



Missing Markets for Innovation: Why Drug Repurposing Remains Undersupplied

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Drug repurposing involves identifying additional therapeutic indications for drugs that are already approved for other uses. For example, a drug originally approved to treat one condition may later be found effective against a different disease, allowing researchers to build on existing clinical knowledge rather than starting from scratch. From a scientific perspective, repurposing can be attractive as safety profiles are often well characterized, and development timelines, costs, and risks tend to be **lower** than for entirely new compounds.

Many approved drugs act on biological pathways implicated in multiple diseases, meaning that repurposing them can **unlock therapies** for conditions that may not have effective treatments—such as some cancers and rare diseases. In these cases, repurposed therapies can generate substantial public health benefits by expanding treatment options, improving outcomes, and reducing development timelines for patients with unmet medical needs. Yet despite this potential, evidence from a recent NBER **working paper** shows that high social value alone is often insufficient to motivate private investment when firms cannot reliably capture the returns from developing new uses. As a result, misalignment between public value and private returns contributes to persistent underdevelopment of this type of biopharmaceutical innovation.

The paper shows that economic incentives for repurposing are often misaligned. While new compounds typically benefit from both patent protection and **market exclusivity**—a period during which a brand-name drug is protected from generic competition to enable the innovator to earn back their costs—new uses of existing drugs often do not. In many cases,



the underlying compound is no longer protected by effective market exclusivity, enabling generic entry and limiting innovators' ability to capture the market value of clinical evidence they generate.

As a result, firms have the strongest incentives to invest in new uses of existing drugs shortly after initial approval. As market exclusivity approaches expiration, those incentives decline. Once exclusivity expires, private incentives to pursue research and development (R&D) for new indications largely disappear, creating what the authors describe as a "missing market" for new uses—one where formal intellectual property rights are needed to incentivize R&D, but these rights are either unavailable or unenforceable.

This reflects a classic appropriability problem. Even when a new use is clinically valuable, firms may be unable to capture sufficient returns to justify the investment required to develop and validate it.

KEY FINDINGS

Innovation in new drug uses is highly responsive to enforceable exclusivity. When effective protection is available, firms invest in developing new uses. When it is absent, research and commercialization activity declines sharply.

The analysis shows that the development of new uses is concentrated early in a drug's commercial life. Roughly a decade before market exclusivity ends, roughly 7 percent of drugs are reapproved for at least one additional use, but the probability of such approvals steadily declines over time, falling to nearly zero once market exclusivity expires. Clinical trial activity follows a similar trajectory, declining markedly over a drug's life cycle. Together, these findings point to a "missing market" for new uses after market exclusivity expires.

The paper finds that the enforceability of exclusivity largely explains the results. Once effective market exclusivity ends, approvals for additional uses become exceedingly rare, even as other types of follow-on innovation—such as new patient populations, dosages, or strengths—decline much less sharply.

Overall, the findings indicate that scientifically viable repurposing opportunities continue to exist but are rarely pursued once market exclusivity is no longer enforceable. The resulting decline in innovation reflects weak incentives rather than a lack of clinical potential.

The authors estimate that if stronger incentives existed, roughly 200 to 800 additional uses for existing drugs could have been developed, pointing to a large amount of unrealized innovation. If missing markets are the underlying constraint, policy responses should focus on improving incentives for firms to invest in drug repurposing R&D, while preserving competition and regulatory rigor.



POLICY TAKEAWAYS

Effective market exclusivity is key to drug repurposing incentives.

When new clinical uses do not confer meaningful market exclusivity, firms may underinvest in repurposing R&D even when potential social value is high.

Market design and reimbursement rules shape incentives for developing new uses.

The ease with which competitors can adopt and benefit from new R&D affects whether private R&D investments are financially viable for an innovator.

R&D gaps may persist where market exclusivity is structurally limited.

In such cases, narrowly targeted approaches—*such as public funding or other push/pull mechanisms linked to successful repurposing R&D*—could help address underinvestment.

These findings underscore a broader lesson for innovation policy: scientific opportunity alone is not enough to sustain innovation at scale. When market incentives fail to reward discovery, investment declines and valuable therapies may go unrealized. For policymakers, drug repurposing thus serves as both a cautionary tale and a policy opportunity. Better aligning incentives with public value could unlock a large pool of underdeveloped innovation—without compromising safety, competition, or scientific rigor. Doing so requires targeted policy responses.

POLICY RECOMMENDATIONS

1. Reduce legal uncertainty around IP for new uses.

Investment in drug repurposing is sensitive to the strength and enforceability of IP protections. Congress should clarify patent subject matter eligibility for novel, clinically validated therapeutic and diagnostic innovations, making clear that such life science inventions can be patentable.

2. Preserve regulatory exclusivity frameworks that support follow-on innovation.

Data exclusivity plays an important role in sustaining biopharmaceutical innovation. Maintaining existing exclusivity periods—12 years for biologic drugs and 5 years for small-molecule drugs—and defending them in trade agreements helps sustain incentives to generate new clinical evidence beyond a drug's first approval.



3. Deploy push and pull incentives when market exclusivity ends.

Public funders such as the NIH can help fill R&D gaps by supporting repurposing research and clinical trials. On the pull side, tools such as advance purchase commitments or indication-specific reimbursement bonuses could reward successful new uses, ensuring a return even when market exclusivity has expired.

Editors' Recommendations

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