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

Thank you for the opportunity to comment on the draft NIH intramural research program policy to promote “equity through access planning.” I am an intellectual property advocate and scholar working for over ten years on equitable access to biomedical innovations. I am a member of the Medicines Patent Pool (MPP) Expert Advisory Group and the Universities Allied for Essential Medicines (UAEM) Board of Directors. I am filing these comments in my personal capacity.

While strongly supportive of embedding binding equitable access terms in license agreements, my comments focus on measures NIH can take to increase the effectiveness of the draft policy. My recommendations propose changes specific to the draft policy along with additional measures NIH can adopt to generally improve its intramural licensing program. Transparency around all aspects of the NIH intramural licensing program will be critical to garner public trust.

Please contact me at luis.gil.abinader@georgetown.edu or 646 417 2520 if you have questions.

A handwritten signature in black ink, appearing to be 'Luis Gil Abinader', written in a cursive style.

Luis Gil Abinader

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1. Start planning for access during the search and selection of prospective licensees

Finding suitable partners will be critical to the success of NIH's proposed intramural access policy. The impact of NIH's proposed policy will depend on how legally sound the contract terms are and also what measures the agency pursues to find partners strongly aligned with equitable access principles. Accordingly, in addition to requiring legally binding access plans and other contract terms, NIH should create institutional guidelines to ensure that technology transfer officials begin planning for equitable access when they start advertising licensing opportunities and select development partners. These guidelines should seek to garner as many expressions of interest as possible from applicants who can demonstrate strong alignment with equitable access.

Embedding access into the search and selection of licensing partners has three main implications for NIH. Besides for profit companies, NIH should actively seek expressions of interest from developers with a public or non-profit mission. This may require mapping out these types of entities and advertising licensing opportunities directly to them. The agency may also need to conduct general efforts to familiarize public and non-profit institutions with the NIH intramural licensing program. NIH could also encourage these types of partnerships by shifting the license financial obligations towards the back end of the product development cycle. In these cases, up-front fees and milestone payments could be greatly reduced or fully dropped from license agreements. NIH already shifts licensing payments under certain circumstances,¹ but the agency

¹ Tara L. Kirby, Ph.D., Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer, How NIH Negotiates License Terms, Office of Technology Transfer, Office of Intramural Research, Office of the Director, National Institutes of Health (July 31, 2023) (slide presentation). (Stating that "for technologies that

could implement this approach deliberately and systematically to accommodate public and non-profit partners. If an applicant has a public or non-profit mission, NIH should weigh that strongly in favor of selecting them as licensee for the development of intramural inventions.

Over the years, NIH has entered into a few licensing agreements with public and non-profit developers. Examples include an exclusive license from 2005 with Fundacao Butantan² and a nonexclusive agreement with PATH Vaccine Solutions from 2014.³ Therefore, some precedents of partnerships between NIH and public or non-profit entities exist. Historically, however, the number of NIH licenses to public or non-profit entities have been only a small fraction of all agreements. By actively advertising opportunities among public or non-profit entities, shifting licensing payments, and implementing other measures, NIH may be able to increase that share.

Additionally, NIH should be prepared to develop promising product candidates intramurally when the agency struggles to find license partners amenable to strong access terms. NIH has technical capabilities and infrastructure to conduct late-stage development. Spending resources to advance product development intramurally will often be better than exclusively licensing without strong equitable access commitments. Likewise, as NIH recognizes, “the level of interest from potential licensees evolves over time.”⁴ Accordingly, NIH may be able to draw greater licensing interest if the agency advances product candidates intramurally and generates additional data about the public health potential of those inventions. The option of developing product candidates intramurally will also give NIH more leverage to secure strong commitments from industry, because the agency will have greater flexibility to withdraw from negotiations that turn difficult and private sector applicants will risk losing promising licensing opportunities.

Lastly, institutional and staff incentives should be aligned with equitable access. Aligning NIH’s incentives with access may require the agency to revise performance metrics. With regards to the selection stage, NIH should avoid performance metrics that would encourage technology transfer officers to finalize an agreement regardless of how weak the access terms are or what equity track record the proposed licensee has. One of such potentially misaligned metrics could be, for instance, evaluating institutional and staff performance solely based on the number of licenses that have been executed or the amount of royalty revenues that is being generated. Conversely, NIH should explore the use of performance metrics that reward technology transfer officers who invest additional time searching for partners that would be better aligned with access principles.

are high risk (e.g., early stage), payments generally shifted towards the “back end” – we succeed when licensee succeeds.”)

² License No. L-068-2005 (2005) (granting an exclusive, foreign license to Fundacao Butantan, Sao Paulo, Brazil, for Multivalent Human-Bovine Rotavirus Vaccine, E-015-1998).

³ License No. L-333-2014 (2014) (granting a nonexclusive, worldwide license to PATH Vaccine Solutions, Seattle, WA, for Wuchereria Bancrofti Specific Molecule for the Immunodiagnosis of Bancroftian Filariasis and for Surveillance Following Successful Control Programs, E-281-2010).

⁴ National Institutes of Health, Transforming Discoveries into Products: Maximizing Levers to Catalyze Technology Transfer, Summary of NIH Workshop Proceedings (July 31, 2023), https://osp.od.nih.gov/wp-content/uploads/2024/03/FINAL_Innovation_Policy_Workshop_Report.pdf

Among other factors, these metrics should acknowledge that searching for partners aligned with equitable access principles may require NIH staff to dedicate more time disseminating licensing opportunities. One way of incorporating this factor into performance metrics is quantifying the number of potentially interested parties that NIH staff reached out to and formally screened.

2. Explain, in each FR notice, NIH’s rationale for departing from the nonexclusive default

Avoiding exclusivity unless it is a reasonable and necessary incentive to encourage investments in product development is one of the most effective safeguards NIH can implement. 35 U.S. Code § 209 permits federal agencies to grant exclusive licenses “only if” such an approach is a “reasonable and necessary incentive” to encourage research and development investments. This means that federal agencies, NIH included, are required by law to grant nonexclusive licenses as a default. Federal agencies can depart from that default only if they determine that exclusivity is a “reasonable and necessary incentive.” Moreover, 35 U.S.C. 209(e) requires federal agencies to issue a public notice “of the intention to grant an exclusive or partially exclusive license on a federally owned invention” and invite public comments about the proposed exclusive or partially exclusive license. Agencies must issue these public notices “in an appropriate manner.” Federal regulations at 37 CFR part 404.7 require agencies to identify “the invention and the prospective licensee” in their public notices but permits them to “include other information as appropriate.”

