Article

Not peer-reviewed version

Balancing Innovation, Access, and Equity in Drug Pricing: Comparative Institutional Lessons for Advancing Universal Health Coverage

Kola Adegoke *, Temitope Kayode , Abimbola Adegoke , Deborah Dawodu

Posted Date: 17 September 2025

doi: 10.20944/preprints202506.2476.v3

Keywords: universal health coverage; drug pricing reform; value-based care; health equity; innovation incentives; comparative health systems; institutional design

 doi:10.20944/preprints202506.2476.v3

Article

Balancing Innovation, Access, and Equity in Drug Pricing: Comparative Institutional Lessons for Advancing Universal Health Coverage

Kola Adegoke [1,*,†], Temitope Kayode [1,†], Abimbola Adegoke [2,‡] and Deborah Dawodu [2,‡]

[1] School of Health Sciences and Practice, New York Medical College, Valhalla, NY, USA

[2] McWilliams School of Biomedical Informatics, UTHealth, Houston, TX, USA

* Correspondence: kadegoke@student.touro.edu

† Kola Adegoke and Temitope Kayode contributed equally to this work and share first authorship.

‡ Abimbola Adegoke and Deborah Dawodu contributed equally.

Abstract

Context: Global efforts to reform prescription drug pricing must navigate the trade-offs between four core objectives: cost containment, innovation incentives, equitable access, and administrative feasibility. In the United States, the Most Favored Nation (MFN) pricing rule and emerging value-based care (VBC) models reflect divergent strategies for aligning prices with therapeutic value. However, comparative analyses across different health systems are limited. **Methods:** A structured trade-off matrix was employed to compare pharmaceutical pricing strategies in the U.S., Canada, and the UK across four dimensions: cost containment, innovation incentives, equity in access, and implementation feasibility. The comparison is drawn from peer-reviewed scholarly literature, policy studies, and regulatory publications spanning the period 2007 to 2025. **Findings:** The MFN model offers short-term savings but can hinder innovation and outcome-based reimbursement in fragmented systems such as the U.S. The UK achieves significant value and pricing alignment through centralized institutions, such as NICE and the VPAG scheme. Canada, via the PMPRB, enforces price controls and international referencing, yet lacks integration of value-based principles and risk-sharing mechanisms. These findings have implications for the pursuit of Universal Health Coverage, illustrating how institutional design influences equity in access to essential medicines. **Conclusions:** Global models offer guiding principles, whereas sustainable pricing reforms must be designed to fit local political, institutional, and market conditions. Value-based incentives combined with cross-country yardsticks in hybrid models, though flexible and transparent, can create a more feasible reform approach for the U.S. Achieving Universal Health Coverage will require institutional designs that balance equity, innovation, and feasibility in pharmaceutical pricing.

Keywords: universal health coverage; drug pricing reform; value-based care; health equity; innovation incentives; comparative health systems; institutional design

I. Introduction

Setting prices for prescription medicines is currently the defining policy challenge in health systems. Despite advances in pharmaceutical science, drug prices remain high, straining public finances, broadening health inequities, and provoking broad political opposition. In high-income countries, the balance between affordability, innovation, equity, and administrative feasibility has never been stark.

Nowhere is this tension more pronounced than in the United States, where individual spending on drugs is many times that in peer nations. According to Kesselheim, Avorn, and Sarpatwari (2016), the average spending per person in the United States in 2013 was $858, whereas the average spending

 doi:10.20944/preprints202506.2476.v3

level across 19 other high-income nations in 2013 was $400. This disparity cannot be attributed to more extensive use or superior performance. These contrasts reflect structural inefficiencies, including extended market exclusivity, ineffective pricing negotiation mechanisms, and diverse insurance systems.

Globally, policymakers have reacted to either of these two approaches. One involves external price benchmarking, such as the U.S. Most-Favored-Nation (MFN) pricing rule, which anchors domestic prices to international prices. Another strategy is Value-Based Care (VBC), which ties payments for drugs to both clinical outcomes and therapeutic value. Whereas MFN strategies aim to achieve short-term price compression, VBC approaches strive to achieve long-term efficiency by rewarding value to volume.

All models had strengths and weaknesses. MFN-type mechanisms can yield rapid savings, but they are also risky due to disruptions to innovation or access. VBC requires robust data, clear outcome measures, and system-wide coordination, all of which vary in their national heterogeneity. Overall, these models embody the essential trade-off in drug pricing reform, balancing expenditure with therapeutic progress and patient equity.

This study contrasts how three countries—the United States, Canada, and the United Kingdom—took this trade-off. Each country has a distinct combination of policy tools.

- The U.S. tried MFN pricing as part of testing VBC in Medicare reform.
- Centralized price controls in Canada are administered by the Patented Medicine Prices Review Board (PMPRB).
- The UK includes health technology assessment (HTA), price limits, value-based reimbursement through the National Institute for Health and Care Excellence (NICE), and the voluntary scheme for brand medicine pricing and access (VPAG).

While often invoked in U.S. policy debates, these international models are in different institutional and political contexts. Adoption is rarely feasible in a one-to-one manner; however, systematic comparisons can identify mechanisms that are best aligned with broader health-system values.

