consequences is not an option. Rather, policymakers must be open about the consequences and make an honest effort to determine what tradeoffs society is willing to make.

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