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Negotiating drug prices without restricting patient access: lessons from Germany

By James C. Robinson, Dimitra Panteli, *and* Patricia Ex

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In the ongoing conversation about high drug prices in the United States, some loud voices argue that the solution is to allow Medicare to negotiate prices directly with manufacturers. The Congressional Budget Office[22] and others say this would lead to the

exclusion of some drugs from coverage, require physicians to obtain prior authorization more often than they already do, and impose more cost sharing on patients — strategies that would keep patients from accessing medications they can benefit from.

That doesn't have to be the case. Germany's approach to negotiating drug prices shows that it can be done successfully without limiting access.

The health insurance and pharmaceutical purchasing system of Germany builds on 110 health plans, referred to as sickness funds[33], that cover health expenses for 90% of the population, plus 48 indemnity insurers, who cover the remainder. As we wrote in the journal Health Affairs[44], these funds collectively negotiate prices with drug manufacturers. The negotiations, conducted after a drug has received market authorization by the European Medicines Agency (EMA), are based on an assessment of the clinical benefit offered by the new drug compared to treatments already in use.

The clinical assessments are conducted and commissioned by a federal committee called the Gemeinsamer Bundesausschuss (G-BA), a quasi-public entity governed by the national associations of physicians, dentists, hospitals, sickness funds, and patient advocates. A statutory principle of the German system is that there will be no incremental price without incremental benefit. The G-BA's assessments are based on patient-relevant clinical endpoints such as overall survival, functional ability, and reduction in symptoms, rather than on intermediate endpoints such as reduced tumor size or a change in biomarker levels.

Related: [55]

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Once the umbrella organization of sickness funds negotiates the price of a drug, the manufacturer is prohibited from unilaterally raising the price in subsequent years. Prices can be adjusted over time only if the G-BA conducts a new comparative effectiveness analysis, followed by a new round of negotiations.

All health plans pay the same collectively negotiated prices.

Since its implementation in 2011, the German system of drug assessment and negotiation

has achieved net prices lower than those in the U.S.[66] The German system is among those cited by the Trump administration[77] and by legislators from both the Democratic and Republican parties as a benchmark for rates that could be paid by Medicare. Yet the prices are high enough to attract manufacturers interested in launching drugs into the German market.

In the U.S., private payers extract price concessions from manufacturers by threatening to restrict physicians' prescribing (by requiring prior authorization and step therapy) and patient adoption (by imposing coinsurance and deductibles). The German system does not rely on these tools. The G-BA provides guidance to physicians on high-cost new medicines that includes the scope of the EMA market authorization, the G-BA's assessment of patient-relevant clinical benefits, safety precautions for use, and the price of the drug compared to those for available alternatives.

Physicians are free to prescribe any EMA-authorized drug that has been assessed by the G-BA without receiving prior approval from their patients' health plans. Regional physician associations develop percentage targets for prescription of generic over branded drugs and for biosimilars over branded biologics, with the goal of reducing expenditures. Consumer cost sharing is capped at a very modest 10 euros per prescription, with caps on out-of-pocket cost sharing for low-income patients and those living with multiple chronic conditions.

The carrots for manufacturers

The German pharmaceutical market has several features that are quite attractive to drug firms and keeps them interested in ensuring a long-term presence in Germany.

By statute, all drugs are covered and available for physician prescription in Germany immediately upon receiving market authorization by the EMA. In a drug's first year on the market, it is available at a price unilaterally determined by the manufacturer. During that year, the G-BA conducts comparative assessments and the sickness fund association negotiates prices, which are applied in the second and following years.

Once the insurer association has negotiated a price, it cannot interfere with physician prescription through prior authorization or with patient access by imposing additional cost sharing.

Pharmaceutical manufacturers can count on the actual volume of sales approximating pre-launch estimates that derive from demographic and epidemiologic factors. This contrasts with the frequent sales shortfalls experienced in the United States due to prior authorization and cost sharing.

