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February 26, 2016

United Nations High-Level Panel on Access to Medicines
c/o Mr. Richard Delate, Project Manager
United Nations Secretariat Building
405 East 42nd Street
New York, NY 10017

Re: Input of the National Association of Manufacturers to the United Nations High-Level Panel on Access to Medicines

Dear Panel Members:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments to the United Nations High-Level Panel on Access to Medicines (UNHLP) as part of its call for contributions.

The NAM is the largest manufacturing association in the United States, representing businesses of all sizes in every industrial sector and in all 50 states. Manufacturing employs more than 12 million women and men in the U.S. alone, accounting for two-thirds of private sector research and development in the United States and contributing $2.17 trillion to the U.S. economy annually. Global manufacturers of all sizes and across sectors depend on innovation to succeed and to develop cost-effective solutions to public policy challenges, including global health issues.

Promoting the innovation required to address public health and other public welfare challenges requires a policy environment characterized by well-functioning markets and stable regulatory environments where businesses and other stakeholders are incentivized to play productive roles. Open markets and strong intellectual property protection and enforcement facilitate access to today's healthcare technologies and drive and sustain investment in tomorrow's advances. For these reasons, the NAM has concerns about the scope of the panel's inquiry and believes that "the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies" can and do work together to advance health access globally.

Given the many forces that determine whether and to what extent investors and innovators dedicate resources to tackle a particular policy challenge, and the long-term horizon that addressing these challenges often requires, it is critical that challenges are considered broadly and that solutions are based firmly and solely on sound economic and policy analysis, considering all possible options.

The NAM is pleased to provide background on the role that the private sector and innovation play in addressing global public health challenges. This submission focuses on enabling factors that can and should be put in place to fuel private sector participation and innovation that are required to develop and disseminate healthcare technologies.

Key Comments and Recommendations

The NAM's comments and recommendations can be summarized as follows:

1. Both public and private sector investments in global healthcare innovation and technology development and dissemination are needed, and governments should seek to enable these investments through various policy approaches.
2. The UNHLP must consider the broad range of barriers that can limit access to healthcare and health technologies, including health resources and infrastructure, tax policy, and open investment policies. The UNHLP must use a well-grounded and evidence-based approach to consider potential solutions. This approach should focus on careful reviews of available economic data, policy evidence, and actual, on-the-ground experience. This approach must recognize the essential role of intellectual property rights ("IPR") and other policy measures in spurring private sector involvement in the development, dissemination, and deployment of health technologies.
3. IPRs serve as an important incentive and catalyst for the development and dissemination of critical public health products and technologies. The UNHLP should focus on evidence-based analysis in its work on important issues such as IPR, and not rely on unfounded misconceptions about the role of IPRs based on prior public health-related IPR and technology discussions.
4. As a supplement to these discussions about innovation and technology enabling factors, the NAM encourages the UNHLP to explore the creation of networks of research institutions and medical centers focused on solving particular public health challenges. Such a model could contribute to positive health outcomes, particularly in the developing world.
5. The NAM also raises the continued presence of import tariffs and other trade-related barriers in global markets that hamper access to public health solutions, and make health products and technologies more expensive. Each of these factors should be discussed and addressed.

Healthcare Products, Technologies and Innovation for the Developing World

Thanks to the efforts of the private sector and many other health stakeholders, a broad range of healthcare technologies are available in the world today. These include traditional "small-molecule" drugs, advanced protein-based biologics, genetics-based molecular diagnostics, complex medical technologies, healthcare services, and even software. Yet despite the array of products and technologies currently on the market, many more public health solutions are needed to tackle both current and emerging public health challenges. The needs of many of the world's poorest and most vulnerable countries are particularly acute – and are not dependent on access to patented medicines. Of products defined by the World Health Organization (WHO) as "essential medicines," 95 percent are off-patent, yet one-third of the world's population does not have reliable access to them. In many of the world's poorest countries, that figure rises to 50 percent of the population – indicating that IPR is not the main challenge.[1]

Private sector innovation and investment has proven to be and will continue to be vital to developing solutions to tackle these and other challenges. For example, the vast majority of important medicines owe their existence to the R&D activities of the biopharmaceutical industry: 91 percent of drugs developed between 1988 and 2005 were developed by the private sector

[1] D. Wayne Taylor, *Pharmaceutical Access in Least Developed Countries: On-the-ground Barriers and Industry Successes*, Hamilton, Ontario: Cameron Institute, accessed February 26, 2016, http://apps.who.int/medicinedocs/en/d/Js17815en/.

with no direct government role.[2] Such private sector-led innovation will only be more critical in developing new technologies to address both the existing health needs of today's rapidly growing global population and emerging healthcare challenges in a cost-effective manner. "Connected health" technology solutions, for example, seek both to harness existing commercial applications and hardware and also to develop new breakthroughs to deliver healthcare to underserved locations.[3] Such innovations can not only improve the lives of patients, but also dramatically lower a country's overall healthcare costs by identifying problems at an earlier stage, minimizing unnecessary treatment, and improving health access.

