SUBMISSION TO THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
“BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT OF POCKET COSTS”:

MSF’s recommendations to put patients’ needs first

July 16, 2018

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Overview

Doctors Without Borders/Médecins Sans Frontières (MSF) would like to submit the following written comments to the U.S. Department of Health and Human Services (HHS), “Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs” request for comments.¹

MSF is an independent, international medical humanitarian organization that delivers medical care to people in 70 countries. Our work focuses on the medical needs of vulnerable people living in developing countries, whose needs are often neglected. We provide medical aid to victims of armed conflict, epidemics, natural and manmade disasters, and to others who lack health care due to social or geographic marginalization. MSF teams provide medical care for people with HIV/AIDS, malaria, malnutrition, tuberculosis, leishmaniasis, and other diseases, as well as primary care, maternal and child health care, immunizations and other services.² For example, in 2017 MSF conducted more than ten million outpatient consultations, provided first- or second-line HIV treatment to more than 215,000 people, started more than 20,000 people on first or second line tuberculosis treatment, and treated more than 2.5 million cases of malaria.³

MSF also advocates for access to and innovation for medical tools to meet the needs of patients in our programs and in communities where we work. This work includes identifying and challenging the political, legal and commercial barriers that stand in the way of access to affordable medicines and that inhibit innovation for patients globally, and promoting consideration of new and better adapted innovation policies to truly meet people’s health needs.

The high prices of medicines, vaccines and diagnostics are global issues, not only because they affect people everywhere, but also because addressing these issues requires every country to develop and implement proper policies. As a medical treatment provider with more than 40 years of experience caring for vulnerable people, MSF teams have seen for decades the deadly consequences of people being unable to access the lifesaving medical products they need. Through our programs, we have experienced and analyzed how, in many different settings, the same primarily monopoly-based system that leaves people around the world forced to pay high prices or excluded from access, also provides little incentive to develop contextually appropriate tools, if there is incentive to develop them at all.

MSF is submitting comments to the Blueprint because we are concerned that some proposals in the Blueprint would hurt people who need access to medicines in other countries, including where MSF works, in addition to failing to solve the problems for the people in the U.S. We also note that current U.S. policies and the Blueprint’s proposals would not deliver transformative change to ensure the production of medical innovations are adapted to the needs of patients and that are accessible. As the

² For additional details about MSF’s work, please refer to MSF’s International Activity Reports. Available from: https://www.msf.org/international-activity-report-2016
³ This data groups together direct, remote support, and coordination activities. Note: these highlights give an overview of most MSF activities but cannot be considered exhaustive. Any additions to the data will be made available on the forthcoming 2017 MSF International Activity Report.
U.S. considers how to address the high prices of medicines domestically, the federal government has an opportunity to make meaningful changes to innovation policies that can help deliver more affordable medical products that respond to health needs for people everywhere.

In order to seize this historic opportunity to better align prices, product development and public health, and avoid inflicting unnecessarily additional harm on people’s health in other countries, the U.S. should take the following steps:

1. **Don’t harm people globally through ineffective policies that waste public resources.** Seeking to raise the price of medicines abroad will not lower the price of medicines domestically, but it will cause harm to people in need of medical products. Trying to shift the burden and the attention to other countries will not address the fact that companies can set prices based on markets’ capacity to pay. As evidence demonstrates, there is not a direct connection between the resources invested in R&D and the price charged for the medicines. All countries, including the U.S., have a right to make use of safeguards to protect public health and access to medicines when medicines, vaccines and diagnostics are priced out of reach of people who need them. We urge the U.S. to respect these rights.

2. **Increase transparency in the biomedical innovation system.** Increasing transparency in the biomedical innovation system can help identify abuses and inform improvements to the current system’s ability to generate innovation for products that meet health needs and are affordable to people. The Blueprint calls for transparency, and Secretary Azar specifically referenced price transparency in his launch speech. Increasing transparency of prices could be beneficial for patients and payers, and America should be much more ambitious on increasing transparency in general, targeting many other areas of medical innovation. Among other areas where transparency would be beneficial, the U.S. government should increase transparency on research and development (R&D) costs and traceability of public funding in R&D; manufacturing costs; intellectual property (IP) monopolies; registration plans; and clinical data and trial protocols.