The sticks for manufacturers

From the manufacturer's perspective, access to the German market is an all-or-nothing case. Failure to reach agreement with the insurer association reduces revenues to zero. In the U.S., by contrast, failure to reach agreement with one payer does not preclude agreement with others, and manufacturers will extract the highest prices from their least sophisticated negotiating adversaries.

Drug price negotiations in Germany function as a repeated game, since each manufacturer can expect to negotiate with the same purchaser for multiple products. Even small single-product pharmaceutical firms typically have signed co-marketing agreements with, and have their prices negotiated by, large multi-product manufacturers with a substantial presence on the German market. A manufacturer's reputation for reasonable pricing on one product will carry over to subsequent negotiations under the watchful eye of the sickness funds, the physician associations, patient advocacy organizations, and the Ministry of Health.

Trending Now: [1010]

CBD is all the rage among patients. It's launching their physicians into uncharted territory [1111]

The negotiation process is highly structured, with a statutory right to four confidential sessions and a constrained opportunity for extension to a fifth. Failure to agree during those sessions results in the drug being referred to an independent arbitration board. This board conducts its own assessment and does not merely split the difference between the insurers' and manufacturer's final price offers. The board does not negotiate, but unilaterally decides on a price it feels best accords with the drug's clinical value and society's need for cost control. From the establishment of the collective price negotiations structure from 2011 through March 2019, 230 drugs have gone through comparative benefit assessment and 35 of these have had their final price decided by arbitration[1212] rather than negotiation.

Manufacturers of drugs assessed by the G-BA as offering no incremental benefit must negotiate a price with the insurer association under a ceiling set by the price of the comparator therapy.

From 2011 to the end of 2018, the G-BA decided that 43% of new drugs[1212] offered no incremental benefit, 18% offered positive but "non-quantifiable" benefits (mainly orphan drugs without comparator arms in their clinical trials), 17% offered only a minor incremental benefit, 23% offered a moderate benefit, and just 1% offered a major benefit.

Conclusion

The German health care system achieves price moderation without the formulary exclusions, prior authorization requirements, and consumer cost sharing used by insurers in the United States. Its structure and processes offer potentially significant insights for drug policy discussions, and for Medicare price negotiations, in the United States.

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Perspective

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

James C. Robinson, Ph.D., M.P.H.

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 nonprofit 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 coinsurance 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.

Disclosure forms provided by the author are available at NEJM.org.

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1. Berkemeier F, Whaley C, Robinson JC. Increasing divergence in drug prices between the United States and Germany after implementation of comparative effectiveness analysis and collective price negotiations. J Manag Care Spec Pharm 2019;25:1310-7.
2. Robinson JC, Ex P, Panteli D. How drug prices are negotiated in Germany. New York: Commonwealth Fund, June 13, 2019 (https://www.commonwealthfund.org/blog/2019/how-drug-prices-are-negotiated-germany).
3. Wineinger NE, Zhang Y, Topol EJ. Trends in prices of popular brand-name prescription drugs in the United States. JAMA Netw Open 2019;2(5):e194791.
4. Biosimilars in Zahlen. Berlin: Arbeitsgemeinschaft ProBiosimilars, November 14, 2019 (https://probiosimilars.de/allgemein/marktdaten-biosimilars-september-2019/).
5. Robinson JC, Howell S, Pearson SD. Value-based pricing and patient access for specialty drugs. JAMA 2018;319:2169-70.

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Specialty Drugs — A Distinctly American Phenomenon

Huseyin Naci, M.H.S., Ph.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H.

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 delivery 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

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Mending the broken social contract for pharmaceutical pricing and innovation

By James C. Robinson

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The biopharmaceutical industry is under unprecedented assault by the public and politicians. Hostility over launch prices for new drugs and post-launch price increases is broad and bipartisan, reflected in increasingly draconian legislative proposals and aggressive rebate payer negotiations.

