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

May 21, 2024 – July 22, 2024

Table of Contents

31. Jishian Ravinthiran - Public Citizen
32. Shion Chang - National Health Council
33. Krish Gupta - Intellectual Property Owners Association
34. Jacqueline Garibay - Patients For Affordable Drugs
35. Claire Cassedy - Knowledge Ecology International
36. Bryce Robinson - Multiple organizations (25)
37. Hans Sauer - Biotechnology Innovation Organization (BIO)
38. Kate Hudson - Association of American Universities
39. Matthew J. Martin - Program On Regulation, Therapeutics And Law (PORTAL)
40. Lindsey Seidlitz - The Pharmaceutical Research and Manufacturers of America (PhRMA)
41. Mihir Mankad - Medecins Sans Frontieres/Doctors Without Borders
42. Alec Orban - Small Business Technology Council
43. Luis Gil Abinader
44. Fred Ledley - Bentley University, Center for Integration of Science and Industry
45. Manar Zaghlula - Innovative Genomics Institute & Global Gene Therapy Initiative
46. Kelly L. Morron - Association of Amicus Counsel
47. Geoffrey Lomax - California Institute for Regenerative Medicine
48. James Love - Knowledge Ecology International

Submit date: 5/21/2024

I am responding to this RFI: On behalf of myself

Name: Babak Sanoury

Name of Organization: Institute of Nuclear Medicine

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.
Most important aspect of this "meaningful access" is "research data".

Right now, Principal Investigators at NIH "believe" they are the "owner" of the data. This perception is not only factually wrong but strategically dangerous. Any scientist/researcher with appropriate request and adequate due process must have access to "ongoing research data". This is the right of public to have controlled access while keeping the confidentiality of the data.

2) Promoting transparency in the biomedical enterprise and return on investment.
It is not the job of NIH to commercialize the inventions. They are in public domain and private industry should take the lead on that with certain commitment to public via interest sharing.

3) Providing flexibility while achieving clear policy objectives.
The potential for abuse will erode the trust of public. Utmost transparency is required. Equal opportunity in access to the information is a must.

4) Helping licensees achieve access goals.
At INM, we are focusing on "sustainable meaningful access" to innovation. We will be happy to share our expertise if needed.

5) Establishing licensee obligations depending on the stage of technology development.
There are three domains to think about:

1. Public interest: since the entire funding is by tax-payers, the public should have "significant share" in the commercial success. However, this interest ownership should be earmarked to foster future innovation in the healthcare.

2. Equal access of private sector to the opportunities through a transparent and fair process with emphasize on collaborative efforts of multiple private agents.

3. Non interference with the other governmental sectors, such as FDA, in order to protect their full capability and ability to protect public.

6) Assessing policy impact.
INM is happy to help with the development of compliance policy.

7) Other Comments

We will be delighted to help upon request.

Please contact Institute of Nuclear Medicine (INM) for further information.

5454 Wisconsin Avenue

Suite 1601

Bethesda, MD 20815

Uploaded File:

Description:

Submit date: 5/22/2024

I am responding to this RFI: On behalf of myself

Name: Alejandra Quiñones

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Other

Role - Other: Doctor of Healthcare Administration

1) Promoting meaningful access approaches.

First, community pharmacies such as CVS and Walgreens should cover for example any COVID-19 or Flu shots for all Medicaid members and undocumented immigrants without the negation of access.

Second, these pharmacies can create a mechanism of logistics with better technologies including AI to give the medicine or drugs to patients. Many of these pharmacies have more than a total of hundreds of medicines without a patient picking them. Maybe create policies to have vehicles to drop off (deliver)the drugs at patients' locations.

2) Promoting transparency in the biomedical enterprise and return on investment.

CMS, CDC, and Pharmaceutical Companies (Pharmacies: CVS, Walgreens, Amazon).

3) Providing flexibility while achieving clear policy objectives.

Policies should always be aimed at better serving people with low incomes (Medicaid and Medicare participants). But also, and no less important, undocumented immigrants. This can help to achieve transparency and access.

4) Helping licensees achieve access goals.

Promoting more expansion or mandatory participation of Medicaid Health Insurance for all pharmacies.

5) Establishing licensee obligations depending on the stage of technology development.

6) Assessing policy impact.

Many ways to achieve compliance and have the best metrics include having people from the different government agencies that promote access for patients visiting and monitoring more regularly the pharmaceutical companies, pharmacies, and hospitals to evaluate that patients have access to and receive their medicines, vaccines, and more on time. Again creating more mechanisms to deliver the products for example at patients' homes.

7) Other Comments

Uploaded File:

Description:

Submit date: 5/22/2024

I am responding to this RFI: On behalf of myself

Name: Chris

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Member of the public

Role - Other:

1) Promoting meaningful access approaches.
This is a good first step. Licensing should involve broad re-use of inventions by federal employees that have been funded with Federal research and development investments should ensure that there is no exclusive license given to any individual. These inventions belong to the public.

2) Promoting transparency in the biomedical enterprise and return on investment.
It's high time that the biomedical and pharmaceutical private Enterprise share some of their profits developed on federally funded research back to the NIH. The NIH should include in its licensing requirements an irrevocable profit sharing expectation from any use of inventions created by the NIH licensed to private sector.

3) Providing flexibility while achieving clear policy objectives.
All aspects of the NIH supported inventions, research, and outputs should be clearly disclosed by the licensee in a transparent and machine-readable capacity. Credit to the inventors should be ensured though a CC-BY license or public domain equivalent that requires attribution.

4) Helping licensees achieve access goals.
The for-profit sector acts in bad faith with their bottom line interests first and patient health. Second. The NIH policy should make it very clear that patient health should come first, return on investment to the NIH second, and profits and future commercialization to the licensee 3rd.

5) Establishing licensee obligations depending on the stage of technology development.
The NIH should ensure that the policy includes steps that the NIH will take to exercise its march-in rights should the licensee failed to appropriately bring the product to market at a reasonable cost in a reasonable time frame.

6) Assessing policy impact.
NIH should partner with the DOC, USPTO, and the FTC to establish a counsel of intellectual property attorneys that specifically address issues related to licensing and compliance with policy. Licensees found to be out of compliance should have significant consequences, including but not limited to, prohibition on applying for sbir or other funding mechanisms and publicly disclosed reasons for non-compliance.

7) Other Comments

While the NIH is making good faith attempt at improving return on investment of NIH invented technologies, The intramural program is only a tiny fraction of the NIH portfolio in which fundamental biomedical research is funded and produces patent s and inventions that should be marketed and available to the public. The NIH should finally develop a plan to exercise its march-in rights under the Bahye Dole Act - not from a cost principal perspective necessarily as everybody fears - but as a forcing function to bring products to market. Bringing products to market increases competition, provides access to new interventions for patients, and lowers costs. One example where the NIH has failed with significant health consequences is Limerix and Nih-Funded derivative Lyme disease vaccines. No company should be able to pull a public health tool that benefited from federally funded research from the market simply because of their lack of commercialization.

Uploaded File:

Description:

Submit date: 5/22/2024

I am responding to this RFI: On behalf of myself

Name: Yvette Madrid

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Other

Role - Other: Global health consultant

1) Promoting meaningful access approaches.

A question in my mind is whether this is intended to cover only intramural research or also university grants and SBIR/STIR reasearch and programs. Without coverage of all three, it seems that placing a higher access burden on NIH intramural funding can be problematic and not fully address the issue of tax payer funding supporting accessand innovation. Placing expectations that organizations licensing technology will have to take steps to address access is important and should be incorporated in agreements. BUT...the truth is that this effort is problematic for several reasons, including: 1. Companies may lack resources to analyze and address the issue particularly if the scale is to include global access in the remit (small startups) 2. They may not understand the full scope of how the technology/product they are developing can impact health (and hence access needs), such as for technology platforms in early stages of development 3. They do not control the vital health infrastructure that may be essential to assure the correct use of the eventual product (such as laboratory capacity for diagnosis) in a wide range of settings 4. Any access plan is very unlikely to meet the full scope of the access need, so how they choose what to focus on and how much will be considered enough presents a risk 5. The plans may be difficult to monitor and regulate limiting the meaningfulness of the exercise. Is it possible to consider into licensing agreements fee to be paid into an "access fund", that will be based on worldwide sales of any and all successful products using the licensed technology? Companies can negotiate to reduce or eliminate the fee by undertaking access measures according to an access plan that is negotiated upon first commercialization. Evidently, ownership and disbursement mechanisms of such an "access fund" would require further work on the part of the NIH and other partners. However, for commercial entities, it would provide much greater clarity regarding the "cost" of access associated with a license while also not distracting from their mission in early stages of development and giving them the flexibility to take more direct action to support access at a time when they are better able to assess the options.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.

As suggested above, would find it helpful for companies to have the option to pay a fee based on eventual sales into a fund in lieu of an access plan.

4) Helping licensees achieve access goals.

Access plans at early stages of development are tough. First, organizations simply may not have the ability to think this through carefully when they are trying to focus their limited financial resources on pushing through the innovation. Second, early access plans can be expected to be almost always "wrong" (sub-optimal) in key ways simply due all the unknowns at play and as such, they require continual updating. Third, if a small biotech is bought by a larger company, the resources available to the latter both to develop and implement plans will be very different, so how much of the initial plan still be valid? It is important for companies to know that they will have to contribute to access in some way if products are successful while limiting the distraction and risks associated with this effort, particularly in the early stages of product development.

5) Establishing licensee obligations depending on the stage of technology development.

I agree that the later in development, the more clear an access agreement can be, but determining what is enough will always be a challenge and present risk to the company. I would suggest having the option for an "access fund" fee rate based on the level of development NIH has achieved that can be applied to eventual worldwide sales of successful products can be a viable additional option to achieve access.

6) Assessing policy impact.

Assessing compliance for some access measures can be relatively simple (sharing IP to the Patent Pool) but for other measures this could well be expensive if it needs third party verification. Where would the financing for this come from?

7) Other Comments

Access provisions are important but they can quickly become messy both for the NIH and the companies involved. It is possible these endeavors can generate a whole industry around this--consultants to develop these, consultants to validate these, consultants to measure compliance. This would be great for consultants such as myself, but I think there is more value for society in terms of innovation and access to look for the simplest "good enough" approach to this commendable effort.

Uploaded File:

Description:

Submit date: 6/5/2024

I am responding to this RFI: On behalf of myself

Name: Brian Jackson

Name of Organization: Hippocratic Capitalism

Type of Organization: Other

Type of Organization - Other: Healthcare consultancy

Role: Clinician

Role - Other:

1) Promoting meaningful access approaches.

The NIH is to be commended for its interest in improving patient access to NIH-developed technologies. However, I believe that access plans in the currently-proposed form are unlikely to lead to substantive behavioural change on the part of licensees. The reason is simple: Unless NIH intends to use march-in-rights as leverage with licensees, something which seems politically challenging if not completely unrealistic, then NIH's leverage to influence access ceases at the point in time when the patent licence is signed.

A more effective approach would be for NIH to require an access plan prior to negotiating the original license terms. Elements of an agreed-upon access plan could then be written into the license itself. Granted, a plan at an early stage of product development would need to focus on general business practices rather than specific product plans. But there are a number of ways in which a licensing contract could promote downstream access to potential products. Examples include a commitment to non-exclusivity of (eventual) distribution channels; structural commitments on pricing such as transparent list prices, prohibitions on rebates or volume-based pricing, etc.; and potentially even restrictions on certain intellectual property practices to prevent the NIH technology from being effectively captured within anti-competitive, evergreened patent thickets.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.

4) Helping licensees achieve access goals.

5) Establishing licensee obligations depending on the stage of technology development.

6) Assessing policy impact.

7) Other Comments

Uploaded File:

Description:

Submit date: 6/8/2024

I am responding to this RFI: On behalf of myself

Name: Jose Sanchez III

Name of Organization: California Health Collaborative

Type of Organization: Non-profit research organization

Type of Organization - Other:

Role: Research participant patient advocate

Role - Other:

1) Promoting meaningful access approaches.
Create or adapt cessation related activities of social media posts from the Center of Disease Control and Prevention in particular California Tobacco Prevention Program (CTPP) as an introduction to platforms of awareness in which the universal community monitor daily such as facebook, twitter, etc.

2) Promoting transparency in the biomedical enterprise and return on investment.
Smoke free housing and apartment complexes incorporating the Federal Office of Rural Health Policy towards new access points approved by city council. Qualifiable education efforts including the interest of it's community members and residents towards promoting health and wellness.

3) Providing flexibility while achieving clear policy objectives.
Advertisement against the fantasy that e-cigarettes are a good alternative towards smoking tobacco , or smokeless tobacco products and it's production is nothing more then an attack against health and wellness.

4) Helping licensees achieve access goals.
Partner with organizations representing or serving rural populations of focus to work on contribute to the projects tobacco projects prevention policy campaign(s). Representing diverse sectors of the communities business, environment, faith, health, housing, labor, youth, social justice, etc. Building partnerships to grow the tobacco endgame movement.

5) Establishing licensee obligations depending on the stage of technology development.
By June 30, 2025, at least one jurisdiction in Merced County will adopt both 1.) a policy that prohibits smoking and vaping of all products from multi-unit housing of two or more units (market rate, subsidized, and public) including 25 feet from all doors, patios, windows, and balconies, and emphasizes a graduated enforcement process. 2.) A policy that eliminates smoking (including burning or heating of tobacco or other plant products, natural or synthetic) in all outdoor recreational or non-recreational public places, without designated smoking areas or distances.

