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Incentivizing Generic Drug Repurposing in the United States

Generic drug repurposing should be a central strategy for the Trump Administration as it looks to achieve better health outcomes while improving the efficiency of government spending.

Value of Generic Drug Repurposing

Generic drug repurposing – the process of researching existing generic drugs to identify new uses – may offer new, effective treatments at lower costs. Generic drugs, if studied further, could unlock new treatments for unmet medical needs and offer improved options for chronic health challenges like diabetes and depression. Repurposing generic drugs can also cut costs of drug development and healthcare spending. Whereas traditional drug development typically costs ~$1.5-2.5 billion, conducting repurposing studies can cut costs by ~85% by leveraging existing preclinical and safety data to bypass early development phases. These medical and financial benefits of generic drug repurposing were recently highlighted by effective treatments identified for COVID-19.

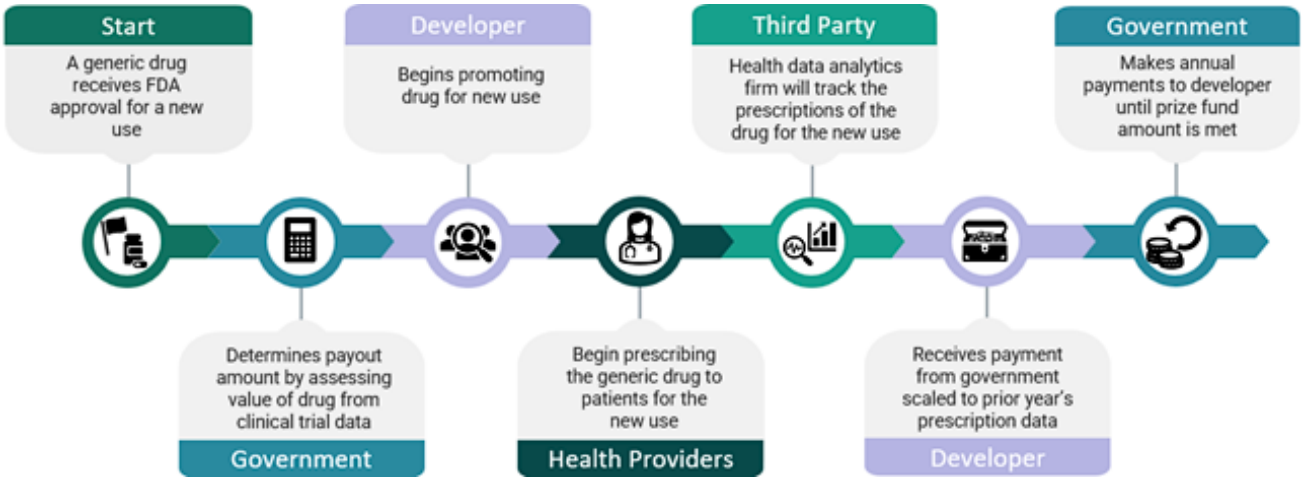
Insufficient Incentives

There is a lack of incentives for exploring the benefits of unpatentable treatment interventions, which may leave possible beneficial therapies unexplored. This includes finding new uses of generic drugs. Although a patent can be obtained for a new use of a generic drug, it is essentially impossible to enforce. Therefore, drug developers rarely conduct new studies on generic drugs due to lower financial returns compared to new drug discovery. The sparse research conducted on potential new uses of generic drugs is typically conducted by academic or nonprofit institutions with limited funding from governments or philanthropic entities. Despite strong research capabilities, these institutions lack the resources to independently navigate the regulatory approval process and connect treatments with patients. Also, the current funding approach may miss out on promising opportunities from organizations with relevant expertise and insights.

Rewarding Generic Drug Repurposing

Creating a financial "pull" incentive that rewards organizations based on results could be an efficient and effective way to identify new affordable treatments. We suggest a mechanism design that would incentivize organizations to research new uses of generic drugs by rewarding successful identification and regulatory approval of a new use. The organization that repurposes the drug would receive payments linked to the use of the repurposed generic drug with amounts based on value (either health impact or cost-savings). To inform payments, a third-party health data firm can support prescription tracking and value determinations.

Given the public benefits of generic drug repurposing, the federal government is well-suited to fund and implement this mechanism. Payments might be made via public healthcare payers like Medicare and Medicaid who may reap the cost-saving benefits of repurposed generic drugs. Preliminary modeling suggests cost savings opportunities for these agencies. Another option is creating a new government-run mechanism. Each of these potential pathways is further explored below.



The **White House** could prioritize the role of generic drug repurposing in its health/science agenda by championing inter-agency efforts and working with the private sector. In addition, the White House can lead efforts to advance solutions that can provide an agency with new authorities, similar to other pull mechanism programs and proposals (e.g. GAIN Act (2012), PASTEUR Act (introduced in 2023)), and work with **Congress** and the public to raise visibility and momentum for passing legislation.

The Centers for Medicare & Medicaid Services (CMS) provides health coverage to over 160 million Americans, including prescription drug coverage for most beneficiaries. Over the past decade, CMS has taken on a range of initiatives to lower costs of prescription drugs for both payer and patient. The CMS Innovation Center (CMMI) tests novel payment models that aim to improve care and lower costs. One approach for implementing a pull mechanism could involve a CMMI model in which a portion of cost savings from repurposed generics is shared with the organization that sponsors the research. Although CMS does not currently have an existing pathway to pay drug developers directly, there may be ways to work around this challenge. If the pull mechanism can demonstrate its utility, there is an opportunity that the model could be congressionally mandated.

The Department of Veteran Affairs (VA) provides health care for millions of veterans. Its Center for Care and Payment Innovation (CCPI), has similar authority to CMMI, enabling it to test payment models. CCPI could also potentially house a generic drug repurposing pull mechanism that shares cost savings with developers. However, unlike CMS, the VA can negotiate directly with drug developers, providing a clearer path for implementation of this model.

The Advanced Research Projects Agency for Health (ARPA-H) has a broad scope to support transformative biomedical breakthroughs by investing in various potential solutions. Through its more flexible mandate, a reward could reflect health impact across a broader US population rather than payer cost savings only. Although likely not a permanent home, ARPA-H could operate a pilot of the model. This model could complement ARPA-H's existing push funding support.

Additional Options: Other government agencies may also be explored as potential implementation opportunities, including the **National Institutes of Health (NIH)** and the **Biomedical Advanced Research and Development Authority (BARDA)**, as the new administration explores new funding approaches.

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