PATIENTS FOR AFFORDABLE DRUGS™

July 22, 2024

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Regarding the National Institutes of Health (NIH) Office of Science Policy: Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

Dear Dr. Tabak and Ms. Rives:

Thank you for the opportunity to present a patient perspective on the National Institutes of Health proposal to "to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer funded inventions."

Patients For Affordable Drugs (P4AD) is the only national patient organization focused exclusively on system-changing policies to lower drug prices. We are bipartisan and independent. We do not accept funding from any entities that profit from the development or distribution of prescription drugs. Since we launched more than seven years ago, we have collected over 35,000 stories[1] from patients from all 50 states struggling to afford their prescription drugs because of high prices. We have also built a community of over three-quarters of a million patients and allies supporting policies to lower drug prices.

We commend the NIH for acknowledging that patients across the country and worldwide are frequently unable to access the life-saving products they need not only because of the rising cost of prescription drugs but also because a treatment for their disease may not yet even

[1] (2024, June 20). *Patients For Affordable Drugs Map*. Patients For Affordable Drugs. https://map.patientsforaffordabledrugs.org/

exist. Drugs don't work if people can't afford them and today nearly one in three Americans cannot afford their prescription medications.
High drug prices disproportionately harm certain Americans more than others. They contribute to the fact that Latinos and Black Americans use 10-40% fewer medications than their white counterparts.[2] Further, Latinos, as well as women in general, disproportionately skip care or fail to take prescription medicines because they cannot afford them.[3] Additionally, high drug prices pose a particular burden on younger patients who live with chronic conditions. More than 50 percent of adults ages 18 to 34 rely on prescription drugs and one in five of those struggle to afford them.[4]

Without the pivotal role of the NIH as the largest funder of biomedical research in the world, a significant majority of vaccines and groundbreaking medicines that are needed by patients, including today's most innovative cell and gene therapies, would not have been conceivable[5]. Indeed, 354 of the 356 drugs approved by the Food and Drug Administration (FDA) from 2010-2019 were supported in part by funding from the NIH. Importantly, the taxpayer funded research through NIH is the early, high risk research that industry is often unwilling to undertake.

As a patient community we are grateful to the NIH for the everyday work to drive new medical research and development for the benefit of the public. We appreciate the opportunity to offer our input in response to the agency's proposal to develop and implement a new policy within the NIH Intramural Research Program (IRP) to promote patient access to taxpayer funded inventions.

Working to address patient access challenges at the licensing stage of the research and development process can help play a critical role in balancing the need for both access and innovation for patients here in the United States and around the world. The inclusion of substantive access provisions in licensing agreements as part of a robust and transparent access plan strategy can help to ensure equitable access to medicines and health technologies for patients. Our general recommendations are included below.

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[2](2021, August 13). *FACT SHEET: How President Biden's Build Back Better Agenda Helps Latino Communities* The White House https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/13/fact-sheet-how-president-bidens-build-back-better-agenda-helps-latino-communities/

[3] (2022, December 6). *Health costs frustrations hitting a boiling point?* STAT News https://mailchi.mp/statnews/tk-621700?e=64349df8a0

[4] (2024, February 27) *How Young Voices Can Shape Prescription Drug Policy*, The Commonwealth Fund https://www.commonwealthfund.org/blog/2024/how-young-voices-can-shape-prescription-drug-policy

[5] (2004). *Strategies to Leverage Research Funding: Guiding DOD's Peer Reviewed Medical Research Programs.* NIH. https://www.ncbi.nlm.nih.gov/books/NBK215472/

Access & Affordability

- We urge the NIH to provide minimum standards for what must be included in *all* access plans for *all* licensees going beyond requiring licensees to engage in one or more strategies to improve goals of "*affordability, availability, acceptability, or sustainability*".
- We encourage the inclusion of price and affordability measures in the minimum requirements for all access plans.
- Plans should require a robust and clearly outlined strategy for ensuring affordable access to medical products for patients including measurable objectives, key milestones, and an appropriate timeline for implementation.

Equity

- We encourage the inclusion of specific provisions that address accessibility and outreach to underserved populations and communities including those that are disproportionately harmed by high drug prices.
- The current draft IRP policy language states that licensees are required to consider *either* global access strategies *or* U.S. access strategies. We urge the NIH to require the inclusion of both a global *and* a U.S. access strategy as a minimum requirement for licensee access plans.

Collaboration

- We encourage the NIH to include provisions that require licensees to collaborate with and/or engage with external organizations such as non-profits, non-governmental organizations, and/or patient advocacy groups when drafting their access plans in order to best address the needs of specific affected communities. All conflicts of interest including funding sources from the pharmaceutical industry and/or other ties should also be disclosed in the plans.

Flexibility

- Under the current draft policy, it may be possible for licensees to receive an exemption from the inclusion of access planning. It is possible licensees could abuse this exemption which would undermine patient access. We urge the NIH to close any loopholes that allow for unnecessary exemptions that could harm patient access. To retain the ability to advise licensees throughout the duration of the agreement we recommend strengthening the existing language that requires licensees to consider NIH suggestions and revisions "in good faith" prior to implementation of the access plan.

Transparency and Accountability

- We encourage the NIH to publish all access plans and as much related information as possible including key exemptions and/or revisions in an easy-to-find, publicly accessible location via its website.
- Whenever possible regular progress reports should be published along with key compliance metrics to help keep the public fully informed.
- We agree with the proposal to require stricter access plans for technologies licensed during later stages of development and urge the NIH to consider requiring the aforementioned minimum standards for access plans to technologies licensed during earlier developmental stages as well.
- We urge the NIH to include follow-through licensing provisions to ensure the minimum access plan requirements remain attached to the technology itself throughout the development lifecycle and in order to better ensure downstream patient access to any product later acquired by private companies.
- The current draft IRP policy provides limited oversight for the NIH to ensure that licensees adhere to their access plans. By retaining the ability to advise licensees on their access plans, the NIH should be able to work with licensees to adapt their access strategies throughout the lifecycle.

We thank the NIH for prioritizing patient access in this first draft IRP policy. Requiring access planning for the IRP program represents an important step toward better ensuring patient access to publicly-funded medicines at prices they can afford. We urge the institution to continue to expand the policy to the extramural research programs and we look forward to continued engagement.

Sincerely,

Patients For Affordable Drugs