The net price of drugs — that's the list price minus rebates and other reductions — is being squeezed[2], and the pressure won't let up. Industry revenues are increasingly derived from a smaller number of orphan and gene therapies with limited competition and from a few specialty blockbusters for chronic conditions that patients are reluctant to switch away from. Those revenue streams are precarious, as are the ones that derive from successful but politically vulnerable strategies such as patent thickets and pay-for-delay arrangements[3] to keep out specialty generics and biosimilars.

The pharmaceutical industry's increasingly fragile revenue stream puts at risk the financing of innovation, since more than half of all research investment is funded by industry, with the remainder funded by governmental and philanthropic entities.

The industry has reason to be worried. The development of new products is not only its economic lifeblood but also its self-image as a solution rather than a problem. It is groping for an effective response.

In a recent and prominent effort, 215 blue-ribbon life sciences executives and thought leaders published an open letter[4] in STAT announcing their "New Commitment to Patients" and their corporate responsibility.

Related: [4]

A new biotechnology and pharmaceutical industry commitment to patients and the public [4]

The motivation is commendable. The action items, however, are remarkably weak. The core of the new commitment is to set launch prices based on "value to patients" and to subsequently raise prices in a manner that is "reasonable."

Not only do the key terms go undefined, but they lend themselves to a

continuation of the status quo. Which pharmaceutical firm is willing to say that its past launch prices did not reflect value and that its price increases were unreasonable?

That wasn't a commitment but a plea: I ain't been misbehaving, but trust me and I'll start behaving.

If the authors of the open letter ask too little of themselves, they also ask too little of the other inhabitants of the pharmaceutical ecosystem. Neither payers nor policymakers are asked to do anything but let the industry do what it wants to do. That is not enough.

The broken social contract

The innovation ecosystem is based on an implicit social contract binding industry, payers, and policymakers. That contract is in serious disrepair.

Pharmaceutical firms enjoy free access to tax-funded scientific and clinical research as well as to tax credits and small business innovation grants that offset part of their development costs. They enjoy patent and regulatory protections against competition for long enough to recoup their research and development expenditures. They benefit from tax-subsidized health insurance that reduces the normal consumer resistance to high prices.

These public policies make it possible for pharmaceutical companies to charge prices and earn profits in excess of those available in other sectors. But with these rights should come social responsibilities. The public expects drug companies to devote a substantial portion of their profits to research and to price their products in a manner that is affordable for patients and society at large.

The public also expects payers to facilitate, not impede, access to these drugs. It expects the government to keep industry and insurers true to their commitments

and to ensure that short-term affordability does not preclude long term innovation.

A new social contract

The social contract for pharmaceutical pricing, patient access, and innovation needs expanded commitments from all participants. Drug firms need to adopt new pricing principles, payers need new patient access principles, and policymakers need to expand alternative supports for innovation.

New commitments by industry: pricing. A new social contract will require drug firms to change their pricing principles, aligning them more closely with comparative clinical effectiveness and cost-effectiveness, as well as with prices charged in other nations. These principles are found in all the major legislative proposals in Washington. Given the intensity of the industry's lobbying, it is hard to imagine any one of the current proposals passing in the short term. But given the intensity of public sentiment, it is hard to believe that some variant of them won't pass in the long term.

The pricing principles of the future are simple. Launch prices must reflect value to patients, not as defined by the industry but as defined by independent third parties, such as the Institute for Clinical and Economic Review, using transparent methods and with input from patients and other stakeholders. Prices should be raised in the years after launch only if new evidence emerges of clinical and social contribution. The limit on unsupported price increases has long been adopted by payers in other nations, and by Medicaid and selected payers in the U.S. It strengthens the incentive for industry to pursue post-launch studies using clinical trials and observational real-world evidence.

New commitments by payers: access. The new social contract will bind not only the pharmaceutical industry but also insurers, employers, and pharmacy benefit managers. These buyers have been relying on formulary exclusions, prior authorization, and consumer cost-sharing to wrest price discounts from

manufacturers (and, unfortunately, often pocket the savings rather than pass them on to patients).

This has created extensive collateral damage in the form of physician frustration, patient non-adherence, and system-wide administrative costs. To the extent that drug manufacturers adopt new pricing principles, payers will need to adopt new principles of utilization management.