6) Assessing policy impact.
Collaborating with volunteers and other funded partners within the targeted media market, completing the communication plan from Otis, which identifies communication objectives.

7) Other Comments

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Overview-^0-Intervention-Activities-REAL-1-1-2.docx

Description: California Health Collaborative Rural Empowerment Advocacy Leadership (REAL) Project 2024 Summer Internship through Health Career Connection HCC

Submit date: 6/28/2024

I am responding to this RFI: On behalf of an organization

Name: Clifford Samuel and Claudio Lilienfeld

Name of Organization: PCMS1 Consulting

Type of Organization: Other

Type of Organization - Other: Consulting

Role: Other

Role - Other: Principal

1) Promoting meaningful access approaches.

We commend this NIH effort to examine and implement ways to bake in access into the development and commercialization of new life-saving biomedical innovations.

One key tool for expanding access that is underutilized but that has demonstrated success is Voluntary Licensing (wherein an innovator licenses its patented biomedical product – especially medicines – to manufacturers of generics in low- and middle-income countries (LMICs) to enable access among the poorest of the poor in LMICs). Voluntary Licensing has been a game-changer in access to life-saving medicines in LMICs, especially as illustrated by Gilead Sciences' use of Voluntary Licenses since 2006 to transform access to its patented medicines - HIV treatments, as well as treatments for Hepatitis B, and cures for Hepatitis C. Most of Gilead's licenses were done directly (bilaterally) between Gilead and manufacturers of generic pharmaceuticals in India and other countries (including Egypt, Pakistan, and South Africa). The Medicines Patent Pool has also played an important role in creating opportunities to broker Voluntary Licensing agreements for access in LMICs.

A key challenge in global access has been the underutilization of Voluntary Licenses by innovator companies. A key reason for this has been the us vs. them debates among global public health stakeholders. Innovators generally view voluntary licenses as a version of charity, and thus corporate leadership devotes scant resources to addressing needs through that mechanism. One reason for this is that innovators often pay little attention to emerging low- and middle-income markets. This is for two reasons: (1) a focus on the most profitable upper income markets, which provide immediate, short-term returns (vs LMICs, where doing business requires thinking for the medium to long term) (2) the difficulty of doing business in LMICs, and thus the difficulty of creating a hybrid business model in LMICs that allows for both doing good (helping the poorest of the poor gain access) and doing well (earning revenues from the wealthier populations in LMICs). On the other side of the us vs. them divide are the stakeholders in the global health community who view innovators with suspicion, often simply because the innovators are profit-seeking. Among other issues, the issuance of patents to innovators is seen as synonymous with hindering access. Gilead Sciences demonstrated through its voluntary licenses that patents needn't hinder access, but there are too few examples of similar results.

NIH through a new policy could help push the debate in a win-win direction – by encouraging stakeholders across the spectrum to view a mechanism such as Voluntary Licensing as a way to bridge the divide. Voluntary Licenses could become a default tool of innovators to expand access to life-saving

medicines for the poorest members of the global community (by licensing to generic manufacturers to produce lower-cost versions for resource deprived populations) in parallel with innovators selling their branded products to those who are in the upper echelons of the economic pyramid (including in LMICs with relatively large populations in that upper echelon, such as India, Indonesia, and Nigeria).

This will take a concerted effort on the part of the US Government (including NIH) to work with global stakeholders (including especially the governments in low- and middle-income countries) to create a more business-friendly environment for innovators – wherein their (innovators') efforts to do good (i.e., voluntary licenses) will be rewarded by their ability to do well (generating revenues and profits from the sale of their branded medicines). Ultimately, for any access model to succeed, it needs to be tied to the acknowledgement of the business motivation of innovators and their investors. Voluntary Licensing within a broadly accepted win-win policy architecture could be a superb tool for NIH, USG more broadly, and innumerable other stakeholders.

A report delving deeply into the subject of Voluntary Licensing was completed under the auspices of the project on Voluntary Licensing and Access to Medicines (VLAM), available via this link: https://globalaccessaction.org/vlam/

Additional ideas relating to how innovators can think anew about doing business in LMICs are elucidated in the work of Harvard Business School on “Business at the Base of the Pyramid” (or “BBoP”). More info available at https://www.hbs.edu/faculty/Pages/item.aspx?num=53662.

2) Promoting transparency in the biomedical enterprise and return on investment.

One benefit of Voluntary Licensing is that it does not require constraints on development costs nor on the deployment of the branded products. This is not to say that either of those goals are not laudable and necessary given broader challenges in the US and elsewhere of the cost of healthcare. But, voluntary licensing could be a relatively more straightforward way to initiate a shorter-term expansion of access (particularly in LMICs) while broader, and perhaps more mid-to-long term efforts in cost containment in the development cycle are sought.

3) Providing flexibility while achieving clear policy objectives.

As stated above, it is important to pair Voluntary Licenses with greater appreciation by innovators of the business opportunities in LMICs (e.g., BBoP) and greater certainty in the climate for doing commercial business in LMICs. This is the win-win equation. Voluntary Licenses (doing good) plus ease of doing business in LMICs (doing well) is the simple equation in concept. This win-win is also an important opportunity to, essentially, develop a global compact (or at least an international "coalition of the willing" among stakeholders such as upper income as well as LMIC governments, and representatives from multilateral organizations, donors, and NGOs) that bridges the perennial us vs. them debate.

4) Helping licensees achieve access goals.

Conditioning and incentivizing access models, including Voluntary Licensing, is a vital initiative. Ideally, the incentives/conditions would happen up front and be tied to the dispensation and availability of NIH research funds. It is vital for NIH to be part of a whole-of-government effort, particularly in the case of Voluntary Licenses, so that the win-win efforts carry the day in the multilateral arena as well as with individual LMIC governments, to negotiate effective improvements in doing business (to assist innovators) alongside US innovators making available technology via Voluntary Licensing.

Further, Voluntary Licensing is most successful when accompanied by technology transfer and sharing of knowhow (a la Gilead). Both tech transfer and sharing of knowhow should be required in conjunction with voluntary licenses that are tied to NIH funding and other USG support (whether diplomatic, financial, or regulatory).

5) Establishing licensee obligations depending on the stage of technology development.
Please see above.

6) Assessing policy impact.
The report cited above (https://globalaccessaction.org/vlam/) should be considered a resource for developing metrics for compliance relating to implementation of Voluntary Licenses. Among other criteria, the following are representative of relevant metrics: number of licensees, number of countries covered by the license(s), inclusion of tech transfer and knowhow sharing.

That said, the above are mainly demands placed on NIH-funded innovators. The policy impact would also have to be measured in terms of advances made by the USG and other actors/allies in moving the global community to incentivize the use of voluntary licenses, including by easing doing business in key LMICs.

7) Other Comments
We are thrilled to have the opportunity to comment here. What your initiative is undertaking is of vital importance, and to the extent that you can advance the principles we have outlined, we believe there is enormous potential to transform approaches to disseminating life-saving bio-medical technologies to all, regardless of their income or resources.

We would like you to consider us to be available to you as needed to discuss any of these issues or ideas for moving forward to advance them. We both previously worked at Gilead Sciences in senior capacities. Mr. Samuel oversaw and innovated the Gilead access model across 140 LMICs - with over 20 years experience there. Mr. Lilienfeld was an advisor to Mr. Samuel, and previously worked as a civil servant n the USG in the international policy arena (20 years).

Thank you,

Clifford Samuel

Claudio Lilienfeld

Uploaded File:

Description:

Submit date: 7/9/2024

I am responding to this RFI: On behalf of myself

Name: Robert Reinhard

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Research participant patient advocate

Role - Other:

1) Promoting meaningful access approaches.

The Access Plan strategies described in Section III of the RFI proposal have been instrumental in widening product access to address the global HIV pandemic. They remain significant and should be supported.

A particular access strategy is also reasonable for clinical trial participants in product development. Consistent with equitable and ethical considerations for biomedical research, clinical trial participants in control/placebo arms could be guaranteed or favored in access to proven therapies. That favored group of participants includes those who helped sponsors determine significant product modifications in early trials, if the marketed product remains safe and efficacious for them. In the case of product development needing a relatively small cohort in pivotal trials and a fully curative outcome without continuous or lifelong therapy for global pandemic diseases such as HIV (e.g. certain gene therapy trials or short course therapeutic vaccines), such access should be at no cost to the control participant as it was for the treated participants. In these examples, a few altruistically help to save large populations. Paragraph 34 of the WMA Helsinki Declaration supports this principle. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.

4) Helping licensees achieve access goals.

NIH, FDA and related agencies partnered with licensees could facilitate necessary and speedy regulatory health agency approvals with global partners, WHO, European Medicines Agency's EU Medicines for All and in country health authorities to accelerate product marketing authorization for globally essential products. Indeed, regulatory approval steps could be anticipated to hit the ground running as soon as possible. Authorization capacity often acts as a time barrier to market products. This is especially important in regions where disease burden is great.

5) Establishing licensee obligations depending on the stage of technology development.

Maximizing access for the greatest public benefit understood as all populations (including subgroups) who may benefit from safe and efficacious treatment starts with smart trial designs along the entire translational path. Inclusion/exclusion criteria should broaden participation as much as possible, of course consistent with genuine, biologically plausible safety considerations. Trials in all phases, certainly by pivotal stages, should not casually exclude groups based on age, sex, gender, presence of comorbidities/coinfections, or other biologically based differences without strongly justified product or outcome specific considerations. Failure to do so often delays implementation and marketing to the results of later expensive trials for subpopulations after initial marketing often for years and inhibits clinical decisionmaking or undue reliance on off label prescribing without insurance coverage..

6) Assessing policy impact.

7) Other Comments

In the case of global HIV disease burdens and access, some countries or jurisdictions criminalize or discriminate against patients based on HIV status, sexuality (including LGBTQ+), gender/gender identity, or sociodemographics. In the interests of justice, equity and inclusion, licensees and NIH could partner with international rights organizations within the UN or elsewhere to secure and advocate distribution of health products for all in medical need. Among the global rights statements, enshrining this strategy is the Yogyakarta Principles # 17

http://yogyakartaprinciples.org/relating-to-the-right-to-the-highest-attainable-standard-of-health-principle-17/

Uploaded File:

Description:

Submit date: 7/14/2024

I am responding to this RFI: On behalf of myself

Name: Gillian M Fenton

Name of Organization: LST Strategies LLC

Type of Organization: Other

Type of Organization - Other: Law practice in life science transactions

Role: Member of the public

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/GMF-Comments-to-NIH.pdf

Description: Substantive comments are in the attached .pdf file.

Submit date: 7/16/2024

I am responding to this RFI: On behalf of an organization

Name: Joseph P. Allen

Name of Organization: Bayh-Dole Coalition

Type of Organization: Other

Type of Organization - Other: 501(c)(4)

Role: Other

Role - Other: Executive Director

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Bayh-Dole%20Coalition%20Comments%20on%20NIH%20Intramural%20Licensing%20Guidelines.pdf

Description:

Submit date: 7/17/2024

I am responding to this RFI: On behalf of an organization

Name: Corey Astill

Name of Organization: Business Roundtable

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH-March-In-Rights_BRT-Comment-Letter_2024.07.17_vSEND.pdf

Description:

Submit date: 7/18/2024

I am responding to this RFI: On behalf of myself

Name: Leslie Mark

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Member of the public

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

I was gobsmacked with the efficiency of medical science in the COVID era… as a lay-person and NON-scientist broadly unaware of the preceding advances that made that giant step forward possible. But I do well understand that the vaccines were produced with funding from the US government — aka my tax dollars. I think I am right that government also purchased COVID vaccines before they were fully developed so as to minimize risk to the companies.

Throughout the pandemic, the greater Kansas City metro communities cooperated for long enough to ensure life-saving vaccines and treatments would be accessible to everyone who needed them. PhRMA companies refused to produce enough medicines for patients around the world. That really restricted the ability of generic companies to step in and supplement production, resulting in a significant loss of life. We have the power to mitigate future losses… why wouldn't we?

Uploaded File:

Description:

Submit date: 7/19/2024

I am responding to this RFI: On behalf of an organization

Name: Bridie Telford

Name of Organization: GHIAA

Type of Organization: Other

Type of Organization - Other: GHIAA - 501(c)(3) non-profit organization; MPP - United Nations-backed public health organization

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Please see the attached file for comments from GHIAA and MPP.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/2023_07_19-NIH-RFI-response_GHIAA-MPP_submission.pdf

Description:

Submit date: 7/19/2024

I am responding to this RFI: On behalf of an organization

Name: Emma Wheatley

Name of Organization: CEPI (Coalition for Epidemic Preparedness Innovations)

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) Promoting meaningful access approaches.

We support the proposed examples of strategies for promoting access and mitigating access challenges. In addition to those proposed in the paper, we offer further strategies to consider below.

There are three key points we would suggest NIH consider:

1. The strategies offered in the paper do not include specific terms for products that treat, diagnose, or prevent infectious diseases in the event of an outbreak / public health emergency. Enabling equitable access to medical countermeasures at speed to those who need it during an outbreak will protect those communities and the rest of the world. Specific provisions / terms in an access plan are required to address these situations. Some examples of terms that may be used for enabling equitable access during outbreaks are listed below.

