RFK Jr. Pitches Trump On Repurposing Drugs To Treat Chronic Disease

Aug 20, 2025, 5:53 PM EDT

(Inside Health Policy)

HHS Secretary Robert F. Kennedy Jr. is pitching the White House on a plan for FDA and National Institutes of Health (NIH) to investigate whether older drugs could be repurposed and quickly approved to treat chronic diseases. The proposal, included in a leaked Make America Healthy Again report, comes as health care experts propose a similar idea.

The draft report sent to the president by the Kennedy-led MAHA commission recommends the NIH and FDA "jointly investigate opportunities to strengthen the use of repurposed drugs for the treatment of chronic disease, while harmonizing authorization processes through collaborative clinical trial designs to achieve FDA approval." But it doesn't provide additional details.

Kennedy's pitch comes as Duke-Margolis Institute for Health Policy's Beth Boyer and the University of Chicago Market Shaping Accelerator's Sarrin Chethik float a drug repurposing initiative in a two-page brief initially released in April. But Boyer and Chethik go a step further, encouraging the creation of a "pull" fund that would financially reward drug developers for the successful identification and regulatory approval of a new use for a repurposed generic medicine.

They argue their plan would help the Trump administration achieve better health outcomes while also reining in federal drug expenditures.

"We've had promising discussions with policymakers about novel funding tools, such as 'pull' funding, to advance generic drug repurposing. The administration has shown interest in these tools in other areas, and repurposing generics supports its goals to improve health, accelerate innovation, and reduce costs." Chethik told *IHP*.

Repurposing generic drugs could reduce drug development costs, which traditionally range from $1.5-2.5 billion, 85% by using existing preclinical and safety data to bypass early development phases, the two-pager says.

An updated version of the April paper says repurposed generic drugs, could unlock treatments for unmet medical needs and improve options for chronic conditions like diabetes and depression. Rather than investing $2 billion to develop a new drug for each disease, the government could repurpose safe, widely available generic drugs to benefit patients at a fraction of the usual costs, the paper says.

“Generic drug repurposing offers a cost-effective approach to bring new treatments to patients who may otherwise not have alternative or affordable options. Although we have seen great promise for generic drug repurposing, there have not been efforts to bring these solutions to scale. The federal government -- from FDA, CMS, to ARPA-H -- can each play a critical role from incentivizing research to adoption.” Boyer told *Inside Health Policy*.

The two-pager says incentives are needed to make the concept work. Despite the potential clinical and economic benefits of drug repurposing, incentives are lacking, rendering the venture an unprofitable, unattractive route for for-profit developers, the paper says. Currently, research of potential new uses of generic drugs is conducted by academic and nonprofit institutions that lack the significant funding needed to navigate obtaining regulatory approval for the repurposed medications and making them accessible to patients.

Under their proposal, companies or organizations that successfully repurpose a drug would receive payments linked to the adoption of the generic drug for the new use, with amounts based on either clinical value, the impact on one’s health, or economic value, the cost savings achieved, or both. A third-party health data company could also be used to support prescription tracking and value determinations to inform how much payment should be.

The two-pager recommends the CMS Innovation Center (CMMI) and Department of Veterans’ Affairs be the key funders of the value-based financial pull strategy.

CMMI could be called on to test novel value-based 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. If the mechanism is successful, Congress could mandate it be implemented at a larger scale.

Meanwhile, the VA has the ability to capture robust data on a consistent population of patients -- veterans -- conduct research and determine reimbursement decisions, which could all be used to implement the pull funding strategy. The VA’s Center for Care and Payment Innovation has similar authority to CMMI, so it could also test payment models and potentially house a pull mechanism that shares cost savings with drug developers for drugs successfully repurposed for new uses.

Boyer and Chethik suggests NIH, National Center for Advancing Translational Sciences (NCATS), Biomedical Advanced Research and Development Authority (BARDA) and Advanced Research Projects Agency for Health (ARPA-H) could provide complementary “push” funding for early studies to demonstrate efficacy of a repurposed generic drug’s new use in patients.

Also, FDA could support the pull funding strategy by exploring new pathways to accelerate the repurposing process, utilize real-world data or allow non-industry sponsors to submit data on new uses, Boyer and Chethik say. FDA could also give drug developers guidance or more tailored support related to drug repurposing, and coordinate with other agencies to establish research protocols on repurposing studies that meet FDA requirements. -

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