3. **Embrace innovative policies to promote and finance biomedical innovation.** In launching a response to address U.S. high prices, the U.S. government has the opportunity to respond in a sustainable way that also supports improved innovation incentives to deliver products that better meet people’s health needs. As the single largest funder of medical R&D in the world, there are significant opportunities for the U.S. government to better leverage and steward this investment.

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for improved health outcomes for people everywhere. We encourage the U.S. government to improve public return on public investment, for example by consider measures like strengthening the conditions for affordable access on public funding and other incentives that ensure people can affordably access the treatments they need. Similarly, encouraging more collaborative ways of working on R&D (such as sharing research and data results, pooling IP, and other collaborative activities) could help improve delivery of accessible new medicines and overcome the current disincentives to collaboration that result in costly delays to people getting the medical products they need.

Below we describe these points in more details and offer some examples of positive steps the U.S. government could take. These examples and recommendations are intended to be illustrative rather than comprehensive. The U.S. should take this opportunity to be a leader for transformative change by implementing new and better-adapted policies that can cure an ailing system of biomedical innovation. Doing so would truly put patients’ needs first.
Respect countries’ rights to protect access to medicines

Every country, including the U.S., has the right to implement a patent system in line with its public health needs to help protect access to medicines for people who need them. Countries can do so in full compliance with obligations of World Trade Organization (WTO) membership, and should.

MSF is deeply concerned that the Administration is proposing to undermine carefully balanced public health safeguards, which the U.S. has committed repeatedly to respect, and which more importantly save lives. We strongly object to pressure exerted by the U.S. government on developing countries for using legal public health safeguards to protect people’s health, and the proposals to continue or heighten this pressure in the context of the Blueprint.

Already, the Administration has been acting on these proposals, in particular via the Office of the U.S. Trade Representative (USTR). This year’s Special 301 report issued by USTR on other countries’ IP regimes calls out a number of countries including developing countries for their use of, consideration of or even “encourag(ing) others to issue” compulsory licenses. Overall more than a dozen countries, ranging in per capita income from less than US $1,800 to more than $48,000, are identified in the report regarding IP provisions that better safeguard public health in compliance with international obligations. USTR has also already announced that it will be conducting Out-of-Cycle reviews on two countries called out for their use of compulsory licensing, Colombia and Malaysia. We urge the Administration not to consider any use of legal TRIPS public health safeguards as grounds for negative pressure or threat of negative consequences for Colombia, Malaysia, or other countries using or considering steps to protect public health. MSF was also concerned to learn that earlier this year Ambassador Lighthizer sent a letter to Colombia in support of pharmaceutical lobby efforts to link Colombia’s bid to join the Organization for Economic Cooperation Development (OECD) to pharmaceutical company demands.

In addition to the inappropriate pressure this represents on countries exercising agreed public health safeguards to protect people’s access to medicines, these efforts risk having a chilling effect on other countries faced with unaffordable medicines prices and wanting to save people’s lives.

Higher prices abroad will not reduce prices in America

These policies will not reduce prices in the U.S., but will restrict access to the medicines, vaccines and diagnostics that people need globally. Prices in the U.S. are initially set by pharmaceutical companies, which do so largely free from competitive market forces, thanks to artificial monopolies granted by the U.S. government in the form of patents, and data or market exclusivities.