These and other types of innovative solutions are particularly important for the developing world, where the needs are often greatest and distribution mechanisms are limited by weak infrastructure. In short, innovation and technology development can play a substantial and highly positive role in addressing developing country needs.

Trade, Public Procurement, Education, and Other Positive Enabling Factors

A vast body of economic and policy literature confirms that successful innovation and technology development and dissemination in any country, including the poorest and least-developed countries of the world, requires a range of enabling factors. Innovation- and technology-enabling measures include competitive tax rates, tax incentives for R&D and investment, and mechanisms to enable the exchange of know-how.[4] Governments can also foster further innovation through investments in transportation infrastructure such as roads, ports, and pipelines, in reliable access to electricity and other utilities, and in widespread high-speed internet access. Other positive tools include policies that encourage and enable foreign investment (FDI) and openness to robust global market mechanisms that can assist in integrating a country into global supply chains. These enabling factors must be in place to realize targeted healthcare innovation and private sector medical technology investments.

Continued trade-related barriers are also an important factor limiting the ability to find cost-effective solutions to public health challenges. These barriers can include old-fashioned import tariffs, non-tariff barriers such as differential tax treatment, local content measures and policies to encourage or require patents or other forms of IPR to be held locally, regulatory delays in granting patents and marketing approvals, and a range of other regulatory measures that discriminate against foreign imports or otherwise make them more expensive for importers, users, and consumers alike. Finally, public health-related procurement issues, including incentives for hospitals or healthcare professionals or institutions to use domestic products or services and requirements for foreign companies to transfer technology or other assets to particular jurisdictions, can also serve as significant impediments to improving healthcare.

The Role of IPR

The scope of the UNHLP and the assumptions made in its formation are not reflective of the broad and positive role that IPRs in expanding access to healthcare technologies. IPRs are not

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[2] Bhaven N. Sampat and Frank R. Lichtenberg, "What are the respective roles of the public and private sectors in pharmaceutical innovation?" Health Affairs 30:2 (February 2011), accessed February 26, 2016, http://content.healthaffairs.org/content/30/2/332.full.

[3] Dr. Robin Lee and Dr. Gillian Davies, "Technology: The Cure for Rising Healthcare Costs?", *MIT Technology Review* (September 3, 2013), accessed February 25, 2016, https://www.technologyreview.com/s/518946/technology-the-cure-for-rising-healthcare-costs/.

[4] *Innovation: Government's Many Roles in Fostering Innovation*, (New York: PricewaterhouseCoopers, January 2010), accessed February 25, 2016, http://pwc.com/gx/en/technology/pdf/how-governments-foster-innovation-2010.pdf.

a barrier to access – particularly when governments and the private sector partner together to improve health outcomes. Indeed, IPRs help to support the development and dissemination of advanced medical technology, thus facilitating better health access. As the UNHLP undertakes it work, the NAM urges the panel to reject misperceptions, including those that might limit its full consideration of the positive impact of IPRs in solving healthcare challenges.

The rapid evolution of health technologies has radically changed the healthcare industry in recent years. For example, new biologics – which now make up 50 percent of all new U.S. Food and Drug Administration drug approvals[5] and are growing at twice the rate of traditional prescription drugs[6] -- have hundreds or even thousands of times more atoms than found in earlier medicines.[7] Molecular diagnostics is another promising area that has demonstrated substantial innovation with work to identify individual genetic variations[8] that has provided allowed the identification of specific genetic variations leading to breast and ovarian cancer. Research, development, production, and deployment of these new health technologies is far more complicated than in the past, requiring greater capital investment and stronger protection of IPRs. Research on emerging technologies shows that robust IPR protection for these technologies enables companies to develop products necessary to detect and treat diseases,[9] and serves as a critical incentive to bring potentially life-saving procedures to the market,[10] while having no negative impact on basic research.[11]

A vast body of economic research confirms that robust IPR protection fosters the development and dissemination of advanced medical technology.[12] Many firms will simply not make the requisite investments in such technologies, which take many years to develop at great cost and often require extensive R&D collaboration and cross-industry licensing. Such investments will not happen without a suitable investment climate, rule-of-law protections, and a stable and

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[5] "Bipartisan Group of Members Introduces 'Promoting Innovation and Access to Life-Saving Medicines Act,'" Rep. Henry Waxman Press Release, March 11, 2009, accessed February 25, 2016, http://votesmart.org/public-statement/417192/bipartisan-group-of-members-introduces-promoting-innovation-and-access-to-life-saving-medicines-act#.Vs9lRE0UVaQ.

