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FOR HEALTH TECHNOLOGY

## Reforming US Drug Pricing: Lessons from the German Experience

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## Overview

- Reform of drug pricing in the US must contain four elements to be meaningful
  - Evidence-based assessment of clinical value
  - Pricing aligned with clinical value
  - Pricing aligned with prices in other nations
  - Limits on price increases after initial launch
- These reforms seem unrealistic, but they have been achieved in Germany, a nation similar economically and culturally to the US
- What is the record of the German system, in terms of price, market access, social legitimacy?
- What are the structural factors responsible?
- Can this be done here?

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## Components of Meaningful Drug Price Reform in the US



Meaningful and sustainable reform of drug prices must include several components:

1. Assessment of every new drug compared to existing treatments
2. Prices aligned with these clinical assessments
3. US prices aligned with those in other nations
4. Limits on price increases not justified by increases in clinical benefits

But can this be done?

## Germany is Similar to the US

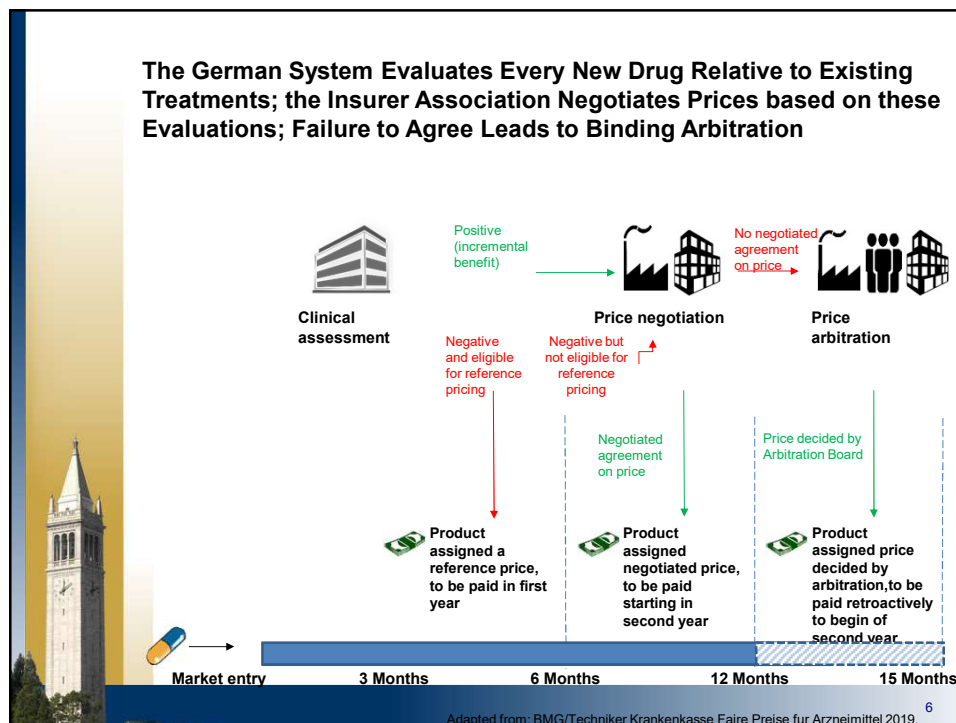


### Germany at a Glance

Population = 82 million  
 Regionalized = 16 states  
 Rank of economy = #1 Europe

No public insurer  
 150 competing private insurers

Culture of patient access  
 Insurers must cover all drugs approved by EMA (FDA)  
 Insurers cannot impose prior authorization on physicians  
 Insurers cannot impose high cost sharing on patients



## Success Factors in Benefit Assessment

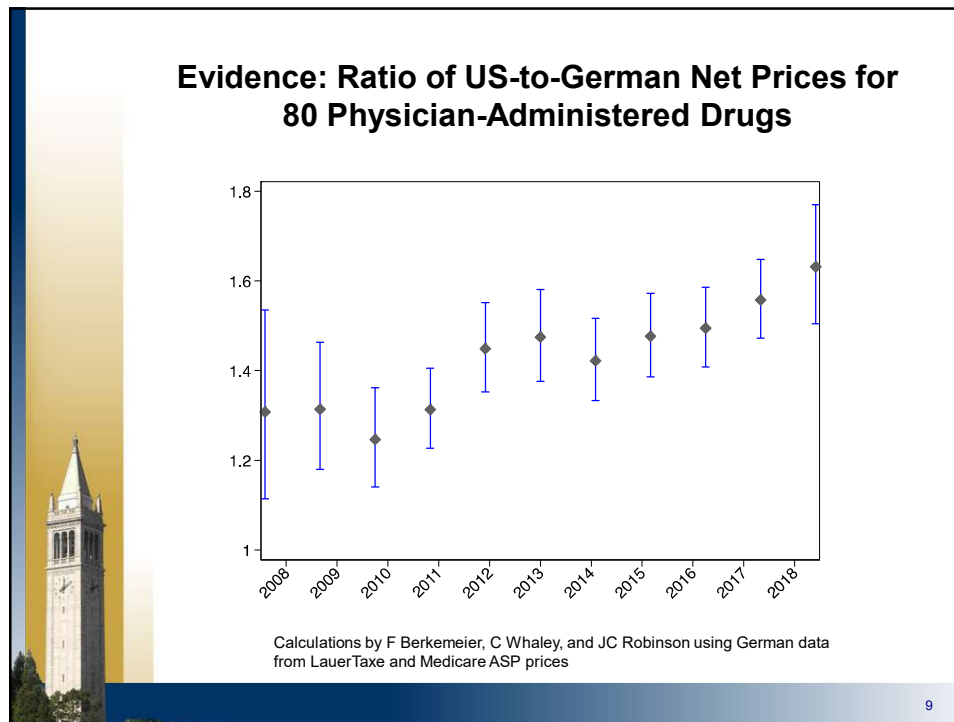
- The German system uses a centralized assessment process managed by the GBA (governed by physicians, insurers, hospitals, patient advocates)
- The process is public and transparent: analytic methods used, hearings conducted, documents used, final assessments
- Technical aspects of the assessments are delegated to the independent IQWiG institute, which focuses on clinical and not on cost considerations
- Participation is encouraged by manufacturers through early consultations, dossier preparation, public hearings
- Participation is encouraged by patient advocates, with insights into patient experience of disease and treatment
- Participation is encouraged by physician associations, to ensure GBA does not abrogate professional authority
- Participation is encouraged by insurers (Sickness Funds) to obtain insights into patterns of utilization and spending

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## Success Factors in Price Determination

- A large, attractive market for drug manufacturers:., prosperous economy, patient demand for access, strong physician authority over prescription, high visibility in other EU nations
- Immediate insurance coverage of drugs after EMA authorization, with free pricing in first year
- Mandatory arbitration: Board does not 'split the difference' between final payer and manufacturer offers, but conducts own assessment and makes its own price decision
- Repeated game: Aggressive price demands by manufacturers for drugs without substitutes could lead to aggressive insurer demands for rebates for drugs with substitutes
- Reputational concerns: Pharmaceutical firms must accept the principle of efficiency underpinning the entire German system, and fear political and public relations consequences

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### Other Components of Price Determination

- All insurers pay the same price for the same drug. A risk adjustment system protects insurers who enroll patients needing very expensive drugs
- No insurer can impose prior authorization restrictions on physicians or onerous cost sharing on patients
- Manufacturers are not allowed to unilaterally increase prices. Drug prices can only change subsequent to new assessment by GBA and new negotiations with insurers
- Price negotiations consider prices in other wealthy EU nations but it is generally recognized that Germany wants higher prices to ensure fastest market access

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