2. The suggested timing for the requirement for an EA plan is late (phase 3). At this point, many of the factors affecting cost and appropriateness have already been defined (usually with a High Income Country (HIC) market or high income population in mind). It would be more effective and there would be greater leverage if licensees start an EA plan from at least phase 1, with updates as the product development progresses. Planning early and developing milestones for updates will have significant benefits for global equitable access as there is more room to impact key features.

3. EA plans will be instrumentally more effective if they are enforceable. This will ensure that careful consideration is given to them and enable NIH to take action if they are not followed. This could be achieved, for example, by attaching a framework for the EA plan to the license agreement from execution. Completion of the EA plan, according to the framework should take place from at least phase 1, and then be updated (see point 2).

a. If not enforceable, NIH should consider what it will do if access plans are not created or followed. NIH may, for example, add termination rights and/or the right to convert exclusive license to non-exclusive in this case.

Additional examples of access terms are listed below. These are focused on medical countermeasures for infectious diseases, but many are broadly applicable. We are happy to provide more detail on the exact language that can be used for these if that would be helpful.

1. Access to and sharing of data and information; publication (open access)

a. Requirements for data sharing, e.g., mandated registration of data in public clinical trial registers, sharing of clinical trial data in relevant data repositories and publication in open access journals in a timely fashion so that all developers can benefit from current knowledge of a disease and interventions. Avoiding data exclusivity tied to regulatory findings is also key. Providing public access to the outputs of funded research can accelerate scientific research and availability of resulting products.

b. Consider requirements for publication of key deal terms in supply agreements. For example, awareness of which products, and in what quantities, were being sold in which markets would have greatly improved the ability of countries and COVAX to plan and negotiate their own agreements.

c. We note this requires alignment with NIH's existing policies on open access.

2. Timely supply

a. Requirements to provide dedicated volumes of medical countermeasures (MCMs) or proportion of supplies to be allocated to low- and middle- income countries (LMICs) and/or a delegated procurement or equitable access entity in a timely fashion, in parallel with HIC supply.

b. Rights/requirements of the funder/procurer to donate/provide a percentage or number of product to LMICs and/or a delegated/designated procurement or equitable access entity, or for research purposes.

c. In times of scarcity of supply and existence of allocation mechanism(s), right to "queue swap" to allow for allocation to countries more in need prior to receiving purchased product.

3. Affordable and economically sustainable pricing

a. Measures to ensure products are affordable for each income tier of countries, recognizing that aggregate pricing/revenues needs to be sustainable for the manufacturer/license holder.

b. Measures could include tiered or pooled pricing arrangements, non-profit pricing for LMICs, price caps, cost of goods plus a percentage and/or other formulas (further information: https://ghiaa.org/mapguide-home/affordable-pricing/).

c. Requirements on pricing should include measures so as not to compromise timely access. For example, products provided to LMICs should be at the same time as those sold to higher income countries.

d. Countries/regions should mitigate/ suspend price referencing practices during any kind of outbreak if it delays doses to any country in need. Countries/regions should promote transparency in pricing and volume for bilateral procurement agreements.

4. Continuity and sustainability

a. Requirements to enable technology transfer to pre-identified, preferred partners in order to geographically diversify manufacturing and/or meet an increased global demand, with clearly defined triggers of action and responsibilities.

b. Requirements for technology transfer in case the original partner cannot or will not continue to supply the vaccine to all populations in need.

c. Requirements for sharing of intellectual property (IP) to enable access to background and development project IP to ensure continuing supply.

d. Rights to assume or reassign the development and/or commercialization of funded products in the event of actual or anticipated failure or shortcoming by a developer to perform its obligations under a funding agreement, including implementing funder rights under a public health license if appropriate.

5. Preparedness and response obligations

a. Obligations in the case of future outbreaks, with defined triggers, such as scaling up production or mandated technology transfers to trusted partners.

6. Territory requirements

a. Commitments outlining necessary licenses, regulatory filing requirements and timely application, if relevant for WHO emergency use license or prequalification, to ensure the widest availability of the funded vaccine/drug as well as the ability of the funder to donate or supply the product outside of its own sovereign territory.

7. Product appropriateness and cost of production

a. If access plans are generated early in the development process, from at least phase I, there can be effective impact on product appropriateness for underserved populations within and outside of the US. For example, delivery methods, cold chain requirements, cost of production / delivery and dosing regimes, populations included in large-scale trials, and other factors are not yet finalized at this stage. Planning early can help target products towards appropriateness for people who need it and lower production and delivery costs.

8. Specific requirements for work involving antigen design for pathogens with epidemic or pandemic potential

a. We recommend non-exclusive licenses be issued in these cases, given the importance of this work to both national and global health security. If an exclusive license must be issued, then the equitable access plan should include commitment from the licensee to sublicense IP and know-how to other developers and manufacturers. This builds on language in the proposed policy that guidance for development of equitable access plans includes sublicensing (section III). It will be more complicated for jointly-owned or researcher-owned IP, but can still remain a principle.

b. For non-exclusive licenses, the 'know-how' part of this is still critical, and therefore we still recommend that the equitable access plan includes commitment from the licensee to sublicense know-how and IP to other developers and manufacturers.

c. Recognizing that antigen design work starts from pre-clinical research, these factors should be considered as early as possible / identified.

NIH should consider its policy for waivers or amendments to access plans, with a particularly stringent policy for products that are tools for global health security, such as medical countermeasures for infectious diseases.

We note in the NIH draft policy, definition of access plans is: ' ''Access Plan'' means Licensee's plan, and incorporating the plan(s) of its sublicensee(s), as applicable, that describes Licensee's strategy to support broad access to Licensed Product(s) for the U.S. population, as well as (a) through the lens of promoting equity for underserved communities … and/or (b) populations in low- and middle-income countries'. We would recommend removing the word 'or,' here and ensuring access plans serve both needs. In specific situations where only one of these two groups relevant, waivers can be made, but we imagine this will be only in exceptional circumstances. Most access provisions will have a dual benefit to underserved populations in the US and abroad, particularly factors that drive down costs and increase appropriateness/acceptability.

2) Promoting transparency in the biomedical enterprise and return on investment.

Access plans could include a section on costs at each stage of the Research and Development (R&D) and manufacturing process, with the greatest transparency possible and should be updated regularly to reflect additional changes. Transparency around costs where possible (understanding some information is proprietary) is an incentive for developers to drive down costs and enables independent organisations to hold them to account, as well as better understand their process.

If access plans are not required until phase 3, they won't have a big impact on cost of production as too many factors (e.g. delivery method) have already been decided.

Thinking about access and producing an access plan early in development is one mechanism to drive down costs as it will incentivise companies to remove unnecessary development costs. During phase 1, access plans can consider factors that will influence price and appropriateness of a product (e.g. delivery method, dosage requirements, cold chain requirements). During phase 2/3, access plans can consider cost of goods in more detail, paving the way for pricing discussions and plans to reach different populations of users, including "cost of goods plus" models, tired pricing models and advanced consideration of appropriate partners to enable access (for example, for technology transfer, procurement and delivery).

3) Providing flexibility while achieving clear policy objectives.

Maintaining public confidence will require the NIH to develop and publish clear criteria it will use to evaluate access plans, along with publishing guidance and personal support if required. Criteria development and evaluation must be carried out by a broad range of experts, with different technical backgrounds, and include those with experience in both promoting access (within and outside of the US) and in business development, who can evaluate products on a case-by-case basis but follow transparent criteria. Examples of products which have successfully maintained business sustainability while promoting access will be helpful to developers who are considering how to do this.

4) Helping licensees achieve access goals.

Mechanisms for the NIH to support licensees both write and implement their access plans:

- Create mechanisms to share guidance and best practices, including guidance documents and support sessions, bringing in experts (including those with experience of making products accessible and writing access plans) who can help licensees consider these issues

- Connect licensees early in their R&D process with key partners required to implement their access plans including: patient/advocacy groups, public procurement agencies, technical/legal experts, licensing organisations, business development experts, manufacturers open to technology transfer. Many of these can leverage existing US government programs.

- Along with guidance, publish criteria for evaluating 'success', to help licensees understand what they are working towards.

- Reporting requirements to NIH must be clear and designed to help licensees identify challenges, which NIH can support them to address.

5) Establishing licensee obligations depending on the stage of technology development.

Access plans should first be considered and agreed early in development, when key factors about the product (e.g. appropriateness) will not yet be certain. As the product development progresses, there should be milestones at which access plans should be updated with more detail.

Access plans should be centred around the four main factors that contribute to equitable access: sustainability, affordability, availability and acceptability/appropriateness. Provisions to support these factors include: defining project access principles; pricing terms; supply commitments; target product profiles; territory considerations; technology transfer; data sharing and publication; regulatory strategy; IP rights management; an access license; reporting requirements; governance; termination rights and other remedies; dispute resolution; audit rights; end-provider and end-user acceptability (e.g. delivery methods, dosage requirements, thermostability, target populations) and any product specific factors. All of these elements can be covered in an access plan, and will have the most impact if the terms are enforceable. The specifics within each of these categories may change throughout the development process, but planning for them from the start of development will enable better outcomes once more detailed information is plausible. NIH could separate these factors into 'must have' and 'target', so that licensees are clear where the priorities are.

For more information on each of these elements, please see our response to question 1, and the GHIAA access pyramid: https://ghiaa.org/mapguide-home/mapguide-commentaries/equitable-access-pyramid/

6) Assessing policy impact.

The NIH can learn from existing examples and share best practices, for example from the Access to Medicines Foundation, or our organisation commissioned independent reviews of the impact on access of our contracts. These could be used to help build a government/public sector version of these scorecards.

Having clear and transparent reporting and audit rights will enable NIH to better assess compliance with the policy and assess impact. Holding workshops and expert advice sessions will better enable licensees to comply and provide feedback to NIH.

Publishing criteria that will be used for compliance and impact assessments will help licensees build better access plans. These criteria should be developed with a broad range of expert input. They

should include assessment of: the clarity and appropriateness of the policy; compliance with the policy; impact on access for products that have reached the market. Publishing results of these reviews will also enable both NIH and other organisations to improve their practices.

Importantly, these measures should be seen as positive incentives and not punitive. The NIH could consider other ways of adding positive incentives for licensees to commit to strong access plans, for example:

- Including the potential licensee's clear commitment to building and implementing an equitable access plan (or even a draft/framework access plan during later stages of development) as part of the criteria for assessing potential licensees and granting licenses. As well as incentivising strong access plans, this will help build the M&E system needed to conduct implementation and impact evaluations over time.

- Providing supplements/perks to licensees with demonstrable commitment and implementation of their access plans, such as:

  - Enabling access to common materials / reagents
  - Technical assistance
  - Invitations to conferences / meetings
  - Improved eligibility for additional training grants or other
  - Potentially, improved eligibility for future license agreements

As well as incentivising better access plan implementation, these perks will also incentivise better monitoring and reporting from licensees, which will improve NIH's ability for M&E.

7) Other Comments

We welcome this proposal and congratulate the NIH on its progress in this critical effort, demonstrating the US government's role as a leader in this space. CEPI looks forward to our continued collaboration.

Public funding for R&D of MCMs represents a significant proportion of overall funding, thereby providing substantial opportunity to leverage it to include obligations for equitable access to the resulting products, tools and data. For example, public sector and public-private-partnerships funding supported 57% of clinical trials for vaccines against Covid-19 during the first 1.5 years of the pandemic (Angelis et al, 2022). Between 2014 and 2020, public sector funding accounted for more than 80% of global investments in R&D for emerging infectious diseases (Policy Cures Research; G-FINDER report 2022). The more public funders who embed access terms in their agreements, the greater domestic and global access to life-saving tools. It will also level the playing field for public funders already doing this and enable all funders to have greater leverage for access terms during contracting. Furthermore, it will increase affordability and sustainability for publicly funded health and drug procurement programmes domestically and internationally.

From the beginning, the access plan framework should be part of the license agreement, so plans are enforceable, which will be especially important for exclusive licenses. This will ensure that these plans

are carefully thought through by licensees, and ensure they have impact, so access plans should be defined from at least phase I with milestones to trigger updates. The earlier access plans are built, the more effective they will be to increase appropriateness, affordability, sustainability and availability to underserved populations in the US and in LMICs.

Eventually, turning these policy approaches into requirements will represent a significant step forward in achieving the equitable access goals of providing new medical products to all populations in need of them. The guidance for access provisions and plans will form the basis for examples of terms that can one day be embedded in the contracts themselves that arise out of licensing and funding policies. These could eventually become requirements of NIH funding or licensing, rather than optional on the part of the licensee. Of course, specific needs for each product and partner must be tailored and business sustainability must be considered.

A critical aspect that we believe should be embedded in this policy is provisions for outbreaks in the equitable access plans. NIH has been the source of data and technology that have proven to be key tools for outbreak response. It is critical that the NIH consider the unique situations of epidemics and pandemics when building this policy, as we described in question 1.

The next step to consider would be applying a similar policy to extramural research program funding vehicles and joint inventions. NIH's proposal for the inclusion of access plans for intramural research programs is clear that achieving equitable access is critical to return on investment for taxpayer funding in R&D for medical products; the same is true for NIH's extramural programs. This can be achieved through flow-through funding terms to universities and other research institutions. We also look forward to discussing options for adding equitable access obligations where there are joint inventions involved.

