AAMC Association of American Medical Colleges
AAU Association of American Universities
APLU Association of Public and Land-grant Universities
AUTM Association of University Technology Managers
COGR Council on Governmental Relations

September 16, 2016

The associations listed below represent most major research universities, medical schools, and university technology transfer officers in the United States. We believe strongly that the September 14 Report of the United Nations High-Level Panel on Access to Medicines misguidedly singles out intellectual property rights — particularly patents — as responsible for hindering equitable access to medicines, vaccines, diagnostics, and other health technologies. In fact, intellectual property rights make the existence of, and access to, these critical drugs and technologies more likely, not less.

Universities and their licensees in the life sciences industries play a critical role in improving global public health; indeed, universities strive to transfer their discoveries to the marketplace via licensing terms and conditions that address unmet needs and promote the broad accessibility of health advances. To that end, in 2015, two of our associations, the <u>Association of American Universities</u> and the <u>Association of Public and Land-grant Universities</u>, released complementary statements unambiguously reaffirming that university technology transfer practices by necessity align with the public service principles that form the basis of universities' missions. In addition, the Association of University Technology Managers offers a publicly available "Global Public Health Toolkit," which includes among its resources examples of verbatim clauses, extracted from license agreements successfully executed by universities, that are designed to further global health priorities.

A strong patent system is what allows universities and related technology transfer organizations to transmit the knowledge and innovations they produce for the public good and broader societal benefit. In the U.S., the Bayh-Dole Act allows universities to hold title to intellectual property derived from federally-funded research. Before Bayh-Dole was enacted in 1980, the U.S. government held patent rights to federally funded university inventions. Consequently, university inventions almost always languished on laboratory shelves, failing to attract the investment from private companies needed to bring those inventions to fruition and, ultimately, to underserved populations in the U.S. and developed and developing nations around the world. Undermining Bayh-Dole and related patent protections would result in fewer novel medicines and medical technologies, not more.

The U.N. Report erroneously suggests that the patenting of university research somehow limits access to academic discoveries and obstructs follow-on innovation. This conclusion is wrong on at least three counts. First, the U.S. patent system requires full disclosure of innovations for

which protection is sought and our federal funding agencies increasingly require grantees to make peer-reviewed manuscripts and data publicly available at no cost. Second, scholarly norms inherently motivate academic researchers to publish their findings and/or use those findings in grant applications. Third, there is scant fact-based evidence – including in the U.N. Panel's Report – that access and follow-on innovation are undermined by patenting; rather, if patent rights are restricted, innovators will rely more and more on trade secrets and fewer open disclosures will occur. In addition, U.S. law provides numerous checks and balances to ensure that patents do not impede further research, such as the safe harbor for patent infringement for those working to obtain FDA approval of a drug or medical device.

Universities stand unified in our commitment to ensure that university research advances worldwide public health. We believe that the proposals in the U.N. Panel's Report would stymie rather than support that goal; accordingly, we hope that those proposals will not serve as the basis for further work within the United Nations. Instead, universities, the federal government, NGOs and the private sector must cooperate to find innovative ways within the current system to optimize global access to new and extant drugs, therapies, and other health technologies and scientific advances.

Association of American Medical Colleges Association of American Universities Association of Public and Land-grant Universities Association of University Technology Managers Council on Governmental Relations