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August 18, 2023

Lawrence A. Tabak, D.D.S. Ph. D.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dear Dr. Tabak:

On behalf of the U.S. PIRG (Public Interest Research Group) and our state affiliates, I am submitting comments relating to the National Institutes of Health Workshop on [Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer](#) on July 31, 2023.

PIRG is a nonprofit advocate for the public interest. We speak out for a healthier, safer world which includes promoting policies that support the delivery of high value healthcare. To succeed in this mission, we must address skyrocketing health care costs, including the cost of prescription drugs.

We have a strong history in finding ways to cut costs without impacting quality. There is no better model than the ability of patients to access lower cost generic and biosimilar prescription drugs. As such, we have been particularly concerned about market barriers and anticompetitive practices that block entry of generic and biosimilar medications. Two-thirds of U.S. adults rely on prescription drugs to live full lives and to treat their illnesses and medical conditions.¹ And yet 1 in 4 people struggle to pay for their medications.² The role of patents in the pharmaceutical market play an important role in whether there is true competition in prescription drug pricing. With even just one generic alternative, prices for that drug go down by as much as 40%.³

For this reason we watched with interest your recent workshop on how the NIH decides whether and how to patent and license discoveries made by publicly-funded NIH scientists. We applaud the public mission of NIH as presented in the workshop slides to act as a "steward of medical and behavioral research for the Nation." NIH should honor this goal in all of your operations. The agency should be a

¹ Emily Ihara, "Prescription Drugs", Georgetown University Health Policy Institute.
<https://hpi.georgetown.edu/rxdrugs/#:~:text=More%20than%20131%20million%20people,United%20States%20%E2%80%94%94%20use%20prescription%20drugs>

² Ashley Kirzinger et al., "Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say it's Difficult To Afford Their Medicines, Including Larger Shares Among Those With Health Issues, With Low Incomes and Nearing Medicare Ages", KFF, March 1, 2019.
<https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

³ FDA, Generic Competition and Drug Prices, Dec. 2019, <https://www.fda.gov/media/133509/download>, p. 2

model for all innovators – to make discoveries that can be shared with the public and built upon by other inventors.

NIH provides the backbone of research that launches many life-saving innovations. As such, you should center your decision-making on whether patients will be able to pay for the medicines which come to market because of NIH's ground-breaking discoveries. Indeed, you have an even greater obligation to consider how your decisions impact drug price competition. President Biden's executive order to end anti-competitive practices specifically called for greater availability of generic and biosimilar drugs in the marketplace to provide low-cost options for the people who need them.⁴

We urge the NIH to use its existing powers to ensure that prescription drugs and other medical products developed with public funds are not kept from the public because of price and anti-competitive practices.

Licensing terms to foster better prices.

The workshop focused on how NIH licenses its discoveries. Several strong ideas were offered to address the high prices of medications (based on NIH science) that are developed and marketed by pharmaceutical companies. We strongly urge NIH to include terms in its licensing agreements that better protect patients from price-gouging and unsupportable prices. Licensing agreements should include reasonable pricing requirements and other mechanisms that incentivize better prices for patients.

Transparency of NIH expenditures and licensures to ensure accountability.

Clear, timely and accurate information builds public trust. NIH should disclose how public funds are expended to bring about NIH discoveries. And recognizing that the public essentially owns NIH patents, the terms of NIH licenses, including royalty rates, should be open to view to the broadest extent possible. NIH should also disclose the costs of clinical trials supported by the agency's funds. Transparency allows for accountability and full assessment of the use of public funds.

Tracking NIH science in patents applications from private entities.

Drug patent applicants are required to disclose any federal funding in their patent applications. The NIH must fully enforce this provision and consider removing patent rights for those applicants who violate this requirement.

March-in rights to overcome price-gouging.

We urge the NIH to use its march-in rights for medications where there is no existing competition and the drugs' prices are not reasonable.

NIH has the opportunity to improve its operations to take the long view of its part in medicine science. By keeping a patient-centric approach to its work, the NIH should do its utmost to not simply help

⁴ The White House, Executive Order on Promoting Competition in the American Economy, July 9, 2021 accessed on Feb 28, 2023 at <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/>

launch the discoveries that make new prescription drugs possible, but the agency should consider how to use its power to ensure the market prices allow the patients to access them. Thank you for your review of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'Patricia Kelmar', with a long horizontal flourish extending to the right.

Patricia Kelmar
Senior Director, Health Care Campaigns
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