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January 9, 2018

Dr. Walter Copan
Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 8930
Gaithersburg, MD 20899

Re: *NIST Special Publication 1234 - Unleashing American Innovation Draft Green Paper*

Dear Dr. Copan,

Public Citizen is a nonprofit consumer advocacy organization with over 400,000 members and supporters. We are writing today to urge the National Institute of Standards and Technology to reject technology transfer policies that would limit the government's existing authority to bring down the prices of federally-funded prescription drugs.

High drug prices are now epidemic. A January 2019 poll found that Americans consider taking action to lower prescription drug prices as the top priority for Congress.[1] Over the next decade, the Centers for Medicare & Medicaid Services project that retail drug spending will increase faster than any other major area of health care spending.[2]

On December 6th 2018, the National Institute of Standards and Technology (NIST) released a green paper proposing revisions to the rules governing the commercialization of technologies funded with federal tax dollars. The stated purpose of the paper is "to move the Nation to a new level of innovation performance that will increase the taxpayers return on their investment in federally funded R&D." But the proposed rules threaten to do just the opposite.

The federal government plays a major role in the research and development of new drugs. The green paper correctly notes that the U.S. innovation system is "substantially fueled by the discoveries and inventions arising from federally funded R&D at the Nation's universities, research institutes, and Federal Laboratories."[3] For example, one study found that the National Institutes of Health helped fund research associated with every one of the 210 new drugs approved by the Food and Drug Administration from 2010–2016.[4]

But since the enactment of the Bayh-Dole Act, the federal government has given away the fruits of the tens of billions of dollars of research it funds annually, granting corporations exclusive rights to commercialize government-funded inventions, with little commensurate benefit.[5] Bayh-Dole was

[1] POLITICO/Harvard T.H. Chan School of Public Health, Americans' Priorities for the New Congress in 2019, December 4 – 9, 2018, available at https://tinyurl.com/y8z5gbof.
[2] CMS, National Health Expenditure Projections 2017–26 (2018), available at https://tinyurl.com/ycwzmtfy.
[3] NIST, Unleashing American Innovation 5 (2017).
[4] Cleary E et al., "Contribution of NIH funding to new drug approvals 2010–2016," PNAS: Vol. 115: Iss. 10.
[5] This was not always the case. In 1947, for example, the Justice Department concluded that the rights to government-financed research and development inventions should always be assigned to the government. The Justice Department further

introduced, under intense lobbying pressure, because valuable inventions were supposedly languishing in laboratories, and incentives were needed for commercialization. But this assumption was always questionable, and much evidence has emerged disputing the need to provide additional incentives.[6] The government has further sweetened the deal for corporations—and against the interests of taxpayers—by repeatedly failing to enforce its authority to demand reasonable pricing on federally-funded inventions.[7] As government giveaways have increased, so too have drug prices. The green paper ignores this context, and the plain text of the Act. Instead, it takes for granted the Act's success and proposes rules that entrench this imbalanced status quo further. The paper recommends explicitly eliminating pricing requirements and narrowing the government's rights in its own inventions.

What the proposals will do, then, is to ensure that the taxpayers continue to pay twice for prescription drugs: first, for the knowledge base fundamental to their development, and then for the monopoly prices charged by manufacturers who piggyback on federal investment. These monopoly prices lead to treatment rationing. They leave legislators to make impossible choices between funding medicines and funding schools, leading to foreseeable and preventable suffering.[8] This is a poor return on investment. NIST should not confer additional monopoly protections to one of the world's most profitable industries.

Instead, NIST should strengthen the government's hand by delineating clear, actionable standards on when an invention is not "available to the public on reasonable terms" due to its price. NIST should also require public disclosure of all information necessary to determine whether licensees are serving the public interest.[9] Affordability must be recognized as a core benefit flowing from federally-funded research.

Sincerely,

Peter Maybarduk
Director, Global Access to Medicines Program
Public Citizen

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recommended that "as a basic policy all Government-owned inventions should be made fully, freely and unconditionally available to the public without charge, by public dedication or by royalty-free, non-exclusive licensing." Investigation of Government Patent Practices and Policies: A Report of the Attorney General to the President," 1947, quoted in Background Materials on Government Patent Policy: The Ownership of Inventions Resulting in Federally Funded Research and Development. Volume II: Reports of Committees, Commissions and Major Studies, House Committee on Science and Technology, August 1976 22.

[6] *See* A So et al., Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience, 6 PLoS Biology 10 (2008). ("Although universities can and do patent much more in the post-BD era than they did previously, neither overall trends in post-BD patenting and licensing nor individual case studies of commercialized technologies show that BD facilitated technology transfer and commercialization. Empirical research suggests that among the few academic patents and licenses that resulted in commercial products, a significant share (including some of the most prominent revenue generators) could have been effectively transferred by being placed in the public domain or licensed nonexclusively.")

[7] Robert Weissman, The Role of Federally-Funded University Research in the Patent System, Testimony Before the Committee on the Judiciary US Senate (2007), available at https://tinyurl.com/ya5x3nh7

[8] Drug Pricing Lab, Louisiana Budget Allocator, available at https://drugpricinglab.org/tools/louisiana-budget-allocator/

[9] Reporting requirements should include information about the number of patents and licenses obtained, the funds expended on patenting and licensing activities, licensing revenues, pricing policies and key terms (e.g., exclusive or nonexclusive, humanitarian access, research exemption, definition of market segmentation or field of use, performance milestones, and march-in rights).