

April 5, 2019

Dear Members of Congress,

We are writing to draw your attention to proposals recently published by the National Institutes of Standards and Technology (NIST) that are designed to limit the government's rights in patented inventions. In particular, NIST is proposing regulations that would greatly narrow the government's ability to curb excessive prices on drugs and other technologies that were invented on federal grants and research contracts.

The proposals have emerged from a little publicized review of relatively uncontroversial aspects of licensing practices by federal labs. During workshops, licensing offices for universities and other research institutions made proposals to gut the public interest safeguards in the federal Bayh-Dole Act for patented inventions.

In December 2018, NIST published a draft Green Paper on its webpage, (NIST Special Publication 1234, <https://doi.org/10.6028/NIST.SP.1234>) with the misleading title: "Return on Investment Initiative for Unleashing American Innovation." A public comment period was only noticed on a NIST webpage that was unavailable during the government shut down.

At a time when drug prices have become increasingly unaffordable for American patients, the administration's proposals in the NIST paper outline provisions designed to protect pharmaceutical companies that sell expensive treatments, and exempt them from obligations to ensure that treatments are affordable and accessible.

If the proposals in the draft Green Paper are allowed to move forward, three major safeguards written into the Bayh-Dole Act are at risk.

1. The federal government's royalty-free right to inventions whose development it funded (as mandated under 35 USC § 202 and 35 USC § 209), would be narrowed to exclude the ability to use the royalty-free right when the government does "does not directly use or consume" the patented goods and services. This change would prevent the government from using the royalty-free right to provide affordable drugs to Medicare, the Ryan White program or other government programs.
2. March-in rights on federally-funded inventions (under 35 USC § 203) would be limited to cases where there is a "compelling national issue or declared national emergency" and would never be available in cases to curb excessive prices on government funded inventions.
3. The obligation to bring federally-funded inventions to practical application, including in particular the requirement that the benefits of the inventions be made "available to the

public on reasonable terms,” would be defined so that “reasonable terms” would never include the price that the public pays.

These proposed changes are motivated by efforts to protect drug companies from increasing demands from members of Congress and the public to use the Bayh-Dole rights to curb excessive prices for treatments for cancer, HIV and other diseases. They will also apply to other areas where the federal government research funding is significant, including for example, for new energy and information technologies.

We believe that when public resources contribute to a collective effort to develop a technology, the government has an additional responsibility to ensure that the public can benefit from those efforts.

The final version of the Green Paper is expected to be released soon. Following its release, NIST will seek to initiate implementation actions, including proposed legislation and regulation processes as laid out in the Green Paper.

We are opposed to any effort to undermine the public interest safeguards in the Bayh-Dole Act.

Sincerely,

Organizations (in alphabetical order)

Health GAP

Housing Works

Knowledge Ecology International (KEI)

Médecins Sans Frontières(MSF)/Doctors Without Borders USA

Public Citizen

Social Security Works (SSW)

The Institute for Agriculture and Trade Policy (IATP)

Union for Affordable Cancer Treatment (UACT)

UNITE HERE

Universities Allied for Essential Medicines (UAEM)

Yale Global Health Justice Partnership