Deciding whether an exclusive license is warranted is “a fact-dependent matter.”⁵ Nevertheless, in public notices NIH typically does not provide facts nor insights about how it determined that exclusivity meets the “reasonable and necessary incentive” requirement in 35 U.S. Code § 209. Instead, NIH’s public notices typically provide only limited information about proposed licenses. Besides boilerplate language about the intent to grant an exclusive license, the public notices that NIH publishes normally lists the (1) patents and applications that would be subject to the license; (2) name and address of the prospective licensee; (3) geographical scope of the proposed license; (4) brief description of the technology; and (5) contact information of the licensing officer. When third parties contact licensing officers, NIH rarely provides additional facts and insights.⁶

Although rarely, other federal agencies have in the past been more transparent than NIH about their decisions to grant exclusive licenses. For instance, in a 1982 notice describing a proposed license to Stromberg Enterprises, the Department of Energy (DoE) attached a memorandum explaining their rationale for favoring an exclusive approach. According to the public notice, neither DoE or the proposed licensee were “aware of any firms other than Stromberg Enterprises

⁵ National Institutes of Health, Transforming Discoveries into Products: Maximizing Levers to Catalyze Technology Transfer, Summary of NIH Workshop Proceedings (July 31, 2023), https://osp.od.nih.gov/wp-content/uploads/2024/03/FINAL_Innovation_Policy_Workshop_Report.pdf

⁶ See: Knowledge Ecology International, Licensing NIH Owned Patents and Data, Including KEI Comments on Proposed Exclusive Licenses, <https://www.keionline.org/nih-licenses> (last visited July 21, 2024).

known to be considering commercial manufacture or sale of the invention.”⁷ After DoE advertised the licensing opportunity, only Stromberg expressed interest. In the public notice, DoE also stated that Stromberg committed to making a \$10,000 investment to manufacture licensed products. Stromberg claimed that “exclusivity is necessary for a small business to justify such an investment,” according to the public notice DoE published in the Federal Register.⁸ Based on these facts, DoE found that “exclusivity is reasonable and necessary to attract expeditiously the capital needed to bring about the desired practical application of the invention.”⁹

Drawing from examples like the Federal Register notice made by DoE concerning Stromberg Enterprises, NIH should disclose a much greater amount of information when the agency proposes an exclusive license. Critically, in each notice NIH should explain its rationale for granting exclusive rights and what facts support the agency’s determination. 35 U.S. Code § 209 permits an exclusive approach only if the agency finds that departing from the nonexclusive default is a reasonable and necessary incentive, but NIH never explains how it reached that determination in its Federal Register notices – it should. Disclosing facts and insights about why exclusive rights are necessary would be consistent with 37 CFR part 404.7, which permits NIH and other federal agencies to “include other information as appropriate” in their public notices.

Exclusive licenses shouldn't be justified solely on the ground that no other entity expressed interest in developing the inventions. Additionally, at least when NIH cites the apparent lack of interest as a ground for exclusive licensing, the agency should explain for how long and through what means it advertised the licensing opportunity. To build trust around NIH’s efforts to broadly disseminate licensing opportunities, in each public notice the agency should disclose how many entities expressed interest in licensing the instant inventions. Similarly, NIH should disclose anonymized data about license applicants that expressed interest but failed to secure a license, such as their geographical location. Moreover, in each public notice NIH should state whether any of the applicants that expressed interest applied to develop the inventions on a nonexclusive basis. Willingness of at least one entity in developing the inventions non exclusively should be treated as proof that exclusive rights are unwarranted, except when NIH finds and publicly discloses evidence clearly disqualifying that license applicant as a suitable product developer.

Even if none of several applicants are willing to develop the inventions nonexclusively, the number of parties that expressed interest is an important insight about the need and scope of exclusivity. High appetite in licensing the inventions would positively reflect on its commercial value. In these cases, NIH will have relatively more leverage to demand stronger access terms. Similarly, when several entities apply, NIH also has more flexibility to determine which of all the applicants expressing interest would be better aligned with equitable access and select the most

⁷ Department of Energy, Stromberg Enterprises; Notice, Intent To Grant Exclusive Patent License, 47 Fed. Reg. 31,598 (July 21, 1982). <https://www.govinfo.gov/content/pkg/FR-1982-07-21/pdf/FR-1982-07-21.pdf>

⁸ *Id.*

⁹ *Id.*

suitable partner. All these factors should be reflected in NIH’s decision to license, and the terms embedded in each agreement. In the aggregate, greater transparency on what efforts NIH makes to disseminate licensing opportunities and how many entities express interest in commercializing each invention would help the public evaluate and increase trust in the NIH licensing program.

Without projecting research and development costs it is impossible for federal agencies to determine the extent of incentives needed to advance a product candidate to market. Therefore, 35 U.S. Code § 209 implicitly requires agencies to project research and development costs in their determination of whether exclusive rights are a “reasonable and necessary incentive.” NIH should clearly articulate and disclose these cost assessments in each public notice announcing exclusive licenses. Particularly, NIH should clearly describe what investments the agency has made to advance the inventions to their current stage. This includes clinical trials conducted by NIH, if any, and their costs. In each public notice NIH should also disclose their own projections of what additional investments would be required to develop the inventions. Cost expectations may vary as product development advances and unexpected challenges can emerge. Yet, if NIH determines that exclusive licensing is a “reasonable and necessary incentive” it must have made at least a projection of what investments will be required. Those projections should be disclosed.

Other factors considered by NIH in its decision to exclusively license also require detailed explanations. For instance, some exclusive licenses involve various patent families. One example is a proposed license over natural killer cell therapies for cancer to Replay Holdings LLC, announced in December 2022, which involved over three hundred patent documents pertaining to three different technology groups.¹⁰ In these cases, NIH has a higher burden to explain how the agency determined that bundling several seemingly unrelated patent families into one large exclusive license to the same entity meets the “reasonable and necessary incentive” criteria. Other notices describe prospective licenses to entities that had already licensed patents from NIH.¹¹ In those situations, NIH again must explain how it determined that layering multiple exclusive patent rights around the same entity constitutes a “reasonable and necessary incentive.”

3. Give more time to file public comments and submit competing licensing proposals

Written objections procedures required under federal law¹² and regulations¹³ are meant to serve various policy goals, including to allow the public to: (1) scrutinize the scope and rationale of

¹⁰ e.g., Prospective Grant of an Exclusive Patent License: Development and Commercialization of Natural Killer Cell Therapies for Cancer, 87 Fed. Reg. 80556 (Dec. 30, 2022)

¹¹ e.g., Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer, 77 Fed. Reg. 3482 (Jan. 24, 2012) and Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer, 79 Fed. Reg. 16,347 (Mar. 25, 2014), both announcing the intent to grant licenses to Kite Pharma.