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7 Consider, for example, the finding of the U.S. Senate Finance Committee’s bipartisan investigation into the pricing strategy by Gilead for the important new hepatitis C treatment, Sofosbuvir. Wyden-Grassley Sovaldi investigation finds revenue-driven pricing strategy behind $84,000
Raising medicines prices abroad will not alter the fact that companies can set any price they consider will maximize their profits. Secretary Azar’s own testimony to the U.S. Senate acknowledged that raising prices abroad was “not necessarily directly tied” to the Administration’s stated objective to lower prices for people in America.8

Excerpted question from Senator Bernie Sanders: “…Do you really think, as our President does, that raising prices on people abroad will actually help people in this country afford the medicine they desperately need?”
Response from Secretary Azar: “That would be a misstatement of the President’s proposal, which is that we need to decrease what we pay here and they need to increase their share of what they pay. They are not necessarily directly tied.”

Unbalanced IP laws reduce access to medicines

International trade and domestic IP rules govern what governments can and cannot do to protect public health and access to affordable medicines. Member States of the WTO, including the U.S., have agreed to these rules, which set standards for what deserves a patent, and for how long a patent should last. In 2001, WTO Member States, including the U.S., also signed the Doha Declaration on TRIPS and Public Health, which affirms the right of governments to implement safeguards and flexibilities to protect people’s health.9 Countries have the right to determine what merits a patent for pharmaceutical products and offer robust pre- and post-grant patent opposition procedures. Countries are not required to grant data or market exclusivities. When necessary, countries can also allow for more affordable production of a lifesaving medicine when the product is priced out of reach of people in need, even if the government has granted a patent, through compulsory license which can be royalty-bearing.

Rules or policies which require monopoly protections for pharmaceuticals beyond what is required by the TRIPS Agreement, commonly referred to as TRIPS-plus measures, represent a harmful and unnecessary further delay for people’s ability to access affordable medicines. These measures have proven to raise the price of medicines or keep them high in countries where they have been implemented.

For example:

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• In Colombia, where MSF has provided comprehensive care to victims of sexual assault and psychological care to people affected by violence,10 an evaluation of the impact of ten years of implementation of data-exclusivity rules, from 2003-2011, found that they resulted in an increase of more than US $396 million in additional expenses for the public health system.11

• An analysis of the implementation of provisions for pharmaceutical protections included in the CAFTA trade agreement in Guatemala, where MSF worked from 1984 to 2012,12 found that in some cases CAFTA rules kept generic drugs from entering the market in Guatemala even after they were available in the U.S.13 Following the enactment of TRIPS-plus data exclusivity, prices for medicines in Guatemala rose by as much as 846%.

• In Jordan, where MSF is providing health care to Syrian refugees and vulnerable Jordanians around the country, the price of medicines was found to have increased by 20% in just five years following the implementation of the U.S.-Jordan trade agreement, which included TRIPS-plus provisions. Data exclusivity delayed the introduction of generic competition on the majority of medicines between 2002 and 2006, and prices of medicines under data exclusivity were up to 800% higher than in neighboring Egypt.14

• Based on MSF’s analysis and interviews with vaccine manufacturers, TRIPS-plus weak secondary patents are increasingly a problem for vaccines affordability, with dozens of patents sought or granted on vaccines as well.15 MSF is currently opposing the granting of a key patent in India16 and South Korea.17 This patent threatens to block price-lowering competition from interested Korean and Indian manufacturers and is not warranted under India and South Korea’s patent laws.

Evidence demonstrates how the negative consequences of high prices due to delayed competition are seen in America too. For example:

• One study documented how secondary patents extend the life of monopolies by an average of more than six years in the United States.18

• The majority of patents granted for pharmaceuticals in the U.S. are secondary patents.19

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10 For more information on MSF’s work in Colombia, please refer to MSF’s Colombia Mission page. Available from: https://www.msf.org/colombia
12 For more information on MSF’s work in Guatemala, please refer to MSF’s Guatemala Mission page. Available from: https://www.msf.org/guatemala
• One well-documented case traced how using TRIPS-plus monopoly protections granted in the U.S. resulted in a 5,000% increase in the price of treatment for gout that had been “widely available” since the 1800s.20

The U.S. may also consider the need to preserve domestic policy space for full consideration of all tools available to US policymakers to address high prices in America. There have been calls in recent years to consider measures such as compulsory licenses, patent challenges, reducing periods of exclusivities, and reforms to the patent system in America at the state and federal levels by policymakers, civil society and experts.21 The U.S. could undermine its own ability to respond to high drug prices if USTR seeks binding international commitments for longer, stronger and broader patent monopolies or threatens negative consequences for countries using or considering compulsory licenses and other legal measures to protect public health.

