Assessing the U.S. Medical Innovation System Extended Abstract
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Introduction

The U.S. medical innovation system is considered among the most productive globally, accounting for 30% to 40% of the global market, 45% of global pharmaceutical sales, and 22% of global production (Santora, 2025). However, concerns persist regarding whether the current standards of innovation appropriately translate scientific advances into widespread population health benefit. Current reward structures are largely based on patent protection, regulatory exclusivities, and pricing power (Nagpal et al., 2021; Thrasher, 2021). These are insensitive to two dimensions of innovation performance: the quality of therapeutic advancement relative to existing standards of care and the reach of approved therapies among clinically eligible populations. As a result, the system may systematically reward innovations that maximize market power rather than population-level health impact.

Proposed Framework

This paper proposes a framework for assessing pharmaceutical innovation that supplements existing measures of output with quality and reach based metrics. Rather than challenging the role of markets or intellectual property in driving innovation, the framework is grounded in a regulatory perspective: markets respond to signals, and current policy signals prioritize approval and exclusivity while underweighing therapeutic value and usage (Kesselheim & Avorn, 2021).

First, this paper defines a quality-based dimension of innovation that is conceptualized as incremental therapeutic benefit relative to standard of care, durability of effect, and generalizability across real-world patient populations. While such dimensions are often discussed qualitatively, they are often not incorporated into post-approval reward structures. As such, drugs offering marginal clinical improvement may receive rewards comparable to those representing substantial therapeutic advances.

Second, the paper introduces market reach as a measure of performance; this can be defined as the number of patients receiving a therapy within a post-market period relative to the total number of patients possibly eligible for the therapy based on its indication.

This metric captures the extent to which an approved innovation is translated into utilization and allows for stratification by insurance status, income, geography, and demographic characteristics. The ratio also distinguishes between economic success (e.g., generation among a subset of patients) and systemic success (e.g., population-level uptake). Under current incentive structures, therapies with low reach but high prices may be considered successful, though contributing inadequately to aggregate health outcomes. Moreover, the market reach measure must be clinically validated, capturing the proportion of patients who are truly eligible for the therapy

based on FDA indications and established clinical criteria, rather than measuring raw sales or prescription volume—a step necessary to prevent potential fraud or abuse.

Comparison

Prior legal scholarship has cautioned that placing pharmaceutical innovation decisions directly under government control would require politically contentious judgments about which diseases to prioritize, how much benefit justifies public investment, and how to allocate limited research funds; in response, these scholars advocate "value-agnostic" mechanisms, like structural pricing or patent reforms (Madl 2019). This perspective encourages the industry to continue making research and development decisions based on expected returns over public valuation. Value-agnostic mechanisms preserve private companies' freedom to pursue innovation based on expected returns, but they do not address how public policy should evaluate or condition those returns. This paper argues that once society grants monopoly protections, it is reasonable to evaluate the outcomes generated by those protections. The proposed framework incorporates value considerations, but it does so in a manner that preserves the industry's freedom to pursue innovation while enabling public policy to assess the outcomes of exclusivity-protected investments.

Other proposals, such as the Health Impact Fund (Hollis & Pogge, 2008), also strive to reward pharmaceutical innovation based on health outcomes. However, these approaches rely on large, sustained global reward pools and complex international coordination. They also alter market incentives by requiring participation in a separate reward system. In contrast, this paper's proposed framework focuses on existing U.S. data to measure quality and reach within the populations actually affected by a therapy, preserving industry autonomy and operating within existing regulatory and reimbursement structures. By focusing on measurable market outcomes, this approach provides a method of synchronizing incentives.

Aligning financial incentives with social value can be feasible and drive innovation toward products with significant health impact (Conti et al., 2021). Rather than prescribing specific regulatory reforms, the analysis emphasizes how incorporating post-market performance evaluations could reshape the direction of innovation without undermining investment incentives. Illustrative examples from high-spend therapeutic areas demonstrate how quality and reach based assessments can contribute to conclusions about innovation value (Radder & Smiers, 2023; EFPIA, 2017).

Conclusion

By evaluating innovation through impact, operationalized as therapeutic benefit and reach, this framework contributes to ongoing discussions surrounding drug pricing, access, and the social value of biomedical innovation. The paper aims to provide a foundation for future empirical

work evaluating how alternative incentives can help improve the alignment between pharmaceutical innovation and public health outcomes.