[6] Henry Grabowski, Iain Cockburn and Genia Long, "The Market for Follow-On Biologics: How will It Evolve?", *Health Affairs* 25:5 (September 2006): 1291-1301, accessed February 25, 2016, http://content.healthaffairs.org/content/25/5/1291.full.pdf.

[7] Sally Pipes, "A Primer for Follow-on Biologics," *Real Clear Politics* (June 6, 2008), accessed February 25, 2016, http://www.realclearpolitics.com/articles/2008/06/a_primer_for_followon_biologic.html.

[8] Identifying particular genetic variations is only more difficult, given that any two individuals typically have roughly 6 million genetic variations. See Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization, and Utilization of Innovative Diagnostic Tests*, Fairfax, VA: Center for the Protection of Intellectual Property, July 2014, accessed February 25, 2016, http://cpip.gmu.edu/wp-content/uploads/2014/04/Holman-Critical-Role-of-Patents-in-Genetic-Diagnostic-Tests.pdf.

[9] John R. Thomas, *Mayo v. Prometheus: Implications for Patents, Biotechnology and Personalized Medicine*, Washington, DC: Congressional Research Service, November 2012, p. 3.

[10] Notably, in a recent U.S. case, a group of individuals affected by Lynch syndrome filed a brief arguing passionately that greater IPR protection for genetic tests for the syndrome could provide an incentive to bring the potentially life-saving procedure to market. In this case, related patents have been non-exclusively licensed, and there is no widely-available test. See Brief for Lynch Syndrome International as Amicus Curiae in Support of Respondents, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (No. 12-398), accessed February 25, 2016, http://www.americanbar.org/content/dam/aba/publications/supreme_court_preview/briefs-v2/12-398_resp_amcu_lsi.authcheckdam.pdf.

[11] *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society*, Washington, DC: U.S. Department of Health and Human Services, April 2010, accessed February 25, 2016, http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf.

[12] Chandra Nath Saha and Sanjib Bhattacharya, "Intellectual property rights: An overview and implications in pharmaceutical industry," *Journal of Advanced Pharmaceutial Technology and Research* 2(2) (April-June 2011): 88-93; Jean O. Lanjouw and Iain M. Cockburn, "New pills for poor people? Empirical evidence after GATT," *World Development* 29(2) (February 2001): 265-289.

predictable contractual and IPR environment. Indeed, this is one of the reasons that so many of these advances continue to occur in the United States, Europe, and other parts of the developed world where such key enabling factors are typically in place. Given the substantial growth in these products and the vastly different development and production processes required to create these new products, policies and legal frameworks that cover IPR and health policy at all levels, in developed and developing countries alike, must keep pace and provide enabling environments to foster further innovation.

In light of these and a range of other developments, and the extensive product scope to which the UNHLP's work pertains, the NAM urges the panel to take an evidence-based approach, seeking and incorporating input from industry and scientific experts, and not simply assuming any particular role that IPR might play. Indeed, ignoring the positive benefits of IPR and the rapid evolution of health technologies and their dissemination, as some seek to do, is simply not supported by the evidence.

Beyond these innovation-related issues, recent studies have also shown that developing countries that adopt strategies that impair IPRs tend to pay more for drugs than those that respect IPRs, undermining the access objectives. For example, in a review of HIV/AIDS antiretroviral medicine purchases reported to the World Health Organisation (WHO) and the Global Fund to Fight Aids, Tuberculosis and Malaria, a team of researchers determined that countries that used compulsory licensing to manufacture or import generic antiretroviral medicines paid more than those who negotiated for the best branded or generic deal.[13] The typical premium paid by countries with a compulsory license program was 83 percent.[14] While this result may initially appear surprising, it is indicative of a dynamic that discourages entry by innovators into markets which need access to medical advances the most. It also shuts the door on collaboration that could develop into solutions to best address local needs.

The NAM also notes the importance of ensuring institutional and legal coherence with respect to IPR-related issues. A key element in ensuring an ongoing positive role of industry and private sector investment is to have a stable and predictable legal and regulatory framework. Today, IPRs are regulated primarily within the World Trade Organization's (WTO) Agreement on Trade-Related Intellectual Property Rights (TRIPS). TRIPS provides a broad set of IPR protection and enforcement obligations across all industries. The WTO, with input from experts across the trade and health care systems, has also worked on the specific implementation of these obligations to medicines and health care issues, authorizing specific flexibility on the application of some IPR provisions in identified circumstances.[15]

Broader legal and institutional discussions as to the role of IPRs for developing countries continue to take place at the WTO and World Intellectual Property Organization (WIPO). Duplicating such discussions elsewhere in the UN system would be highly confusing and could lead to legal and institutional uncertainty and confusion for years to come. The most appropriate forum to discuss global IPR-related issues in detail remains the WTO's TRIPS Council, where subject-matter experts gather, including participants from other UN organizations (such as the

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[13] Amir Attaran, "Opinion: Negotiation is best way to make drugs affordable," *Financial Times* (April 6, 2015), accessed February 25, 2016, http://www.ft.com/cms/s/0/fd8453aa-cd85-11e4-9144-00144feab7de.html#axzz40rA60VNF.

