



Lower Prices and Greater Patient Access — Lessons from Germany's Drug-Purchasing Structure

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Drug prices are lower in Germany than in the United States, despite similarities between the two countries in terms of average household income, reliance on private in addition to

public health insurance plans, and cultural preferences for negotiation over regulation.¹ The experience of Germany and other countries has traditionally been dismissed as politically irrelevant to the United States, but this sentiment has changed over the past year as drug pricing has become a salient theme in the 2020 presidential election. President Donald Trump has contributed heavily to this shift with his proposals to align U.S. prices with those in other countries. The Senate Finance Committee has developed bipartisan legislation that would sharply limit a manufacturer's ability to raise a drug's price after its initial market launch, and the House of Representatives has passed legislation

establishing a structure for Medicare to negotiate prices with manufacturers. These proposals share important features with each other and with the German structure for determining drug prices. Important features of the German system include limits on postlaunch price increases and rules prohibiting insurers from imposing prior-authorization requirements and other access barriers on patients.

In Germany, all new drugs are covered by insurance and are available for physicians to prescribe immediately upon receiving marketing authorization from the European Medicines Agency (EMA). Manufacturers are paid list prices for drugs for the first year after market launch. During this year,

each drug is subject to an additional clinical analysis in which it is compared with existing treatments for the same indication. These assessments are conducted by the Joint Federal Committee (Gemeinsamer Bundesausschuss [G-BA]), a semipublic entity governed by associations of health insurance plans, physicians, hospitals, and patient advocates.

Once this assessment is complete, the manufacturer and the association of health plans negotiate a price for the drug. Individual health plans do not conduct their own clinical assessments, set coverage criteria, or negotiate prices. The factors considered during negotiation, which are set by statute, include the magnitude of the new drug's incremental clinical benefit over a selected existing treatment option, the price of the comparator treatment, and the prices charged for the new drug and its comparator in other European countries.² Germany

does not measure clinical effects in terms of quality-adjusted life-years (QALYs), use cost-effectiveness analysis to compare incremental benefit with incremental cost, or demand price reductions for drugs predicted to be widely prescribed and hence to have a substantial effect on payers' budgets. In these respects, Germany's process is similar to that in the United States, where QALY measurement, cost-effectiveness analysis, and budget implications only indirectly influence pricing decisions.

Drug prices are higher in the United States than in other countries in part because manufacturers are free to increase prices annually or semiannually. The cumulative effect of such increases can be substantial. An analysis of the top-selling drugs in the United States found that prices increased by more than 50% between 2012 and 2017 for more than three quarters of the drugs that had been available since 2012 and more than doubled for nearly half of them.³ The non-profit Institute for Clinical and Economic Review has highlighted the absence of new clinical justification for some of these price increases.

In contrast, the German pharmaceutical system prohibits unilateral price increases after the initial phase of clinical assessment and price negotiation. Manufacturers may request a clinical reassessment of their product on the basis of new data and then seek to obtain a higher price. But claims of enhanced performance must be evaluated in a new comparative clinical assessment and approved by the G-BA, and the price change must then be negotiated with the insurer association.

Prices and spending for some

major drugs and biologics in Germany decrease over time because of the launch of therapeutically comparable products such as biosimilars. The prices of two of the most widely prescribed biologics, etanercept (Enbrel) and adalimumab (Humira), more than doubled in 6 years in the United States, where they face no biosimilar competition. In Germany, by contrast, prices for the originator biologics have remained stable and spending has decreased because of rapid penetration by biosimilars. After only 3 years on the German market for etanercept and 1 year for adalimumab, biosimilars accounted for more than 60% and 40% of prescriptions for these drugs, respectively.⁴ Similar price-reducing effects have yet to be observed in the United States because manufacturers of brand-name biologics have created secondary patent "thickets" around their products and successfully litigated against prospective biosimilar manufacturers seeking to enter the market.

In both Germany and the United States, drug spending is highly concentrated among the relatively small number of very sick patients who require specialty drugs, biologics, and gene therapies. Insurance executives in the United States worry that their plans will attract a disproportionate share of enrollees who need these expensive medications, which would force them to raise premiums to cover their higher costs. In turn, higher premiums could cause insurers to lose their healthy enrollees, who don't care about coverage of expensive drugs but do care about premiums. Insurers defend themselves against this adverse selection by creating administrative hurdles that discourage enrollment by people who

need expensive drugs, including prior-authorization requirements for physicians, and financial hurdles such as deductibles and co-insurance for patients.

