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MSF HEARING STATEMENT FOR THE USTR 2017 SPECIAL 301 REVIEW (DOCKET ID: USTR-2016-0026-0001)

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Doctors Without Borders/Médecins Sans Frontières (MSF) would like to offer testimony in the 2017 United States Trade Representative (USTR) Special 301 Review.

MSF is an independent, international medical humanitarian organization that delivers medical care to patients in nearly 70 countries. We provide medical aid to victims of armed conflict, epidemics, natural and man-made disasters, and to others who lack health care due to social or geographic marginalization. Our work often focuses on the medical needs of marginalized and difficult to reach populations living in developing countries, whose needs are often neglected. MSF is in need of both affordable access to and innovation for medical technologies. Through our work, MSF witnesses the everyday impacts on people of having limited or no access to medicines because they are too expensive or they don't exist.

As a medical treatment provider with more than 40 years of experience caring for vulnerable people, MSF is able to speak about the relationship between intellectual property (IP) rules, access to medicines and innovation. This includes key political, legal and commercial barriers that stand in the way of production, distribution and access to affordable and appropriate medicines, vaccines and diagnostics and that inhibit patient-driven medical innovation.

MSF would like to provide testimony to the USTR 2017 Special 301 Review process regarding the critical importance of respecting countries' rights to uphold the public health safeguards enshrined in the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and to implement these safeguards in national law, policies and practices to balance private commercial interests with the right to life and health.

Specifically, we would like to highlight the important role India plays in manufacturing lifesaving medicines and vaccines for millions of people around the world. This is possible in part due to the public health safeguards in India's patent law and policies. Thanks to price-lowering competition from India, millions of people around the world are able to access the affordable medicines and vaccines they need, including through Ministries of Health, humanitarian treatment providers like MSF and U.S. government-funded treatment and prevention programs, like the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance.

We urge the USTR to respect legal safeguards such as India's strict patentability criteria; its right to issue compulsory licenses when deemed necessary in the interest of ensuring the right to health; and a balanced approach in the enforcement of private IP protections.

Additionally, pharmaceutical corporations' TRIPS-plus demands such as data exclusivity that go beyond the WTO TRIPS obligations and create regulatory barriers in the registration of price-lowering generic medicines should not be requested to be implemented by India.

We specifically request that USTR refrain from demanding any excessive IP enforcement measures in India that undermine public health and Article 21 (right to life) of the Constitution of India and that interfere with judicial discretion. The multinational pharmaceutical industry is increasingly demanding that India's judiciary implements IP enforcement measures in a manner that goes beyond the requirement of the TRIPS Agreement and that include mandatory and stricter injunctions and patent-registration linkage. These demands would have a range of harmful effects on the registration and dissemination of generic medicines and provide opportunity for abuse from multinational pharmaceutical corporations.

We would also like to highlight the importance of respecting countries' rights to issue TRIPS compliant compulsory licenses on patented medicines. In this regard we are deeply concerned by the interference by U.S. government officials last year, in an effort to prevent Colombia's Minister of Health from issuing a compulsory license on a lifesaving cancer medicine.

Countries should not be penalized or discouraged from making use of the public health safeguards that are intended to protect access to medicines and which are legally permitted in accordance with international trade rules. At a time where the high prices of medicines are a concern for countries all over the world, including here in the United States, countries' efforts to ensure people can access the lifesaving medicines they need should not only be respected, but promoted more than ever.

Instead of unilateral trade pressure to create stronger monopoly protectionism for pharmaceutical companies, the U.S. government should seek to establish improved incentives and norms to fix the world's broken research and development (R&D) system. The reliance on high medicine prices, backed by exclusivities and monopolies, is a flawed paradigm for funding innovation. This leads to unaffordable prices while failing to stimulate innovation for diseases where patients have limited purchasing power, like neglected diseases or where drugs have to be used sparsely like antibiotics. MSF supports the importance of rewarding innovators for undertaking the costs and risks of biomedical innovation. Instead of doubling down on a broken innovation model, the U.S. government should collaborate with other funders of R&D and lead in the introduction of new approaches that promote both innovation and access to medicines, as recommended by the 2016 UN Secretary-General's High-Level Panel on Access to Medicines.