Research Objective

This study compares pharmaceutical pricing reforms in the U.S., Canada, and the United Kingdom across four interdependent dimensions:

- **Cost containment**
- **Incentives for innovation**
- **Equity of access**
- **Implementation feasibility**

Equity in access to medicine is essential to Universal Health Coverage (UHC); however, it is still challenged by various drug pricing systems in most high-income countries. This analysis uses a structured policy matrix to compare how three national systems—the United States, Canada, and the United Kingdom—manage four interconnected priorities: cost containment, promotion of innovation, equity, and practical implementation. By examining how each system balances these trade-offs, the analysis offers practical guidance for developing reforms that are more responsive and sustainable, while also tailoring these ideas to the American context. The findings highlight the potential of hybrid approaches that combine international price benchmarking with value-based payment systems to improve access, maintain affordability, and foster innovation.

 doi:10.20944/preprints202506.2476.v3

II. Conceptual Framework and Methodology

1. Study Design

This study employs a comparative qualitative policy analysis design, utilizing a trade-off structured matrix, to examine drug pricing reforms in national health systems across the United States, Canada, and the United Kingdom. Conceptually, this study is founded on Bardach and Patashnik's eight-fold path, which places policy analysis in a systematic series of defining problems, building alternatives, and extrapolating outcomes, not as linear steps, but as cyclical phases that require simplification, modelling, and decision-making in the context of ambiguity (Bardach and Patashnik 2024). These principles guided the choice of trade-off dimensions and the design of the structured matrix in this cross-national comparison.

However, policy models are tools for simplification rather than for prediction. This approach emphasizes institutional logic and policy trade-offs for precise outcome predictions. Acknowledging these methodological constraints, this study prioritizes comparative logic and design structures over quantification and stakeholder elicitation.

The matrix evaluates policy formulation and implementation on four interdependent axes: cost containment, innovation incentives, health equity, and feasibility. This strategy is based on comparative health policy research and value-based pricing theory (Walt et al., 2008; Porter, 2010; Paris and Belloni, 2013; Garrison et al., 2013). A matrix approach was employed to facilitate cross-case comparisons while preserving system-specific nuances, particularly in complex reforms such as MFN pricing and VBC.

2. Country Selection and Rationale

The Countries were sampled using purposive theoretical sampling, not to achieve statistical generalizability but to capture the maximum variation in pharmaceutical pricing design. Each country has a distinct setting of regulatory systems, coverage arrangements, and policy tools, ranging from market-oriented models to centralized single-payer systems. Table 1 summarizes the selection logic. Refer to Appendix B (Comparative Policy Tables) for the complete trade-off matrix and country-specific summary.

Table 1. Country Typology and Selection Rationale.

Country	System Type	Rationale
U.S.	Market-based, fragmented	MFN pilot rule, ongoing VBC experimentation, political constraints (CMS 2020)
Canada	Hybrid public–private	Price ceilings via PMPRB, new 2024 Guidelines, HTA use increasing (Health Canada 2024)
UK.	Single-payer NHS	Strong centralized HTA (NICE) and value-linked VPAG scheme (DHSC 2023)

These systems have been frequently compared in health policy literature (Anderson, Frogner, and Reinhardt 2007) and are often referenced in U.S. debates on international price benchmarking (Kesselheim, Avorn, and Sarpatwari 2016).

3. Conceptual Framework

The analysis is structured as a four-dimensional policy trade-off matrix that characterizes the systemic pressures between the

- Cost containment – downward pressure on pharmaceutical prices
- Innovation incentives – retaining Research and Development (R&D) while controlling cost
- Equity – consistent and fair distribution between populations
- Fitness – administrative & political viability

 doi:10.20944/preprints202506.2476.v3

This framework is an extension of previous studies on value-based health systems (Porter 2010), performance-based risk-sharing (Garrison et al. 2013), and cost-effectiveness modelling in HTA systems (Neumann et al. 2011; Paris and Belloni 2013).

4. Data Sources and Search Strategy

This research uses 30+ sources from between 2007 and 2024, including:

- Peer-reviewed articles in Health Affairs, Value in Health, JAMA, etc.
- Government and agency reports (Centers for Medicare & Medicaid Services (CMS), PMPRB, the Department of Health and Social Care (DHSC), NICE, OECD)
- Industry and think tank briefings (QVIA Institute 2021, WHO Europe)

A semi-systematic search of documents was conducted between May and August 2025 using PubMed, JSTOR, Google Scholar, and grey literature collections, including the Centers for Medicare & Medicaid Services (CMS), QVIA Institute (2021), OECD iLibrary, WHO IRIS, and reports from think tanks. We employed Moher et al.'s (2009) strategy by constructing a PRISMA-style flow diagram (Appendix A) to outline the process of document selection. Of the 240 records initially identified, 37 were included in the final synthesis after screening for eligibility.

Inclusion criteria:

- Aiming towards drug pricing policy, MFN mechanisms, value-based pricing, or value-based care (VBC)
- Cross-country health technology assessment (HTA) models
- Australia or New Zealand policy context
- Peer-reviewed or authoritative gray literature

Exclusion criteria:

- Non-English publications
- Non-OECD countries
- Sources unrelated to pricing trade-offs

Gray literature was incorporated to reflect the latest policy trends, notably where research studies lag behind implementation (Paez 2017; QVIA Institute 2021).

5. Data Analysis Strategy

Documents were coded using deductive thematic content analysis, with coded text assigned to one of four trade-off dimensions: cost containment, innovation incentives, equity, and feasibility (Table 2). In turn, these are encoded in a comparative matrix to facilitate cross-country synthesis. The analysis was conducted based on policy logic and institutional design, rather than attempting to quantify outcomes due to variations in data availability and reporting patterns.

Table 2. Comparative Policy Trade-Off Matrix: U.S., Canada, and the UK.