In contrast, the German system ensures that the financial burden of drug payments doesn't fall on patients. By statute, cost sharing is limited to a maximum of €10 (about \$11) per prescription; even this nominal amount is waived for children, low-income adults, and people with multiple chronic illnesses. The German system also ensures that whichever health plan happens to enroll the sickest patients isn't on the hook for disproportionately high costs. All health plans pay the same price for the same drug (e.g., large national plans aren't favored over small regional plans), and all face a reallocation of premium revenues on the basis of the risk profiles of their enrollees.

Physicians in Germany are expected to adhere to the principle of efficient prescribing, meaning prescribing that is in keeping with the EMA's product labels, the G-BA's assessments of comparative benefit, and the clinical guidelines developed by their specialty societies. Within these broad and evidence-based boundaries, however, physicians are authorized to make decisions about the appropriate treatment for each of their patients without interference from insurers. Health plans are not permitted to exclude drugs from coverage (they don't have "formularies" and must cover all prescription drugs approved for the German market). They cannot demand prior authorization from physicians as a condition of reimbursing a drug claim. They can, however, conduct retrospective audits of physicians whose prescribing patterns are substan-

tially outside the recommendations of the EMA, the G-BA, and clinical guidelines. Such audits are very rare in practice. Limits on insurer interference reflect the recognition by health insurance plans that moderation in drug spending is to be pursued by means of control over prices rather than control over physician prescribing and patient adherence. Some observers have recommended that the United States adopt an analogous model, under which manufacturers agree to accept value-based prices in exchange for insurers reducing prior-authorization requirements and cost sharing so as not to impede appropriate patient access.⁵

The German system for determining drug prices features collective negotiations on the part

of competing health plans rather than price regulation by a single government agency. A statutory framework that creates incentives for agreement, limits price increases not justified by new evidence, and avoids heavy burdens on physicians and patients ensures that public interests are represented in private negotiations. Perhaps most important over the long run, the German structure has gained legitimacy among its principal stakeholder groups, including physicians, patient advocates, drug manufacturers, health plans, and the broader public. It remains to be seen whether the contemporary policy debate and political turmoil in the United States will also generate an economically efficient and socially accepted drug-pricing system.

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Specialty Drugs — A Distinctly American Phenomenon

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According to a report by the Congressional Budget Office, roughly 1% of prescription drugs dispensed under Medicare Part D and Medicaid accounted for about 30% of net drug spending in each program in 2015.¹ The agency found that between 2010 and 2015, net spending on these so-called specialty drugs rose from \$8.7 billion to \$32.8 billion in Medicare Part D and from \$4.8 billion to \$9.9 billion in Medicaid. Similarly, spending on specialty drugs by commercial plans nearly quadrupled between 2003 and 2014.²

The origins of the specialty-drug label can be traced back to the 1970s, when specialty pharmacies emerged in response to the need for preparation and de-

livery of new injectable and infusion products. Only a handful of drugs required such handling at the time and were called “specialty drugs.” Today, various stakeholders in the pharmaceutical supply chain assign the specialty label to drugs on the basis of a combination of several unrelated factors, such as whether a drug treats a rare condition, requires special handling, or needs post-marketing risk-management plans.

But the single most common feature of specialty drugs is high cost. Indeed, the Centers for Medicare and Medicaid Services (CMS) defines specialty drugs as those with monthly costs exceeding \$670. The specialty-drug label has important consequences for patients. When Medicare Part D

went into effect in 2006, CMS explicitly permitted plans to place specialty drugs on the highest cost-sharing tiers of their formularies. Today, virtually all Part D plans have a specialty tier. The maximum allowable coinsurance for drugs on such tiers is 33%. A new proposed rule from CMS would allow Part D plans to implement a “preferred” specialty tier with a lower cost-sharing rate.

The economic burden of these cost-sharing requirements on patients can be substantial. Part D enrollees not receiving low-income subsidies can pay thousands of dollars out of pocket per year for a single specialty-tier drug.³ Numerous disease-modifying therapies used for treating multiple sclerosis are considered specialty