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HHS and DOC Announce Plan to Review March-In Authority

Today, the U.S. Department of Health and Human Services (HHS) and the Department of Commerce (DOC) announced efforts to pursue a whole-of-government approach to review its march-in authority as laid out in the Bayh-Dole Act, which promotes commercialization of research results, maximizes the potential for federally-funded technologies to become products, and serves the broader interest of the American public. The Interagency Working Group for Bayh-Dole will develop a framework for implementation of the march-in provision that clearly articulates guiding criteria and processes for making determinations where different factors, including price, may be a consideration in agencies' assessments.

"The Biden-Harris Administration is committed to increasing access to health care and lowering costs. And march-in authority is a powerful tool designed to ensure that the benefits of the American taxpayer's investment in research and development are reasonably accessible to the public," said HHS Secretary Xavier Becerra. "We look forward to updates from the Bayh-Dole Interagency Working Group, and at my direction, HHS will review the findings, engage the public, and better define how HHS could effectively utilize our authority moving forward."

"The Bayh-Dole Act is a cornerstone of our innovation system in the U.S., which carefully balances the interests of the taxpayer, government, and the private sector. Maintaining that successful balance is critical as we work with HHS and other agencies to develop a framework and criteria for the use of the march-in provision," said Commerce Secretary Gina Raimondo.

The Bayh-Dole Act was designed to facilitate the commercialization of inventions developed with public funds, by granting the recipient of those funds the option to retain ownership and seek patents on those inventions. At the same time, the law provides the federal government with residual rights for inventions developed using federal dollars, including the authority to grant licenses to such inventions to third parties when the benefits of the invention are not available to the public on reasonable terms.

HHS, the National Institutes of Health (NIH), and other agencies have been petitioned on several occasions to initiate march-in proceedings, but to date have not invoked this authority. Most recently, the NIH declined a petition to initiate a march-in proceeding for the prostate cancer drug Xtandi®.

Today, DOC's National Institute of Standards and Technology published the revised Bayh-Dole Act rule, "Rights to Federally Funded Inventions and Licensing of Government Owned Inventions," that is intended to streamline and clarify procedures, apply technical corrections, and remove or correct outdated references that had accumulated in the regulations over time. These revisions were made in response to more than 80,000 comments received to a January 2021 notice of proposed rulemaking from a broad array of stakeholders.

Consistent with President Biden's Executive Order on Promoting Competition in the American Economy, the DOC has not finalized any provisions on march-in rights in this revised rule that would have prohibited the government's use of march-in solely on the basis of product pricing.

HHS will convene a workshop in 2023 to further refine the cases for which HHS could consider exercising march-in authority. HHS will seek input from a diverse array of stakeholders – including patient groups, industry, universities, small business firms, and nonprofit organizations, as well as experts in technology transfer and innovation policy. The goal of the workshop will be to assess when the use of march-in is consistent with the policy and objectives of the Bayh-Dole Act.

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