¹² 35 U.S. Code § 209

¹³ 37 CFR § 404.7

proposed licenses; (2) influence decisions to license intramural inventions; (3) learn about technologies available for licensing; and (4) submit competing licensing proposals. As NIH is aware, civil society organizations have filed numerous comments on proposed licenses.¹⁴ Some notices inviting public comments have also led to expressions of interest from other product developers. This occurred, for example, with a public notice describing inventions NIH sought to license exclusively to Protein Design Laboratories,¹⁵ which led to an expression of interest by Serono.¹⁶ Given the interest expressed by Serono, NIH granted co-exclusive licenses to both.¹⁷

Before November 2000, federal agencies had to give at least 60 days for the general public to file comments and competing licensing proposals.¹⁸ In November 2000, however, the Bayh-Dole Act was amended to reduce the public comment and written objection period to “at least 15 days before the license is granted.”¹⁹ Following this amendment, the implementing regulations were also amended to reduce the public comment and objections period from 60 to “at least 15 days.”²⁰ Current regulations maintain the requirement to give “at least 15 days” to file comments.

Research by Knowledge Ecology International (KEI) has shown how the time NIH gives interested parties to file comments on proposed exclusive licenses has shrunk since 2010.²¹ Until 2010, NIH typically allowed 60 days for interested parties to file comments on a proposed exclusive license. Most of the NIH license agreements that led to the development of biomedical products launched on the market were executed under that policy of allowing 60 days for filing comments.²² Around 2010, however, the length of time NIH gave to file comments began to shrink. Now NIH typically gives 15 days to file comments on a proposed exclusive license.

Graph 1 shows that other federal agencies have also decreased the average number of days they allow for public comments. This finding is based on my hand-review of 1757 notices published by all agencies from 1990 to 2020. Like NIH, notices published by other federal agencies on

¹⁴ See: Knowledge Ecology International, Licensing NIH Owned Patents and Data, Including KEI Comments on Proposed Exclusive Licenses, <https://www.keionline.org/nih-licenses> (last visited July 11, 2024). Nevertheless, civil society’s ability to file meaningful comments is undermined by the lack of details provided by NIH in its notices.

¹⁵ Prospective Grant of Exclusive License: Zenapax (Humanized Antibody Against the IL-2 Receptor Alpha Chain) as a Novel Treatment for Multiple Sclerosis, 68 Fed. Reg. 70826 (Dec. 19, 2003).

¹⁶ Prospective Grant of Co-Exclusive License: Monoclonal Antibodies Against the IL-2 Receptor Alpha Chain as a Novel Treatment for Multiple Sclerosis, 69 Fed. Reg. 58933 (Oct. 1, 2004).

¹⁷ National Institutes of Health, Transforming Discoveries into Products: Maximizing Levers to Catalyze Technology Transfer, Summary of NIH Workshop Proceedings (July 31, 2023), https://osp.od.nih.gov/wp-content/uploads/2024/03/FINAL_Innovation_Policy_Workshop_Report.pdf at 43

¹⁸ James Love, Marshall Pentec & Luis Gil Abinader, The NIH Has Radically Reduced the Time for the Public to Comment on Exclusive Licenses, KEI Briefing Note 2023:1 (Aug. 11, 2023) <https://www.keionline.org/bn-2023-1>

¹⁹ *Id.*

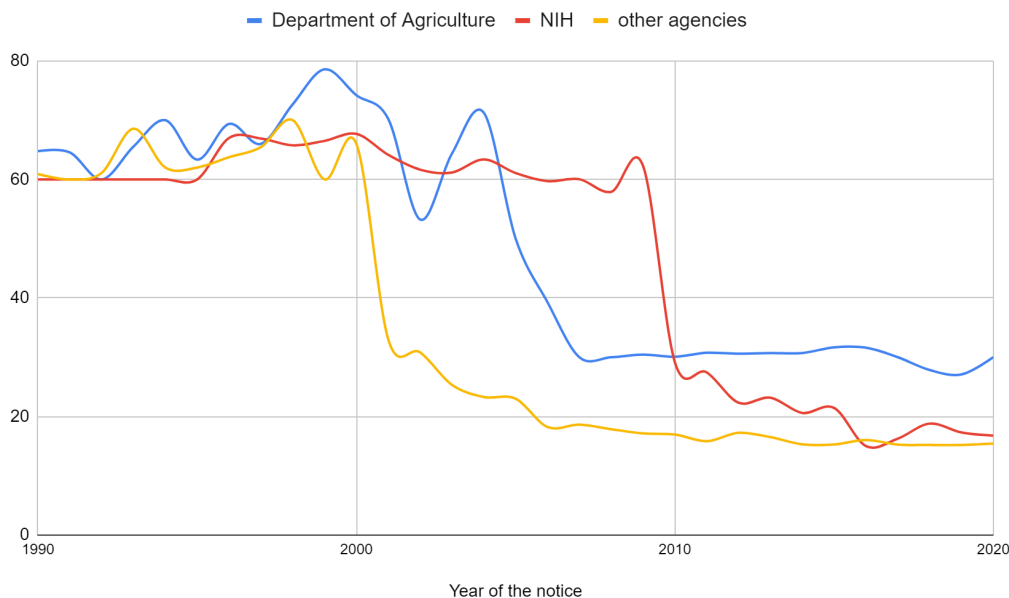
²⁰ *Id.*

²¹ *Id.*

²² U.S. Gov’t Accountability Off., GAO-21-52, Biomedical Research: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property (2020), available at <https://www.gao.gov/products/gao-21-52>. at 67 (Stating that the “majority of these licenses were granted in the 1980s and 1990s.”)

average now give 15 days to submit public comments on proposed exclusive licenses. Yet, there are some exceptions. The Department of Agriculture is one of the federal agencies with the most proposed licenses during the 1990 to 2020 period, with 372 notices. While the comment period provided by the Department of Agriculture has also reduced since 37 CFR § 404.7 was amended in 2002, their average length plateau from 2007 to 2020 at about 30 days. Although the Department of Agriculture worsened over the years, this data shows that a federal agency can run a large licensing program while voluntarily exceeding the minimum of 15 days comment period.

Graph 1. Average number of days to file comments on proposed licenses, 1990-2020



Source: my own hand-review of 1757 notices in the Federal Register from 1990 to 2020.

Assessing and submitting comments on a proposed license often requires complex research.²³ It is often impossible for third parties interested in commenting on the proposed exclusive license but provided with limited information by NIH to complete their research within a period of two weeks. For instance, researching patent landscapes globally is critical to understand the scope of the intellectual property rights that would be covered by the license. In recent years NIH has provided Patent Cooperation Treaty (PCT) numbers and identifiers for applications that have entered into the national phase. However, interested parties may still need to cross-check the list given by NIH in the Federal Register notice with additional information available in databases from national intellectual property offices. Without this cross-checking, the procedural status, geographical scope, claimed subject matter, and legal strength of the patent rights may be unclear. Due diligence on these questions often takes significant time. Completing this type of

²³ For a longer discussion, see: James Love, Marshall Pentes & Luis Gil Abinader, KEI Briefing Note 2023:1 at 5-6

due diligence within 15 days after a license is announced is difficult, often preventing meaningful comments and possibly discouraging competing applications by third parties.

By shrinking comment periods, over the years NIH has made it harder for the public to influence its exclusive licensing decisions. Short comment periods are probably also discouraging third parties from filing competing licensing applications.²⁴ Along with the scarce information the agency typically provides in notices, the shrinking length of comment periods has contributed to the public distrust around how NIH manages its patent licensing program. NIH now appears to be taking serious, systematic, and good faith steps to increase public trust around its licensing program. To consolidate these efforts and build public trust, one relatively easy but important measure the agency can take is to give 60 days for public comments as a default. Before 2010, the average length of comment periods allowed by NIH was 60 days. NIH should return to this 60-days policy and consider giving longer periods when proposed licenses are more complex.

4. Limit exclusive periods to shorter terms, renewable only if certain conditions are met

Patents generally can last up to twenty years, but the investments made to develop a biomedical product might be recouped long before that term ends. 37 CFR § 404.5(b)(1) permits NIH and other agencies to grant exclusive licenses for the entire life of licensed patents or a shorter period.²⁵ Nevertheless, the term of exclusive licenses that NIH grants normally last for the entire life of licensed patents. The policy of granting exclusive licenses until the last patent expires is reflected in the Public Health Service (PHS) model agreements, which NIH rarely deviates from. NIH typically grants licenses for the entire patent life regardless of how much investment is needed to bring an invention into the market or how much revenue licensees stand to make. This can lead to exclusive rights that extend for a period longer than is reasonable and necessary.

While rare, some university licenses have granted exclusive periods ending before the patents expire. In 1993, Stanford University granted an exclusive license to Genelabs Technologies with a field of use concerning therapeutics for the treatment of systemic lupus erythematosus. Stanford granted Genelabs exclusive rights, commencing at the effective date and ending seven years from the first commercial sale of licensed products. After seven years from the first sale, the license would become nonexclusive until the last patent expires. Within one year prior to the end of the exclusive period, Genelabs could ask Stanford for an extension. Stanford could extend the exclusive period at its sole discretion, if that was consistent with its policies and regulations.

²⁴ In fact, the Federal Register notice that led to an expression of interest by Serono had a 60 days comment period.

²⁵ 37 CFR § 404.5(b)(1) (stating that the duration of the license “shall be for a period specified in the license agreement, unless sooner terminated in accordance with this part.”)

Box 1. Lupus license between Stanford University and Genelabs Technologies, 1993.

“Said license is Exclusive, including the right to sublicense pursuant to Article 13, in the Licensed Field of Use for a term commencing as of Effective Date and ending, in each country, 7 years from the date of first commercial sale of a Licensed Product(s) by LICENSEE or sublicensee(s) in such country; LICENSEE agrees to promptly inform STANFORD in writing of the date of first commercial sale. Thereafter, said license shall be nonexclusive until expiration of the last to expire of Licensed Patent(s). Within one year prior to the end of the Exclusive period STANFORD agrees to consider extending the Exclusive term herein defined upon request by LICENSEE, and if such extension is not in conflict with STANFORD policy or regulations.”

Drugs for Neglected Diseases initiative (DNDi) has also conferred limited exclusive periods in licensing agreements with developers.²⁶ When partners insist on departing from the nonexclusive default, “DNDi carefully weighs the justifications for such requests.”²⁷ If deemed warranted, “in the majority of cases” DNDi has conferred “a limited exclusivity of 3 to 5 years after the first marketing authorization.”²⁸ In those agreements, DNDi also limits the geographical scope.

Consistent with legal and policy requirements to grant exclusive licenses only to the extent necessary to incentivize the development of intramural inventions,²⁹ NIH should limit exclusive periods to a length shorter than the entire life of the patent. This period could be, for instance, five years after the first commercial sale of a licensed product. Like the approach used by Stanford in their agreement with Genelabs, in each license NIH should stipulate the possibility of extending the exclusive period for one year at a time. However, the right of NIH to extend the exclusive period should be discretionary and exercised only if certain preset conditions are met. If an extension is denied or an NIH partner becomes ineligible for renewals, the license should be turned into nonexclusive for the remaining patent years. Renewal procedures should be consistent and predictable to reassure NIH partners, but also transparent to garner public trust.

When determining whether to extend exclusive periods, NIH should take into consideration the amount of revenues made from the sale of licensed products. Under this model, exclusive licenses would state a predetermined revenue threshold. NIH would then renew exclusive periods only if the revenues made from the sale of licensed products are still below the predetermined threshold. Once the predetermined threshold is exceeded, the licensee would no longer be eligible for a renewal of the exclusive period. To request a renewal, the licensee would

²⁶ Dominique Junod Moser, Pascale Boulet, Michelle Childs, Mae Shieh & Bernard Pécoul, Striking Fair Deals for Equitable Access to Medicines, 18 J. Intell. Prop. L. & Prac. 323 (2023), <https://doi.org/10.1093/j>

²⁷ *Id.*

²⁸ *Id.*

²⁹ 35 U.S. Code § 209

have to submit data on their research and development costs. Licensees would also have to provide up to date data on sales and profits made from licensed products. NIH would then assess this information to decide whether renewing the exclusive period for one year is necessary for the licensee to recover research and development costs and obtain sufficient profits. Licensees would have to request renewals every year until the last patent expires. Under this or similar approaches, renewal procedures would have to be transparent and open to public participation.

NIH can also use renewal procedures to ensure that other policy goals are met. For example, NIH could deny requests for renewal if the licensee fails to meet developmental or commercialization milestones. NIH could also use renewals to gather information and adjust the remaining years of a license to the scope of exclusive rights that – with the new insights – the agency finds necessary, as well as the efforts that the licensee has made to comply with their obligations. In this sense, if a licensee can justify the need for additional years of exclusivity but only for a narrower field of use, NIH could renew the exclusive period but with a narrower field. Similarly, NIH could renew exclusive periods only for certain members of the patent family and pull back the geographical scope. In these cases, the field of use and the members of the patent family no longer subject to an exclusive period should be made available for licensing to interested parties.

5. Require detailed access commitments from the outset, regardless of development stage

NIH proposes a tiered approach where licensees would only be required to submit “one or more strategies to mitigate access” once a licensed invention has entered a pivotal trial. Licenses on early-stage inventions will only have a vague commitment to submit an access strategy in the future, if the product candidate enters a pivotal trial. While recognizing NIH’s good faith efforts to create a flexible and workable policy that recognizes factors like uncertainty, the proposed policy will probably be ineffective in many situations. NIH often licenses early-stage intramural inventions to privately owned biotech companies with a nascent product development pipeline and limited commercial expertise. In these circumstances, NIH has strong leverage to require detailed access plans. Once a candidate reaches a pivotal trial, the agency will lose significant leverage to demand strong access commitments from a partner which already has a NIH license.

Licensees developing early-stage inventions will increase their leverage relative to NIH in several ways. NIH licensees can for instance invent manufacturing methods to make licensed products at a commercial scale. Licensees could keep these inventions secret or claim them in patent applications. Additionally, as the product candidate comes closer to regulatory approval, NIH licensees will likely attract greater interest and commitments from investors. Formerly a small biotech, those licensees might become publicly traded before the start of a pivotal clinical trial. By this point, such licensees might have different executives and governance structures.

With private knowledge, patents, and investments these licensees will have much more leverage compared to their starting point when they entered into an agreement with NIH. If a licensee trades their stocks publicly, their incentives could also be far less aligned with equity. Some of these licensees may still cooperate with NIH to adopt access plans. Yet, with their own patents and misaligned incentives, the risks that these licensees will become uncooperative is great.

Relatedly, if an exclusive licensee refuses to adopt detailed and suitable access plans once it reaches a pivotal trial, NIH could theoretically threaten them with termination. Another approach NIH could evaluate is turning the license into nonexclusive. Similarly, NIH could also consider pulling back the scope of the license to a narrower field of use. However, NIH might have a weak posture to adopt any of these possible remedial actions against recalcitrant licensees that have secured private patents and investments. As explained in section 7, the threat of terminating or narrowing a license will be less credible if NIH struggles to find a different partner willing to continue with product development. Knowing about these challenges, exclusive licensees that have secured commitments from investors and can leverage their own private patents against competitors could refuse to collaborate with NIH in the elaboration of a suitable access plan.

Negotiating detailed access commitments from the onset as default, including partnerships involving inventions still in early stages of development, would help address these challenges.

NIH's preference for a tiered approach appears to be motivated by two main concerns. One concern seems to be that requiring detailed access plans even for early-stage inventions could discourage prospective licensees from partnering with NIH.³⁰ If that was the case, perhaps this is an indication that those potential licensees wouldn't have agreed to a suitable access plan once they reach a pivotal trial either. Moreover, if NIH struggles to find developers willing to license early-stage inventions while committing to equitable access, the agency could use its expertise and clinical trials networks to advance those product candidates intramurally. Through intramural research NIH could gain a greater understanding of market potentials, which would give the agency more leverage to find suitable licensing partners and require detailed access plans.

Another concern appears to be that requiring detailed access plans for early-stage inventions would lead to over and under inclusion of some key elements, given the uncertainties intrinsic to biomedical development. When the ideal scope of an access plan is unclear, NIH should aim for over inclusion to address as many scenarios as possible. NIH could then use discretion to revise provisions that the licensee can demonstrate to be in tension with reasonable commercial efforts

³⁰National Institutes of Health, Transforming Discoveries into Products: Maximizing Levers to Catalyze Technology Transfer, Summary of NIH Workshop Proceedings (July 31, 2023), https://osp.od.nih.gov/wp-content/uploads/2024/03/FINAL_Innovation_Policy_Workshop_Report.pdf at 26 (echoing workshop participants who stated that “proscriptive provisions in license agreements can stall efforts to advance products to patients or prevent technology commercialization from moving forward altogether.”)

to bring products into the market. Over inclusion should be preferred to under inclusion because it would give NIH leverage to accommodate needs discovered in later stages of development.

Alternatively, if NIH proceeds with the tiered approach, the agency should at least revise how the obligation to provide detailed access plans would be triggered. Besides a pivotal trial, NIH should also require licensees to provide a detailed access plan within three months of filing a patent application arising from the licensed inventions. This would include patent applications claiming manufacturing processes, methods of treatment, among other relevant subject matter as defined by the agency in further guidance. Additionally, NIH should also require licensees to provide a detailed access plan within three months of filing a prospectus in preparation of an initial public offering under the U.S. Securities Act³¹ or an equivalent foreign procedure. Similarly, NIH should require licensees to provide detailed access plans when other developers express interest in the inventions – either in response to a public notice or after a license was granted. In those cases, NIH should use the proposed access plan to consider whether pulling back the scope of an exclusive license to enable partnerships with additional developers is warranted. Triggering the requirement to provide detailed access commitments at least based on these additional events could help the agency address some of the challenges explained here.

Yet, even if these additional triggers are adopted, licensees will be able to strengthen their leverage relative to NIH through other means difficult to monitor and govern. For example, licensees would still be able to invent manufacturing processes and keep these methods secret. Licensees could then use these manufacturing processes as leverage to negotiate weaker access plans while discouraging NIH from terminating their agreement. Given challenges like these, the preferable approach should be to require detailed plans in all licenses regardless of their stage.

6. Select from model access terms drafted based on product and market characteristics

Recipients of “biological materials” under the World Health Organization (WHO) global influenza surveillance and response system (GISRS) are required to select from among various possible commitments identified in the Standard Material Transfer Agreements (SMTA2) article 4.1.1 (a) to (c). Licensing technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants is one of the options recipients could choose from. None of the SMTA2 agreements that have been signed by vaccine and antiviral manufacturers to date, however, have committed to licensing technology, know-how, processes or products. Instead of that option, all of the material transfer agreements that manufacturers have signed include commitments to donate and reserve a fraction of their production to WHO.

³¹ 15 U.S. Code § 77b

When presented with the requirement of identifying “one or more strategies” to “mitigate access challenges,” as the NIH draft policy proposes, many licensees will probably act like GISRS recipients and gravitate around the same few options. Stated differently, many access “strategies” will likely have a heavy focus on narrow measures like donations. Based on how the draft NIH policy is currently framed, it appears that licensees would even be able to fulfill their obligation to identify an access “strategy” solely by “preparing tailored, culturally sensitive educational materials for a range of domestic and global patient populations.” If the finalized policy allows this as an option, many licensees will propose this minor measure as their “access” “strategy.”

While useful in some cases, narrow measures like these alone will be insufficient to address structural drivers of inequitable access. The “strategies” licensees submit will probably also have vague language and differ from each other on important features. Vague language and a wide range of features might prevent NIH from developing institutional learning and consistent remedial actions across agreements to ensure that licensees comply with access commitments.

Table 1. Commitments made by WHO GISRS recipients in their SMTA2, 2013-2024

GISRS recipient	commitments made in SMTA2 article 5.1.1	year signed
Adimmune Corporation	donate 8% to WHO, reserve 2% to WHO	2024
China National Biotech Group	donate 8% to WHO, reserve 2% to WHO	2016
Denka Seiken	donate 8% to WHO, reserve 2% to WHO	2017
Glaxo Group Limited	donate 8% to WHO, reserve 2% to WHO	2022
Government Pharmaceutical Organization	donate 5% to WHO, reserve 5% to WHO	2020
Green Cross Corporation	donate 7% to WHO, reserve 3% to WHO	2017
Kitasato Daiichi Sankyo Vaccine	donate 8% to WHO, reserve 2% to WHO	2017
KM Biologics Co., Ltd.	donate 8% to WHO, reserve 2% to WHO	2019
MedImmune	donate 9% to WHO, reserve 1% to WHO	2016
BIKEN	donate 8% to WHO, reserve 2% to WHO	2017
Sanofi Pasteur	donate 7.5% to WHO, reserve 7.5% to WHO	2014
Seqirus UK Limited	donate 10% to WHO, reserve 2.5% to WHO	2017
Serum Institute of India	donate 8% to WHO, reserve 2% to WHO	2013
Sinovac Biotech Co.	donate 8% to WHO, reserve 2% to WHO	2017
Takeda Pharmaceutical Company Limited	donate 8% to WHO, reserve 2% to WHO	2018
Source: Own review of SMTA2 with GISRS recipients available from: https://www.who.int		

Using its leverage as owner of intramural inventions, NIH can and should secure much stronger access commitments than, for instance, donations or educational materials. By default, all of the

NIH licenses should secure minimum technology transfer and pricing safeguards. The safeguards secured by NIH must also ensure access for U.S. and global populations. This requires eliminating language from the draft NIH policy suggesting that licensees will be able to meet their obligations by supporting access in the U.S. “/or” low- and middle-income countries.

NIH could maintain flexibility while securing meaningful and appropriate safeguards by crafting various access model terms based on market and technological characteristics of each licensed product candidate. Particularly, NIH could draft a set of default access commitments that include conditions and milestones taking into consideration the need to accommodate various types of (1) interventions being developed, which may for instance be gene therapy, biologic drugs, small molecules, platform technologies, etc.; (2) diseases, whether emerging or reemerging infectious, rare genetic conditions, etc.; (3) market demand, which can be global, driven by low- and middle-income countries, unpredictable (e.g., disease x), etc.; (4) likely commercialization strategy, which can be predominantly selling to public entities, a mix of public and private sales, stockpiling in preparation for health emergencies, etc.; among other relevant characteristics.

Once drafted by the agency, NIH and licensees would then reach an agreement on which of the various access terms models best apply. NIH could also have a general access term model that could be used if none of the specific approaches are suitable. Each access model would include default access developmental and commercial milestones requirements reflecting the specific technological and market characteristics of the product candidates which licensees agreed to develop. Notices about exclusive licenses would indicate which of the access models will apply.

7. Obtain rights on intellectual property owned by licensees to ensure projects continue

NIH proposes to exclude “patents solely owned by NIH’s collaborators and partners” from the scope of the access policy. Explaining this limitation further, NIH has indicated that the policy will exclude intellectual property that licensees “develop on their own.”³² Based on these NIH explanations, it appears that the agency intends to exclude background intellectual property but also foreground improvements on licensed inventions. Excluding background and foreground intellectual property could significantly undermine the effectiveness of NIH’s access policy.

While the agency has several mechanisms to promote compliance, contract termination is the most important lever NIH can use to enforce agreements. Other important remedies are pulling back the scope of a license by narrowing its field of use and turning an exclusive license into nonexclusive. Nonetheless, without rights over follow-on private patents, NIH will often have a weak posture to threaten with terminating or pulling back the scope of an agreement against recalcitrant licensees. If NIH terminates or narrows an agreement, the former licensee could still

³² Webinar on Draft NIH Intramural Research Program Policy: Promoting Equity through Access Planning, NIH, June 11, 2024, <https://videocast.nih.gov/watch=54905>.

assert its secondary patents against any subsequent licensee selected by the agency. Finding parties interested in developing and commercializing inventions under the risk of patent litigation could be extremely difficult. In turn, this means that in practice NIH could be discouraged from using the stronger lever at its disposal to demand compliance with the access contract terms.

Drawing from the WHO mRNA Technology Transfer Hub template agreement, one approach NIH can take is to require default grant backs for all improvements – broadly defined. All of the WHO mRNA Technology Transfer Hub spokes have agreed to default grant backs in foreground inventions and data.³³ Modeled on Section 6.3 of the mRNA hub template agreement, the clause provides for a nonexclusive, sublicensable, irrevocable, fully paid-up, royalty-free, worldwide license to the Medicines Patent Pool (MPP).³⁴ The mRNA hub template agreement defines “inventions” as “all ideas, inventions, discoveries, data or Know-How conceived, first created or made in the performance [of] the Project.” MPP can sublicense those inventions and data for the purpose of “fulfilling its mission to facilitate the development and equitable access of health technologies.” MPP can also audit spokes to ensure compliance with this provision, which survives in the event that the technology transfer agreement terminates. The technology transfer agreements signed by spokes so far show only small departures from the template,³⁵ indicating that the companies working with the mRNA hub have been amenable to grant back provisions.

Box 2. Grant back of project inventions under the mRNA hub template agreement

“[spoke partnering with the mRNA hub] grants to MPP a non-exclusive, non transferable, but sublicensable, irrevocable, fully paid-up, royalty-free, worldwide licence to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in the Territory. In the event that MPP wishes to make such Inventions available for other purposes, MPP and [mRNA spoke] will enter into good-faith negotiations. [mRNA spoke] agrees to provide to MPP a licence in relation to any of its background rights only to the extent necessary to enable the use and exercise of the Inventions made by [mRNA spoke] hereunder.”

Another approach NIH could embed in its agreement is requiring a nonexclusive license on improvements made by its partners, exercisable in the event of termination. The University of Texas has secured this safeguard in several exclusive licenses. For instance, under an exclusive license granted in 2010 to Arrowhead Pharmaceuticals, the University of Texas could terminate the agreement, among other reasons, if the company failed to meet any of its diligence

³³ Medicines Patent Pool, mRNA Technology Transfer Programme Agreements, <https://medicinespatentpool.org/what-we-do/mrna-technology-transfer-programme/agreements#pills-Partners--Agreements>.

³⁴ Id.

³⁵ Id.

milestones. Upon termination of the agreement, Arrowhead Pharmaceuticals is required to grant the university a nonexclusive royalty bearing license with the right to sublicense with respect to improvements made on the licensed inventions. The university agreed to negotiate in good faith the royalty rate for the nonexclusive license. According to the clause, the right to sublicense improvements is solely for the purpose of permitting others to develop and commercialize the technology package. This type of clause can address some of the concerns explained here.

Box 3. Termination clause in license between Arrowhead and University of Texas, 2010.

“Upon termination of this AGREEMENT: [...] (e) LICENSEE grants to BOARD and UTMDACC a nonexclusive royalty bearing license with the right to sublicense others with respect to improvements made by LICENSEE (including improvements licensed by LICENSEE from third parties) in the LICENSED SUBJECT MATTER. LICENSEE and UTMDACC agree to negotiate in good faith the royalty rate for the nonexclusive license. BOARD’s and UTMDACC’s right to sublicense others hereunder is solely for the purpose of permitting others to develop and commercialize the entire technology package.”

DNDi similarly requires, in the event of termination, that partners transfer to them copies of information, documentation, and materials in their possession relating to the project.³⁶ The purpose sought with this safeguard is permitting DNDi to proceed with further research, development, manufacture, registration, and commercialization of products after termination. Partners are also required to continue manufacturing and supplying products according to contract terms until the necessary technology and documentation has been transferred.³⁷ NIH should embed similar safeguards in its contracts to protect public interests and its own leverage.

8. Avoid waivers or, if adopted, clearly state what criteria NIH will follow to grant them

Federal agencies can waive the requirement in 35 U.S.C. 204 that awardees of extramural funding manufacture subject inventions “substantially in the United States” if these grantees made “reasonable but unsuccessful efforts” to fulfill this obligation. Evidence suggests that NIH has historically been permissive when considering requests to waive the domestic manufacturing requirement.³⁸ Last year, the Biden administration stated the policy to enforce the Bayh-Dole domestic manufacture requirement “whenever feasible and consistent with applicable law.”³⁹

³⁶ Drugs for Neglected Diseases initiative, Pro-access Policies for Intellectual Property and Licensing, available at <https://dndi.org/advocacy/pro-access-policies-intellectual-property-licensing/>.

³⁷ Id.

³⁸ Knowledge Ecology International, NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs, 2011 to May 2015, <https://www.keionline.org/23156> (last visited July 6, 2024).

³⁹ Federal Research and Development in Support of Domestic Manufacturing and United States Jobs, Exec. Order No. 14,104, 88 Fed. Reg. 51203 (Aug. 2, 2023)

In the draft policy, NIH is proposing a procedure to waive the requirement to submit an access plan or modify them. NIH has indicated in the draft policy that a waiver or modification would have to be (1) requested in writing; (2) obtained in advance; and (3) considered in good faith. Moreover, NIH would consider waiver or modification requests “on a case-by-case basis and evaluate them according to criteria that would be identified in the guidance for access plans.”

Unchecked NIH discretion to waive or modify access plans could render the policy ineffective. Waivers could prevent the public from developing trust in the finalized policy, particularly if decisions to grant them are untransparent. Discretion to grant waivers could, paradoxically, take leverage from NIH officials to firmly demand strong access plans. Furthermore, NIH has not explained why flexibility to depart from the requirement to submit access strategies is necessary given that, as currently proposed, the draft policy permits significant maneuvering space to accommodate access plans to the needs of each licensee. Considering all of this, NIH should drop the proposal to waiver or modify plans at least until the policy is more clearly explained.

Yet, if NIH adopts a waiver and modification procedure each decision and the policy more broadly must be transparent. Waivers and modifications should be available only in narrow circumstances clearly stated in a transparent and consistent policy. NIH should publicly disclose all requests for waivers and modifications and explain what decision the agency took in each case. Periodically, NIH should report how it is implementing this policy. At least annually, NIH should (1) disclose how many requests licensees have submitted; (2) explain the grounds for each of these requests; and (3) indicate how many and which requests the agency has granted.

Additionally, if the final policy permits waivers or modifications of access plans, NIH must adopt a participatory procedure allowing public scrutiny and influence over each decision taken under this mechanism. NIH could adopt various participatory approaches to achieve this. One possible approach is to describe each request in the Federal Register and allow for public comments, a procedure NIH is already familiar with. If this approach is adopted, each notice should include detailed information about the grounds for the request and NIH would have to publicize its final determination including a rationale. Another approach NIH could take is creating an Access Advisory Council with a diverse set of experts⁴⁰ and delegate the evaluation of each request to its members. Each recommendation from the council will have to be public.

9. Actively monitor compliance, including through periodic and off-cycle reviews

Federal awardees are required to report their inventions to NIH and declare government support in any patent application filed thereon. Historically, NIH has relied heavily on information

⁴⁰ See the comments submitted on the draft policy by Melissa Barber, Anthony So, Joseph Ross, and Reshma Ramachandran from the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT).

voluntarily reported by awardees to monitor whether they are complying with these obligations. Audits to corroborate whether grantees are properly disclosing federal support in their patents appear to be rare and normally driven by high-profile controversies.⁴¹ Predictably, the heavy reliance on voluntary reporting has led to many failures to comply with Bayh-Dole requirements. Advocates,⁴² academics,⁴³ and other federal agencies⁴⁴ have documented many of these failures. Remarkably, some of these failures have flown under NIH's radar for years or even decades.⁴⁵

Failures to comply with reporting obligations and other contract terms probably also occur among licenses on intramural inventions. Nonetheless, NIH has historically shared limited insights about how it monitors compliance with the terms of these licenses. NIH appears to have a team of specialists dedicated to monitor that licensees are complying with the terms of their agreements.⁴⁶ According to NIH staff, this team tracks compliance through "periodic reviews" based on "progress reports," "benchmarks," "payments," and "review of public information."⁴⁷ Yet, various details about these efforts remain unclear. Particularly, it is unclear how frequently NIH conducts "periodic reviews," what is the scope of the audits made by the agency, and which remedial actions NIH typically takes to address violations. Moreover, it is unclear whether NIH conducts these reviews only periodically or whether some events can trigger them off-cycle.

