Incentivizing Generic Drug Repurposing for Common Diseases in the United States

Policy Memo

Introduction

Generic drug repurposing – the process of conducting research on existing generic drugs to identify new indications – may offer a faster and cheaper option for drug development. Estimates of the average cost of bringing a new drug to market range from $1.5- $2.5 billion and can take on average 10.5 years to complete.[i,ii] Research and development for repurposed drugs, however, costs an estimated $300 million and can be completed in as few as 3 years.[iii] This is because drugs targeted for repurposing have already been proven safe through clinical trials, allowing developers to bypass early stages of testing and mitigate some risk of initiating new clinical trials. Generic drug repurposing presents a unique opportunity to identify alternatives to expensive treatments and identify treatments for diseases where there is unmet medical need or limited funding.

Insufficient incentives

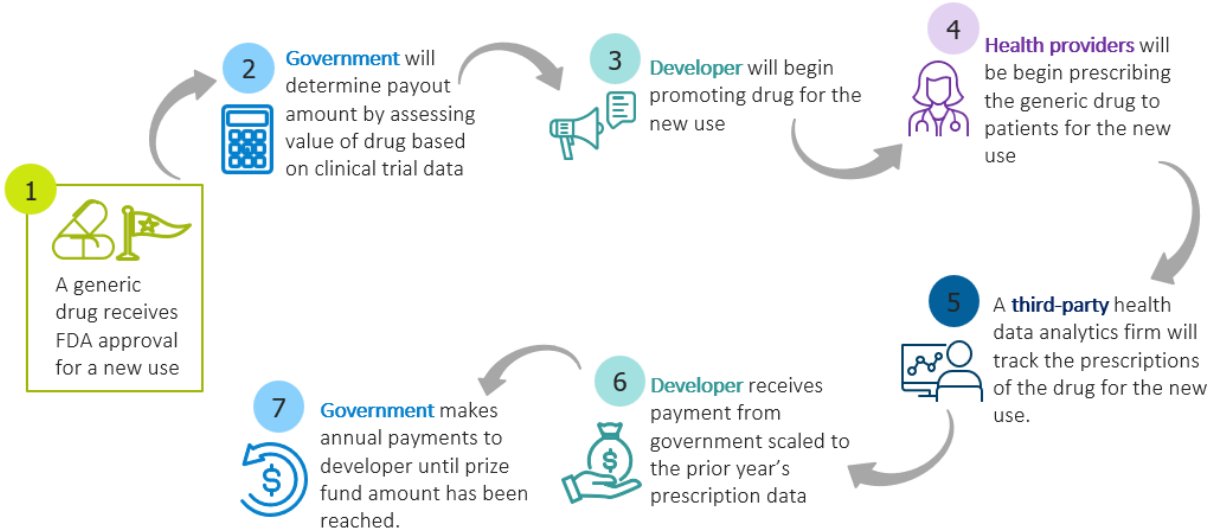
Despite the benefits of generic drug repurposing, developers are not interested in conducting studies on existing drugs for new indications once generic competitors enter the market. When generics become available, a drug's price is lowered substantially – about 80% lower than the brand name within 5 years.[iv] This reduces the firm's ability to recoup costs of R&D from researching additional uses and limits its profit margins. Firms therefore lack incentives to invest in additional research on the drug. Creating incentives for generic drug repurposing can address this market failure. Current approaches rely on push funding, such as research grants, but this approach selects a "winner" for the funds in advance. However, firms often have private information about potential new uses of drugs that funders may not be aware of. Therefore, pull funding may be a complementary strategy since it does not pre-select winners, but rather rewards any firm that successfully discovers new uses.

Solution description

We propose a pull incentive mechanism with the following design characteristics:

- The reward will take the form of a cash prize linked to the use of the generic drug for the new indication and paid out in installments over a set period.
- Payment amounts will be linked to the value of the repurposed therapy.
- The prize will be paid to the firm that conducts the repurposing studies and achieves success.
- Success will be defined as regulatory approval for the new indication (i.e., label expansion).
- The mechanism will be disease agnostic, or in other words, any common disease affecting the US population is eligible as the target indication for a repurposed generic drug.

Payments would work like this:



Benefits and costs analysis

The reward amount paid to the firm must be large enough to attract firms' investments, but also reasonable for the funder and not exceeding the value of the drug. We first estimated the 'necessary reward amount' to attract firms by considering the cost of trials, risk of failure, expected rate of return, and time value of money since the reward will be paid out over a number of years. However, we also want to scale the payments to reflect the value, or health impact, of the repurposed drug. We do this by linking the reward total to disability adjusted life years (DALYs) averted. Depending on the drug's effectiveness for the new indication, this may be more or less than the 'necessary reward amount.' Higher value drugs though may result in excessive reward payments, and we therefore proposed a limit to ensure a reasonable cost to the funder while still recognizing the value of the drug. Firms could therefore be rewarded **up to $550 million** per repurposed drug.

We also want to determine that the benefits of a reward for generic drug repurposing would justify the costs (i.e., reward payment and monitoring costs). To calculate benefits, we measured health impact from a repurposed generic drug in DALYs averted and the resulting societal economic gains for three example diseases/conditions: stroke, long COVID, and preterm birth. Analyzing the costs and benefits together, we determined that for every $1 invested by the funder in simple repurposed drugs, societal returns would amount to would amount to the following per disease:

Disease/Condition	Societal returns per $1 invested
Stroke	**$45.10**
Long COVID	**$6.50**
Preterm Birth	**$8.10**

Implementation and Funding

The funder and implementer of the mechanism will be responsible for setting the reward payment expectations, engaging third parties to track indication-specific prescription data, assess the value in DALYs and total payment amount, and making the annual payment to the developer. Various types of funders may have an interest in this proposed mechanism, including philanthropies and private payers. However, we posit that the US government would be the most suitable implementer of a pull mechanism for generic drug repurposing because it aligns with federal efforts to lower drug prices and find innovative approaches to developing biomedical solutions, and it would stand to benefit from the cost savings and outcome improvements of drug repurposing. Identifying the right home within the federal government for this mechanism is not straightforward since new authorities from Congress may be required to implement it. We recommend that a pilot focused on some promising leads for repurposed generics could be implemented by ARPA-H, a new agency focused on solutions to support biomedical innovations. If a pilot program can demonstrate success and confirm the anticipated cost savings and benefits, there may be a path for broader adoption and support for any legislative action that may be needed to establish the mechanism.

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[i] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. 2016;47:20-33. doi:10.1016/j.jhealeco.2016.01.012

[ii] Wouters OJ, McKee M, Luyten J. Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. *JAMA*. 2020;323(9):844-853. doi:10.1001/JAMA.2020.1166

[iii] Pillai M, Wu D. Validation approaches for computational drug repurposing: a review. *AMIA Annual Symposium Proceedings*. 2023;2023:559.

[iv] Informatics II for H. *Price Declines after Branded Medicines Lose Exclusivity in the U.S Introduction*.; 2016.