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Single-Payer Drug Pricing In A Multipayer Health System: Does Germany Offer A Model For The US?

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An increasing number of presidential hopefuls, [most recently Senator Kamala Harris](#), are proposing “single payer” or “Medicare for All” proposals that seek to extend insurance coverage and reduce the cost of care. They face the challenge that the US has a deeply entrenched multipayer health care financing system that includes federal, state, regional,

national, nonprofit, and for-profit health plans, each with its own strategy, political constituency, and will to survive. An obvious question is whether the Democrats' policy objectives could be achieved without turning the status quo upside down.

The short-term political appeal, and the long-term economic sustainability, of the Democrats' goal of universal coverage depends on moderating costs. This, in turn, requires mastering the unjustified variation and inflationary rise in prices of the components of care, particularly drugs.

To this end, it is instructive to look at pharmaceutical assessment and pricing in Germany, a prosperous nation that features universal coverage, a private multipayer health insurance system, a large pharmaceutical industry, and drug prices that are lower and more directly linked to clinical benefit than those in the US. In this post, we examine the German system and discuss how the US might adopt some of its strong points.

A Multipayer Health Care Financing System

The German health care financing system features 110 "Sickness Funds," or health plans, that collectively cover health care expenses for 90 percent of the population. Forty-eight indemnity insurance firms cover the remainder. [There is no governmental health insurer, much less a single payer.](#) Most of the health plans are employer-based, in a manner somewhat analogous to self-insured employers in the US. The majority of the population, however, is enrolled in the national Ersatzkassen (or Sickness Funds, mostly organized around occupations and professions) and regional AOK funds (the largest German statutory health insurance funds somewhat analogous to BlueCross BlueShield plans in the US).

The AOK funds are subject to extensive regulation and support from the federal and state governments, including special reimbursement for those funds that attract the sickest enrollees. The funds are represented in their negotiations with pharmaceutical firms and provider organizations by their umbrella association, the GKV-Spitzenverband (GKV-SV). The indemnity insurers are subject to less regulation but enjoy fewer subsidies. They pay the same case rates as do the Sickness Funds to hospitals and drug firms but determine their own physician fees (mostly on an indemnity structure).

The German pharmaceutical pricing system builds on this multipayer insurance system. New drugs that are authorized for market launch by the European Medicines Agency (EMA, equivalent to the US Food and Drug Administration) are subject to clinical evaluation by two quasi-public entities. The Institute for Quality and Efficiency in Health Care (IQWiG) prepares an evaluation of comparative effectiveness based on clinical

evidence, including but not limited to the studies submitted by the manufacturers to the EMA. The Federal Joint Committee (Gemeinsamer Bundesausschuss; G-BA) combines the IQWiG reports with testimony gathered in public hearings from the manufacturer, patient advocacy groups, physician associations, and other stakeholder groups.

No use is made of formal cost-effectiveness analysis or quality-adjusted life-years (QALYs). Rather, the G-BA assesses the new drug as offering major, moderate, minor, positive but nonquantifiable, or no incremental benefit compared to existing treatments for the targeted condition. The “positive but nonquantifiable” benefit is accorded to orphan drugs and other products where comparators are lacking or other methodological factors impede a traditional assessment.

Drug manufacturers are permitted to establish an initial list price for their products after EMA authorization, and they are paid these prices for the first year after launch. During this first year, however, the IQWiG and the G-BA conduct their assessments and—for those drugs demonstrating some extent of added benefit—turn it over to the GKV-SV to negotiate a new price. The GKV-SV negotiations are based on the drug’s comparative effectiveness, the market price of the comparator drug used in the G-BA assessment, the prices of other drugs that treat the same condition but were not chosen as the comparator, and the prices charged by the manufacturer for its new drug in other European markets.

New drugs without added benefit are assigned to [therapeutic classes subject to reference pricing](#), with the Sickness Funds and private insurers limiting the reimbursement amount based on the prices of the existing alternatives within each class. If they do not fit into an existing reference-price class, they are subject to negotiations with the proviso that their negotiated price cannot exceed that of their comparator drugs.

Negotiations In The Context Of Bilateral Monopoly

The price negotiations formally are structured as a bilateral monopoly, with a single buyer, the GKV-SV representing the Sickness Funds (and indirectly the indemnity insurers), facing a single seller, the drugmaker. It would be easy to predict negotiating gridlock, with the GKV-SV insisting that the manufacturers’ request for high prices threatens the solvency of the system and the manufacturers insisting that Funds’ request for low prices threatens innovation. However, both sides are under strong public and political pressure to come to an agreement. If none can be negotiated, the drug’s price is

established by an arbitration panel consisting of representatives of each side plus an appointed chair. The manufacturer can refuse the arbitrators' price but then forgoes all sales in the continent's largest market and knows it will enter price negotiations for its next drug with a noncollaborative reputation, always a bad thing in a culture that emphasizes cooperation over conflict.

The German structure of comparative effectiveness assessments and collective negotiations was established in 2011, building on an existing system where drugs were subjected to across-the-board discounts off list price that were not aligned with the clinical benefit offered. From 2011 to the end of 2017, the [German pharmaceutical system has conducted assessments and pricing for 186 drugs](#). Of these, [35 drugs went to arbitration and 30 were withdrawn](#) from the market by their manufacturers.