Related: [2]

Wholesale drug prices have been falling, and so have net prices [2]

As I argued in a Viewpoint article[7] in the Journal of the American Medical Association authored jointly with Scott Howell of Novartis Pharmaceuticals and Steven Pearson of ICER, payers will need to offer value-based patient access in exchange for value-based product pricing. Once prices are aligned with clinical value, payers will no longer be justified in maintaining today's obstacles to access. This will allow drug firms to obtain the normal business reward for lower prices through higher sales volumes, and thereby recoup some of the revenues they will lose from charging lower prices for each unit sold.

New commitments by policymakers: innovation. An industry commitment to pricing moderation will reduce the margins that heretofore have funded research and development investments. The new social contract, therefore, will require governmental and philanthropic organizations to expand alternative funding sources and non-financial supports. This can include:

- Expanded support for basic science and applied clinical research[8] funded by the federal and state governments and by philanthropic entities.
- Expanded tax credits for R&D[9], with especially generous credits for investments in areas of high need, such as drug-resistant infections and cardiovascular disease.
- Expanded direct public grants to support product commercialization, including the Small Business Innovation Research[10] and related programs for technology-based startups.
- Expanded innovation prizes[11] that reward achievement of important developmental milestones, following the model of venture capital investment but without diluting owners' equity.

- Targeted tax reductions[12] on profits obtained from patent-protected and other innovation-intensive products.
- Continued acceleration of market authorization through greater reliance on post-market data generation and real-world evidence[13].

Additional benefits from a new social contract

A new social contract that reduces the dependency of research investments on high prices and industry profits will create additional social benefits.

A greater reliance on alternative funding sources will encourage the industry to prioritize innovation for treatments that have fared poorly under the status quo. Today's reliance on prices and profits has pushed R&D investments into narrow therapeutic niches and induced the industry to shift away[14] from treatments for cardiovascular disease, diabetes, drug-resistant infections, and other major health challenges.

A change in the mix of incentives could cause a dramatic move in the direction of investment, as demonstrated by the 1984 Orphan Drug Act. This act, which combined research grants, R&D tax credits, accelerated FDA review, and extended market exclusivity protections, led to an explosion of innovation[15], highlighting the sensitivity of investment to incentives. A new social contract could target areas of special need using the Orphan Drug Act model but with less reliance on extended market exclusivity.

Compared to the price-based status quo, the new social contract could better support the U.S. life sciences sector in the context of global competition for knowledge-based industries[16]. The traditional method of financing pharmaceutical research and development through higher prices in the U.S. than in other wealthy nations does not differentially support domestic research, commercialization, and manufacturing. Foreign firms can repatriate the outsized profits they earn in the U.S. to the economic benefit of their home nations.

In contrast, most alternative funding sources favor domestic investment and

production. Governmental and philanthropic grants, tax credits, Small Business Innovation Research awards, and innovation prizes usually are directed at U.S. universities, research institutes, startups, and established firms, with spillover benefits that include increased employment, higher wages, manufacturing investments, and export revenues.

Conclusion

The U.S. pharmaceutical system needs a new social contract binding manufacturers, payers, and policymakers. Manufacturers need to reduce their prices in line with evidence-based benchmarks developed by independent third parties. Payers need to relieve physicians and patients of onerous utilization management and cost sharing. Policymakers need to expand non-price incentives for R&D, including research grants, tax credits, and innovation prizes. Physicians and patients will need to support this new social contract by selecting the most cost-effective options within the range of clinically effective treatments for their conditions.

Without such a realignment, the pharmaceutical will remain locked in the contemporary war of all against all.

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ISSUE BRIEF
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Reference Pricing in Germany: Implications for U.S. Pharmaceutical Purchasing

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ABSTRACT

ISSUE: The German health care system resembles that of the United States in important ways — it is financed by multiple private payers and relies principally on negotiation rather than regulation to establish prices. New drugs that offer minimal benefits compared with existing alternatives within a therapeutic class are subject to reference pricing; those with incremental benefits are subject to price negotiations. Together, the reference and negotiated pricing systems have held German prices substantially below U.S. equivalents.

