MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

40 Rector Street, 16th Floor
New York, NY 10006
Tel: (212) 679-6800
Fax: (212) 679-7016
Web: www.doctorswithoutborders.org

For more information, contact:
Jennifer Reid, policy analyst
(Jennifer.reid@newyork.msf.org) &
Leonardo Palumbo, U.S. advocacy adviser
(leonardo.palumbo@newyork.msf.org)

To: Walter G. Copan, Ph.D.
Under Secretary of Commerce for Standards and Technology
Director, National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899
via email: roi@nist.gov

Doctors Without Borders/Médecins Sans Frontières Comments to NIST Special Publication 1234: *Return on Investment Initiative for Unleashing American Innovation*

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Doctors Without Borders/Médecins Sans Frontières USA (MSF) provides the following comments regarding the report issued by the National Institute of Standards and Technology, "NIST Special Publication 1234: Return on Investment Initiative for Unleashing American Innovation," (December 2018).

MSF is an international medical humanitarian organization providing care to people affected by armed conflicts, epidemics, natural disasters and exclusion from healthcare. In 2017 we worked in 72 countries. Among other healthcare activities, MSF provided more than 10 million outpatient consultations, treated 2.5 million cases of malaria, and administered millions of doses of vaccines and immunological products.[1] To do this work we rely on biomedical innovations that improve medical outcomes and are accessible and affordable.

We write to request that the National Institute of Standards and Technology (NIST) extend the deadline for the comment period on this report. Many links on the NIST website, including for Special Publication 1234 currently redirect to the homepage,[2] which bears the following notice: "NOTICE: Due to a lapse in government funding, this and almost all NIST-affiliated websites will be unavailable until further notice. Learn more NIST websites for programs using non-appropriated funds (NVLAP and PSCR) or those that are excepted from the shutdown (such as NVD) will continue to be available and updated." We are concerned that this will have negatively impacted stakeholders' ability to adequately review the report and any potential additionally

[1] For more information see: https://www.msf.org/international-activity-report-2017
[2] www.NIST.gov

relevant materials, such as documents, transcripts or information from past meetings and requests for information referenced in the report and related to this initiative.

In the event that the comment period is not extended, we also take this opportunity to share the following initial comments on the report.

U.S. public funding plays a key role in R&D for important medical products

As the largest funder of biomedical innovation in the world, the U.S. government plays a key role in researching and developing medicines, vaccines and diagnostics to address health needs. To date, through public funding contributed by American taxpayers, the U.S. government has contributed to the development of hundreds of medical products. A recent study found that funding from the NIH contributed to each of the 210 products approved between 2010 and 2016.[3] An earlier study found that when specifically considering a product's intellectual property, public-sector research institutes contributed to the development of 153 drugs, vaccines or new indications in under 20 years.[4] This funding has led to the development of lifesaving medical products used by MSF in our operations as well as other healthcare providers both in the U.S. and internationally.

However, MSF and people in America and around the world can only fully benefit from the important contributions from U.S. taxpayers if the resulting medical products are effective, safe, available, affordable and suitable for use in contexts where they are needed. MSF teams witness every day the consequences of people unable to access the medical tools they need. Existing U.S. law includes some assurance that action can be taken if federally funded inventions are not benefitting the public in key ways. These important protections should not be undermined, which several proposals within the green paper would do.

Regulations should not undermine the public's ability to benefit from publicly funded inventions

We are concerned by the proposed "intended actions" in Strategy 1 to narrow the scope of existing law that offer some safeguards to protect public access to publicly funded inventions through march-in rights. If enacted these changes would tip the balance away from an appropriate return on investment for public investments in R&D for medical technologies. Agencies relying on public funds to develop lifesaving medicines should not seek to curtail the public's right to appropriate, affordable access to the products developed with public support by this proposed unilateral regulatory action.

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[3] Clearly et al. Contribution of NIH funding to new drug approvals 2010–2016. PNAS (2018). Available from: https://www.pnas.org/content/115/10/2329

[4] Stevens et al. The Role of Public-Sector Research in the Discovery of Drugs and Vaccines. NEJM (2011). Available from: https://www.nejm.org/doi/10.1056/NEJMsa1008268?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

MSF objects to the "intended action" to "define the circumstances under which the government may exercise march-in rights" to exclude considerations of affordability. We urge the U.S. government not to "implement regulatory change under the Bayh-Dole Act to make explicit that the use of march-in rights specified in statute is reserved for a compelling national issue or declared national emergency when other remedies have failed." Having an overly narrow definition could tie the hands of federal agencies in the future to take action to ensure technologies are accessible for the public. Doing so goes against the stated goals of the administration to lower drug prices and call by more than 50 Members of Congress to use march-in rights to address "soaring" pharmaceutical prices.[5]

With regard to medical products, if the U.S. government does "require that the agency first conduct an informal consultation with the contractor, grantee, or licensee to understand the nature of the issue and consider other potential alternatives to remedy the concern [when considering exercising march-in right]," the agency should also be required to conduct a meaningful consultation with various affected stakeholders or those who make the request.