Public health safeguards save lives

In contradiction to the above described pressure, the U.S. has made commitments to recognize the importance of public health, in addition to affirming the Doha Declaration. For example, through the 2007 New Trade Policy, the U.S. recognized the importance of respecting public health safeguards for developing countries in trade agreements.22 The U.S. again committed to the importance of protecting public health in the 2008 World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA).23 Just this past May, the Administration committed to a plan to implement the GSPOA beginning with prioritized actions. In the UN High-Level Declarations on HIV/AIDS and AMR, the U.S. again joined other Member States in committing to respecting countries rights to exercise public health safeguards in IP rules.

Public health safeguards offer opportunities to limit or mitigate situations where monopolies represent a threat to people’s lives primarily by enabling competition. Competition’s effects on reducing prices and improving people’s access to the affordable medicines they need is well documented globally and domestically. For example, the U.S. Food & Drug Administration (FDA) reports that, with sufficient competition, the average price of a medicine falls by 80% and that significant price reduction can be achieved when two generic manufactures enter the market.24

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MSF’s medical humanitarian operations have benefitted from countries’ use of public health safeguards. For example, for many years India has been a model of acting in full compliance with the World Trade Organization obligations, but implementing these obligations in a manner that better balances public health. The safeguards India has implemented are of critical importance to protect the health of millions of people across the world and has earned the country the nickname the “pharmacy of the developing world”. The majority of medicines MSF uses to treat HIV, tuberculosis, malaria are generics from India. It is thanks in large part to competition from generic manufacturers in India that prices for first-line HIV treatments have fallen by 99%. U.S. government-funded treatment programs like the President’s Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria also rely on generic competition to ensure that these important investments can save more lives.

Dramatically more affordable versions of hepatitis C treatments are also available through generic manufacturing. MSF is able to sustainably procure a hepatitis C combination treatment for $120 per treatment course, improving our ability to provide these treatments to more than five thousand people with hepatitis C in eleven countries so far.

Compulsory licenses can serve as a public health safeguard to enable access to medicines, in compliance with international trade obligations. For example, in 2012, India issued its first and so far only compulsory license in the interest of public health on a cancer treatment priced out of reach of 98% of people eligible for treatment. Doing so reduced the price by 97%. The Indian courts also recognized the innovation behind the drug and in accordance with international law requested that the generic manufacturer pay a seven percent royalty to the patent holder, Bayer.

MSF urges the U.S. government to respect the legality of the decisions made by other government that adhere to international trade rules, and to further recognize the important positive impact of these decisions on public health.

**Increase transparency in the biomedical innovation system**

Increasing transparency in the biomedical innovation system can help identify abuses in the system and provide important information to improve the current system’s ability to generate innovation for affordable products that meet health needs.

In May 2018, MSF and 26 US-based groups concerned by high drug prices domestically and globally wrote to HHS to ask for increased transparency in the biomedical innovation system. Specifically, we asked for increased transparency of prices, “costs of research and development (R&D), costs of

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manufacturing, IP monopolies, clinical data and trial protocols, and registration plans.” We noted that increasing transparency in these and other areas “can enable improvements to and design of more effective innovation policies to deliver the products that people need in America and globally.”

