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NEW STUDY:	**How Agencies Should Decide Which Costly Drugs to Target with Government March-In Rights**
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US taxpayers provide enormous contributions to global biomedical research and drug development but face the highest brand-name drug prices in the world. In December 2023, the Biden-Harris Administration proposed guidance that could, in certain limited circumstances, help address excessive pricing of medicines with government-linked patents through the principled exercise of "march-in rights." In cases when a government-funded invention has been patented and exclusively licensed to a company for commercialization, march-in rights allow the government to open up the technology to new licensees if the previous license holder is not making the product available to the public on "reasonable terms." The proposed guidance clarifies that, under existing law, agencies can march-in on an excessively priced taxpayer-funded product. In the case of an excessively priced new medicine, the government could license alternative manufacturers to make competing versions of the same drug, which would consequently lower the drug's price for patients.

This *Health Affairs Forefront* discusses seven key factors that agencies should consider when considering whether to exercise march-in rights on a prescription drug consistent with this guidance. After reviewing new small molecule drugs with government-linked patents approved between 2010 and 2024, the authors discuss how revenues earned to date, patient non-adherence and health coverage restrictions, anticipated duration of march-in proceedings, non-patent exclusivities, other patent barriers, and interest from potential competitors to supply the drug can guide agencies' consideration over exercising march-in rights on taxpayer-funded prescription drugs.

The authors conclude that there are multiple brand-name prescription drugs on which the administration could explore exercising march-in rights. Enzalutamide (Xtandi), apalutamide (Erleada), and tafamidis (Vyndaqel and Vyndamax) have already earned billions in revenue, are priced higher for US residents than in other comparable markets, have health coverage restrictions limiting availability, few non-patent barriers to generic entry, and multiple manufacturers seeking to produce alternatives. Initiating proceedings is still worthwhile despite other patents on these drugs because it may help pressure companies to drop prices, prevent patent extensions from delaying competition, and supplementing march-in rights with other federal authorities can overcome other patent barriers to deliver more affordable options for thousands of patients facing life-threatening cancers and heart diseases.

A draft of the *Health Affairs Forefront* can be made available upon request. For more information, contact Jishian Ravinthiran (jravinthiran@citizen.org).