USG can support improvements to transparency and traceability of public funding

We note that strategy 4 includes some proposals that seek to improve public access to information on IP resulting from federal R&D programs. We hope that this will include timely information regarding proposals to license medical technology by the U.S. government.[6] It should also include clear and reliable data on the expenditures by the U.S. government that contributed to the development of the technology.

By promoting increased transparency of publicly funded and publicly developed biomedical R&D, the U.S. government can contribute to the dearth of reliable and transparent data on R&D expenditures and can improve understanding of the public's role in the biomedical innovation system.[7]

Evaluate public benefits by accessing new medicines they need

We note that strategy 5 includes proposals to evaluate the impact of federal funding on innovation. In order to measure the public benefits of these investments, such an evaluation should consider the extent to which the public is benefitting through access to any resulting medical products. Metrics could include the price of the product, any changes in price of the product, the number of countries where the product has been registered, estimated number of people who would benefit from the treatment who are receiving treatment.

[5] https://www.keionline.org/22983
[6] See for example: https://www.keionline.org/29538; https://www.keionline.org/sites/default/files/KEI_MSF_NIH_Zika_Vaccine_License.pdf;
[7] https://www.doctorswithoutborders.org/sites/default/files/2018-06/us-based_groups_letter_to_hhs_on_increasing_transparency.pdf

Consider alternatives for improved public "returns" in the form of affordable and appropriate new technologies

The initiative considers "return on investment" (ROI) broadly in terms of benefits to society. However, premising the green paper on the notion that "reliable and predictable intellectual property rights are essential to incentivize innovation," overlooks the opportunity to also consider alternative incentives for innovation that may better deliver returns to the public in the form of accessible and affordable products to meet global health needs.

With suitably tailored incentive mechanisms the U.S. government could encourage innovators to deliver appropriate and affordable health technologies to patients in the US and beyond, instead of accepting high prices as inevitable and allowing R&D investments to be skewed towards the financial priorities induced by the patent system.

In addition to upholding safeguards intended to address failures of licensing agreements to protect access to publicly development medicines, the U.S. government could consider introducing more stringent conditions for public licensing and grants that ensure recipients to commit to timely and appropriate further development of a potential medical products, and widespread access to successfully developed products to ensure the greatest public return on these investments from the outset. MSF has offered more specific recommendations for such conditions in our submission to the U.S. Department of Health and Human Services' "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs."[8]

Furthermore, examples of initiatives that have developed needed medical treatments and vaccines without relying on exclusivity as the method to incentivize innovation exist in several areas. The Meningitis Vaccine Project (MVP) in which the National Institutes of Health (NIH) played a crucial role is one such example. [9] The new all oral sleeping sickness treatment developed by the Drugs for Neglected Disease *initiative* (DNDi) and licensed by the European Medicines Agency (EMA) in 2018 is another.[10] Both of these examples show that a collaborative approach to product development which takes patient needs as the starting point can deliver affordable innovations at low cost.

Prize funds are another incentive mechanism to be explored. With a history that predates the patent system, prizes involve giving out payments on the achievement of pre-determined results. Prizes allow several promising research proposals to be pursued in parallel as they do not pick a winner early in the process. Prizes could serve as an alternative incentive to the granting of exclusive monopoly rights and should include contractual conditions to guarantee affordability through the surrender of exclusivity rights. This allows costs of medicines to get closer to the cost of production

[8] https://doctorswithoutborders.org/sites/default/files/2018-07/HHS_Blueprint_Submission.pdf
[9] https://www.path.org/resources/meningitis-vaccine-project-website/
[10] https://www.dndi.org/2018/media-centre/press-releases/ema-recommends-fexinidazole-first-all-oral-treatment-sleeping-sickness/

through competition where market size permits. Dozens of Members of Congress endorsed legislative proposals last year to introduce prize funds for biomedical innovation in the 115th Congress.[11]

Conclusion

For the past twenty years MSF has raised concerns with unaffordable medicine prices in contexts where we work, and in recent years this has been increasingly recognized as a global concern. Millions of people in America and around the world struggle to afford the medicines they need to live healthy and productive lives. In a time of skyrocketing medicine prices, we urge the U.S. government to not only uphold existing safeguards in U.S. law, but to also consider alternative incentives and initiatives to promote transparency, access and affordability for biomedical innovation to improve the public "return on innovation" to the benefit of all patients in need.

[11] See for example, H.R. 1776 (2017) and S. 3411 (2018).