Trade-off	U.S. (MFN/VBC)	Canada (PMPRB)	UK (NICE/VPAG)
Cost	MFN anchors prices downward	Price ceilings + public negotiation	VPAG caps growth; NICE enforces cost-effectiveness
Innovation	Potential undercutting of returns	Managed entry agreements are emerging	Balanced incentives via cost/QALY
Equity	Gaps in coverage, esp. Medicare	Drug access varies by province	The NHS ensures a universal baseline
Feasibility	Strong political opposition	Federal-provincial complexity	Strong central implementation

Note: This matrix synthesizes policy designs across systems and does not reflect empirical outcome measurement. (Adapted from author's analysis based on CMS 2020; Patented Medicine Prices Review Board 2025; DHSC 2023; NICE 2025.).

 doi:10.20944/preprints202506.2476.v3

6. Limitations

This policy analysis has several limitations:

- Divergences in value-based care (VBC) definitions and managed entry agreements between countries
- Inadequate outcome data on newer reforms, specifically after-2023 initiatives like VPAG
- No stakeholder interview or expert consultation was involved
- Clinical effectiveness and patient-level outcomes were not in the scope

These findings should be interpreted as system-level policy comparisons rather than empirical evaluations of health or economic outcomes (Leão et al., 2023; Dusetzina et al., 2019).

7. Ethical Considerations

As this research was based solely on secondary analysis of available document data, no ethics approval was required.

III. American Landscape: MFN and VBC in Tension

A. Regulatory Framework

For many years, the United States has wrestled with rising pharmaceutical spending, particularly in Medicare Part B. Two distinct policy frameworks, the Most Favored Nation (MFN) drug pricing regulation and the broader value framework of Value-Based Care (VBC), have emerged as alternatives to address the weaknesses of the fee-for-service (FFS) payment model. While both methodologies hold the promise of maintaining value and affordability, they are founded on divergent assumptions about how value enhancement and cost management can be best achieved.

MFN as a Price Control Mechanism

The Most Favored Nation Model, released as an interim final rule by the Centers for Medicare & Medicaid Services in 2020, proposed tying Medicare Part B drug payments to the lowest OECD-adjusted price among OECD nations. The 50 most costly physician services were replaced by a fixed fee add-on payment of 6 percent, thereby fragmenting pay-for-price pressures (CMS, 2020). Backed by the ASPE's report, which found that American Part B drug prices were up to 205% higher than those of their peers (ASPE 2020), the rule promised to achieve $85.5 billion in savings over seven years. However, due process, as well as opposition to the rule, highlighted that it acted against these principles, leading to the decision to suspend the rule.

B. Innovation and Cost Trade-offs

Compared to MFN, Value-Based Care offers a systematic reform mechanism by linking reimbursements to clinical outcomes and performance. The 2021 CMS Innovation Center strategy is founded on accountable care, health equity, and innovation (CMS Innovation Center, 2021). Only four of the 50 VBC models were successful in saving money, indicating that implementation challenges were present. (Miller 2009) advocated for episode-based payments and virtual bundling, while Neumann et al. (2011) argued for the promise of risk-sharing arrangements. Performance-based reimbursement models have been categorized into various taxonomies depending on their outcome metrics and payment structures (Carlson et al. 2010). However, these models are underutilized owing to challenges in outcome measurement and regulation.

C. Implementation Feasibility

The introduction of MFN was deficient in procedural legitimacy as it was introduced with low stakeholder involvement, which prompted litigation. VBC models offer a progressive and

 doi:10.20944/preprints202506.2476.v3

consultative mechanism through pilot and voluntary adoption. Given their adaptability to local contexts, especially in decentralized systems such as the United States, their practicality is strengthened. However, broad-based infrastructure and political will are still required.

D. Alignment with VBC or MFN

MFN and VBC are typically written as mutually exclusive, although both are designed to promote both value and affordability. MFN is based on extrinsic price anchoring, whereas VBC is based on rewarding internal performance. Having both is complex; the form that MFN takes may hinder the pricing variation that the VBC requires.

Bridging them would require

The use of international prices as negotiation baselines rather than ceilings

- Including outcome-based contracts in pricing negotiations.
- Strengthening real-world evidence infrastructure.

E. Summary Assessment

Table 3 compares the American setting with the trade-off between short-term spending control and long-term changes in the health system. The MFN approach has a direct, albeit short-run, path to reduced prices but is exposed to potential legal and political volatility, as well as conceivable disincentives to pharmaceutical innovation (CMS 2020; ASPE 2020). Value-based care (VBC) is more aligned with end-focused reform intentions, but requires intensive spending on infrastructure, stakeholder readiness, and administrative capacity (CMS Innovation Center, 2021; Neumann et al., 2011; Miller, 2009). Additional strategies, including patent reform and international referencing, are recommended to mitigate concerns regarding affordability (National Academies of Sciences, Engineering, and Medicine, 2018).

Table 3. Summary of U.S. Drug Pricing Reform Trade-Offs.

Dimension	Summary Assessment
Cost Containment	Moderate – MFN targets high prices but was suspended; VBC offers indirect levers
Innovation	Mixed – MFN may suppress R&D; VBC supports innovation tied to outcomes
Equity	Low-Moderate – Coverage gaps and fragmentation remain under both models
Feasibility	Low-Moderate – MFN lacked buy-in; VBC adoption is slow and infrastructure-dependent

Source: Author's synthesis based on CMS (2020), ASPE (2020), CMS Innovation Center (2021), Miller (2009), Neumann et al. (2011).

A hybrid strategy that integrates international reference pricing as a guide and embeds risk-sharing contracts within negotiated pricing frameworks may provide a balanced and politically viable pathway.

IV. Canada: PMPRB and Pricing Strategy

A. Regulatory Framework

Canada has traditionally employed centralized control over pharmaceutical prices to manage costs, while maintaining access to affordable medications. Central to this regime is the Patented Medicine Prices Review Board (PMPRB), an independent, quasi-judicial organization designed to ensure that the prices of patented medicines are not exorbitant. The PMPRB is involved in federal-provincial negotiations, often citing cost-effectiveness thresholds and internationally based price comparisons.