GOAL: To describe the German reference-pricing system and compare it to tiered formularies and consumer cost-sharing in the United States.

METHODS: Document review and interviews with leaders in payer, policy, and pharmaceutical industry organizations in Germany.

KEY FINDINGS AND CONCLUSIONS: The German pharmaceutical pricing system uses modest levels of consumer cost-sharing to influence consumers' choices for drugs with therapeutically equivalent alternatives. Manufacturers are free to set the prices of their products, but insurers will not pay more for a new drug than for its comparators unless it offers an additional clinical benefit. For drugs covered by reference pricing, the insurers' payment maximum is set at a level that ensures sufficient choices of low-priced options. These models offer an alternative to the U.S. system of tiered formularies.

TOPLINES

- In Germany, prescription drugs are priced relative to existing therapies for the same medical conditions, with drugs offering extra clinical benefit priced higher.
- New prescription drugs in Germany are subject either to reference pricing or price negotiation; together, these pricing systems have held prices substantially below those in the U.S.

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INTRODUCTION

In reference pricing — a component of health insurance design — a health care purchaser establishes a maximum payment it will contribute toward covering the price of a drug. It is used when there is a wide variation in the prices for therapeutically similar products. The payment limit is set at the minimum, median, or other point along the range of drug prices within a therapeutic class. If a patient's physician prescribes a drug with a price at or below the reference limit, the patient pays only a modest copayment. If a more expensive option is selected, he or she pays the copayment plus the full difference between the reference limit and the price of the chosen product.

Reference pricing offers several advantages over the most commonly used insurance designs in the United States, such as annual deductibles and coinsurance, which expose consumers to financial obligations without providing an affordable option or guidance on how to select products offering the best value. To date, however, reference pricing has been applied only by a limited number of purchasers and only to drug classes that feature multiple generic or therapeutically equivalent alternatives. For these therapeutic classes, it can reasonably be assumed that all products work similarly. Purchasers can limit their payments to the level charged for the cheaper products in each class and patients desiring a higher-priced option reasonably can be required to pay the difference themselves. Patients with physician-identified clinical needs for higher-priced options can be granted an exception.

In its efforts to improve the effectiveness and efficiency of pharmaceutical purchasing, the U.S. can learn from Germany, which manages traditional drugs using reference pricing and novel drugs using comparative-effectiveness pricing. Germany has developed evidence-based methods to assess the clinical benefit of new products, establish reference-based payments for drugs that do not offer incremental benefits over existing products, and negotiate new prices for drugs that do offer incremental benefits.[1] This approach enjoys considerable social legitimacy as a mechanism for ensuring patient access while moderating payer expenditures.

The health care system in Germany resembles that of the U.S. in several important respects yet differs in others. (See box.) Both feature multiple nongovernmental insurers rather than a single governmental payer, favor

The Institutional Framework of Pharmaceutical Pricing in Germany

In Germany, reference pricing falls within an institutional system that features publicly regulated and accountable associations of insurers, physicians, and other stakeholders. Statutory and case law establish the rules governing interactions among these entities, and the Ministry of Health continuously monitors and supports their processes. But the government does not directly assess the comparative clinical benefit of new drugs or negotiate their prices. In this regard, it resembles the U.S. framework more than other European systems where the heavy lifting in pharmaceutical cost control is done directly by governmental payers.

The German institutional framework does differ from its U.S. counterpart in important respects. The organization that assesses the comparative clinical performance of new drugs, the Federal Joint Committee (GBA), consists of representatives of the national insurance, physician, and hospital organizations. Patient advocacy organizations have nonvoting seats on the board. The GBA, in turn, delegates the clinical evaluation of new drugs to a privately governed but publically accountable entity, the Institute for Quality and Efficiency in Health Care (IQWiG). IQWiG bases its evaluations on: dossiers submitted by manufacturers, which include a systematic review of the incremental benefit of the drug; the clinical trials for initial market authorization by the European Medicines Agency, as well as other clinical trials; reports by technology assessment agencies in other nations; and other available evidence. GBA then makes its official assessment of each drug's contribution based on the IQWiG study, further input from the manufacturers, and follow-on testimony at public meetings.