[14] Id.

[15] For instance, in 2003, WTO members made it easier for countries to import medicines produced under compulsory licensing if they are unable to manufacture the medicines themselves ("Paragraph 6 System"). On November 6, 2015, the Council decided that the Least-developed Countries ("LDCs") will be exempt from WTO obligations to provide patent protection for pharmaceutical products to support access to medicines until at least 2033.

WHO and WIPO) and have already begun discussing the role of IPR in relation to a wide range of issues, from climate change[16] and public health[17] to issues related to traditional knowledge.[18]

Medical Technology Centers and Collaboration

In addition to the enabling factors discussed above, a network of global research institutes and medical technology centers could play a key role in accelerating health innovation, technology development and dissemination, particularly to the poorest and least-developed countries. Such networks could be focused, practical and built around targeted objectives, with the structure, functions, and operation determined by the specific health needs and challenges they are set up to address.

These networks could have broad health and development benefits, providing a forum for local scientists, engineers and policymakers within the developing world to work with top international institutes, global experts, foreign government officials, and the private sector. As such, they can boost developing countries' efforts to build of a local research base, foster an educated, technology-savvy workforce, and improve health and innovation-related policies and regulations, ultimately assisting developing countries to become more fully integrated in global technology value chains and climb the innovation and technology development ladder.

Beyond such more local or regional initiatives, global initiatives could be developed as well, particularly in areas where rapid and groundbreaking additional research and development is most urgently needed. One potential model is the Asia-Pacific Partnership on Clean Development and Climate (APP), which from 2006 to 2011 brought together seven countries – Australia, Canada, China, India, Japan, Korea and the United States – to cooperate and accelerate the development and deployment of clean energy technologies in each of their countries. The partnership includes task forces focused on particular challenges faced in the aluminum, buildings and appliances, cement, fossil fuel, coal mining, power generation and transmission, renewable energy, and steel sectors. The APP was a voluntary, non-legally binding framework for international cooperation on fostering enabling environments to meet environmental goals, to facilitate partners' efforts to attain national pollution reduction, energy security and climate change objectives, and providing a forum to explore policy approaches. The Asia-Pacific Partnership included active private sector participation and was fully consistent with commercial and market principles, and international trade and IP rules.

Conclusion

The NAM and its members appreciate the opportunity to contribute to the UNHLP's public dialogue. Most fundamentally, the NAM believes an inclusive, evidence-based, solutions-focused approach that seeks to foster and not undermine innovation is a necessary component to address global public health challenges.

The NAM believes that that the UNHLP's discussions on IPRs and access to medicines should be evidence-based and focus on positive enabling factors. This includes core factors such as incentives for key new technology development and innovation to address particular challenges

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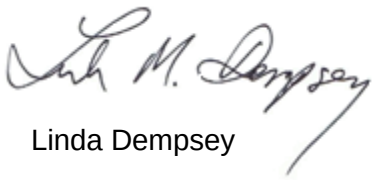
[16] "Climate change and the WTO intellectual property (TRIPS) agreement," World Trade Organization, accessed February 25, 2016, https://www.wto.org/english/tratop_e/trips_e/cchange_e.htm.
[17] "TRIPS and public health," World Trade Organization, accessed February 25, 2016, https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.
[18] "Article 27.3b, traditional knowledge, biodiversity," World Trade Organization, accessed February 25, 2016, https://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm.

facing the poorest and least-developed countries and populations, reducing barriers to trade and procurement of key public health solutions. Other innovative solutions – such as the creation of technology networks – could also be important tools to promote better healthcare and economic development.

IPR issues also act as a positive enabling factor for innovation and technology development, dissemination, and deployment. Given the importance of IPR to a wider range of stakeholders, and given that IPR issues are already regulated and under further discussion at the WTO and WIPO, the NAM strongly encourages the UNHLP to use the careful, evidence-based approach described above in considering the role and interaction of of IPR with any particular policy and legal framework and to consider the legal and institutional consequences of referencing them in the UNHLP or any other context.

The NAM looks forward to working with the UNHLP and other key stakeholders to identify critical needs and foster outcomes to address healthcare challenges for patients around the world.

Sincerely,



Linda Dempsey