The PMPRB published new guidelines (effective January 1, 2026) on June 30, 2025, which shifted the agency from a strict ceiling-price strategy to a procedure-oriented strategy. The two-step review structure is as follows:

 doi:10.20944/preprints202506.2476.v3

- **Initial/Annual Review**: Screens based on monitoring and complaints.
- **In-Depth Review**: Triggered by red flags; involves therapeutic comparisons, HDAP input, and multivariate pricing analyses.

Typically, the Guidelines do not impose binding limits, but rather guide staff in their recommendations for section 85(1) or section 85(2) hearings under the Patent Act (PMPRB 2025). This modification is attributed to court rulings such as Merck Canada Inc. v. Attorney General of Canada (2022 QCCA 240), which restricted the board's authority to impose formula pricing without due process of law.

B. Innovations and Cost Trade-offs

Canada applies price comparison to PMPRB11, a peer group of countries. Although these guidance prices are nonbinding, their price reviews and negotiations are significantly influenced. Several studies have shown that benchmarking nations pay roughly half the price of non-benchmarking nations (OECD, 2021; Anderson et al., 2019).

From a value standpoint, CADTH provides cost-effectiveness analyses (typically in terms of cost per quality-adjusted life year, or QALY) to inform public coverage deliberations. However, the PMPRB focuses on price reasonableness rather than value, which creates a gap between pricing controls and VBC-type payment models.

Another weak area is industrial transparency. Reports voluntarily filed by Innovative Medicines Canada (IMC) between 2016 and 2020 indicate that payments to doctors totaled $345 million; however, no recipient-level information or detailed descriptions of the purposes were provided. Lexchin (2022) noted that:

"Even if IMC requires all of its members to make disclosures, such reforms will not suffice to provide transparency to company payments."

This opacity is problematic not only in terms of pricing legitimacy but also in relation to the underpinning of value-based contracting.

C. Implementation Feasibility

Centralization in Canada theoretically enables high administrative feasibility, although the differences between provinces complicate the uniform adoption of this approach. The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates prices, although provinces are free to exercise discretion in their decisions regarding drug coverage and reimbursement.

The 2025–2026 PMPRB Guidelines are a shift towards procedural defendability and flexibility, responding to prior legal weaknesses while endeavoring to maintain the board's power to the constitutionally permitted extent.

D. Alignment with VBC or MFN

Rationality in Canada's prices is closer to the Most Favored Nation-type benchmarking than to the VBC. Value-based care and outcome-based payments are rare in the Canadian environment.

The PMPRB does not incorporate performance-based risk-sharing, and the entire system lacks many levers or infrastructure that can integrate this type of model. There is an increasing convergence towards VBC in CADTH's HTA processes, although this is more indirect in relation to pricing.

E. Summary Assessment

Canada’s approach is characterized by stringent cost control and widespread access, primarily through regulatory price controls and cross-country benchmarking regimes (PMPRB, 2025; OECD, 2021). However, the approach is weak in innovation, adaptability, and transparency, primarily because of rigid pricing directives and ambiguous payment disclosures (Lexchin, 2022). While provincial variation remains a challenge to apply universally across countries, the approach

 doi:10.20944/preprints202506.2476.v3

demonstrates that national control can preserve both affordability and equity, albeit with a failure to transition towards value-based pricing (Table 4).

Table 4. Summary of Canada's Drug Pricing Reform Trade-Offs.

Dimension	Summary Assessment
Cost Containment	High – driven by PMPRB regulation and international reference pricing
Innovation	Moderate – conservative pricing may limit returns on high-risk R&D
Equity	High – public plans and price controls support universal baseline access
Feasibility	Moderate-High – central processes are strong, but provincial variation remains a barrier

Source: Author's synthesis based on PMPRB (2025), OECD (2021), Lexchin (2022).

The 2025–2026 Guidelines signal a shift towards a more procedurally grounded and judicially resilient pricing regime that is less reliant on static ceilings and better aligned with legal precedents (PMPRB 2025). Although not yet a complete value-based model, these reforms lay the groundwork for a more adaptive and integrated oversight of cost, innovation, and health system value.

V. The UK Model: NICE, VPAG, and NHS Centralization

The United Kingdom strikes a balance between centralized price setting, value-based decision-making, and formal adoption of innovation through institutions such as the National Institute for Health and Care Excellence (NICE) and the Department of Health and Social Care (DHSC). This approach represents a mature model for reconciling affordability, access, and innovation in a single-payer NHS environment.

A. Regulatory Framework

NICE is the centerpiece of the UK strategy, considering both the clinical and cost-effectiveness to inform NHS coverage. In 2024–25, NICE enhanced its role by accelerating health technology assessment (HTA) timelines and integrating a broader range of evidence, including genomic, digital, and AI-based technologies (NICE, 2025).

NICE's "severity modifier" reforms also shifted towards appraising medicines first for diseases that most severely affect quality of life, rather than the less encompassing "end-of-life" designation (NICE, 2025). A wider and equity-focused approach to appraisal characterizes these reforms. The updated appraisal model incorporates a severity modifier that prioritizes diseases with highly unmet needs (NICE 2025).

Supplementing appraisals by NICE is a voluntary scheme for brand medicine pricing, access, and growth (VPAG), implemented in 2024. The VPAG requires manufacturers to pay back rebates as well as cap revenue growth, with designs differing between old and new products (DHSC 2023).