The GBA assessments are used by the umbrella organization of Sickness Funds, the GKV-SV. The GKV-SV works within a statutory and regulatory framework that assigns it special rights and responsibilities, and interprets its role as negotiating the best prices from the point of view of the health system, and not merely that of its constituent insurers.

negotiation over regulation for determining prices, enjoy declining expenditures for many traditional, nonspecialty drugs but face rising expenditures for novel specialty products, and are embedded in a culture that values patient access to even the most expensive treatments. However, in Germany, the clinical assessment of each new drug is centralized and the negotiation of drug prices is done collectively by the umbrella organization of health insurers, rather than by each insurer individually. This issue brief describes the structure of drug assessment and pricing in Germany and its potential applicability to the U.S. market.[2]

ASSESSMENT OF COMPARATIVE EFFECTIVENESS

In the German pharmaceutical system, new drugs are assessed and priced relative to existing treatments for the same conditions. Drugs that offer additional clinical benefits are paid higher prices; reference pricing is applied to new drugs with clinical performance similar to products already on the market. Comparative-effectiveness pricing applies to new products that perform better than their comparators.

All drugs authorized for market access by the European Medicines Agency (EMA) are immediately available after launch for physicians to prescribe and patients to use. The manufacturer unilaterally sets the new drug's price at time of launch and is reimbursed in full at that price for the drug's first year. During this first year, an assessment is conducted of the drug's comparative clinical safety and efficacy by the Federal Joint Committee (GBA), a self-governing but publicly accountable entity representing associations of nongovernmental insurers (also known as "Sickness Funds"), physicians, and hospitals.

The GBA makes several important decisions regarding the assessment of each drug's incremental benefit, with input from the Institute for Quality and Efficiency in Healthcare (IQWiG), the pharmaceutical manufacturer, relevant medical associations, patient advocacy organizations, and other interested entities. First and often most importantly, GBA decides which drug will be used as the comparator against which the new product is to be assessed; a drug treating multiple indications may have multiple comparators. If the new drug is found to offer incremental benefits, its price will be negotiated upwards from the comparator's price, and so the manufacturer has an interest in having the GBA select a high-priced comparator. However, if GBA picks as the comparator a drug with high price but also high efficacy, the new drug faces a more difficult challenge in demonstrating incremental benefit. A finding of no incremental benefit leads to the drug being assigned to a therapeutic class subject to reference pricing. All products are reimbursed at a level based on the lowest prices charged within the class, if it falls within a therapeutic class for which reference prices have been established. If the new drug is found not to offer an incremental benefit but also does not fall into a reference-priced therapeutic class, its price is subject to negotiation with the proviso that the negotiated price not exceed that of its comparator drug.

Second, the GBA chooses the metrics that will assess the new drug's benefit. These metrics may differ from those used by the EMA, the European equivalent of the U.S. Food and Drug Administration (FDA), in its review of the drug for initial market authorization and for which the manufacturer has conducted clinical trials. In some cases, GBA has rejected metrics acceptable to EMA, such as "progression free survival" for cancer drugs, as it deems them not relevant to the patient's quality of life. Progression free survival indicates how many months the patient survives posttreatment without an increase in the size of his or her tumors. This metric is correlated with the more important overall survival metric, which indicates the number of months the patient remains alive posttreatment, but is often not correlated with patient quality of life. In other cases, GBA has required that pharmaceutical firms provide metrics that EMA does not require, principally quality-of-life indicators such as change in pain and nausea.

