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**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:

We, the undersigned organizations, work to protect the right of all people to access safe, effective, and affordable prescription medications.

We write this submission in response to the Request for Information (RFI) by the National Institutes of Health (NIH) regarding NIH's proposal to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer-funded inventions.

We commend this significant step by NIH to advance access to medicines developed with the technologies owned by the agency and the public. Access planning can advance health equity while balancing commercial concerns, preserving reasonable income streams while ensuring companies do not unjustly deprive underserved communities of medicines developed using taxpayer-funded research.

Drawing on our collective experience in working towards fairer access to medicines, we strongly recommend the following steps to ensure that NIH's proposed policy can make a meaningful contribution to health outcomes and equity.

***Access for all***

1. **Licensees should be required to present meaningful and comprehensive Access Plans.** NIH should amend the definition of "Access Plan" to require licensees to present strategies for mitigating access challenges—including plans, timelines, and milestones—and should remove language in the draft policy that would allow licensees to use one minimal access strategy to satisfy the Access Plan requirement.

2. **NIH licensing agreements should require licensees to take steps to ensure the affordable supply of medical products developed using NIH technology in the U.S. and in LMICs.** To the extent that a licensee is unable or unwilling to provide timely, affordable supply in LMICs, agreements should include a commitment to sharing know-how and providing freedom to operate for other manufacturers to supply licensed products to those countries (including by granting necessary sublicenses to qualified third parties seeking to supply the product, and sharing clinical data necessary for registration).

### *Accountability*

3. **NIH must play a more active role in reviewing and contributing to the development of proposed Access Plans to ensure that they meaningfully advance the policy's objectives.** The draft policy envisages no role for the NIH in the development of Access Plans—licensees need only submit an Access Plan, with no input from NIH, after which NIH may only suggest modifications annually that licensees are not obligated to adopt. NIH should reserve the right to approve Access Plans. At a minimum, NIH should assess proposed Access Plans and make recommendations to licensees on needed improvements, before the Access Plans are finalized.
4. **Licensees must regularly report their progress against Access Plans and against equitable access obligations in NIH licensing agreements.** NIH should require licensees to submit reports, no less frequently than annually, describing the actions they have taken and reporting the progress they have made against measurable milestones included in Access Plans.

### *Transparency*

5. **NIH should publish Access Plans and other key documents on its website.** All Access Plans should be made public once submitted to NIH, subject only to the redaction of confidential information protected by the law of trade secrets. NIH should also publish: (a) any decision to waive or modify access planning obligations, together with a justification; (b) any comments, assessments, or recommendations made by NIH regarding Access Plans; and (c) regular progress reports submitted by licensees.

### *NIH has the power to ensure access*

6. **Access planning must support broad access for both vulnerable or underserved communities in the U.S. and those living in LMICs.** Licensees should not be able to choose between advancing access for either underserved communities in the U.S. or LMICs, as currently allowed by the draft policy. NIH should amend the proposed definition of "Access Plan" (Appendix, Section II) to replace "*and/or*" with "*and*".

7. **NIH should require equitable access obligations to survive any the transfer of licensed technology to new parties.** Particularly for early-stage NIH inventions, licensed technology may be transferred or licensed to other parties as they advance to later stages of development. Licensees should be required to ensure that all equitable access obligations are assumed in full by parties to whom they transfer or license NIH technology.
8. **NIH should include fair pricing commitments in its licensing agreements.** Similarly to the Administration for Strategic Preparedness and Response (ASPR), NIH can make fair pricing a standard part of contract negotiations for all medical products developed using publicly-funded technologies.
9. **NIH should extend the proposed policy to its extramural research program.** The agency's extramural program constitutes 83% of its budget. NIH has the ability, and the opportunity, to improve fair access to medicines developed using public funds on a much broader scale.

We commend NIH for taking the first steps toward tackling grave challenges in the availability and affordability of medical products developed with the agency's technology. We strongly encourage NIH to adopt these recommendations, which will help to ensure that the benefits of its research are available to all.

Sincerely,

AIDS Healthcare Foundation	NETWORK Lobby for Catholic Social Justice
Beta Cell Action	Public Citizen
Center for Popular Democracy	Revolving Door Project
Consilium Scientific	Rise Up WV
Doctors for America	Salud y Fármacos USA
Health Care Voices	Social Security Works
Health GAP	SPACeS In Action
Knowledge Ecology International	T1International USA
Labor Campaign for Single Payer	U.S. PIRG
Medicare Rights Center	Unity Fellowship of Christ Church NYC
MomsRising	Universities Allied for Essential Medicines
National Committee to Preserve Social Security and Medicare	VOCAL-NY
	West Virginia Citizen Action Group