A Statutory Scheme serves as the default option for non-VPAG companies. Its revenue controls are more stringent, with a 2022–2023 payment rate of 24.4% to maintain pricing parity (DHSC 2022). Both schemes incorporate cost control within a broader framework of agreed-upon flexibility.

B. Innovation and Cost Trade-offs

Unlike rigid MFN models, the UK pricing approach values commercial flexibility. VPAG facilitates outcome-oriented pricing, flexible access arrangements, and horizon scanning for the adoption of early innovations (DHSC, 2023). These tools facilitate variations in value-based pricing, while maintaining long-term research and development (R&D) incentives.

The updated NICE procedures also facilitate innovation by paving the way for ultra-rare or high-impact therapies, particularly those with very sparse clinical data, but significant unmet needs. By adopting a lifecycle evaluation method, NICE can revise its recommendations when new information emerges, supporting iterative access while maintaining cost-effectiveness (NICE, 2025).

 doi:10.20944/preprints202506.2476.v3

C. Implementation Feasibility

The single-payer nature of the UK facilitates high administrative simplicity and efficient policy alignment through pricing, reimbursement, and access to healthcare. The centralized position of the NICE, buttressed by commissioning in the NHS and MHRA approval, minimizes the time between regulatory approval and clinical implementation.

Existing NHS proposals, such as the 10-Year Health Plan, also envision a shift from hospital-centered to community- and digitally delivered care. NICE has responded to this by streamlining its appraisals of diagnostics, digital therapeutics, and AI technologies, thereby bringing rapid innovation adoption closer to wider systemic change (NICE, 2025).

D. Alignment with VBC or MFN

While the UK is technically not applying MFN-type cross-border benchmarking, the VPAG, together with the Statutory Scheme, simulates MFN controls in the guise of revenue caps and rebate clauses (DHSC, 2022, 2023). This allows for cost regulation that is independent of changing world price benchmarks.

otably, both frameworks are strongly aligned with the principles of VBC. The VPAG links rebate obligations and commercial agreements with the NICE appraisals. NICE reforms, such as the removal of stringent cost-saving thresholds for device access, prioritize patient outcomes and value over short-term cost savings (NICE 2025).

E. Summary Assessment

The UK serves as a prime example of centralized, value-based pricing regulation for drugs. Through health technology assessment by NICE, the Department of Health and Social Care's VPAG and Statutory Schemes have developed a pricing regime that optimally balances affordability, innovation, and access (DHSC, 2023; NICE, 2025). In contrast to the Most Favored Nation (MFN) approaches, which incorporate external price setting, domestic value assessment is privileged in the UK systems, as this allows for a more dynamic and outcome-congruent pathway (Table 5).

Table 5. Summary of UK Drug Pricing Trade-Offs.

Dimension	Summary Assessment
Cost Containment	High – enforced through VPAG revenue caps and statutory fallback mechanisms
Innovation	High–outcome–based pricing and faster appraisals support access to high-value drugs
Equity	High – universal NHS coverage ensures population-wide access
Feasibility	Highly centralized infrastructure enables coordination and speed

Source: Author's synthesis based on DHSC (2023), NICE (2025).

Ultimately, the UK provides a scalable and stable framework for balancing the trade-offs between cost control and innovation adoption in a publicly financed healthcare system. Its experience illustrates how the strategic alignment of pricing, reimbursement, and HTA can produce a cohesive and responsive model, particularly instructive for more fragmented systems, such as that of the United States.

VI. Trade-off Matrix: Comparing Cost, Innovation, Equity, Feasibility

Pricing reform in pharmaceuticals entails striking four interdependent trade-offs that must be balanced: cost control, incentives for innovation, equity in access, and the feasibility of implementation. The institutional structure, political will, and organization of the health system in every nation shape these tensions. These cross-system trade-offs, such as the trade-off between access speed and affordability, or predictability and innovation, are similar to what Bardach and Patashnik describe as the nature of the challenge to "establish commensurability" in practical policy decision-making (Bardach and Patashnik, 2024).

 doi:10.20944/preprints202506.2476.v3

This section consolidates the findings from American, Canadian, and UK studies in a comparative matrix (Table 6.1), highlighting the existence of similar or divergent policy models, particularly in relation to most-favored-nation (MFN) pricing and value-based care (VBC).

A. Cost Containment

All three systems attempt to regulate pharmaceutical expenditures, albeit to varying degrees. The U.S. MFN strategy promotes exogenous price control by using global references. Although estimated to yield $85.5 billion in savings over seven years (CMS, 2020), the strategy was statutorily weak and withdrawn. VBC projects offer more subtle instruments, such as shared savings and risk-based payments, but have achieved sparse short-run reductions (CMS Innovation Center, 2021; Leão, Silva, and Teles, 2023).

In contrast, Canada utilizes statutory authority through the Patented Medicine Prices Review Board (PMPRB) to impose price limits, which are aligned with those of 11 peer countries. These tools have again offered lower prices than in the U.S. (PMPRB, 2025; Anderson, Frogner, and Reinhardt, 2007).

In Britain, the VPAG program imposes yearly revenue limits on branded medicinal sales, with manufacturers paying back rebates when these thresholds are exceeded. This national regulatory mechanism avoids the fluctuations inherent in cross-country comparisons while achieving robust cost control (DHSC, 2023).

D. Implementation Feasibility

The feasibility depends on both administrative coherence and institutional capacity. (Table 6). MFN's inability in the U.S. was due to poor political legitimacy, hurried implementation, and disjointed payers (CMS, 2020). VBC adoption is more feasible; however, slow progress occurs as a consequence of weaknesses in data infrastructure, as well as regulatory ambiguity (Leão, Silva, and Teles, 2023).