Again, we commend NIH on this important effort and look forward to collaborating. We are happy to participate in further discussion about this important policy.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/CEPI-response-to-NIH-access-policy-RFI_final.pdf

Description: Copy of submitted answers from CEPI

Submit date: 7/19/2024

I am responding to this RFI: On behalf of an organization

Name: Anne-Charlotte Douard

Name of Organization: Access to Medicine Foundation

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Other

Role - Other: Policy coordinator

1) Promoting meaningful access approaches.

2) Promoting transparency in the biomedical enterprise and return on investment.

The Access to Medicine Index evaluates whether companies both measure and publicly disclose outcomes of health systems strengthening initiatives. NIH could request the innovator to create a plan on how they will publicly disclose the outcomes of health systems strengthening of their initiatives once the product has reached the market.

See page 38: https://accesstomedicinefoundation.org/resource/the-methodology-for-the-2024-access-to-medicine-index

3) Providing flexibility while achieving clear policy objectives.

The Access to Medicine Foundation suggests implementing a plan which is informed by a guidance document highlighting which components should be included. NIH can use the Stewardship and Access Plan Development Guide to develop their own guidance document. The Stewardship and Access Plan Development Guide was published in 2021 by a working group of experts, including the Access to Medicine Foundation. This guide is a crucial resource in the fight against Antimicrobial Resistance. It equips pharmaceutical companies and product developers with practical steps to expedite access to new antibacterial products while maintaining responsible usage practices. Access plans could be reviewed on a case-by-case basis by an expert advisory group.

https://accesstomedicinefoundation.org/resource/the-stewardship-and-access-plan-development-guide

4) Helping licensees achieve access goals.

The Access to Medicine Index analyses access plans that are project specific and tailored to the needs of countries in scope of our analysis: 108 low- and middle-income countries (LMICs). There is no one-size-fits-all approach to access planning, but a comprehensive plan considers availability, affordability and sustainable supply of the product. This is in line with what the NIH draft states. The Access to Medicine Foundation recommends companies to have access plans by Phase II and onwards, as discussed further in Question 5. Our recommendation is that, once the licence is granted, the licensee should develop a comprehensive access plan.

The Index has identified several components of an access plan that are conducive to access. These clear components can add clarity and valuable guidance to the list currently in the NIH draft. Clearer guidelines regarding LMICs will make access plans more applicable and effective to address the lack of access challenge in these specific countries for the NIH-funded innovators. These components are:

1) Plans to register the product in many of the countries in scope

To make a product available, companies must file for registration with the national regulatory agency of the country where they intend to market the product. Once the product receives regulatory approval, it can be marketed in that country. To ensure that the largest unmet medical needs are addressed for each project, companies must consider burden of disease when deciding where to launch the product on the market.

2) Plans to apply for WHO prequalification

Prequalification means WHO has deemed the product to meet acceptable standards of quality, safety and efficacy. This process can accelerate the registration process in LMICs where national regulatory capacity may be lacking.

3) Post-trial access guarantees for clinical trial participants

Once clinical trials have ended, companies can provide continued access to the investigational products that have demonstrated significant benefits.

4) Plans to engage in technology transfers or local manufacturing arrangements

Companies can transfer knowledge on a medicine and its established manufacturing processes to local manufacturers. This ensures that the product is available in sufficient quantities to meet demand locally.

5) Plans to make product donations

Companies can donate products to increase availability in countries within scope of the Index.

6) Supply and demand planning

Companies can plan by forecasting the anticipated quantities of a product required in countries within scope of the Index. This can help to guarantee supply chains and prevent drug shortages.

7) Commitments to engage in non-exclusive voluntary licensing agreements

If a company does not intend to register a product in countries within scope of the Index, it can engage in non-exclusive voluntary licensing. These agreements allow selected manufacturers to produce generic versions of the drug and supply them in countries where the product may otherwise be unavailable.

8) Plans to apply equitable pricing strategies

To ensure accessibility, companies must ensure that products are affordable. Each project should be accompanied by an equitable pricing strategy that considers ability to pay in different countries. As

best practice companies should include intra-country differential pricing with special prices for the public sector and/or health insurance; this is especially relevant for upper-middle income countries with large private markets.

9) Commitments to future patent waivers

Companies can waive intellectual property rights for products in LMICs. This enables generic manufacturers to produce the product without the risk of infringing patents.

A comprehensive plan includes several of these 'access components' to expedite access to the product while it is still in the R&D stage. Furthermore, the access plan should have a broad geographic scope to maximise the number of patients reached.

Although the 2022 Access to Medicine Index found progress in the proportion of late-stage R&D projects with access plans, the quality of access plans for projects in the pipeline varies widely. To be comprehensive, an access plan must consider several factors to ensure a medicine is available and affordable. We therefore encourage NIH to emphasize in their next policy draft the point of having several factors in the projects' plans.

More information can be found in the 2022 Access to Medicine Index, pages 73 to 76.

https://accesstomedicinefoundation.org/resource/2022-access-to-medicine-index

5) Establishing licensee obligations depending on the stage of technology development.
The Access to Medicine Foundation argues that access plans should be initiated no later than Phase II of development. This is a reasonable target as the 2022 Access to Medicine Index demonstrated that 6 large R&D (Astellas, Boehringer Ingelheim, Johnson & Johnson, Merck, Novartis and Takeda) already have access plans for 100% of their late-stage R&D projects in scope of the research.

Aiming to have a first access plan from phase II holds different benefits:

It starts the access conversation earlier, which leads to more integrated and comprehensive plans at the end of the R&D process;

It gives more time to adjust the plans in phase III, to better overcome barriers you have identified in phase II;

Large scale clinical trials usually take place during phase III. It is necessary to already have access plans in phase II to ensure the participants in these clinical trials will have continued access to this product once the R&D process is completed.

Regarding R&D on antibiotics, NIH can use the Stewardship and Access Plan Development Guide, published in 2021 by a working group of experts, including the Access to Medicine Foundation. This guide is a crucial resource in the fight against Antimicrobial Resistance. It equips pharmaceutical companies and product developers with practical steps to expedite access to new antibacterial products while maintaining responsible usage practices.

It is essential that these plans also ensure that access needs in LMICs are taken into consideration during the R&D stage. Access plans can be developed in-house or in collaboration. They can include

commitments and strategies, as well as more concrete access provisions, such as specific measures developed in partnership with other organisations that can enforce accountability. Plans should aim to target a variety of LMICs, including low-income countries. The 2022 Index highlighted that on average, an access plan includes only six of the 108 LMIC countries in scope of the Index, and only 38 out of 257 projects (15%) are covered by an access plan that includes at least one low-income country. NIH should therefore request that its licensees create high quality and comprehensive access plans, with a varied geographic reach. In particular, the research entity must do more to ensure a wider and more diverse range of countries are included in access plans, specifically low-income countries who are currently not included in more than 85% of plans. It is vital that this is planned out during the R&D stage to ensure that innovative products are widely and rapidly available to those that need them most.

On the specific topic of IP, pharmaceutical companies can engage in voluntary licensing by transferring intellectual property (IP) rights to a licensee, enabling them to produce generic versions of their product under certain terms and conditions. Voluntary licensing agreements can expand availability and affordability by facilitating generic supply, and are particularly valuable for expanding access in countries where the originator company does not intend to market the drug that it has patented.

Increasingly, companies are widening access to their products through non-exclusive voluntary licensing (NEVL). NEVLs have the potential to improve access, as if there is uptake of the licence from generic medicine manufacturers, supply and affordability can increase as generic versions enter the market.

When companies choose to engage in technology transfers with licensees, they can improve and speed up regional availability of medicines, while building manufacturing capacity that can be used for the future production of medicines. Bristol Myers Squibb, Gilead and GSK (via its majority-owned business specialising in HIV products, ViiV Healthcare) stand out for voluntarily licensing some of their products, while also supporting local manufacturers to build technical capacity through technology transfers. The 2022 Index highlights in detail their actions in a Best Practice on page 141.

https://accesstomedicinefoundation.org/resource/2022-access-to-medicine-index

https://accesstomedicinefoundation.org/resource/the-stewardship-and-access-plan-development-guide

6) Assessing policy impact.

Based on its independent research on the pharmaceutical industry, the Access to Medicine Foundation argues that at the R&D stage, a good access plan includes multiple access components Access plans must address availability, affordability and sustainable supply. Various combinations of access components can be incorporated to fulfil these requirements. Diving into the Index' Methodology can help the NIH to assess the robustness of the licensee's access plans.

The 2022 Access to Medicine Index found that R&D projects developed in collaboration with access-oriented organisations such as Wellcome Trust, Bill and Melinda Gates Foundation and DNDi have more comprehensive access plans than those which aren't. These projects consider on average 4.1 access components (compared with 1.9 components for other projects). This means these access plans are more likely to consider a variety of factors to enable access (e.g., availability, affordability and supply). Almost 30% of priority R&D projects are developed in partnership with access-oriented organisations and almost half are in partnership with partners that receive public funding.

https://accesstomedicinefoundation.org/resource/2022-access-to-medicine-index

7) Other Comments

The Access to Medicine Foundation suggests this reformulation of the paragraphs in the policy requirement section:

[...]

The Access Plan shall include, but not be limited to, a brief description of the Licensed Product(s); the anticipated patient population(s); other products, tools, facilities, or unique resources that would be necessary for use of the Licensed Product; and one or more strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability. To the extent such Access Plan includes proprietary information [to be defined], upon NIH's request Licensee will also provide a non-confidential version or statement of such Access Plan that NIH may publish or otherwise make available to third parties.

[Addition of: registration commitments, equitable pricing strategies, sufficient supply commitments, and applying for World Health Organization prequalification]. This is aimed at clarifying examples of actions taken to increase access of products to LMICs, as the current examples focus on the domestic market].

Within 3 months of a Licensed Product entering a first pivotal clinical trial (a Phase II trial or the equivalent), Licensee will provide NIH with an Access Plan (as defined), unless a written waiver or modification is obtained in advance from NIH. NIH agrees to consider such requests for waivers or modifications in good faith.

[Edit: change from Phase III to Phase II, based on the rationale shared in Question 5]

[...]

Uploaded File:

Description:

Submit date: 7/19/2024

I am responding to this RFI: On behalf of an organization

Name: Thad Flood

Name of Organization: CSL Behring

Type of Organization: Industry

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) Promoting meaningful access approaches.
See attached letter.

2) Promoting transparency in the biomedical enterprise and return on investment.
See attached letter.

3) Providing flexibility while achieving clear policy objectives.
See attached letter.

4) Helping licensees achieve access goals.
See attached letter.

5) Establishing licensee obligations depending on the stage of technology development.
See attached letter.

6) Assessing policy impact.
See attached letter.

7) Other Comments
See attached letter.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/2024.07.19-NIH-RFI-Access-to-Taxpayer-Funded-Innovations_Final.pdf

Description: CSL Behring's response to the RFI is included in the attached PDF letter. Thank you.

Submit date: 7/21/2024

I am responding to this RFI: On behalf of myself

Name: Julie Moonga

Name of Organization: King's College London

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.

Licensees must balance profits and accessibility by adopting good pricing practices. They must engage in multi-dimensional and sectorial engagement, communication and collaboration to close the gaps in inequality, improve accessibility and availability of drug and treatment. In addition, licensees need to be more transparent about how prices are set, and consider value-based pricing. By addressing pricing issues, licensees can find better strategies to help mitigate access challenges, scrutinize cost/benefits to better align costs more closely with patient outcomes.

2) Promoting transparency in the biomedical enterprise and return on investment.

Transparency, as a foundation for building trust and credibility can strengthen investor relations. By promoting and prioritizing transparency licensees foster long term partnership that can increase value for high return on investment. Furthermore, the adoption and implementation of responsible AI technology can bring added value. It is evident AI can be powerful tools that can increase speed of process and productivity while driving down cost of operation and products. But, AI systems must risk assessed carefully. Licences must identify value drivers. For example, easy to solve problem, difficult to make error and easy to fix error. In addition, they must stay ahead of regulation.

3) Providing flexibility while achieving clear policy objectives.

Licensees need collaboration to break down the siloes while achieving clear policy objectives. Policy objectives should be made with the voice of all stakeholders involved, not in silo. Most policy makers are not necessarily experts on specific area they make the policy for. It is crucial to involve those experts who are highly trained with the expertise and knowledge to better calibrate the technical element that the policy needs to address. Licensees need to understand integrated policy planning and research as an iterative approach to avoid negative spillover in the policy and implementation. Consequently, gaps can be filled to increase salience of policy.

4) Helping licensees achieve access goals.

Licensees can leverage AI technologies to speed up process, improve accessibility and delivery of products to patients. One way they can further improve efficiency is by maximise all resources including from government programs. Another way is to collaborate with government agencies to minimize administrative barriers, create standards and transparent processes for better decision making. Access to products on the basis of cost-effectivity based on evidence E.g., negotiate price of products between manufacturer, distributor and dispensary.

5) Establishing licensee obligations depending on the stage of technology development.