In practice, manufacturers usually only withdraw from the German market if the price resulting from the process described above is so low as to undermine the prices that can be charged elsewhere. One unique feature of the German system is that the final negotiated and arbitrated prices are not confidential. Numerous other nations reference both the initial and the final German prices when administering or negotiating their own rates. [The Trump administration has proposed an analogous system of international reference pricing](#) to cap rates paid for physician-administered drugs under Medicare Part B.

This centralized assessment and pricing framework for new active substances is supplemented by a variety of decentralized negotiations. The price of drugs used in the inpatient hospital setting are negotiated between manufacturers and hospitals. Sometimes the GKV-SV participates if the drug is to be reimbursed by the Sickness Funds to the hospitals as an add-on to the basic diagnosis-related group (DRG) payment. Manufacturers are willing to negotiate rebates for some ambulatory drugs during the first year after EMA authorization, even though they have the right to demand the full list price. These voluntary negotiations can accelerate adoption by physicians, who receive reassurance from the Sickness Funds that the newly discounted drugs will not trigger audits or penalties. In addition, they generate evidence of efficacy under real-world settings that can be useful to manufacturers when negotiating prices collectively with the GKV-SV.

Although German payers do not require prior authorization for the prescription of expensive drugs, they can conduct retrospective audits and impose penalties on physicians exhibiting patterns of prescription significantly outside the EMA and the G-BA therapeutic boundaries. Few audits and penalties ever are imposed, but the threat exerts a substantial deterrent influence on risk-averse German physicians.

Generic drugs and biosimilars do not go through G-BA assessment and GKV-SV negotiation because they do not fall under the same regulations as new active substances. They are assumed, by definition, not to offer incremental benefits over comparator products. In most cases, they are assigned to therapeutic classes subject to reference pricing; while payers limit reimbursement to a reference price calculated based on existing alternatives within each class, manufacturers are free to determine the price they will charge for their own product. Individual Sickness Funds negotiate supplemental rebates for generics and biosimilars as a condition for favorable treatment in their utilization management programs.

Summing Up

The German health care system has several important features that resemble but go beyond those prevalent in the US. Its insurance sector is composed of more than 100 independent health plans that compete for enrollees based on customer service but collaborate in negotiating with pharmaceutical manufacturers. Prices are based on evidence-based assessments of comparative clinical assessment but also on testimony and supplemental documents obtained through public meetings that involve patient advocates, physician organizations, and other stakeholders.

The outcomes seem largely to have been positive from the perspective of the purchasers. [Drug prices in Germany tend to be at the high end of the range for European nations but substantially below US levels.](#) This difference cannot be ascribed solely to the centralized assessment and negotiation structure, since [even prior to 2011 manufacturers were required by regulation to offer rebates](#) off list prices. However, today's prices are better aligned with the clinical benefit offered by each product. Prior to 2011, all drugs faced the same mandated percentage rebate. Now discounts are major for drugs that offer little or no incremental benefit but modest for drugs where G-BA and IQWiG find a [meaningful contribution to patients' health.](#)

Most importantly, perhaps, the system appears to have gained substantial political and social legitimacy. Proposals for reform center on minor technical issues rather than the basic structure of private, collective, and transparent price negotiations. The atmosphere is largely free of the vitriol so characteristic of the US system. Sickness Funds are not accused of "rationing," and pharmaceutical firms are not accused of "gouging." There seems to be a consensus that drug prices need to be high enough to finance innovation but low enough to sustain affordability and that prices for innovative drugs should be higher than prices for me-too products.

So what steps could the US take to incorporate some of the experiences of the German system, without violating deeply embedded institutional and cultural tenets of our system? This could be a long discussion but also can be short.

First, the US needs a mechanism for assessing the incremental clinical benefit offered by each new drug in comparison to alternative treatments, as a standard against which discussions of pricing can take place. Pharmaceutical manufacturers currently conduct clinical and cost-effectiveness studies for the G-BA and payers in other nations. US payers conduct back-of-the-envelope assessments through their pharmacy and therapeutics committees when deciding whether and how to include a drug on their formulary. But currently no one has to follow standardized methods established by a credible third party; open their processes to input from patients, physicians, and other stakeholders; or be transparent with the results. This needs to happen.

Second, the US needs a mechanism by which clinical assessments are used to negotiate the prices of newly launched drugs and to justify price increases after launch. The private Institute for Clinical and Economic Review performs these functions on a voluntary basis, and its [assessments are being used by some payers and manufacturers](#) in price discussions. Many US insurers and pharmacy benefit managers have enrollments comparable to the entire population of European nations and so already have sufficient scale to negotiate in a meaningful way for prices that are aligned with clinical value. This needs to happen.

The lesson to the United States from consideration of its German counterpart: This is possible here. Let's get on with it.

Authors' Note

This post derives from site visits, interviews with key opinion leaders, and reviews of published documents obtained as part of an ongoing study of the German pharmaceutical pricing, supported by the Commonwealth Fund. Findings from this work were also discussed in a [Commonwealth Fund Issue Brief](#).

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