Canada achieved reasonable viability. Despite the provision of statutory instruments and procedural transparency, provincial fragmentation continues to hinder cohesion (Patented Medicine Prices Review Board, 2025). Current court challenges, as with Merck Canada Inc. v. Attorney General, have also requested regulatory fine-tuning (Lexchin, 2022).

In the UK, NICE and the Department of Health and Social Care's central governance allows for smooth reform. NICE's 2025 strategy review specifically identifies responsiveness as a priority to enable quicker HTA recommendations and improved VBC integration (NICE 2025). European systems have increasingly relied on managed entry agreements to facilitate earlier access to therapies while managing budget impacts (Kanavos and Ferrario 2013).

Table 6. Comparative Trade-Off Matrix.

Trade-Off	U.S. (MFN/VBC)	Canada (PMPRB)	UK (NICE/VPAG)
Cost	MFN targeted prices but was suspended; VBC offers levers	Central regulation + benchmarking (PMPRB11)	VPAG caps revenue; NICE enforces cost-effectiveness
Innovation	MFN may deter R&D; VBC supports outcome-tied incentives	Conservative pricing may limit returns on high-risk R&D	Balanced: faster appraisals + outcome-based pricing flexibility
Equity	Fragmented coverage and affordability gaps	Broad access; some provincial inconsistency	The NHS ensures population-wide access
Feasibility	Low: MFN lacked buy-in; VBC faces infrastructure barriers	Moderate: strong central tools but interprovincial variation	High: centralized and coordinated implementation

Source: Author synthesis; see CMS (2020), PMPRB (2025), NICE (2025), and related references.

 doi:10.20944/preprints202506.2476.v3

E. Explaining the Differences

Institutional capacity is the most visible throughout the system. Highly centralized systems (the UK) are best suited to balance cost control with equity and innovation. Systematically divided systems (in the U.S. and Canada) are constrained in their application of policy tools by political fragmentation and jurisdictional boundaries.

The structure of the payers is key here. Large numbers can more easily integrate value-based reimbursement into single-payer systems, whereas risk sharing and coordinated pricing face insurmountable barriers (Garrison, Towse, and Udsen 2013; Leão, Silva, and Teles 2023).

Political viability ultimately determines the duration of the reform. Despite the strong cost justification, failure to implement MFN is symptomatic of poor convergence among stakeholders. Gradual negotiated paths, such as the VPAG, provide a model for building concordance around reform aims without abrupt interruption (DHSC, 2023; NICE, 2025).

VII. Policy Implications for the U.S.

Following Bardach and Patashnik (2024) in their approach to iteration and adaptive problem-solving, American policymakers should not view drug pricing reform as a binary choice between the Most Favored Nation (MFN) mechanism and Value-Based Care (VBC) approaches. Reform must be viewed as a portfolio of multi-layered approaches, best suited to the political, institutional, and legal realities. Practical incremental approaches, such as piloting hybrid models or combining value thresholds in Medicare negotiations, may have greater political feasibility than radical, structurally transformative approaches. Following the footsteps of the reform proposals introduced by Kesselheim et al. (2016), a multifaceted American approach should incorporate patent law reform, grant Medicare the authority to negotiate prices, and offer incentives for outcome-based pricing, as seen in the models of NICE and PMPRB.

Drawing on lessons from Canada and the UK, valuable insights can be gained.

Initially, efforts to use MFN-style international reference pricing were fortified by being situated in broader institutional arrangements involving value appraisals. The UK National Institute for Health and Care Excellence (NICE) and Canada Patented Medicine Prices Review Board (PMPRB) provide good examples of integrating cost containment with robust health technology assessment (HTA), allowing pricing to be constrained without resorting to strict instruments (DHSC, 2023; PMPRB, 2025).

Second, the hybrid frameworks are promising. MFN price anchors are possible, as are VBC arrangements, such as outcome-based agreements and indication-specific pricing, which can incentivize innovation while rewarding therapeutic value (Garrison et al., 2013; National Academies of Sciences, Engineering, and Medicine, 2018). This multilayered approach aligns with Bardach and Patashnik's (2024) concept of structured flexibility, in which feasible alternatives are specified, potential political objections are anticipated, and iterative adjustments are made in light of practical constraints.

Nonetheless, important institutional obstacles were identified. The American health system remains fragmented, with silos for payers, and weak federal authority over prices, especially when compared to the single-payer UK's NHS or integrated federal–provincial systems in Canada (Ridic, Gleason, and Ridic 2012). Legal obstacles, including statutory regulations governing Medicare drug negotiations and the risk of litigation, continue to hinder reform (CMS 2020).

Ultimately, transparency with stakeholders is crucial. Public trust requires transparent disclosure of pricing rationales, manufacturer–provider contracts, and robust systems of accountability to underpin outcome-based arrangements (Lexchin, 2022). Open government arrangements are ethically superior and vitally necessary to achieve sustainable consensus in a fractured policy environment.

 doi:10.20944/preprints202506.2476.v3

VIII. Limitations

This study has several methodological and contextual limitations that should be considered when interpreting the findings.

This research initially relied on secondary sources of information, including policy documents, peer-reviewed publications, and government reports. While triangulation was used to verify claims, primary interviews or consultations with stakeholders did not occur. As such, important fine points in political viability, administrative behavior, and industry responses can potentially remain underrepresented.

Secondly, the comparative matrix in the study documents system-level characteristics in designs rather than empirical health or economics endpoints. While cost containment and innovation incentives are discussed in conceptual frameworks, the comparison is unable to quantify the downstream effects of policies such as MFN or VBC on R&D pipelines, patient adherence, and mortality endpoints due to the use of uniform cross-national metrics.