As products move closer to market launch, manufacturers stand at a crossroad ,facing many challenges toward commercialization including ethical challenges. Licensees need to take a multi-dimensional, multi-stakeholder collaboration approach that includes healthcare professional, regulatory bodies and patient advocacy group could help ensure dialogue for clear responsibility and understanding in various stage of development. In addition, regulatory bodies as crucial role stakeholders, can provide strategic and technical advice, and at the highest level to significantly contribute both scientifically and commercially. High level expertise would ensure products are developed, manufactured and controlled at all stages of optimal quality assurance, patient safety and product efficacy. A collaborative approach is critical for risk mitigation and adopting transparency and good practice. At the end of the day, the patient is the most important stakeholder. Any decision needs to be patient-oriented and patient-focused to optimize outcomes.

6) Assessing policy impact.

Rapid expansion of technology and expanding regulatory environment require compliance authorities to quicken their pace as they grapple with emerging technologies. The future of compliance relies on its legal foundations and a strong focus on ethics and responsibility of all stakeholders involved. For optimal policy impact, compliance should be assessed through key external forces; legal, technological, innovation, educational, financial, demographics and cultural. In addition, compliance must be assessed and measured through behavioural change, emerging trends, risks management, data ethics, communication both internal and external as well as technology. The NIH needs to foster mining risk management and intelligence to deliver actionable insights.

7) Other Comments

I would welcome the opportunity to contribute further to help develop this document.

Uploaded File:

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Barbara E Bierer MD

Name of Organization: Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.

In the Appendix of the Draft Policy, NIH-OSP lists several examples for how licensees might promote equitable access. These include "committing to keep prices in the U.S. equal to those in other developed countries; not raising costs above inflation; preparing tailored, culturally sensitive educational materials for a range of domestic and global patient populations." 89 Fed. Reg. 45005. We worry that the presentation of the development of educational materials as tantamount or equivalent to price controls in this context may affect the success of the Draft Policy's goal to promote equity through access planning. Licensees are unlikely to subject themselves to price controls voluntarily: we strongly recommend differentiating proposed price control mechanisms for licensees from other aspects of access planning. NIH-OSP is likely to meet resistance from licensees from private enterprise when suggesting price controls in any case, but NIH-OSP could amend the Draft Policy to require both a price control element to address "persons…adversely affected by persistent poverty of inequality" and an educational element to address cultural barriers.

2) Promoting transparency in the biomedical enterprise and return on investment.

The actual manufacturing and development costs, fully burdened with overhead and sunk costs, are are at best inexact estimates; such a proposal would be met with strong resistance and could be misinterpreted by the public. Even the economics of the basic science to potential product license within the IRP is hard to estimate: does one include the years of misdirection and failed experiments? And in the IRP, the NIH has a firm handle on the accounts. Generally, pharmaceutical manufacturing achieves economies of scale during the lifecycle of a drug, biologic, vaccine, or device patent, but the investment is greater earlier than later—how would that factor into the access plan? Would the public (and Congress) then anticipate that "transparent cost accounting measures" are auditable? And any such estimate is subject to misinterpretation: the published cost accounting for the development of NIH-licensed Drug A through manufacturing might be mistaken for the unpublished development cost of non-licensed Drug B.

To help avoid potentially fractious drug pricing discussions that radiate out beyond NIH's book of licensed products, NIH may want to reevaluate how transparency in development costs meets the objectives laid out in NIH's definition of "access" – product affordability, availability, acceptability, and sustainability. In our opinion, none of these characteristics is based on the costs of development and manufacturing, but rather the need to provide access to essential products.

We offer an alternative approach. For those products developed with public funds invested in the research of the IRP, some percentage of total revenue should be invested back into the public good. This cannot be presented as a 'tax' but rather, essentially, a form of a royalty stream. That percentage could be variable based on time on the market or other factor, but it will reflect the success and impact of the product. Those funds could be ear-marked to the NIH, HHS, the very patient populations who cannot afford the product, or other specified purpose (e.g., insurance for participant injury as a result of participation in investigational clinical research). This model has certain advantages: it is easy to calculate, the funds transfer is visible and directed to the public good, and the pharma industry is accustomed to this model in that licensing and royalty streams are common in academic centers that license their discoveries. Note that the percentage of revenue (rather than "net profit" which again is a financial calculation that can be modified depending on numerable factors and is very difficult to audit) need not be large to have a substantial financial impact (e.g., 1% of a $1B product is $10M year over year).

3) Providing flexibility while achieving clear policy objectives.

The Draft Policy appears to take into account the wide range of development costs incurred from drug to drug and from medical device to medical device. However, the Draft policy's differentiation between "late-stage" and "early-stage" inventions seems incomplete. Because so few early-stage inventions eventually to reach the market, NIH-OSP should consider a boilerplate option for licensees that is balanced by the stage of discovery. For instance, given the model proposed above (percentage of revenue), the specific percentage may be less if early-stage and somewhat greater if later stage. This simplicity also has other advantages: the opportunity costs of developing access plans are minimized when considered against bespoke access plans for each of NIH's licensed assets. We would suggest NIH-OSP develop a single (but flexible) framework to apply to all assets, determined at licensing or another date certain (e.g., when the asset reaches a first pivotal trial) and reviewed every 5-8 years to assess workability and impact.

4) Helping licensees achieve access goals.

Each licensee is likely to have different strengths and weaknesses when it comes to promoting equity access. For example, a global pharmaceutical company would be considerably more likely to have the capability to bring a drug to populations in low- and middle-income countries – see appendix at 89 Fed Reg 45005 – than would a start-up or a small biotech firm. With that in mind, the entire group of licensees across NIH's portfolio are likely to require a wide array of support to help promote patient access for their individual licensed products. Therefore, we suggest that organizations seeking NIH licenses be evaluated or submit self-evaluations to identify the patient access strengths and shortcomings in their capabilities. Simply put, the best way NIH could help licensees deliver patient access is to know what they need. These needs would be best assessed at the "early-stage" of the tiered approach described in the Draft Policy (if that tiered approach is retained in the final policy) to give both the licensee and NIH sufficient time to respond to whatever the need may be.

5) Establishing licensee obligations depending on the stage of technology development.

We fully support the early-stage and late-stage distinction between requirements for licensed products. NIH-OSP should consider developing specific guidance for each of the options provided in the bulleted list in Part III of the Draft Policy's appendix at 89 Fed Reg 45005. For some licensed

products – e.g., vaccines or next-generation antibiotics – partnering with public health organizations may make sense, while for other licensed products – e.g., a medical device implant – it may not. Consequently, NIH-OSP should develop guidance or a checklist for licensees to help them distinguish how best to promote patient access impactfully.

Furthermore, the MRCT Center has long been a proponent of "clear and understandable" language to promote health literacy.* Access plans should always keep the intended patient population in mind throughout their development from early-stage to late-stage to marketed products. The access plans should be culturally and linguistically appropriate for the populations intended to benefit.

Lastly, we suggest that NIH-OSP consider flexibility as to the stage of development when access plans would be required. For example, phase IIb trials as a time when, at least for a number of products (e.g., oncology), the potential product has been derisked significantly. Device development often proceeds at a different pace. The timing should be conditioned on the product.

* Especially if the licensee intends to develop educational materials to promote tailored access, suggest leveraging the MRCT Center's health literacy resources and plain language glossary, the latter of which has already been indexed by NIH and adopted as a global standard by the Clinical Data Interchange Standards Consortium (CDISC).

6) Assessing policy impact.

Because the Draft Policy applies to products in development, it appears the best to measure the policy's impact would be two-fold. First, independent, multi-stakeholder reviewers could assess the strength or completeness of access plans to measure uptake and incorporation of the Draft Policy's goals and ideals among licensees. Second, once a licensed product reaches the market, direct engagement with community stakeholders and patient advocacy groups by NIH may be an important way to evaluate which elements of a particular product's access plan deliver value to communities and patients. NIH should consider formalizing internal infrastructure to perform this function as part of its own access by design planning.

As mentioned above, the MRCT Center supports NIH-OSP's efforts to equity through access planning. The MRCT Center appreciates the opportunity to comment on this Draft Policy. We would welcome an opportunity to discuss. Please feel free to contact the MRCT Center or me (bbierer@bwh.harvard.edu), if we can be helpful.

7) Other Comments

The MRCT Center is a research and policy center that seeks to improve the ethics, conduct, oversight, and regulatory environment of international, multi-site clinical trials. Founded in 2009, it functions as an independent convener to engage diverse stakeholders from industry, academia, patients and patient advocacy groups, non-profit organizations, and national drug and device regulatory agencies. The MRCT Center focuses on pre-competitive issues, to identify challenges and to deliver ethical, actionable, and practical solutions for the global clinical trials enterprise. The responsibility for the content of this document rests with the leadership of the MRCT Center, not with its collaborators nor

with the institutions with which its authors are affiliated (Brigham and Women's Hospital, Mass General Brigham, Harvard Medical School, and Harvard University.)

The MRCT Center applauds NIH-OSP's efforts to promote greater access—and equitable access—to therapeutic interventions derived from taxpayer dollars invested in research performed by investigators at the IRP. We offer the comments below to further NIH-OSP's efforts.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/MRCT-Center-NIH-OSP-IRP-Equity-Access-Plan.pdf

Description: Letter in response

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Christopher Moran

Name of Organization: Wellcome Trust

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Other

Role - Other: Legal - IP and Translation Associate General Counsel

1) Promoting meaningful access approaches.

The GHIAA MapGuide is a useful source of different access strategies and precedent clauses. It may be very challenging however to (in advance) define what is commercially reasonable in relation to future fact patterns or product types. An alternative approach might be to define a set of example of behaviours which is highly unlikely to be considered commercially reasonable, i.e. (i) failing to even consider how a product might be made available in one or more LMIC countries where there is a demonstrable patient need and where the licensee has no present intention of themselves marketing the product. (ii) failing to address product stewardship in the context of AMR if the product is a novel antibiotic.

2) Promoting transparency in the biomedical enterprise and return on investment.

It is a good idea to encourage licensees to flag inefficiencies in the R&D and regulatory pathways, which could then be targeted for improvement in order to speed up, and reduce the costs of, getting a new product to patients. However, without transparency on revenues and profits there is no way to be certain that reducing costs wont simply increase profits instead of driving down costs and thereby improving access.

3) Providing flexibility while achieving clear policy objectives.

NIH should consider rolling this approach out to co-owned IP and IP arising from NIH funded external projects as soon as practicable. This will boost the health impact from NIH funding and raise awareness/adoption of the underlying access plan approach by other funders and research institutions. The ultimate (medium-long term) goal should be to try and drive this approach as an standard (minimum default provision) when it comes to public/philanthropic funding of medical R&D. Doing so would greatly increase its impact (benefiting funders and patients) whilst also benefitting industry by virtue of access planning becoming a familiar and ingrained approach with (as far as practicable) consistent application by different funders in order to reduce the complexity of compliance.

Rather than the Access Plan referring to undeserved communities “and/or” populations in LMICS, could NIH delete the “/or”. Clearly stating that licensees have to address both patient groups in their plans would provide greater certainty to licensees over what is required of them. It would also help mitigate the risk that licensees do the bare minimum to comply, by picking a single group and a single measure to address access for them.

Consider making it express that each of the criteria of affordability, availability, acceptability and sustainability, must be addressed in each plan. Currently a licensee may be able to comply by providing a single strategy dealing with sustainability and claim they have complied.

4) Helping licensees achieve access goals.

Pushing the date of the plan back to 3 months after entering Phase III (or equivalent) is a good idea in order to avoid the burden of generating unnecessary plans. However, this means that the thinking about access in order to produce the plan will likely not have influenced the trial design and specifically how that trial design could itself advance the future use of the product by underserved communities. NIH could (without changing the deadlines) include a requirement in the policy that the access plan discusses how the research and trial design has addressed the goal of broadening access to date. Awareness of this requirement may help bring forward the licensee's thinking about access, even if the plan isn't due until later. This requirement could link to any NIH (or third party) guidance about how inclusive trial design can support uptake of the product down the line.

We anticipate licensees frequently requesting that the date for the plan be pushed back to 3 months following a successful phase III, on the basis that producing a plan during the phase III trial will be redundant if the trial is not successful and the product does not advance further. We would recommend against that as it would be interesting to see as a part of the plan which countries the licensee is conducting the trial in, which communities are represented in the trial, and how the trial design links to the goal of advancing access. The earlier NIH see than, and can feedback any requested modifications to the plan, the better.

NIH could consider building in the right for NIH to engage third parties to look at and support the licensees' plan (specifically the confidential version). The confidentiality provisions might otherwise prohibit this.

5) Establishing licensee obligations depending on the stage of technology development.

The tiered licensing approach, with more specific access-oriented provisions for late-stage inventions, is a key strength of this proposal. However, we suggest that NIH be explicit that the access plan applies as a constant, with additional licence provisions added where appropriate. The access plan approach has value in terms of transparency even if more specific provisions are layered on top. At the moment it could be read that the access plan wouldn't apply for later stage inventions, which we think would be a missed opportunity.

6) Assessing policy impact.

