National Coalition on Health Care Policy Priorities: U.S. Drug Pricing and the German Model

The United States and Germany

As drug prices continue to rise, policymakers debate drug pricing reform. The United States spends more on prescription drugs per capita than any other developed country. For example, Germany spends an average of $685 on retail prescription drugs per capita, while the United States spends over $1,000. Yet, Germany has a similar health care system to the United States. The government has a limited role in the delivery of care and workers usually receive insurance through statutory health insurance paid for by both the worker and the employer. Further, patients are responsible for copayments and deductibles. The German model affirms that drug prices can be lowered in a privatized health care system.

Table 1. Similarities in the US and Germany Health System

The United States	Germany
Health insurance is not mandatory, but citizens may qualify for a range of subsidized or publicly financed programs (Medicare, Medicaid), or subsidized private insurance depending on geographic location and income level	Health insurance is mandatory, but some citizens are eligible to opt out of statutory health insurance (SHI) for private insurance (PKV) (e.g., those who make more than $68,000 per year)
Multi-payer health care delivery system, primarily via privately-run health insurance companies, except most Americans over 65 (Medicare) or the poor who meet conditions for state insurance (Medicaid)	Multi-payer health care delivery system, primarily via privately-run health insurance companies
Government has limited role in the direct delivery of care, but has regulatory authority	Government has limited role in the direct delivery of care, but has regulatory authority
Co-payments and deductibles range greatly depending on the type of coverage (Medicare, Medicaid, or private insurance) – some programs have caps and others do not	There are capped co-payments and deductibles for inpatient services and drugs
Drug coverage decisions range depending on the plan's formulary and pre-determined covered services	Coverage decisions are based on evidence from comparative-effectiveness reviews
Drug pricing process does not prioritize demonstrated medical benefit	Transparent drug pricing process based on demonstrated medical benefit
A large and innovative pharmaceutical system	A large and innovative pharmaceutical system
Hospitals are a mixture of for- or non-profit, privately run or public hospitals. Public hospitals are about 19% of hospitals.	Hospitals are a mixture of for- or non-profit. Public hospitals make up about 50% of beds.

Source: The Commonwealth Fund

The German Model

The German health care system has drastically lower drug prices than the United States while maintaining quality of treatment, access to treatment, and innovation. The German health system features 110 sickness funds, which cover nearly 90% of the populations. Sickness funds, like Medicare Advantage plans in the United States, are privately operated, receive risk-adjusted payments from the government to manage population health, and they compete on quality and supplemental benefits. Most Germans receive health care coverage through their employer, financed via a payroll tax. In Germany, health care coverage is connected to your employment, but you do not lose your coverage if you become unemployed like in the United States.[1] Germany does not have any governmental health insurer, unlike the United States, which has Medicare and state-based Medicaid plans. In Germany, manufacturers and sickness funds negotiate drug prices, where both sides are under public pressure to negotiate the fairest price without sacrificing innovation.

How Prices are Negotiated in Germany

Prices are negotiated through a single buyer, or GKV-SV, the organization representing the sickness funds, and the manufacturer. Both sides are under pressure to negotiate a fair price. Every negotiated or arbitrated price is public knowledge, so consumers understand the mechanisms and evaluation criteria used to determine the price. When a drug is authorized by the EMA, manufacturers have freedom to price the drug with limited restrictions. However, during this first year, the G-BA conducts medical benefit assessments on the drugs, and the GKV-SV negotiates prices. These new prices are applied to the drug in the following years.

The following steps outline the German pharmaceutical pricing scheme:

1. The European Medicines Agency (EMA) authorizes new drugs for launch (similar to the American FDA).
2. The Institute for Quality and Efficiency in Health Care (IQWiG) collaborates with the Federal Joint Committee (G-BA) to evaluate these drugs and the comparative effectiveness of these therapies. The evaluation also considers input from manufacturers, patients advocacy groups, and provider groups.
3. The G-BA designates a drug as offering: major, moderate, minor, positive but nonquantifiable, or no incremental benefit compared to existing therapies.
4. Manufacturers establish an initial list price for the new therapy.
5. Sickness funds, then negotiate a new price for the therapy via an organization known as GKV Steinerian (GKV SV). The negotiated price depends on the G-BA's evaluation, the drug's comparative effectiveness, and the price of similar therapies.
6. If a drug has no added benefit, its price is subject to reference pricing based on existing drugs in the same class.

[1] Although Americans can elect to keep their coverage under the Consolidated Omnibus Budget Reconciliation Act (COBRA), the premiums for this are often cost-prohibitive when the employer does not keep subsidizing the employee's total out-of-pocket premium

The German system protects payers from high drug prices because prices are pre-negotiated between the payers and the manufacturers. Pharmacy benefit managers (PBMs) in the United States serve as an intermediary between the manufacturer and the purchaser. However, in Germany, negotiations occur directly between the association representing all sickness funds, or GKV-SV, and the manufacturers.