Thirdly, in conceptually borrowing Patashnik and Bardach's (2024) eight-fold path, application is unavoidably partial. This study favors structured comparisons and trade-off modelling. However, it does not extensively draw on cost-benefit analysis, political mapping, or implementation forecasting, all steps that would deepen the policy design dimension.

Fourthly, Value-Based Care (VBC) and Managed Entry Agreements (MEAs) are defined differently across countries. Different definitions hinder a straightforward comparison of implementation intensity or effectiveness.

Fifthly, as reforms are ongoing, particularly in Canada (PMPRB Guidelines, 2025–2026) and the UK (VPAG reforms, 2024–2025), the policy environment remains dynamic. The long-term effects remain unknown and may only be best understood through a longitudinal study.

Lastly, gray literature, though usually up-to-date and policy-relevant, may lack the methodological rigor found in peer-reviewed literature. However, inclusion is necessary to capture real-time developments and complement gaps in the academic literature.

In line with Bardach and Patashnik's (2024) caution against "false precision," this study aims to identify broad trade-offs rather than recommending particular solutions, given the inherently complex and adaptable nature of cross-national health policy reform.

IX. Conclusion and Future Research

This analysis found that neither MFN pricing nor VBC could remake the American drug market. MFN mechanisms can trigger short-run affordability but potentially undermine innovation and access if pursued single-mindedly. Nevertheless, VBC is aligned with long-term system goals; however, it requires substantial institutional investment, as well as regulatory cooperation (Chandra and Skinner 2012; Neumann et al. 2011).

Effective reform entails reconciling the trade-offs between cost control, innovation incentives, equity, and achievability. The UK and Canada demonstrate that value-based pricing approaches, supported by institutional arrangements, can reconcile these objectives better than others (DHSC, 2023; PMPRB, 2025; NICE, 2025). For the U.S., achieving country-sensitive hybrid approaches is more practical than importing wholesale foreign design (Anderson, Hussey, and Petrosyan 2019).

Further empirical research is needed to evaluate:

- The real-world impact of outcome-based pricing contracts.
- Innovation responses to price controls;
- The Effect of Transparency Initiatives on Formulary and Prescribing Decisions.

Ultimately, sustainable U.S. reform must integrate evidence-based pricing, transparent value thresholds, and adaptive policy tools that reflect the system's unique constraints and opportunities. Building such an outcome-linked pricing architecture is vital to ensuring both innovation and affordability.

 doi:10.20944/preprints202506.2476.v3

Author Contributions: Conceptualization, K.A. and T.K.; methodology, K.A.; validation, K.A., T.K., and A.A.; formal analysis, K.A.; investigation, K.A. and T.K.; resources, K.A. and T.K.; data curation, K.A.; writing—original draft preparation, K.A.; writing—review and editing, T.K., A.A., and D.D.; visualization, K.A.; supervision, A.A.; project administration, K.A.; funding acquisition, A.A. All authors have read and agreed to the published version of the manuscript.

Funding: No external funding was received for the study.

Institutional Review Board Statement: This study did not involve human or animal subjects, and no new data were collected.

Informed Consent Statement: This study did not require ethics approval as it used publicly available data

Not applicable.

Data Availability Statement: Data supporting this study's findings are openly accessible on the **Open Science Framework (OSF)** at https://doi.org/10.17605/OSF.IO/AU9WK. This includes all coded documents, case summaries, and analytic frameworks cited in the manuscript. The dataset consisted only of publicly available records and did not contain any identifiable or sensitive personal information.

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical Considerations: This research utilized only publicly available documents; therefore, institutional ethics approval was not necessary. It is, however, worth noting that ethical diligence was observed in the presentation of sensitive content, avoiding sensationalism and framing case narratives within a systemic analysis rather than individual blame.

References

Anderson, Gerard F., Peter Hussey, and Varduhi Petrosyan. 2019. "It is Still the Prices, Stupid: Why the US Spends So Much on Health Care." *Health Affairs* 38 (1): 87–95. https://doi.org/10.1377/hlthaff.2018.05144.

Bardach, Eugene, and Eric M. Patashnik. 2024. *A Practical Guide for Policy Analysis: The Eightfold Path to More Effective Problem Solving*. Washington, DC: CQ Press. https://research.ebsco.com/linkprocessor/plink?id=204b0780-6889-3ebc-bc6b-0462740ccbef.

Berwick, Donald M., and Andrew D. Hackbarth. 2012. "Eliminating Waste in US Health Care." *JAMA* 307 (14): 1513–16. https://doi.org/10.1001/jama.2012.362.

Carlson, Josh J., Richard G. Sullivan, Seema Garrison, and Sean D. Neumann. 2010. "Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance-Based Reimbursement Schemes between Healthcare Payers and Manufacturers." *Health Policy* 96 (3): 179–90. https://doi.org/10.1016/j.healthpol.2010.02.005.

Centers for Medicare & Medicaid Services (CMS). 2020. "Most Favored Nation (MFN) Model Interim Final Rule." *Federal Register*, November 27, 2020. https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model.

Centers for Medicare & Medicaid Services (CMS). 2021. *Driving Health System Transformation: A Strategy for the CMS Innovation Center's Second Decade*. Accessed August 27, 2025. https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper.

Chandra, Amitabh, and Jonathan Skinner. 2012. "Technology Growth and Expenditure Growth." *Journal of Economic Literature* 50 (3): 645–80. https://doi.org/10.1257/jel.50.3.645.

 doi:10.20944/preprints202506.2476.v3

Department of Health and Social Care (DHSC). 2022. *Statutory Scheme Impact Assessment*. https://assets.publishing.service.gov.uk/media/6294d952e90e0703a32feb89/Statutory_Scheme_impact_assessment_medicine_pricing_v3.0_FINALdated_May_2022.pdf.

Department of Health and Social Care (DHSC). 2023. *2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth*. https://assets.publishing.service.gov.uk/media/657b2977095987001295e139/2024-voluntary-scheme-for-branded-medicines-pricing-access-and-growth.pdf.

Dusetzina, Stacie B., Youngmin Kwon, Nancy L. Keating, and Haiden A. Huskamp. 2025. "Medicare Part D Redesign Savings May Be Lower for Beneficiaries with Spending Below the Out-of-Pocket Cap." *Health Affairs* 44 (6): 650–58. https://doi.org/10.1377/hlthaff.2024.01527.

Garrison, Louis P., Adrian Towse, Andrew Briggs, Mike De Pouvourville, Bengt Jonsson, Michael J. Kissick, and Michael Drummond. 2013. "Performance-Based Risk-Sharing Arrangements." *Value in Health* 16 (5): 703–19. https://doi.org/10.1016/j.jval.2013.04.011.

Health Canada. 2024. "PMPRB Overview." https://www.canada.ca/en/patented-medicine-prices-review.html.

IQVIA Institute. 2021. *Global Medicine Spending and Usage Trends: Outlook to 2025*. https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends-outlook-to-2025.

Kanavos, Panos, and Alessandra Ferrario. 2013. *Managed Entry Agreements for Pharmaceuticals: The European Experience*. Brussels: European Commission. https://core.ac.uk/reader/16379320.

Kesselheim, Aaron S., Jerry Avorn, and Ameet Sarpatwari. 2016. "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform." *JAMA* 316 (8): 858–71. https://doi.org/10.1001/jama.2016.11237.

Leao, Diogo L. L., Jeroen N. Struijs, Pim P. Valentijn, and Diana M. W. J. M. Dujardin. 2023. "The Impact of Value-Based Payment Models for Networks of Care and Transmural Care: A Systematic Literature Review." *Applied Health Economics and Health Policy* 21 (3): 441–66. https://doi.org/10.1007/s40258-023-00790-z.

Lexchin, Joel. 2022. "Pharmaceutical Company Payments to Healthcare Professionals and Healthcare Organizations in Canada: An Observational Study." *Healthcare Policy* 17, no. 3 (2022): 42-48. https://www.longwoods.com/content/26729/healthcare-policy/pharmaceutical-company-payments-to-healthcare-professionals-and-healthcare-organizations-in-canada-

Merck Canada Inc. v. Attorney General of Canada. 2022 QCCA 240. https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

Miller, Harold D. 2009. "From Volume to Value: Better Ways to Pay for Health Care." *Health Affairs* 28 (5): 1418–28. https://doi.org/10.1377/hlthaff.28.5.1418.

Moher, David, Alessandro Liberati, Jennifer Tetzlaff, Douglas G. Altman, and The PRISMA Group. 2009. "Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement." *PLoS Medicine* 6 (7): e1000097. https://doi.org/10.1371/journal.pmed.1000097.

National Academies of Sciences, Engineering, and Medicine. 2017. *Making Medicines Affordable: A National Imperative*. Washington, DC: National Academies Press. https://doi.org/10.17226/24946.

National Institute for Health and Care Excellence (NICE). 2025. *Annual Report and Accounts 2024 to 2025*. https://indepth.nice.org.uk/nice-annual-report-and-accounts-2024-25/index.html.

Neumann, Peter J., James D. Chambers, Françoise Simon, and Lisa M. Meckley. 2011. "Risk-Sharing Arrangements That Link Payment for Drugs to Health Outcomes Are Proving Hard to Implement." *Health Affairs* 30 (12): 2329–37. https://doi.org/10.1377/hlthaff.2010.1147.

 doi:10.20944/preprints202506.2476.v3

OECD. 2021. *Pharmaceutical Innovation and Access to Medicines*. Paris: OECD Publishing. https://www.oecd.org/content/dam/oecd/en/publications/reports/2018/11/pharmaceutical-innovation-and-access-to-medicines_g1g98d77/9789264307391-en.pdf.

Paris, Valérie, and Annalisa Belloni. 2013. *Value in Pharmaceutical Pricing*. OECD Health Working Papers No. 63. Paris: OECD Publishing. https://doi.org/10.1787/5k43jc9v6knx-en.

Patented Medicine Prices Review Board (PMPRB). 2025. *Guidelines for PMPRB Staff: Administrative Process for Excessive Price Hearing Recommendation*. https://www.canada.ca/en/patented-medicine-prices-review.

Peterson-KFF Health System Tracker. 2025. "U.S. Health Spending vs. Other Countries." https://www.kff.org/health-costs/health-spending-in-the-u-s-as-compared-to-other-countries-slideshow/.

Porter, Michael E. 2010. "What Is Value in Health Care?" *New England Journal of Medicine* 363 (26): 2477–81. https://doi.org/10.1056/NEJMp1011024.

Ridic, Gordana, Suzanne Gleason, and Ognjen Ridic. 2012. "Comparisons of Health Care Systems in the United States, Germany and Canada." *Materia Socio-Medica* 24 (2): 112–20. https://doi.org/10.5455/msm.2012.24.112-120.

U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2020. *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures*. Washington, DC: U.S. Department of Health and Human Services. https://aspe.hhs.gov/reports/comparison-us-international-prices-top-medicare-part-b-drugs-total-expenditures.

Walt, Gill, Lucy Gilson, Ruairi Brugha, and David Buse. 2008. "'Doing' Health Policy Analysis: Methodological and Conceptual Reflections and Challenges." *Health Policy and Planning* 23 (5): 308–17. https://doi.org/10.1093/heapol/czn024.