The published versions of the plans will be a valuable source of information for third parties to use to assess access efforts, not just from NIH funded research but from other research which has lead to the generation of access plans. However, licensees are likely to take a conservative approach to the contents of the non-confidential (publishable) version of the plans. A significant driver for proper licensee engagement with the policy is the moral/reputational public pressure that could come from poor plans and/or the failure to deliver on commitments set out in the plans. Therefore any reduction in content of the published plan may weaken that driver, allowing licensees to use commercial sensitivity to hide information in the confidential version. To mitigate this risk, NIH could consider

giving each confidential plan a rating against one or more criteria and commit to publishing each rating. Alternatively (or ideally in addition) the policy could allow NIH to share the confidential version of each plan with the Access to Medicines Foundation or a like organisation, for the purpose of rating the plan (i.e. as part of their Access to Medicine Index).

With this in mind, NIH could consider a definition of "proprietary information" (i.e. content which would be found in the confidential plan but not the published one) which allows the licensee to withhold any confidential technical information about the product, but which does not allow the licensee to classify information about the anticipated roll-out (in which countries it will/will not be marketed etc) as confidential. The risk with a broad definition is that the published plan will have little to no substantive content and its publication will therefore not be valuable in terms of either creating pressure on the licensee to deliver or being able to assess the value of this policy over the long term via third parties analysing the published plans.

To aid transparency and assessment of the policy, NIH could publish overall waiver numbers (numbers requested and granted etc) and for each waiver a non-confidential explanation could be published by NIH setting out why it agreed to a waiver.

NIH should consider potential sanctions for bad faith/token efforts. Whilst we appreciate that NIH does not want to dissuade potential licensees (and so the policy is deliberately not prescriptive), NIH could encourage more active engagement with these plans by indicating that any licensees deemed to be paying lip service to the policy and/or failing to deliver on their plans without justification, may be barred from future NIH licenses/partnerships. Reporting by NIH annually on the need to apply such sanctions would help drive, as well as assess, policy impact.

7) Other Comments

Other groups have been using and advocating similar access plan approaches (such as the Medicines Patents Pool). It would be helpful if NIH, when progressing its own plans, could indicate a willingness to consider revising its policy in the future if a consensus emerges over the use/content of such access plans. Avoiding unnecessary variations between the detailed requirements for such plans, and harmonising how they are used to broaden access, could reduce the burden for industry of complying with multiple similar but slightly different policies. For example, having one repository for the public version of such plans (irrespective of the original funder) would help in terms of transparency and efforts to analyse the impact of such plans.

The guidance for the plan should ideally include the licensee stating the countries in which they intent to market the product and those in which they do not. For countries where the licensee has no plans to market the product they should have to indicate what steps they propose to facilitate access through other means, such as facilitating others to do so.

The information provided about the policy states that the parties commit to revisit access considerations as product development progresses. The policy itself however does not put the onus on the licensee to maintain or update the original access plan, save in response to NIH instigated discussions (which will be no more than annually). It may be difficult in practice for NIH to identify

new information/updates or changes which ought to be added to the plan to keep it current. We recommend that the policy requires the licensee to review the plan at least annually and revise it as necessary to ensure it is up to date (providing updated confidential and public versions to NIH if they materially change).

Whilst step in/march in rights have not historically been used by the NIH, could the guidance on the access plans draw a link between failure to deliver on a plan (and therefore failing to meet the needs of patents) and the potential for exercise of the march-in right.

Uploaded File:

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Maya M. Durvasula, Lisa Larrimore Ouellette, and Bhaven N. Sampat

Name of Organization: Stanford University and Arizona State University

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.

[The text below is copied from the attached PDF. Please see the PDF for background and citation information.]

We applaud the NIH for its commitment to improving public access to products stemming from NIH intramural research, and for the draft policy's flexible approach and recognition of the range of strategies for promoting access. As Hemel and Ouellette (2023b) have explained, "the tradeoff between incentivizing medical innovation and ensuring access to medical technologies is largely a false choice." Policymakers can use a pluralistic array of innovation policy tools to promote both innovation and access (Hemel and Ouellette 2019). In this spirit, we recommend three revisions to the draft policy.

First, the new policy for intramural NIH inventions should recognize that in some situations, a traditional license to a private firm may not be the best way to commercialize the invention. Conventionally, late-stage pharmaceutical development has been almost entirely funded by the private sector. But in some cases, the public sector may have a comparative advantage in financing commercialization and navigating the government regulations involved in bringing a new product to market (Sampat 2020; Hemel and Ouellette 2019). Operation Warp Speed illustrated that the federal government could take a more hands-on approach to all stages of developing pharmaceutical products, and it could go even further (Ouellette 2024).

Second, we recommend that the new policy explicitly address the value of global access. Improving global access to medicines and reducing global disease burden is not only a humanitarian responsibility; it also serves U.S. interests. For example, it can reduce global public health threats to Americans' health and resources, expand global markets, improve global stability and security, and enhance the United States' reputation. Voluntary licenses to produce low-cost medicines for low- and middle-income countries, such as those organized by the Medicines Patent Pool, have already proven effective at expanding global access (Fisher et al. 2023; Galasso and Schankerman 2022; Wang 2022). NIH licensees should be encouraged to commit to this strategy as part of their access plans.

Third, the new policy should include, in its list of access-promoting strategies that licensees may consider, efforts to reduce the costs of drug development and manufacturing. As the NIH's request for information notes, "access" is not a simple concept and incorporates factors including affordability, availability, and acceptability—or what Hemel and Ouellette (2023a) describe as the inescapable "trilemma" of having products that are low price, sufficient in quantity, and of acceptable quality. An

exclusive focus on reducing prices would likely exacerbate problems with drug shortages and inadequate quality. But some approaches can reduce the tradeoffs in the price-quantity-quality trilemma, such as manufacturing innovations that would allow firms to more rapidly adjust production in response to demand (Hemel and Ouellette 2023a). For example, a recent National Academies report describes the benefits of switching from batch to continuous pharmaceutical manufacturing and the regulatory barriers that have deterred firms from doing so (NASEM 2021). Licensee initiatives to accelerate this switch could improve access to the licensed drug by reducing price-quantity-quality tradeoffs such that the drug would be less likely to go into shortage. More importantly, such initiatives could have substantial spillovers for improving access in the pharmaceutical market more broadly by providing a clearer regulatory pathway for other firms that would reduce drug development costs and increase the manufacturing pipeline's responsiveness to demand fluctuations.

2) Promoting transparency in the biomedical enterprise and return on investment.
[The text below is copied from the attached PDF. Please see the PDF for background and citation information.]

Little is known about key aspects of biomedical research. How expensive is it to bring a new health technology to market? How—and why—do these costs appear to be increasing? How often is product development halted because a clinical trial failed? How often is development halted because some other commercial factor made continued development unprofitable? (Durvasula et al. 2024) Given that government agencies—including the NIH, NSF, and FDA—provide direct and indirect support for much of this research, development, and commercialization, the lack of evidence on seemingly simple questions is surprising. To design the type of evidence-based, pluralistic policies we describe above, policymakers must have access to evidence on the basic features of this market. In implementing this policy, the NIH has an opportunity to produce such evidence.

For aspects of product development that include clinical testing, the NIH should require sponsors to disclose details about patient recruitment. The Food and Drug Administration Amendments Act of 2007 (U.S. Public Law 110-85) already requires sponsors to collect recruitment details, including patient race and sex. Few firms comply with this requirement (Alsan et al. 2024). Without imposing any requirements beyond what is already required by law, the NIH can collect this information from all licensees. Additional information about the costs and challenges of, for example, recruiting a representative sample of patients would be helpful in understanding how other forms of public sector support might be deployed. Anecdotally, recruiting patients from historically underrepresented populations is much more expensive, in part because patient registries do not exist in the United States (Durvasula 2023) and in part because sponsors encounter high levels of mistrust in some historically excluded communities (Alsan et al. 2024). With more detailed evidence about where, and why, these challenges arise, the NIH can better target its own efforts to ensure that testing of federally-funded inventions is representative. Alsan et al. (2024) suggest that representative clinical data can have a significant impact on documented racial "prescribing gaps."

Similarly, the NIH should require licensees to disclose disaggregated data on the costs of each aspect of preclinical and clinical development. The NIH already collects similarly detailed data for product testing conducted by its intramural research groups. Recipients of grants are also required to submit proposed and revised budgets at regular intervals. Such data collection is standard, and the NIH already restricts access to much of the commercially sensitive data that it collects. This requirement is no different, then,

than other reporting obligations for beneficiaries of federal research support. An important, and difficult, question in this setting is whether incentives for research are properly calibrated and whether more expansive policies such as this one, to expand patient access, may make certain investments unprofitable. With this information, policymakers will have sufficient information to make decisions based on concrete estimates of the magnitude of private sector investment required to bring NIH-licensed technologies to market.

Evidence on the costs of technology development is an important input into the design of evidence-based policy, beyond determination of prices. Any proposal to improve the evidence base associated with new technologies, reduce the costs of research, or realign incentives with social value requires, first, understanding how resources are currently being allocated. Filling the gap in this data landscape is a straightforward first step for this new policy initiative.

3) Providing flexibility while achieving clear policy objectives.

4) Helping licensees achieve access goals.

5) Establishing licensee obligations depending on the stage of technology development.

6) Assessing policy impact.

[The text below is copied from the attached PDF. Please see the PDF for background and citation information.]

There is limited empirical evidence about how access policies—or other forms of patent policy—affect the commercialization of federally-funded inventions. In implementing this new policy, the NIH has the opportunity to produce the type of rigorous evidence that is most useful to policymakers, which can help evaluate the effects of this policy and also inform the design of similar, future efforts. The NIH should incorporate some aspect of randomization in exposure to the patient access plan requirement or, at a smaller scale, in the content of license terms or the extent of agency support provided to licensees. Any element of randomization allows the NIH to produce causal estimates of the effects of the policy, making it possible to determine, definitively, whether a particular element was beneficial. Randomization aside, the NIH should commit to gathering data—in the short- and long-term—on outcomes associated with each aspect of the licensing process.

Assessing the impact of the proposed policy is critical because there is little rigorous evidence about the tradeoffs between the commercialization benefits and access costs of patents on publicly funded research, either for the intramural research that is the focus of the new policy (for which patents are governed by the Stevenson-Wydler Act of 1980) or for extramural research (governed by the Bayh-Dole Act of 1980). As summarized by Ouellette and Sampat (2024a):

Both at the time of Bayh-Dole's enactment and today, policymakers have had little rigorous evidence about the impact of patent policy on the commercialization of federally funded inventions (Eisenberg 1996; Ouellette and Weires 2019). This is true both in general and for specific policy interventions such

as price-related restrictions on patent rights. In our view, we lack evidence on the magnitude of the potential tradeoff between price-related restrictions and commercialization.

The evidence developed since 1980 is limited to a few anecdotes. There have not been significant efforts to limit Bayh-Dole patent rights based on pricing, but from 1989-95, the NIH attempted to impose price-related limits under the separate Stevenson-Wydler Act, which governs intramural research and collaborations between intramural laboratories and private firms. In particular, the NIH required "fair pricing" clauses in Cooperative Research and Development Agreements (CRADAs), or agreements to share government facilities and personnel (but not funding) with private-sector partners. The NIH said it abandoned this effort because drug companies refused to sign the new CRADAs but kept collaborating with government scientists, leading to confusion about the resulting IP ownership (Contreras 2020; Rohrbaugh and Wong 2021; Sarpatwari et al. 2020). But this thirty-year-old experience may not reflect public-private collaborations today, and it also reveals little about whether licensing of patents developed under federal grants would be markedly different if those patents came with additional price-related restrictions. Pre-Bayh-Dole anecdotes and statistics on commercialization rates when the government retained title to inventions (Eisenberg 1996) also do not inform the much narrower question of whether, to what extent, and under what conditions using march-in to ensure "reasonable" pricing would affect commercialization incentives.

Answering the question of how the proposed policy will impact commercialization of and access to NIH-funded inventions requires specifying a counterfactual of how these inventions would have been developed in the absence of the new policy. As summarized by Ouellette (2023), "For the same reason that the NIH funds randomized controlled trials (RCTs) to provide the best evidence of a medical intervention's clinical efficacy, the agency should consider RCTs to assess the efficacy of its policy interventions, as many scholars have suggested (e.g., Azoulay and Li 2020; Watney and Williams 2022)."

Ouellette and Sampat (2024b) made a similar suggestion to NIST in response to its request for information on its proposed revision of the Bayh-Dole march-in regulations:

A rigorous . . . policy experiment could be implemented in multiple ways (J-PAL 2023), but one approach is randomizing across similar technologies (Ouellette 2015). For example, the natural divisions within grantmaking agencies could be used to initially apply the framework to only a random subset of divisions. The NIH has 27 distinct Institutes and Centers (ICs), which have different research agendas that focus on different diseases, body systems, or other health-related issues. Each of these ICs has its own subdivisions; for example, the National Cancer Institute houses the Division of Cancer Treatment and Diagnosis, which houses programs such as the Developmental Therapeutics Program and the Radiation Research Program. Given the uncertain effect of the [proposed policy], it seems prudent to initially implement it in only some of these ICs or divisions, and outcomes from those units can be compared with outcomes from the "control" group of units that maintained the status quo policy. The NIH has some experience in piloting changes in peer review in some ICs (or for some grant types) and not others (Sampat 2023); there is no reason why a similar approach can't be taken for commercializing the results of its peer-reviewed research. Such experiments must be implemented carefully to produce reliable evidence, guarding against gaming, anticipation effects, and other potential confounders. Scholars and practitioners have considerable experience from other

contexts that could be leveraged for assessing the impact of price-based march-in on commercialization (J-PAL 2023).