The GBA delegates the clinical evaluation of the new drug to IQWiG,[3] which considers the portfolio of evidence used for market authorization by EMA plus other studies conducted by the manufacturer. The final assessment of the drug's benefit then is decided by the GBA. Drugs can

be judged by the GBA to offer a major, substantial, minor, positive but nonquantifiable, or no incremental benefit, relative to the comparator treatment. The nonquantifiable benefit is used when the drug is considered likely to offer incremental benefit but lacks sufficient evidence for a confident judgment of the scale. Orphan drugs, which often have no direct comparator and for which the clinical evidence may be based on very small patient samples, usually are awarded a nonquantifiable benefit. The GBA also evaluates the strength of the available evidence (weak, moderate, or strong). The clinical benefit of a drug can be reassessed by GBA in response to changes in the available evidence, sometimes triggering a renegotiation of the price.

Reference Pricing for Products That Do Not Offer Incremental Benefits

If the GBA considers a drug not to offer an incremental benefit over existing treatments, it usually assigns it to one of the therapeutic classes covered by reference pricing. Manufacturers are permitted to set whichever price they feel is appropriate for drugs falling into these classes, but the umbrella organization of health insurers (GKV–SV) establishes a limit to what individual insurers will contribute toward payment. The GKV–SV sets its payment limit near the 30th percentile in the distribution of prices within each therapeutic class, high enough to ensure that patients have more than one choice but low enough to ensure that the payer is not responsible for paying the highest prices within the class. Most generic drugs fall into the reference pricing system. Approximately 34 percent of drugs, 80 percent of prescriptions, and 33 percent of drug spending in Germany is for drugs subject to reference pricing.[4]

Patients must pay out of pocket the difference between the price set by the manufacturer and the reference-based reimbursement limit set by the purchaser organization. Many patients are unwilling to contribute out of pocket and prefer drugs priced below the reference limit and their physicians will prescribe drugs at or below the limit. Of products subject to reference pricing, approximately 84 percent are priced by their manufacturers at or below the reference price limit and therefore not subject to additional cost-sharing.[5] These products make up 92 percent of all prescriptions made for reference-priced drugs. Manufacturers can submit new prices up to twice a month for drugs in the reference pricing system. The umbrella organization of insurance firms is required to update the therapeutic classes every quarter and the payment limits at least annually. Manufacturers are permitted to lower their prices to the reference limit to avoid the otherwise inevitable reduction in sales volume; many do.

For drugs included in the reference pricing system, patients may be required to pay additional copayments, depending on which drug they select in consultation with their physicians. Patients selecting a drug priced above the reference maximum for their class contribute a copayment plus the difference between their drug's price and the reference maximum. These extra copayments do not count toward the patients' annual out-of-pocket cost-sharing maximum. However, the extra copayments are modest, since most of the drugs included in the reference pricing system are older, generic medications with typically low prices. For drugs not included in the reference pricing system, German health insurers require patients to pay the cost-sharing amount only.

Aside from the requirement that patients pay the difference between the reference limit and the full price of a product, which applies only in contexts where the patient can choose a low-priced option, Germany places tight limits on patients' out-of-pocket financial responsibilities. The statutory copayment ranges from a minimum of EUR 5 to a maximum of EUR 10 per prescription, up to an annual out-of-pocket maximum (for all health care services) of 1 percent of gross income for people with chronic diseases and 2 percent for others. Approximately one-quarter of enrollees also have complementary private insurance, which covers these cost-sharing requirements.[6]

Negotiated Pricing for Products That Offer Incremental Benefits

If a new drug is judged by the GBA to offer an incremental benefit over existing treatments, it is referred to the GKV–SV for price negotiations with the manufacturer. The insurer umbrella association uses the GBA's assessment of clinical benefit, as well as the prices of the comparator drug, therapeutically similar medications, and prices charged in other European nations to negotiate a discount off the new drug's launch price.

Some drugs are judged by the GBA not to offer an incremental benefit yet do not fall into an existing reference-priced therapeutic class, as there must be at least three therapeutically equivalent drugs to constitute a class for reference pricing. These drugs also have their prices negotiated between the manufacturer and the insurer association, but with the proviso that the price of the new drug cannot exceed that of the comparator product chosen by the GBA.

If negotiations between the insurer umbrella association and the drug manufacturer do not conclude with a price agreeable to both sides, the drug is referred to arbitration. In this process, a three-person panel selected by the manufacturer, the insurance organization, and the GBA assesses the evidence and renders a decision. Through the end of 2017 one of five (35 of 186) new drugs assessed by the GBA received a final price through arbitration rather than negotiation; for another 24, the negotiating parties reached an agreement after an arbitration process had been initiated.[7]

If a manufacturer cannot obtain an acceptable price either through negotiation or arbitration, it can withdraw its product from the market. Between 2011 and 2017, 148 drugs were subjected to comparative-effectiveness assessment and had their prices negotiated by the insurers and manufacturers. Of these, 29 were removed by the manufacturer from the German market by 2018.[8] For 12 of these, the manufacturer chose to withdraw the product immediately following the results of the GBA evaluation — this is known as "opting out" of the pricing process. In 16 cases, drugs were withdrawn in reaction to the determined price, mainly through arbitration, and one was withdrawn because its manufacturer went bankrupt.[9]

LESSONS FOR THE UNITED STATES

The German system uses modest levels of cost-sharing as an instrument to influence consumer choices for drugs with therapeutically equivalent alternatives. However, it does not apply cost-sharing to new drugs that lack alternatives. Comparative-effectiveness pricing is used for new specialty medications that offer clinical benefits over existing treatments. Manufacturers are free to set the prices of their products, but insurers will not pay more for a new drug than for its comparators unless it offers an additional clinical benefit. For drugs covered by reference pricing, the insurers' payment maximum is set at a level that ensures sufficient choices of low-priced options. These models offer an alternative to the U.S. system of tiered formularies.

In the United States, the level of cost-sharing and the resulting financial burden on patients is high, especially for patients with complex medical conditions. U.S. payers often impose modest copayments on low-cost drugs with many direct substitutes but onerous coinsurance on high-cost drugs with few substitutes. Coinsurance does not point the patient toward the most cost-effective drug choices. In contrast, insurance designs built on reference pricing identify drugs that are priced below the insurer's payment maximum and require only minimal cost-sharing.

NOTES

1. Sophia Schlette and Rainer Hess, *Early Benefit Assessment for Pharmaceuticals in Germany: Lessons for Policymakers* (Commonwealth Fund, Oct. 2013).

2. This issue brief is based on several dozen interviews conducted in May and December 2017 with executives, analysts, and policymakers in Sickness Funds, pharmaceutical associations, the Ministry of Health, GBA, GKV-SV, universities, consulting firms, and nonprofit organizations active in the German health care system.

3. Treatments for orphan conditions are assessed in-house by GBA and are not delegated to IQWiG.

4. Melanie Schröder and Carsten Telschow, "Der GKV-Arzneimittelmarkt 2017: Trends und Marktsegmente," in *Arzneiverordnungs-Report 2018,* ed. Ulrich Schwabe et al. (Springer, 2018).

5. Federal Ministry of Health, *Zuzahlung und Erstattung von Arzneimitteln* (BfG, 2018).

6. Dimitra Panteli et al., "Pharmaceutical Regulation in 15 European Countries: Review 2016," *Health Systems in Transition* 18, no. 5 (2016): i–125.

7. Wolfgang Greiner and Julian Witte, *AMNOG-Report 2018: Nutzenbewertung von Arzneimitteln in Deutschland* (Medhochzwei Verlag GmbH, June 2018).

8. Greiner and Witte, *AMNOG-Report,* 2018.

9. Product withdrawals are often driven by manufacturer fears that accepting a low price in Germany will lead to low prices in other European nations, 16 of which link their prices to those reported in the German market. If a product is withdrawn from the German market, its official price remains the one established unilaterally by the manufacturer at the time of launch. This list price is then used by other nations in international reference pricing comparisons, even if the drug in question is not in fact sold in Germany.

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