

The Honorable Joseph R. Biden, Jr.  
President of the United States  
The White House  
1600 Pennsylvania Ave. NW  
Washington, D.C. 20500

June 1, 2022

Dear President Biden,

As organizations focused on promoting affordable access to health care in the United States and around the world, we are deeply concerned about ensuring that health care technologies developed with public support are made universally available at prices that facilitate widespread access and that recognize taxpayers' contributions. We urge you to appoint as Director of the National Institutes of Health (NIH) an individual who will prioritize patient access and public health in their role as the world's premier steward of biomedical research.

The United States government is the largest funder of biomedical research in the world, foremost through more than \$40 billion dollars in annual funding of the NIH, the vast majority of which supports extramural research at universities and other research institutions.<sup>1</sup> Recent research found that NIH funding contributed to research associated with every new drug approved from 2010-2019, totaling \$230 billion in public funding.<sup>2</sup>

Increasingly, NIH also plays a pivotal role in financing and resourcing clinical trials for novel health technologies such as biologics and gene therapies critical for treating those with serious illnesses such as cancer with few to no alternatives. You have also proposed to establish a new Advanced Research Projects Agency for Health (ARPA-H) at NIH, seeking revolutionary advancements in medical technologies to combat cancer, infectious diseases, and Alzheimer's disease. COVID-19 demonstrated the incredibly important role of the NIH in undergirding the successful discovery and development of novel mRNA COVID-19 vaccines, therapeutics, and diagnostics. The potential of these critical health technologies has only been stifled by the NIH's inability to make them available equitably and globally, prolonging the pandemic further.

We are concerned that too often, medicines developed with essential public support are not widely available to people who need them, due to price. For example, the prostate cancer medicine enzalutamide (brand name Xtandi) is priced 2-4 times higher in the United States than in other large, wealthy countries.<sup>3</sup>

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<sup>1</sup> <https://www.nih.gov/about-nih/what-we-do/budget>

<sup>2</sup> <https://www.ineteconomics.org/research/research-papers/government-as-the-first-investor-in-biopharmaceutical-innovation-evidence-from-new-drug-approvals-2010-2019>

<sup>3</sup> <https://www.keionline.org/wp-content/uploads/enzalutamide-march-in-royalty-free-Clare-Love-David-Reed-Army-4Feb2019.pdf>

In the case of Xtandi and numerous other publicly-funded medicines, the NIH Director is empowered to remedy price gouging and access constraints through licensing competition using march-in and worldwide royalty-free rights.<sup>4</sup> The NIH can also proactively support access by adopting upstream policies that build transparency and reasonable pricing conditions into funding and cooperative research and development agreements.

The next NIH Director will be tasked with making decisions, which COVID-19 has shown us, may impact access not only for patients in the United States, but people around the world. We urge you to choose a Director who will promote biomedical research and ensure the fruits of such research are accessible and priced fairly.

Signed,

Action Center on Race and the Economy  
Center for Popular Democracy  
Doctors for America  
Doctors Without Borders/Médecins Sans Frontières (MSF) USA  
Health Care Voices  
Health Global Access Project  
Indivisible  
Initiative for Medicines, Access, & Knowledge (I-MAK)  
Justice is Global  
Knowledge Ecology International  
Oxfam America  
Partners In Health  
Patients For Affordable Drugs Now  
People's Action  
PrEP4All  
Public Citizen  
Revolving Door Project  
Social Security Works  
T1International  
U.S. PIRG  
Universities Allied for Essential Medicines (UAEM) North America

Cc: The Honorable Patty Murray, Chairwoman, U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)  
Members of the Senate HELP Committee

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<sup>4</sup> See the appendix below for a description of relevant licensing authorities available to the NIH Director.

## Appendix

Publicly-funded and publicly-owned inventions developed through federal funding are governed through rules under the Bayh-Dole Act. These rules afford funding agencies, like NIH, certain rights over inventions developed with taxpayer funding to protect the public interest, including:

- 1) the right to “march-in” and license competition when a drug corporation is failing to make a medicine available on reasonable terms, or to alleviate health or safety needs not being met by the manufacturer;<sup>5</sup> and
- 2) a nontransferable, irrevocable, paid-up license to practice or have practiced the invention for or on behalf of the United States throughout the world.<sup>6</sup>

The Stevenson-Wydler Act, which governs so-called cooperative research and development agreements (CRADAs), provides government laboratories participating in such agreements rights analogous to those above, including the right to require a collaborator to grant (or to grant itself) a nonexclusive license, to meet health and safety needs not reasonably satisfied by the collaborator; and a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world on behalf of the Government.<sup>7</sup>

U.S. Government scientists also often invent or co-invent biomedical technologies embodying pivotal components of treatments and vaccines. For example, the federal government has filed multiple patents covering mRNA-1273 (also known as the NIH-Moderna vaccine), likely providing significant rights.<sup>8</sup> The U.S. government can use its patents to share knowledge through open licenses, promoting scientific advancements and access to medicines. Additionally, Bayh-Dole confers the Federal government with rights over any invention it licenses, including retaining a nontransferable, irrevocable, paid-up license to practice or have practiced the invention throughout the world on behalf of the United States Government.<sup>9</sup>

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<sup>5</sup> 35 USC 203(a)(1) & (2)

<sup>6</sup> 35 USC 202(c)(4)

<sup>7</sup> 15 USC 3710a(b)(1)(A) & (B); See also 15 USC 3710a(b)(2) & (3)(D)

<sup>8</sup> <https://www.citizen.org/article/the-nih-vaccin>

<sup>9</sup> 35 USC 209(d)(1)