The NIH should commit to collecting data at regular intervals for both the outcomes of primary interest—access and affordability—and for intermediate outcomes that can be measured in the short- to medium-term. Especially for licenses granted for early-stage inventions, the effects of this new policy on access and affordability will be clear only with a considerable delay. In the interim, however, the NIH can collect detailed information about the number of suitors for particular licenses, the characteristics of potential licensees, the outcomes of licensing negotiations, and the progression of technologies through phases of pre-clinical and clinical development. Outcome reporting is valuable as a tool for agency learning only if all licensees are compliant: it is difficult to assess the effects of any policy if, say, only the most successful or profitable licensees provide measures of progress. The NIH should ensure that its expectations for outcome reporting are clearly communicated to licensees and that these requirements are consistently enforced.

7) Other Comments

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Durvasula-Ouellette-and-Sampat.pdf

Description: Full text of comments, including background and references

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: N/A

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Other

Role - Other: Former active technology transfer practitioner for 4 decades in Canada, the US and now a consultant in many foreign countries

1) Promoting meaningful access approaches.

I am opposed to the implementation of the suggested approaches. Others have commented on how expensive, risky and problematic commercialization of basic research results is, whether the research is internal to federal laboratories or financed by government in other institutions. The academic technology transfer community, as a community realized a number of years ago that access to the life saving new products could save lives, improve health and increase corporate productivity and competitiveness. Our community issues the 9 Points document to encourage licensing universities to introduce mechanisms similar to those now proposed by NIH in less developed countries. This is now an accepted approach to ensure access in these foreign countries. I am opposed to the implementation of the suggested approaches inside the USA to the named communities. Why? Because there are much more effective methods of long standing of achieving the desired results to the targeted communities. Or, if not yet considered optimal, can be adjusted by small tweaks, rather than imposing totally new, broad brush mechanisms, such as proposed. As a rich country, America has a long history of successfully looking out for these less visible Americans, starting with Social Security, nearly a century ago. Numerous programs have been created and modified over this same time period. Adjusting the current programs to new communities will cause less of a disruption, than the blanket approach NIH suggests. It is well known that new program are relatively broad brush and have unintended consequences due to the broad approach. It is also well known that such broad scale approaches open the door to unexpected players who are gaming the system to their personal advantage.

So, in summary, I oppose the current NIH approach, as there are other, better methods of achieving the stated goals, which will not disrupt the high risk and fragile current process of commercializing research results, whether underway in government agencies or in other organization with government funding. END.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.

4) Helping licensees achieve access goals.

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File:

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Melissa Barber, Anthony D. So, Joseph S. Ross, Reshma Ramachandran

Name of Organization: Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT)

Type of Organization:

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.
Please see attached.

2) Promoting transparency in the biomedical enterprise and return on investment.
Please see attached.

3) Providing flexibility while achieving clear policy objectives.
Please see attached.

4) Helping licensees achieve access goals.
Please see attached.

5) Establishing licensee obligations depending on the stage of technology development.
Please see attached.

6) Assessing policy impact.
Please see attached.

7) Other Comments
Please see attached.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/CRRIT-Public-Comment_NIH-RFI-Access-Planning_22July2024_FINAL.pdf

Description: Thank you for the opportunity to comment on the updated draft NIH intramural research program policy. We are members of the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT), an interdisciplinary initiative aligning research on

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Abigail Lore

Name of Organization: California Life Sciences

Type of Organization: Industry

Type of Organization - Other:

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/CLS-Response-to-NIH-Access-Planning-RFI_7.22.2024.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Rachel M. Cohen

Name of Organization: Drugs for Neglected Diseases initiative

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) Promoting meaningful access approaches.
See uploaded written comments

2) Promoting transparency in the biomedical enterprise and return on investment.
See uploaded written comments

3) Providing flexibility while achieving clear policy objectives.
See uploaded written comments

4) Helping licensees achieve access goals.
See uploaded written comments

5) Establishing licensee obligations depending on the stage of technology development.
See uploaded written comments

6) Assessing policy impact.
See uploaded written comments

7) Other Comments
See uploaded written comments

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/DNDi-Response-to-RFI-on-Draft-NIH-Policy_July-2024.pdf

Description: DNDi Response to RFI on Draft NIH Policy

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Kevin Wozniak

Name of Organization: COGR

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH-Equity-Access-COGR-Comments.pdf

Description: COGR Comments on NIH Equity Through Access Planning

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Justin Mendoza

Name of Organization: Universities Allied for Essential Medicines

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH_Letter_Jul22.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Fred Reinhart

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Member of the public

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Fred-Reinhart-NIH-comments-7-22-24.docx; http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH-comments-7-22-24.docx

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Tom Quaadman

Name of Organization: U.S. Chamber of Commerce

Type of Organization: Other

Type of Organization - Other:

Role: Other

Role - Other:

1) Promoting meaningful access approaches.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

2) Promoting transparency in the biomedical enterprise and return on investment.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

3) Providing flexibility while achieving clear policy objectives.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

4) Helping licensees achieve access goals.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

5) Establishing licensee obligations depending on the stage of technology development.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

6) Assessing policy impact.
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

7) Other Comments
Please see the attached comment letter from Thomas Quaadman, Executive Vice President, Global Innovation Policy Center

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/U.S.-Chamber-of-Commerce-Comments-on-NIH-Intramural-Research-Program-Final-07-22.pdf

Description: The U.S. Chamber of Commerce ("Chamber") Global Innovation Policy Center ("GIPC") appreciates the opportunity to comment on the proposed plan to promote access to taxpayer-funded inventions created through the National Institutes of Health's ("NIH") intra

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Stephen Susalka

Name of Organization: AUTM

Type of Organization: Other

Type of Organization - Other:

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/AUTM-Comments-on-Docket-No-2024-11188.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Jordan Alyssa Heyman

Name of Organization: National Association of Manufacturers

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NAM-Response-to-NIH-RFI-on-Promoting-Equity-Through-Access-Planning-7.22.24-FINAL.pdf

Description: NAM Response to NIH RFI on Promoting Equity Through Access Planning - 7.22.24

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Jishian Ravinthiran

Name of Organization: Public Citizen

Type of Organization: Other

Type of Organization - Other: Consumer Advocacy Organization

Role: Organizational official

Role - Other:

1) Promoting meaningful access approaches.
Please see attached.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.
Please see attached.

4) Helping licensees achieve access goals.

5) Establishing licensee obligations depending on the stage of technology development.
Please see attached.

6) Assessing policy impact.

7) Other Comments

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/2024.07.22-Public-Citizen-Response-to-RFI-NIH-Intramural-Research-Access-Planning.pdf

Description: 2024.07.22 Public Citizen Response to RFI - NIH Intramural Research Access Planning

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Shion Chang

Name of Organization: National Health Council

Type of Organization: Other

Type of Organization - Other: Patient Organization

Role: research-participant-patient-advocate

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NHC-Comments-to-NIH-RE-Draft-Policy-to-Promote-Access_07.22.24.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Krish Gupta

Name of Organization: Intellectual Property Owners Association

Type of Organization: Other

Type of Organization - Other:

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: https://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/IPO%20Comments%20on%20NIH%20IRP%20Policy%20Proposal.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Jacqueline Garibay

Name of Organization: Patients For Affordable Drugs

Type of Organization: research-participant-patient-advocacy-organization

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH-IRP-Policy-Comments.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Claire Cassedy

Name of Organization: Knowledge Ecology International

Type of Organization: Non profit research organization

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Examples of Terms that KEI has Recommended for Inclusion in NIH Licenses

July 22, 2024

Claire Cassedy

Knowledge Ecology International (KEI)

Re: National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning (89 FR 45003)

Since 2015, Knowledge Ecology International (KEI) has commented on 114 prospective exclusive licenses as noticed by the National Institutes of Health (NIH) in the Federal Register. In our comments, KEI has requested the NIH include license terms promoting affordable and equitable access in the US and globally. The following are non-exhaustive examples of terms requested by KEI in our comments submitted to the NIH for various licenses.

PRICING AND ACCESS IN USA

1. Price discrimination/International High Income Country Reference pricing. (used for most of the comments). The license should place restrictions on charging US residents higher prices than the median prices charged in countries with the seven largest GDP and per capita incomes of 50 percent or more than the United States per capita income.

2. Pricing cap. (used for some but not all licenses). In any case, and in addition to any other considerations of what constitutes a reasonable price, the licenseholder is expected to limit the cost of the products or services to U.S. residents to no more than the lesser of either (a) the average annual per capita income in the United States, or (b) the amount of the average annual per capita income in the United States, per quality adjusted life year (QALY) benefit of the product.

3. Years of exclusivity. (used in several licenses). We propose the license include terms that reduce the years of exclusivity when revenues are large. The NIH has many options, including by providing an option for non-exclusive licensing, such as was done in the ddI case. We propose that the terms stipulate that the exclusivity of the license be reduced when the global cumulative sales from products or services using the inventions exceed certain benchmarks. For example, the period of exclusivity in the sublicense could be reduced by one year for every $500 million in global cumulative revenue after the first one billion in global sales. This request is consistent with the statutory requirements of 35 U.S.C. § 209, which requires that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application."

4. Alternative years of exclusivity. (Used in at least one case). The exclusive rights will extend to five years from the first sale of a product receiving approval by the U.S. FDA, or until the license holder recovers at least $1 billion in cumulative global sales from the product, whichever is shorter, and thereafter, the license will become non-exclusive. After the first five years of exclusivity, the NIH can extend the exclusivity by another 3 years, upon a showing that such extension is reasonable in light of the risk adjusted R&D costs to bring the product market, and the net revenues from sales.

5. Exclusivity outside the US (in high income countries). We ask that if exclusive rights are granted, that this only be in high income countries, but not in the United States. Or at a minimum, have the U.S. exclusivity shorter than the exclusivity in other high income countries, perhaps after global revenue targets are reached.

GLOBAL ACCESS

6. Global registration and affordability. The license should require the licensee to disclose the steps that each will take to enable the timely registration and availability of the medical technology at an affordable price in the United States and in every country with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC) and/or the World Health Organization (WHO), either by supplying a country directly at an affordable, publicly disclosed price and with sufficient quantities, or by providing technology transfer and rights to all intellectual property necessary for third parties to do so.

7. Medicines Patent Pool. The NIH should retain a right to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patent rights to procure the medical technology from

competitive suppliers, including technology transfer, in developing countries, upon a finding by HHS or the WHO that people in these markets do not have sufficient access to the medical technology.

8. Non-exclusivity in low and middle income countries. The exclusive license should not extend to countries with a per capita income less than 30 percent of the United States, in order to ensure that the patents do not lead to restricted and unequal access in developing countries. If the NIH rejects this suggestion, it needs to provide some mechanism giving effect to the policy objective in the "United States Public Health Service Technology Transfer Policy Manual, Chapter No. 300, PHS Licensing Policy," which states the following: "PHS seeks to promote commercial development of inventions in a way that provides broad accessibility for developing countries."

9. Option for license to WHO. The license should provide that under 35 USC 202(c)(4), the World Health Organization (WHO) may request from the NIH a license to practice or have practiced on its behalf, the patented invention, subject to the following procedures:

a. The WHO can identify an important public health concern that is not being met by the holder of the license to the NIH owned invention, including but not limited to the goal of access to medicine for all;

b. The WHO can explain the steps it has taken to address the issues, including attempts to negotiate voluntary licenses from the holder of the license to the NIH owned invention; and

c. The WHO can explain how its proposed use and licensing of the invention will address the unmet health need, without unreasonably prejudicing the legitimate interests of the license holder, taking into account the legitimate interests of third parties and the goal of access to medicine for all.

10. Technology Transfer. The NIH should include a provision to provide for technology transfer, including licenses to inventions and data, manufacturing know-how, and access to biologic resources, to companies or other entities that could provide access to the technology in developing countries, in the event that licensees do not serve these markets, or if the prices it charges are not reasonably affordable in developing countries.

TRANSPARENCY

11. Transparency of R&D outlays. The licensees should be required to file an annual report to the NIH, available to the public, on the research and development (R&D) costs associated with the development of any product or service that uses the inventions, including reporting separately and individually the outlays on each clinical trial. We note that this is not a request to see a company business plan or license application. We are asking that going forward companies be required to report on actual R&D outlays to develop the subject inventions. Reporting on actual R&D outlays is important for determining if the NIH is meeting the requirements of 35 U.S.C. § 209, that "the proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application[.]" Specifically, having data on actual R&D outlays on each clinical trial used to obtain FDA approval provides evidence that is highly relevant to estimating the risk adjusted costs of bringing NIH licensed inventions to practical application.

12. Sales and Access Transparency. (Units sold by country are the best evidence of access, and tracking sales is important for judging adequacy of incentive). With regard to sales we request an annual report that provides data on the following variables:

a. Units of sales, by country

b. Revenue for sales, by country.

13. Transparency of government subsidies. With regard to government subsidies for research, we request a report that provides data for the following, by year:

a. Grants and research contracts from government agencies, with data on the funding agency, the identifier of the grant or contract, and the amount of the grant or contract;

b. Tax credits associated with R&D for the product, including the U.S. orphan drug tax credit, broken out by the type of credit and the expenditure the credit was associated with (such as a specific trial); and

c. Other government R&D subsidies.

