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Incentivizing Generic Drug Repurposing in the United States

Generic drug repurposing can help the US administration achieve its priority goals of making Americans healthier by accelerating innovation, addressing unmet public health needs, and unlocking unprofitable opportunities currently over-looked by the pharmaceutical industry.

Old drugs, new public health wins

Generic drug repurposing – researching new uses for established drugs – may offer new, effective treatments and lower costs. Generic drugs, if studied further, could unlock treatments for unmet medical needs, improve options for chronic conditions like diabetes and depression, and lower costs for patients and payers. Rather than investing $2 billion to develop a new drug for each disease, we can repurpose safe, widely available generic drugs to benefit patients at a fraction of the cost.

Broken incentives, missed opportunities

Despite its potential health and cost-saving benefits, repurposing generic drugs is often unprofitable and, therefore, unattractive to private companies. Patents can be granted for new uses of generic drugs, but they are difficult to enforce. As a result, for-profit developers invest little in these efforts.

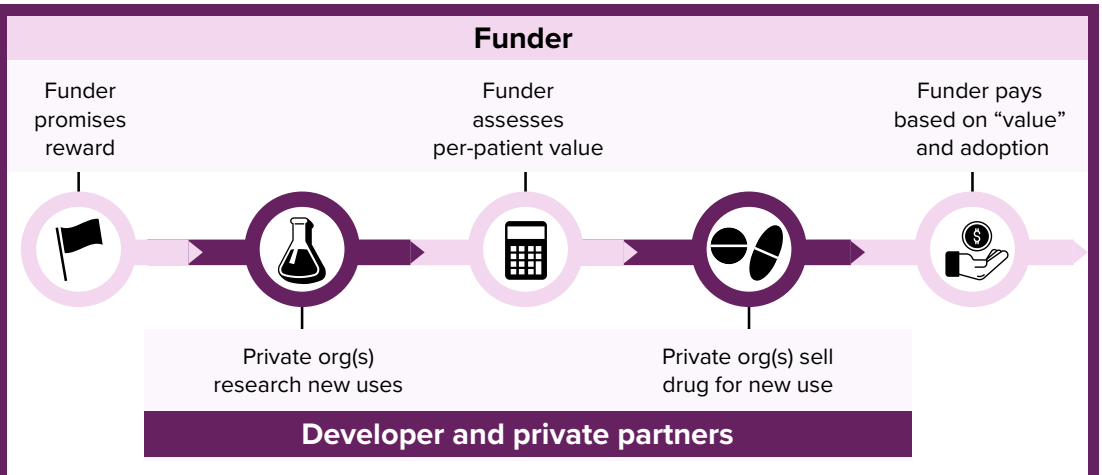
The sparse research conducted on potential new uses of generic drugs is typically performed by academic or nonprofit institutions with limited funding from governments or philanthropic entities. Despite strong research capabilities, these institutions lack the resources to independently navigate the regulatory approval process and connect treatments with patients.

A solution that rewards results

A financial "pull" fund – i.e., value-based payment – could be the solution to finding an efficient and effective way to identify new affordable treatments. **We suggest financially rewarding successful identification and regulatory approval of a new use.** The organization that successfully repurposes the drug would receive payments linked to the adoption of the generic drug for the new use, with amounts based on value (health impact and/or cost savings). To inform payments, a third-party health data company can support prescription tracking and value determinations.

Key design features

- Payments linked to value (health impact or cost savings)
- Reward company that sponsors research based on total adoption
- Require FDA approval
- Any drug-disease combo is eligible



Why government must lead the charge

The federal government is uniquely positioned to implement pull funding to drive cost-effective solutions for the benefit of patients and public health. Multiple agencies may play a role, and coordination will be necessary. Reward payments might be made via public healthcare payers, like Medicare and Medicaid, who may reap the cost-saving benefits of repurposed generic drugs, as suggested by preliminary modeling. Other agencies may also play a supporting role through reducing barriers, guiding research, and providing insights on cost-saving/health impact estimates.

Potential funders and implementers of a generic drug repurposing pull mechanism

The Centers for Medicare & Medicaid Services' Innovation Center

- CMMI could use its authority to test novel payment models to implement a pull mechanism that shares a portion of cost savings from a repurposed generic drug with the organization that sponsors the research.
- Although the Centers for Medicare and Medicaid Services does not currently have an existing pathway to pay drug developers directly, there may be ways to work around this challenge in a model.
- If the pull mechanism can demonstrate its utility, there is an opportunity that the model could be congressionally mandated and sustainably implemented.

The Department of Veterans Affairs

- The VA system, which provides health care for millions of veterans, is unique in its ability to capture robust data on a consistent population of patients, conduct research, and determine reimbursement decision – all capabilities that could support implementation of the pull mechanism.
- The Center for Care and Payment Innovation, has similar authority to CMMI, enabling it to test payment models and could also potentially house a mechanism that shares cost savings with developers.

Role of other agencies

Supporting research

Health research funders, such as **NIH**, **NCATS**, **BARDA**, and **ARPA-H**, can offer complementary **"push" funding** for research to identify potential new uses and conduct early studies to demonstrate efficacy of the new use in patients. For example, ARPA-H's funding of Every Cure represents a government-funded effort to find high-probability matches between drugs and diseases/conditions using AI.

Supporting developers

The Food and Drug Administration can offer a supportive role for the pull mechanism, which incentivizes developers to pursue label expansion. The FDA can take actions to support developers in the development process to help lower risks and costs, such as:

- Exploring new pathways that can expedite the process, utilize real-world data, or allow non-industry sponsors to submit data on new uses.
- Providing support to developers in the form of guidance or more tailored support in the case of non-industry developers
- Coordinate with other agencies (e.g., NIH) to support establishing research protocols on repurposing studies that meet FDA requirements

Coordination

HHS Immediate Office of the Secretary can provide support through leadership and strategic direction for agencies within the Department to coordinate on research, payment, and analytical support for a pull mechanism and broader, complementary efforts to advacne drug repurposing.

Illustrative example of annual payments

Category	Multiplier		Est. annualized per-patient benefit		Measured adoption		Annual payments
Cost-savings version	50% of savings	×	$5,000 per patient	×	40,000 patients	=	$100 million
Where does the data come from?	*Government funder choice*		*Government assessment based on clinical trial outputs*		*Health data analytics company (e.g., IQVIA)*		

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