The current lack of transparency undermines innovation

The current biomedical innovation system suffers from a lack of transparency that enables abuses, entrenches inefficiencies that delay providers’ knowledge of how to best use new treatments and stymies necessary discussions about how to better deliver affordable innovation that prioritizes people’s health needs. This lack of transparency extends throughout the biomedical innovation system and beyond:

**Pricing, registration and other information.** There is a lack of transparency in the pricing of key medical technologies for different populations in need of the same tools. Both within the U.S. and internationally, prices for the same lifesaving products can vary widely. To understand how much high product prices are paying for the costs and incentives of innovation, as well as having a better understanding of who has access and who does not, more transparency on the product price landscape and companies’ pricing and registration strategies is needed.

MSF has supported efforts to address this lack of transparency. Since 2001 we have endeavored to promote product price transparency in our pricing reports for key HIV treatments, TB treatments and vaccines to help equip ministries of health and patients with information to help secure fair, more affordable prices.

**Clinical information and research.** Reliance on patents and market exclusivity as an incentive for R&D pushes scientists and companies to work in isolation from, and in competition with, one another. Researchers may repeat the same mistakes and may not be able to benefit from the advancements of scientific knowledge in a timely way. Clinical data reporting currently suffers from incentives for selective reporting and an undermining of comprehensive knowledge of safety and efficacy. The result is a system that is slower, less efficient, less safe and effective, and more expensive.

The U.S. has taken initiative in government-funded research to promote open access, for instance through the National Institutes of Health (NIH) and other efforts by HHS. HHS also provides an online database with access to information on publicly and privately supported clinical studies on a

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32 e.g., HealthData.gov has more than 3,000 open datasets. See: Unleashing the Power of Data and Innovation to Improve Health. HealthData.gov [Online]. 2017 [Cited 2017 Mar 15]. Available from: https://www.healthdata.gov/content/about
wide range of diseases and conditions, although contributions are currently optional. Researchers, companies and ultimately patients in all countries benefit from this access to information.

**Costs of R&D and manufacturing.** Policymakers, media, pharmaceutical industry groups and others have claimed that it costs “billions of dollars” to bring a new drug to market. This claim is based on analysis from the industry-funded Tufts Center for Drug Discovery. However, that analysis has been widely criticized for methodological concerns including inflated “costs of capital,” and non-transparent data. In fact, estimated costs of R&D can vary widely. Of nearly twenty sources analyzing or estimating costs of R&D, figures range from $30.3 million to $2.6 billion in 2013 dollars. Transparent and reliable data is widely lacking, and information is particularly scarce for costs of vaccine and diagnostic R&D.

Unfortunately, HHS again undermined discussions globally about how to promote costs of R&D transparency among ministries of health worldwide at this year’s World Health Assembly in May 2018, following similarly concerning statement at the World Health Organization Executive Board meeting in January 2018. As stated in the U.S. intervention of Agenda Item 11.6, “...as we noted in January, policies requiring companies to disclose research and development costs are impractical and unlikely to be effective. Furthermore, such approaches could result in the abandonment of high risk types of investment in research that ultimately may be the most beneficial for patients....”

**IP monopolies and access barriers.** Increasing transparency on patents and data or market exclusivities granted or sought will help manufacturers that are interested in offering medical products at a more affordable price understand the legal space to operate and what if any potential barriers to competition exist. As MSF identified in our recent analysis of patent barriers’ effects on vaccine competition, understanding the patent landscape is a prerequisite for manufacturers seeking to offer more affordable versions of lifesaving medical products, where products can be covered by more than one hundred patents. This time-consuming, skill-intensive process can result in unnecessary costs and delays to bringing a more affordable version of a lifesaving medical product to the market. Increasing transparency of access barriers for all medical tools will allow policymakers and innovators to see where these access barriers exist and take appropriate measures to promote competition where it is lacking.

