

Secretary Alex Azar  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building,  
200 Independence Avenue, S.W., Washington, D.C. 20201

CC:

G. Garrett Grigsby, Assistant Secretary for Global Affairs, U.S. Department of Health and Human Services  
Daniel Best, Senior Advisor for Drug Pricing Reform, U.S. Department of Health and Human Services

May 18, 2018

Dear Secretary Azar,

As U.S. stakeholders concerned by unaffordable prices of medicines, we write to request that the U.S. engage constructively and positively in discussions of how to better promote access to existing lifesaving treatments and better align incentives for needs-driven affordable innovations, both domestically and internationally. Specifically, we ask that the U.S. support efforts to increase transparency in the biomedical innovation system.

In addition to increased price transparency as you highlighted at the launch of the U.S. “blueprint” on high drug prices, greater transparency on costs of research and development (R&D), costs of manufacturing, intellectual property monopolies, clinical data and trial protocols, and registration plans, among other areas can enable improvements to and design of more effective innovation policies to deliver the products that people need in America and globally.

Biomedical innovation involves costs and risks and everyone benefits from ensuring that innovation is appropriately paid for and incentivized. Yet reliable and transparent data on the costs of R&D and costs of manufacturing are scarce.<sup>1</sup> Currently pharmaceutical companies are neither incentivized nor required to disclose the product’s R&D or manufacturing costs. Despite existing transparency on clinical trials data and intellectual property monopolies, more should be done to increase transparency and avoid costly, time-wasting duplication of research for many urgently needed new treatments, vaccines and diagnostics and to promote competition.

More comprehensive information on costs, prices, registration and access barriers would enable a more robust and evidence-based discussion about how to sufficiently and efficiently pay for the costs associated with the innovation we need while better protecting access to medicines. Active proposals in the U.S. at the state and federal level provide evidence of the growing appetite within America<sup>2</sup> to shed light on what taxpayers, treatment providers and patients are paying for and why.<sup>2</sup>

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<sup>1</sup> MSF. Lives on the Edge: Time to align medical R&D with people’s health needs. Doctors Without Borders [Internet]. 2016 May [cited 2017 Dec 22]. Available from: [https://www.msfaccess.org/sites/default/files/R&D\\_report\\_LivesOnTheEdge\\_Updated29Sept\\_ENG\\_2016.pdf](https://www.msfaccess.org/sites/default/files/R&D_report_LivesOnTheEdge_Updated29Sept_ENG_2016.pdf)

<sup>2</sup> As of 2017 there were also [21 bills introduced in 13 states](#) that required R&D cost transparency. See also: the Fair Accountability and Innovative Research Drug Pricing Act of 2017, the Stopping the Pharmaceutical Industry from Keeping Drugs Expensive (SPIKE) Act of 2017, the Improving Access To Affordable Prescription Drugs Act and the Transparent Drug Pricing Act of 2017.

People in the U.S. and all over the world are struggling to afford the medicines they need to live healthy and productive lives. For millions of Americans, [high prices](#) cause them not to fill their prescriptions. Spending growth on prescription drugs in the U.S. is expected [to double](#) this year. More than two dozen individual countries and the regions of EU, AFRO and EMRO spoke on the need to improve access to medicines and innovation at the World Health Organization (WHO) Executive Board meeting this past January. Nearly a dozen countries called for the UN Secretary-General's High-Level Panel Report<sup>3</sup> recommendations to be advanced, which includes recommendations for transparency in the innovation system.

Everyone is similarly affected by what our current innovation system fails to deliver. Despite growing antibiotic resistance responsible for the deaths of 23,000 people in America each year and tens of thousands more globally, no new classes of antibiotics have been developed in more than 30 years. We have seen the devastating consequences of when the world is ill equipped to deal with neglected and emerging infectious diseases like Ebola and Zika. Policy changes to improve incentives for innovation and better align R&D with people's health needs are long overdue.

Transparency can identify and help prevent abuses in the system resulting from excessive pricing, lack of competition and the inefficiencies and delays due to lack of data sharing. More fundamentally, it can serve as an important tool to ensure proposed solutions address the failures of unaffordable medicines and 'me-too' products, while still appropriately funding and incentivizing our continued need for new medical tools and biomedical advances.

We are concerned by U.S. government comments at the World Health Organization Executive Board meeting earlier this year, criticizing proposals to increase transparency of costs of R&D as "unlikely to be effective" and suggesting that it could undermine research for "vulnerable communities and humanity as a whole."<sup>4</sup> We urge the U.S. to support, not undermine these efforts at the World Health Assembly when they come under discussion this May.

U.S. elected officials, many Ministers of Health, experts and civil society groups around the world are working to advance solutions that seek to mitigate and ultimately end the tradeoff between access to the lifesaving medicines people need today and the incentives to deliver the innovations that could save lives in the future. We hope the U.S. will embrace these efforts and consider working together with other countries to ensure all patients benefit from a biomedical innovation system that delivers the affordable medicines we all need.

Thank you for your consideration. We are available to discuss these issues further at your convenience.

Sincerely,

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<sup>3</sup> Report of the United Nations Secretary General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies (2016). Available at: <http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf>

<sup>4</sup> Karlin-Smith S, Wheaton S. Trump's 'America First' agenda on drug pricing could backfire around the world. Politico. 2018 May 9. Available from: <https://www.politico.com/story/2018/05/09/trump-drug-pricing-prescriptions-514925>

AIDS Action Baltimore

AIDS Foundation of Chicago

Chronic Illness Advocacy & Awareness Group

Clinician Action Network

Doctors Without Borders/Médecins Sans Frontières USA

End AIDS Now - New York, NY

Families USA

Health GAP

Hep Free Hawaii

Housing Works

Interfaith Center on Corporate Responsibility

Knowledge Ecology International

Life Foundation

NASTAD

National Physicians Alliance

National Viral Hepatitis Roundtable

Other98

Oxfam America

Patients For Affordable Drugs

People of Faith for Access to Medicines

Public Citizen

Social Security Works

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Treatment Action Group

The Community Health Outreach Work (CHOW) Project

Universities Allied for Essential Medicines (UAEM)

Young Professionals Chronic Disease Network Baltimore Chapter