Contrary to how the agency has historically managed invention reporting obligations among extramural grantees, NIH should actively monitor whether licensees are complying with their equitable access obligations. Actively monitoring compliance requires NIH to independently corroborate the information submitted by licensees, for instance, with public disclosures made to investors. Moreover, when certain triggers are met, NIH needs to automatically initiate off-cycle audits to assess whether a licensee is complying with their equitable access obligations. For example, one of the events that should trigger an investigation includes a compulsory license request on licensed products even if it involves patents not owned by NIH.⁴⁸ NIH also needs to be transparent about what measures it takes to remediate noncompliance. As explained in more detail in the next section, NIH needs to state what criteria it uses when determining whether to terminate a license under failure to report grounds and how frequently it does this.

⁴¹ Eg., Memorandum from June Gibbs Brown, Inspector General of the Department of Health and Human Services to Philip Lee, the Assistant Secretary of Health. "Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute." June 15, 1994.

⁴² Eg., Luis Gil Abinader and James Love. Failure to disclose government funding associated with cancer immunotherapy patents that name Gordon Freeman as inventor and are assigned to the Dana-Farber Cancer Institute. December 20, 2019. <https://www.keionline.org/32076>;

⁴³ Rai, Arti K., and Bhaven N. Sampat. "Accountability in patenting of federally funded research." *Nature biotechnology* 30, no. 10 (2012): 953-956.

⁴⁴ Technology Transfer: Reporting Requirements for Federally Sponsored Inventions Need Revision RCED-99-242 Published: Aug 12, 1999, <https://www.gao.gov/products/rced-99-242>

⁴⁵ Eg., the failure by Novartis and others to declare NIH funding in U.S. patent 6,958,335 for nearly two decades.

⁴⁶ Webinar on Draft NIH Intramural Research Program Policy: Promoting Equity through Access Planning, NIH, June 11, 2024, <https://videocast.nih.gov/watch=54905>.

⁴⁷ *Id.*

⁴⁸ This could happen, for instance, if the licensee obtains secondary patents on a country where NIH did not file.

10. Clearly state NIH’s policy for terminating licenses and report when these cases occur

NIH has the discretion to terminate or modify license agreements, if the agency determines that certain conditions have been met.⁴⁹ Historically, however, NIH has not been transparent about how frequently and under which circumstances the agency uses its discretion to terminate licenses. NIH does not periodically report on the enforcement actions it takes against licensees.

Along with requiring detailed access plans, the model PHS agreement should be revised to clearly state that NIH can terminate licenses when the agency determines that the access plan has been breached. Similarly, NIH should have legal rights to narrow down the field of use and turn an exclusive license into nonexclusive when an access plan is breached. Importantly, NIH should also clearly state a consistent and transparent policy for terminating licenses when access plans are breached. In some cases, the public interest may be better served when NIH works with licensees to address lack of compliance with access terms.⁵⁰ If breaches are always curable, however, licensees will have few incentives to comply with access commitments. NIH should be willing to terminate licenses when the access commitments have been breached, at least if certain criteria is met. To promote accountability, NIH should publicly state what those criteria are.

Furthermore, NIH should increase transparency around its license termination policy. At least yearly, NIH should report data on how many violations it found during the covered period for all active licenses. NIH should also report data on what actions it took in those instances and, in particular, how many licenses were terminated due to breach. NIH should report each time a license is terminated for breach of terms related to access, including, if adopted, the need to submit access strategies after the start of a pivotal trial. If NIH selects another potential exclusive licensee, that previous termination should be flagged in the respective Federal Register notice.

11. Experiment with policy options by leveraging rigorous pilots and transparency

NIH has extensive leverage to build access into its intramural program, given that it funded the discovery and owns the inventions. However, NIH may also have some legitimate concerns about the potential detrimental effects of shifting away from institutional policies and procedures

⁴⁹ Section 13.5 of the model PHS agreement permits NIH to terminate or modify exclusive licenses when the agency determines that one of several events occurred. These events include failure to execute the commercial development plan submitted with the license request; willfully making a false statement or willfully omitting a material fact in the license application or annual reports; and a finding that the licensee “cannot reasonably satisfy unmet health and safety needs.” The nonexclusive PHS model agreement provides the same grounds for termination on Section 13.5. NIH can exercise its right to terminate licenses on a discretionary basis.

⁵⁰ Webinar on Draft NIH Intramural Research Program Policy: Promoting Equity through Access Planning, NIH, June 11, 2024, <https://videocast.nih.gov/watch=54905>. (see NIH staff stating that licenses have levers that the agency can use when licensees are not performing; that the agency works with licensees “to resolve problems if we can,” and that the end goal is to promote the commercialization of technology “to benefit the public.”)

that have been implemented for decades with relatively few changes. Status quo bias can lead to policy paralysis. Yet, legitimate concerns about departing from existing policies should not necessarily lead to paralysis. NIH can deal with legitimate questions about policy shifts under consideration by implementing rigorous pilots where the agency temporarily introduces changes to its licensing program to learn using well-designed methods⁵¹ and transparent assessments.⁵²

Rigorous policy pilots can be implemented, for instance, to test the impact of extending public comment periods. Before 2010, NIH typically allowed 60 days for public comments on proposed exclusive licenses. Starting that year, the time NIH allowed for comments on proposed exclusive licenses began to shrink. Like other federal agencies, NIH now normally gives only 15 days for comments on proposed exclusive licenses but has the legal and policy space to allow more time. As explained before, the trend that began in 2010 has undermined public participation in NIH's licensing decisions and the agency should revert to allowing *at least* 60 days for public comments. Because the agency used to allow approximately 60 days for public comments before 2010, NIH already has data to explore what the impact of reverting back to that policy could be.

Nonetheless, NIH could consider allowing an even greater deadline than 60 days for public comments on proposed exclusive licenses. If there are legitimate concerns about the potential effects of allowing more than 60 days for public comments, NIH could test the implementation of that policy through a rigorous pilot. NIH could work alongside other federal agencies to implement a comment period pilot. In that pilot, some licenses would be subject to notices that last 60 days but others to 90 or 120. There are various things NIH and other agencies could observe by taking this pilot approach. For instance, NIH could measure how many competing license applications it receives when the deadline for comments is 90 or 120 days versus only 60.

⁵¹ Chien, Colleen V. "Rigorous policy pilots: Experimentation in the administration of the law." *Iowa L. Rev.* 104 (2018): 2313.

⁵² Colleen V. Chien, How Federal Agencies Have Used Rigorous Policy Pilots to Learn, Reg. Rev. (Dec. 6, 2019), <https://www.theregreview.org/2019/12/06/chien-federal-agencies-used-rigorous-policy-pilots-learn/>. (Explaining that "randomizations should be carried out with transparency and integrity to enhance government credibility.")