Support for increased transparency in biomedical innovation system is proliferating

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35 Webcast videos of discussions, including U.S. remarks on agenda item 11.6 at the 71st Annual World Health Assembly. Geneva (Switzerland); 2018 [Cited 2018 Jul 10]. Available from: http://www.who.int/world-health-assembly/seventy-first
American policymakers, academics, civil society and others are joining a growing chorus of calls for better information and greater transparency into the scientific, economic and legal landscape of our current system. Active proposals in the U.S. at the state and federal level provide evidence of the growing appetite within America to shed light on what taxpayers, treatment providers and patients are paying for and why. At the state level, there were at least 21 bills introduced in 13 states requiring some level of transparency of costs of R&D in 2017. Many of these proposals similarly call for transparency on costs of manufacturing. At the federal level, there have also been bipartisan calls for increasing transparency on R&D and manufacturing costs as well. Elected Members of Congress were inhibited in their work by a lack of transparency when pharmaceutical company Gilead refused to comply with requests for information on the costs of developing sofosbuvir, despite repeated requests.

The need for greater transparency is also recognized internationally. For example, consider the Report of the UN Secretary-General’s High-Level Panel on Access to Medicines, the 2015 World Health Assembly Resolution 68.6 to promote vaccine price transparency and the V3P price reporting database – already with 120 countries reporting, and the report of the World Health Organization’s Consultative Expert Working Group on Research and Development: Financing and Coordination.

Some of the ways the US Government could increase transparency to provide greater benefit to patients with a better balance on innovation and access include:

- Publish clinical data relied upon by the FDA for a product’s approval or rejection in an accessible open database, and mandate that sponsors publish all data from any trial initiated regardless of outcome. HHS could also invite voluntary disclosures from manufacturers until appropriate mandates can be implemented.

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• Mandate that medical product application sponsors report on prices and registration plans. HHS could also invite voluntary disclosures from manufacturers until appropriate mandates can be implemented.
• Publish information on patents and exclusivities for all medicines, vaccines and diagnostics.
• For federally-funded clinical trials, share the costs, number of patients enrolled, trial duration and other disaggregated information.
• Mandate that medical product application sponsors provide clear, disaggregated and verifiable information on R&D and manufacturing costs when seeking approvals. HHS could also invite voluntary disclosures from manufacturers until appropriate mandates can be implemented. Given the complexity of R&D costs it will be important to ensure that the information reported offers an appropriate degree of specificity and includes some measure of verification. We recommend that HHS hold a separate public hearing and/or open a comments period regarding the specific requirements of disclosures.

Consider innovative policies to promote and finance biomedical innovation

The Blueprint lacks policy proposals that get to the root of the problem by addressing high drug prices where they start, recognizing high drug prices as a symptom of a deeply flawed system of innovation. Evidence demonstrates how monopolies can be ill-suited incentive for innovation, at odds with public health objectives.45

As highlighted above, MSF’s teams face every day the consequences of what the current innovation system fails to deliver, not only with medicines priced out of reach, but also with tools that are not suitable for use in contexts where we work, or not developed at all due to the misalignment of our current incentives. MSF and treatment providers in America and globally go without the appropriate tools to combat antimicrobial resistance, Ebola, neglected diseases and conditions like snakebite.

The U.S. Government plays a key role in biomedical innovation globally

The U.S. Government is the single largest funder of biomedical R&D in the world. The National Institutes of Health (NIH) has a budget of more than $37 billion.46 The U.S. Government also funds biomedical R&D through other agencies at HHS and other departments such as the Department of Defense, the Department of State47 and the Department of Veteran’s Affairs.48 In addition to direct funding, tax breaks offered by the U.S. government for orphan disease-designated products cost an

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estimated $2.28 billion in 2017, and other R&D tax credits are available; other incentives include, but are not limited to, priority review vouchers (PRVs) worth hundreds of millions of dollars for neglected disease, rare pediatric and medical countermeasure products, and waivers of several million dollars each in FDA user fees for products earning priority review designation. Last year, this designation applied to the majority of novel drugs approved by the FDA. These outlays do not include adjustments for risk or cost of capital and are in addition to the basic scientific research investments overwhelmingly funded by the public that underpin downstream medical advances.

This public funding already contributes significantly to important therapeutic advances. A recent study identified that NIH funding contributed directly or indirectly to the R&D of all 210 new drugs approved between 2010 and 2016. MSF has used many products developed with U.S. federal funding support in our operations, including but not limited to: bedaquiline, an important new treatment for drug-resistant tuberculosis; miltefosine, a treatment for visceral leishmaniasis; HPV vaccine, a tool to help prevent certain cases of cervical cancer; MenAfriVac, a meningitis vaccine developed through an innovative public health needs-driven model; Genexpert diagnostic platform, a tool to detect drug resistant tuberculosis; and several HIV and malaria treatments.

The U.S. is uniquely positioned to be a leader in innovation with policies that truly put patients’ needs first and that pay for and incentivize innovation in ways that can benefit people, product developers and public health.

Make better use of existing incentives

America could be doing much more to ensure the important investments already made through public funding result in more affordable treatments, vaccines and diagnostics that better meet health needs for people everywhere.

Conditions on public funding and licenses. The U.S. government could be negotiating a better deal for all people who need access to medicines, including Americans, by asking grantees and licensees benefiting from public investments to commit to access and affordability conditions. For example, grants and licensing terms could include the following conditions and requirements:

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54 MSF has submitted similar recommendations for specific products. See for example MSF’s joint submission with KEI on a Zika vaccine candidate license, available here: https://www.keionline.org/sites/default/files/KEI_MSF_NIH_Zika_Vaccine_License.pdf
• Conditions for R&D milestones or targets that must be met for timely further development of the product in relevant populations for federally licensed products.
• A requirement to disclose the steps a grantee or licensee commits to take to enable the timely registration and availability of the product at an affordable price in the United States and in every county with a demonstrated need, according to the Centers for Disease Control and Prevention (CDC)/WHO. This could be achieved 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 IP necessary for third parties to do so.
• The ability of the U.S. government to grant the WHO, the Medicines Patent Pool or other governments the rights to use the patents of federally licensed inventions to procure the relevant product 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 product.
• A requirement for licensees and grantees to provide annual public reports on the R&D costs incurred, the manufacturing costs of the product, the number of units sold in every country, as well as the status of any patents on the product and all country registrations.

Fix the FDA neglected disease priority review voucher program. MSF and seven other global health groups based in the US have called on Congress for years to amend the FDA’s Priority Review Voucher (PRV) program for neglected diseases. This decade-old program, intended as an incentive to spur needed innovation for neglected diseases, has critical loopholes in the rule of the program that have enabled misappropriation of a promising alternative incentive mechanism. The Administration should work with U.S. Congress to enact two key amendments to the FDA PRV program for NTDs:

1. The PRV program for neglected diseases should have a novelty requirement. The product should be a new therapeutic or prevention option for a neglected disease in order to qualify. If the product has already been available to treat or prevent the neglected disease for years elsewhere in the world, it shouldn’t be eligible to win this publicly-resourced incentive.
2. The PRV program for neglected diseases should have an access strategy. If the sponsoring company doesn’t intend to register the product in countries where it’s needed most, or doesn’t plan to make it affordable to neglected disease patients and treatment providers, it shouldn’t be eligible to win this publicly-resourced incentive.

Consider delinked approaches and rewards with appropriate safeguards

The U.S. should consider supporting incentives to pay for and promote innovation in ways that delink or separate reimbursement for the costs of innovation from the expectations of high prices or high volumes of sales. Incentives should catalyze patient-needs-driven R&D for new health tools that address public health needs in an equitable, cost-effective, and sustainable way. They should come with appropriate conditions and safeguards to ensure therapeutic benefit and affordable access for

people regardless of where they live, and should facilitate collaboration, data sharing and pooling of IP rights. Incentives and financing mechanisms should focus on delivering affordable therapeutic advances to address people’s health needs, even if there is no potential for significant profits, providing maximal public access in exchange for public investments.

**Patient-centered priority setting.** Incentives should strive to meet all people’s health needs with a R&D focus on new health tools that are affordable, accessible, and adapted for use in even poorly resourced health settings. In terms of disease focus, illnesses with high public health impact should be prioritized. Research should include exploring opportunities to better use existing, possibly forgotten, sidelined, or withdrawn products, as well as identifying promising new candidates, and where appropriate assess the value of using drug combinations. It should similarly promote treatment delivery options that meet people’s needs, (for example, oral formulations, fixed-dose combinations, pediatric formulations and heat-stable products that do not require refrigeration as applicable).

**Incentivize R&D collaboration.** R&D incentives should foster R&D collaboration and accelerate delivery time of a new product from “bench to bedside”, through the sharing of research results, clinical trial data and protocols, and compound libraries, as well as the pooling of IP rights. These conditions will speed up development, reduce costs and increase efficiency.

**Governance voice of patients and other civil society stakeholders.** To best inform discussions and decision making in establishing new or improved innovation incentives, the perspectives and guidance of patients, providers, independent civil society organizations and experts should be considered in these processes. The inclusion of the voice of these stakeholders is not only important due to their experience and expertise, but also helps assure the design and implementation of incentives puts the needs of people at the center of all efforts. Large corporation pharmaceutical companies are already extensively represented in policy discussions – HHS should strive to ensure that input is well balanced with consideration of the needs of people most deeply impacted by these policies and what they aim to deliver.

**Countries can share in the responsibilities and the benefits to deliver better and more affordable innovation**

If the U.S. truly wants to engage other countries in sharing the responsibilities and benefits of biomedical innovation that meet people’s needs, the government should support proposals to address these issues globally, by endorsing and implementing the recommendations of the Report of the UN High-Level Panel on Access to Medicines and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

The U.S. has already joined other Members States in making commitments to improving innovation and affordable access through UN High Level Declarations on HIV and Antimicrobial Resistance and should affirm these strong commitments in a UN High-Level Declarations on Tuberculosis and Non-
Communicable Diseases this September. These commitments should be translated into action with policies that prioritize patient needs including affordability.

MSF also urges the U.S. government to participate constructively in the ongoing World Health Organization efforts to develop a roadmap for access to medicines. Specifically, the U.S. should support and prioritize action on innovation and access in five areas to develop a bold roadmap that ensures patient-centered innovation – and access to medicines, vaccines and diagnostics for all people:

1. Promote alternative R&D approaches and actively pursue an R&D agenda that is driven by health needs, fosters sustainable innovation and access, ends reliance on high prices and monopolies to finance R&D, and addresses innovation and access concerns for all diseases, all health technologies and all countries.

2. Address IP barriers to access to medicines and vaccines by strengthening WHO’s leadership role and the technical assistance it provides Member States working to address IP barriers and to effectively adopt and use public health safeguards in IP laws and policies.

3. Strengthen WHO’s mandate to improve data, cost and price transparency across all aspects of R&D, manufacturing and marketing to improve access to affordable medicines, vaccines and diagnostics.

4. Provide the additional, sustained resources required for WHO to support and strengthen the quality assurance of safe, effective medicines, vaccines and diagnostics that meet public health needs – specifically through additional investment in the WHO Prequalification of Medicines Programme.

5. Ensure effective policy coherence between the roadmap and WHO and UN health programs and interventions, promote leadership and accountability among UN agencies to safeguard public health, and fund the development of a roadmap that builds on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the recommendations of the UN High-Level Panel on Access to Medicines.

Conclusion

We have highlighted in this submission some of the key opportunities we see for the U.S. to end unwarranted negative actions and to expand and implement better solutions to deliver the new treatments people need regardless of where they live. As the Administration prepares to enact specific policy responses, given the complexity of many of these issues, public hearings or additional comment periods may be appropriate. We would also be pleased to discuss these matters further directly, please contact MSF for a meeting at your convenience.

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