14. Acknowledgement of federal funding - publication and publicity. (Stevens Amendment obligation). The licensee should be required to include, when issuing statements, press releases, and other documents describing the development of any product that includes the licensed inventions, a statement that describes the role of the licensed inventions and the total and proportionate contribution of federal funding to the research and development performed to bring the inventions to market.

15. WHO Transparency Resolution. In 2019, the United States endorsed the adoption of the World Health Assembly (WHA) Resolution 72.8, titled "Improving the transparency of markets for medicines, vaccines and other health products." In this license, the NIH should incorporate, to the extent possible, transparency norms that meet or exceed the standards outlined in WHA72.8.

Attachment:

KEI NIH Comments on Exclusive Licenses (as of July 22, 2024) - Selected Metadata.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/KEI-NIH-Comments-on-Exclusive-Licenses-as-of-22July2024-Selected-Metadata-22July2024.xlsx

Description: Please find attached a spreadsheet indicating key metadata from the comments submitted by Knowledge Ecology International (KEI) to select National Institutes of Health (NIH) prospective exclusive licenses as noticed in the Federal Register. Since 2015, K

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Bryce Robinson

Name of Organization: Multiple organizations (25)

Type of Organization: Other

Type of Organization - Other: Multiple types (e.g., non-profit research & advocacy organizations, patient advocacy groups)

Role: Organizational official

Role - Other:

1) Promoting meaningful access approaches.
See attached letter.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.
See attached letter.

4) Helping licensees achieve access goals.

5) Establishing licensee obligations depending on the stage of technology development.
See attached letter.

6) Assessing policy impact.
See attached letter.

7) Other Comments
The comments in the attached letter are jointly submitted by the following 25 organizations, which work to protect of the right of all people to access safe, effective, and affordable prescription medications. Please direct any communications to Public Citizen (jravinthiran@citizen.org; brobinson@citizen.org).

AIDS Healthcare Foundation

Beta Cell Action

Center for Popular Democracy

Consilium Scientific

Doctors for America

Health Care Voices

Health GAP

Knowledge Ecology International

Labor Campaign for Single Payer

Medicare Rights Center

MomsRising

National Committee to Preserve Social Security and Medicare

NETWORK Lobby for Catholic Social Justice

Public Citizen

Revolving Door Project

Rise Up WV

Salud y Fármacos USA

Social Security Works

SPACEs In Action

T1International USA

U.S. PIRG

Unity Fellowship of Christ Church NYC

Universities Allied for Essential Medicines

VOCAL-NY

West Virginia Citizen Action Group

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/NIH-RFI-Joint-Submission-25-Organizations-22-July-2024.pdf

Description: Letter to NIH OSP from 25 organizations dated July 22, 2024

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Hans Sauer

Name of Organization: Biotechnology Innovation Organization (BIO)

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/BIO-Comments-on-NIH-access-plan-licensing-Final07222024.pdf

Description: Please find attached the comments of the Biotechnology Innovation Organization (BIO) to the NIH OSP May 22 Federal Register notice on promoting equity through access planning in intramural licensing, 89 FED.REG. 45003

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Kate Hudson

Name of Organization: Association of American Universities

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/FINAL-AAU-APLU-NIH-RFI-Accessibility-Plans.pdf

Description: Comments on behalf of AAU and APLU

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Matthew J. Martin

Name of Organization: Program On Regulation, Therapeutics And Law (PORTAL)

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.

The NIH could suggest the inclusion of specific commitments in companies' access plans to market the product at a reasonable price. For example, such a commitment could be drafted along the lines of the reasonable pricing clause that the Department of Health and Human Services (HHS) recently included in an investment contract with Regeneron to develop a monoclonal antibody therapy for COVID-19. In that case, Regeneron committed to choosing a list price (at wholesale acquisition cost) for commercial sales substantially equivalent to or less than the approved price for commercial sales in high-income countries outside the US, provided such sales are comparable sales within the same period. Previously, Senator Sanders had also put forward a similar proposal in the draft of the Pandemic and All-Hazards Preparedness Act (PAHPA), which suggested the use of a reasonable pricing clause in any contract, grant, license, cooperative agreement, or other transaction for medical product used against public threats funded or developed by the Biomedical Advanced Research and Development Authority (BARDA). The bill included a "most favored nation" provision, which provided that pricing could not exceed the lowest price for the same product offered in comparable countries, including Canada, France, Germany, Italy, Japan, and the United Kingdom.

We recognize that pharmaceutical companies have long opposed attaching reasonable pricing clauses to government funding for drug research and development. For example, the NIH started to include reasonable pricing clauses in CRADA agreements in 1990 and reversed the policy in 1995 based on concerns raised by drug companies that reasonable pricing clauses had led to a decline in the number of CRADA agreements between the NIH and industry. However, such concerns were not well-founded: the reasonable pricing clauses were not consistently implemented, plagued by vague wording, and empirical reviews of NIH-industry CRADAs issued during that era show no evidence that the new policy reduced the number of CRADAs.

Thus, the NIH should suggest companies commit to reasonable pricing in their access plans. Reasonable pricing clauses could include more flexible language for products at an earlier stage of development and more specific language for products at a later development stage. To ensure licensees fulfill reasonable pricing requirements, NIH-approved access plans should include tangible commitments that can be readily and quantitatively measured by the agency, including commitments to not raise costs above inflation or cost-plus purchasing agreements with the US government or other NIH-designated entities. These strategies would increase the likelihood that the benefits of NIH breakthroughs are accessible to a broad set of patients.

2) Promoting transparency in the biomedical enterprise and return on investment.

3) Providing flexibility while achieving clear policy objectives.

Access plans should provide clear and specific commitments from companies that benefit from NIH-funded research to prioritize taxpayers' access to the products. Given the public nature of the investment, the NIH should ensure that access plans proposed by pharmaceutical companies are made publicly available. We understand that companies might be worried that public disclosure of the access plans could reveal strategic or proprietary information relating to the development of the drug. However, the scope of access plans should not need to provide any proprietary information as to the development of the drug but rather describe policies such as approaches to fair pricing strategies that companies plan to take. The current draft does not require companies to disclose information other than a brief description of the licensed product; the anticipated patient population; other products, tools, facilities, or resources that would be necessary for the use of the licensed products; and one or more strategies to mitigate access challenges. None of these should invoke proprietary information.

4) Helping licensees achieve access goals.

5) Establishing licensee obligations depending on the stage of technology development.

The tiered approach proposed in the initial draft would provide reasonable flexibility to pharmaceutical companies in drafting the access plan according to the stage of development of the licensed product. We appreciate the need for flexibility for early-stage licenses, on which pharmaceutical companies may still need to make a substantial investment. The NIH should further consider other potentially relevant elements when evaluating access plans, such as the type and quality of patents licensed or whether the license is exclusive or non-exclusive.

While drugs typically start with a key patent on the active ingredient (a so-called "primary" patent), successful drug products usually end up being covered by many more—in some cases dozens or even over a hundred—patents covering other aspects of the drug, including secondary features such as metabolites, alternate formulations, or methods of manufacture or use ("secondary" patents). A recent study showed that many secondary patents are obtained even after initial FDA approval of the drug.5 In evaluating access plans, the NIH should consider whether the licensed patent is the primary patent covering the drug's active ingredient or whether it covers ancillary features.

The NIH should also consider whether the license is exclusive or non-exclusive. If the patent has been licensed exclusively to a company, the NIH should allow less flexibility, given the impossibility of other companies to obtain a license. For example, access plans for NIH technologies licensed exclusively could include commitments to sublicense the technology to other companies in situations of great public need, such as public health emergencies or in times of shortage.

6) Assessing policy impact.

The NIH already employs rigorous monitoring standards for research institutions that receive funding. These standards include, for example, the submission of progress reports describing accomplishments toward the goal of the project and the description of challenges in achieving the goal. Similarly, companies that obtain NIH licenses should submit annual reports explaining how the

policies described in their access plan have been practically implemented, whether any challenges have arisen in implementing the policies, or if different policies would be best suited to increase access. NIH should make summaries of these annual reports publicly available to provide stakeholders adequate insight into licensee progress. Metrics on the total number of licenses and licensees with agreed-to access plans, the development stage of the underlying technology (e.g., early or late-stage), the number of licenses with access plans in force or withdrawn, and other details should be incorporated into preexisting NIH technology transfer reporting.

To further enhance licensee accountability, all policies proposed in access plans should include concrete time horizons within which the licensee is expected to meet its access commitments, with the opportunity for revisions to be made as the technology moves through clinical development. Systematic monitoring of access plans would allow the plans to be adapted and updated as necessary once the product is launched on the market.

7) Other Comments

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/PORTAL-Comments-NIH-Licensing-Proposal_7.22.24_Final.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Lindsey Seidlitz

Name of Organization: The Pharmaceutical Research and Manufacturers of America (PhRMA)

Type of Organization: Other

Type of Organization - Other: Trade Association

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/PhRMA-Comments-to-NIH-Draft-IRP-Access-Planning-Policy-RFI-7.22.2024.pdf

Description: The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments in response to the National Institutes of Health Office of Science Policy's Request for Information on its Draft Intramural Research Program Policy: Promo

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Mihir Mankad

Name of Organization: Medecins Sans Frontieres/Doctors Without Borders

Type of Organization: Other

Type of Organization - Other: Non-profit/international medical humanitarian organization

Role: Other

Role - Other: Director of Global Health Advocacy and Policy

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/MSF-USA-NIH-RFI-Submission-Final-7.22.24.pdf

Description: MSF USA NIH RFI Submission

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Alec Orban

Name of Organization: Small Business Technology Council

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Organizational official

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/SBTC-Comment-on-NIH-RFI-on-Access-Planning-Notice.pdf

Description: Please see attached document for Small Business Technology Council's comment on NIH RFI for Access Planning policy

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Luis Gil Abinader

Name of Organization:

Type of Organization:

Type of Organization - Other:

Role: Member of the public

Role - Other:

1) Promoting meaningful access approaches.
Please see the attached document for my full comments.

2) Promoting transparency in the biomedical enterprise and return on investment.
Please see the attached document for my full comments.

3) Providing flexibility while achieving clear policy objectives.
Please see the attached document for my full comments.

4) Helping licensees achieve access goals.
Please see the attached document for my full comments.

5) Establishing licensee obligations depending on the stage of technology development.
Please see the attached document for my full comments.

6) Assessing policy impact.
Please see the attached document for my full comments.

7) Other Comments
Please see the attached document for my full comments.

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Gil-Abinader-Luis-access-policy.pdf

Description:

Submit date: 7/22/2024

I am responding to this RFI: On behalf of myself

Name: Fred Ledley

Name of Organization: Bentley University, Center for Integration of Science and Industry

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) Promoting meaningful access approaches.
See uploaded document

2) Promoting transparency in the biomedical enterprise and return on investment.
See uploaded document

3) Providing flexibility while achieving clear policy objectives.
See uploaded document

4) Helping licensees achieve access goals.
See uploaded document

5) Establishing licensee obligations depending on the stage of technology development.
See uploaded document

6) Assessing policy impact.
See uploaded document

7) Other Comments
See uploaded document

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Ledley-response-to-request-for-information-on-access-plan-for-OSP-.docx; http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/Ledley-response-to-request-for-information-on-access-plan-for-OSP-.pdf

Description: This document provides our response to the Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, (89 FR 45003; May 22, 2024) Document number: 2024-11188

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Manar Zaghlula

Name of Organization: Innovative Genomics Institute & Global Gene Therapy Initiative

Type of Organization: Academic institution

Type of Organization - Other:

Role: Investigator researcher

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/IGI-GGTI-Joint-Response-to-NIH-access-planning-RFI.pdf

Description: Joint Response from the Innovative Genomics Institute and the Global Gene Therapy Initiative to the Request for Information

Submit date: 7/22/2024

I am responding to this RFI: On behalf of an organization

Name: Kelly L. Morron

Name of Organization: Association of Amicus Counsel

Type of Organization: Professional organization association

Type of Organization - Other:

Role: Member of the public

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/22/072224-Morron-Final-Comment-NIH-RFI-re-Access-Planning-Policy.pdf

Description: Comments responsive to NIH RFI regarding Equity Through Access Planning Policy

Submit date: 7/23/2024

I am responding to this RFI: On behalf of an organization

Name: Geoffrey Lomax

Name of Organization: California Institute for Regenerative Medicine

Type of Organization: Other

Type of Organization - Other:

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/CIRM_Comment_2024-11188.pdf

Description:

Submit date: 7/25/2024

I am responding to this RFI: On behalf of an organization

Name: James Love

Name of Organization: Knowledge Ecology International

Type of Organization: Other

Type of Organization - Other:

Role: Other

Role - Other:

1) **Promoting meaningful access approaches.**

2) **Promoting transparency in the biomedical enterprise and return on investment.**

3) **Providing flexibility while achieving clear policy objectives.**

4) **Helping licensees achieve access goals.**

5) **Establishing licensee obligations depending on the stage of technology development.**

6) **Assessing policy impact.**

7) **Other Comments**

Uploaded File: http://osp.od.nih.gov/wp-content/uploads/ninja-forms/19/KEI-additional-comments-on-NIH-access-plans-July-25-2024.pdf

Description: