

**Congress of the United States**  
Washington, DC 20515

National Institute of Standards and Technologies  
Rights to Federally Funded Inventions and Licensing of Government Owned Inventions  
Docket No.: 201207-0327  
Docket ID: NIST-2021-0001-0001  
Federal Register 2020-27581

**RE: Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, National Institute of Standards and Technologies (NIST), United States Department of Commerce, Notice of proposed rulemaking. 86 FR 35, Agency/Docket Number: Docket No.: 201207-0327**

To Whom It May Concern:

We write in strong opposition to the National Institute of Standards and Technologies (NIST) proposal to revoke the federal government's authority under the Bayh-Dole Act to protect the public from unreasonable prices on taxpayer-funded inventions.

Reining in out-of-control prescription drug prices is one of most pressing challenges facing the United States, and taxpayers are investing more than ever in biomedical research, sometimes funding 80 to 100 percent of the cost of developing a new medical product. As the angel investors underwriting the risk of development, taxpayers deserve access to these products on reasonable terms, including fair pricing that accounts for the investment made.

One of the most important federal authorities to prevent price-gouging is the authority to march in and issue a compulsory license to a taxpayer-funded invention when a contractor charges an unreasonable price for the resulting product. Or to more accurately describe the process, the government may exert taxpayer protection rights and authorize generic competition on an unreasonably priced drug, thereby driving down the price with American competition. The patentholder receives a fair royalty and consumers receive fair access to essential medicines.

Under NIST's dangerous proposal, this critical tool would be rendered nearly meaningless by adding language to 37 C.F.R. § 401.6 stating that march-in "shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention." What this proposal fails to recognize is that an invention cannot be made available on reasonable terms without also assuring reasonable pricing. Charging Americans outrageous prices for prescription drugs they paid to develop is unreasonable and unjust. NIST's proposal undermines federal efforts to protect taxpayers from such predatory tactics.

The fact that the National Institutes of Health (NIH) and other federal agencies have failed to utilize march-in rights is not a reflection on issues with implementation of the authority, but an indication of how industry narratives have negatively impacted agency behavior.

One example of a case where a march-in petition should have been granted involves the prostate cancer drug Xtandi, which was invented and entered clinical trials with the support of grants from the NIH and the U.S. Army. The price to U.S. prostate cancer patients is more than

\$150,000 per year, three to five times what it costs residents of any other country. Many of us supported a petition to march-in on this technology.

The \$2.1 million gene therapy marketed as Zolgensma treats spinal muscular atrophy, a frequently fatal childhood condition, and was developed with federal grants and subsidies, but access is limited by the high price tag. It is unreasonable and morally repugnant for patients to be unable to afford treatments that they need to extend their lives, when their tax dollars helped finance its development.

It is well within the competence of federal agencies to determine what constitutes an unreasonable price and respond accordingly. It is unreasonable, for example, for a company to charge Americans three to five times more for a taxpayer-funded drug than they charge residents of other high-income countries, and agencies can address this issue by exercising march-in rights. Agencies may also use reasonable pricing clauses as the NIH did in contracts with Bristol-Myer Squibb for the cancer drug Taxol and HIV drug ddI. And more recently, the Department of Defense used a reference pricing ceiling in a contract with Sanofi for the COVID-19 vaccine.

It is also well within agencies' statutory authority to protect the public from unreasonable pricing. The Bayh-Dole Act requires that products arising from taxpayer-funded inventions be made available to the public on reasonable terms, and provides that the government can intervene when a company price gouges on a federally-supported invention. A stated policy of the statute is to "ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions." NIST's proposal would defy this objective by supporting the pharmaceutical industry's continued unreasonable use of taxpayer-funded inventions to pad profits instead of protect patients.

Pharmaceutical companies extract the highest prices from the sick and dying, and this proposal would embolden them to charge even higher prices by allowing them to price gouge with impunity. American consumers, who financed these very products, would be left without federal protection or legal remedy.

The NIST proposal is a grave misjudgment and would likely exacerbate the already exorbitant cost of prescription medicines. It is a one-side proposal that prioritizes the desires of industry over the rights and needs of Americans. We strongly oppose this proposal and encourage NIST to instead pursue measures to support access to medicines and fiscal responsibility, such as a requirement of reasonable pricing clauses in all federal funding contracts.


Sincerely,

A handwritten signature in black ink, appearing to read "Lloyd Doggett". The signature is fluid and cursive, with a long horizontal stroke at the end.

Lloyd Doggett



Tammy Baldwin



Jeff Merkley



Bernard Sanders



Elizabeth Warren



Earl Blumenauer



Cori Bush



Matt Cartwright



David N. Cicilline



Steve Cohen



Peter A. DeFazio



Rosa DeLauro



Mark DeSaulnier



Theodore E. Deutch



Veronica Escobar



Jesús G. "Chuy" García



Al Green



Raúl M. Grijalva



Alcee L. Hastings



Brenda L. Lawrence



Sheila Jackson Lee



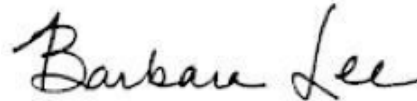
Pramila Jayapal



Mondaire Jones



Ro Khanna



Barbara Lee



Andy Levin



Eleanor Holmes Norton



Chellie Pingree



Mark Pocan



Katie Porter



Ayanna Pressley



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