The German pricing system does not limit access for consumers. In fact, lower prices allow German consumers broader (and more straightforward) access to prescription drugs, primarily because there is no gatekeeping. Unlike the United States, the German system does not rely on prior authorization or step therapy to restrict physicians' prescribing. The German system provides physicians with guidance and relevant information on new drugs, such as the G-BA's assessment and safety recommendations, which allows physicians to make educated decisions.

In addition, German patients pay 10 euros, or about $11, for each prescription, even those that are traditionally more expensive in the United States. Because the United States does not rigidly restrict the out-of-pocket costs of consumers, prescription costs are much higher for the average person with prescriptions. For example, in the United States, people ages 65 to 79 pay an average of $456 out-of-pocket for prescription drugs. Interestingly, manufacturers benefit from the German drug pricing system as well: they can introduce novel drugs to the market while charging higher prices if they can prove demonstrated medical benefit.

Unlike the United States, all stakeholders benefit from the Germany drug pricing scheme.

Source: The Commonwealth Fund

Binding Arbitration in Germany and the United States

What happens if the manufacturer and the insurers do not agree on a price? In such a case, the drug price enters arbitration. Since 2011, the German pharmaceutical scheme has assessed and priced 230 drugs. However, only 35 drugs went to arbitration. This demonstrates that, usually, the pharmaceutical system in Germany uses a fair pricing structure that satisfies both the manufacturer and the sickness funds. However, if the manufacturer and the sickness funds cannot agree upon a price, then the drug's price is reviewed by an arbitration panel with representatives from both parties. If the manufacturer does not agree with the arbitrated price, then they can withdraw their product from the market. Yet, if a manufacturer withdraws their product, they lose out on a large and profitable market share in Germany. In the United States, binding arbitration could be used to settle disputes of high-costing Part D drugs.

United States Policy Proposals

The United States is considering a variety of proposals to address high drug prices. The Senate issued the Prescription Drug Pricing Reduction Act (S.2543), "PDPRA" or the Grassley-Wyden bill, while House Democrats released the Elijah E. Cummings Lower Drug Costs Now Act (H.R.3). Both bills address drug pricing reform differently but have some overlapping policies. For example, both the Grassley-Wyden bill and H.R.3 advocate for Medicare Part D benefit redesign with a cap on out-of-pocket cost and inflation-based limits on Part B and Part D drugs. The Grassley-Wyden bill requires Part D plans to offer concessions and fees to negotiate the price beneficiaries pay out-of-pocket. Comparatively, the H.R.3 bill allows the Health and Human Services (HHS) Secretary to negotiate drug prices for select number of high-priced drugs based on an international reference price. Government negotiation of prices has long been a controversial policy option.

In July 2020, the Administration released executive orders (EOs) that focus on reducing drug prices. The EOs allow for the importation of drugs, allow the HHS Secretary to withhold funds from federally-qualified health centers (FQHCs) if they fail to set prices for certain drugs, and direct the HHS Secretary to sign the 2019 Proposed Rule requiring payers and pharmacy benefit managers (PBMs) to pass along rebates directly to consumers.

Although the above bills and executive action may lower some drug prices, or shift costs around, none of these proposals resemble the Germany pharmaceutical pricing model. H.R. 3 allows for negotiation, but negotiation is not completed by an independent, objective process to set prices based of demonstrated medical benefit.

A relevant distinction between the United States and Germany is direct to consumer advertising (DTCA); Germany does not allow DTCA and the United States does (one of only two countries to do so in the world). There are mixed theories on the relationship between DTCA and prices (in theory they could increase competition and lower prices, but also spur unnecessary demand). Based on price comparisons between countries, research and development alone does not account for high prices in the United States.

Key Takeaways and Policy Recommendations

The United States health system resembles the Germany health system in many respects, yet Germany has drastically lower drug prices than the United States. Germany uses an outcomes-based drug pricing scheme that values quality and rewards true innovation. Multiple stakeholders inform the negotiation processes between the sickness funds and the manufacturers, therefore negotiated prices take in account stakeholder opinions, clinical benefit, and innovation. The German system also discourages high drug prices for novel treatments with no proven improvement or outcomes as compared to existing therapies.

The German drug pricing system has also been accepted by manufacturers, sickness funds, patient advocacy groups, and broader society. Because each stakeholder benefits differently from the German system, policy experts believe that the United States can benefit from adopting a drug pricing system similar to Germany. The National Coalition on Health Care (NCHC) believes that the following policy recommendations would lower drug prices and improve the quality of care:

- Adopt a drug pricing scheme similar to the German model that prioritizes quality, demonstrated medical benefit, and innovation.
- Conduct and assess incremental clinical benefits of new drugs and use this information to directly inform drug prices.
- Use binding arbitration to evaluate prices if successful negotiation between insurers and manufacturers cannot be achieved.
- Reform cost-sharing responsibilities for Part D drugs and change the Part D reinsurance program.