

## PHILADELPHIA CONSENSUS STATEMENT

### *On University Policies for Health-Related Innovations*

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According to the World Health Organization, ten million people—most of them in developing countries—die needlessly every year because they do not have access to existing medicines and vaccines. Countless others suffer from neglected tropical diseases such as sleeping sickness, lymphatic filariasis, and blinding trachoma. Because these neglected diseases predominantly affect the poor, they attract very little research and development funding, leading directly to a paucity of safe and effective treatment options.

We believe that access to medical care and treatment is a basic human right.<sup>1</sup> Lack of access to medical treatment in developing countries stems from several factors, including high prices for medicines, underfunded health care systems, and a global biomedical research agenda poorly matched to the health needs of the world's destitute sick. Comprehensive solutions are thus needed to increase both access to existing medicines and research on neglected diseases.

We believe that universities have an opportunity and a responsibility to take part in these solutions. University scientists are major contributors in the drug development pipeline. At the same time, universities are committed to the creation and dissemination of knowledge in the public interest. Global public health is a vital component of the public interest. Therefore, universities best realize their objectives when they promote both innovation and access to health-related technologies.

To this end, we, the signatories of this Statement, urge universities to adopt the following recommendations.

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As owners of intellectual property, universities have the ability to promote widespread availability of their technologies in the developing world. When university-owned intellectual property is necessary for the development of a health-related end product—including but not limited to drugs, vaccines, diagnostics, monitoring tools, know-how and technical expertise—universities should:

#### PROMOTE EQUAL ACCESS TO UNIVERSITY RESEARCH

- 1. Require the inclusion of licensing terms in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in the developing world.** The Equitable Access License (EAL)<sup>2</sup> is one example of a model license promoting access to university intellectual property in which all qualified entities<sup>3</sup> are permitted to supply the product to public and private sector markets in low- and middle-income (LMI) countries.<sup>4</sup>
- 2. Develop a transparent, case-by-case global access strategy to ensure access to health-related technologies where licensing provisions like the EAL will not serve the access objectives defined above.** For example, biologicals (e.g., complex macromolecules and vaccines) and healthcare devices (e.g., diagnostic tests) are subject to different scientific and technical constraints than synthetic small molecules and may require different methods to ensure access. Components of a global access strategy could include (a) forgoing the university's share of royalties to incentivize the licensee to facilitate access by offering discounts in developing countries; (b) actively seeking a third-party organization to participate in research, development, and distribution to facilitate access in developing countries; and (c) incorporating licensing provisions, such as non-patenting requirements, that guarantee access to data and materials necessary to promote generic production or adaptations for developing countries.

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<sup>1</sup> See Article 25, Universal Declaration of Human Rights.

<sup>2</sup> See <http://www.essentialmedicine.org/EAL.pdf>.

<sup>3</sup> Qualified entities include, but are not limited to, public or private generic manufacturers registered in the country of production.

<sup>4</sup> We use the categories of low- and middle-income countries as defined by the World Bank at <http://www.worldbank.org/data/countryclass/classgroups.htm>.

Neglected diseases are those for which treatment options are inadequate or do not exist and for which drug-market potential is insufficient to attract a private-sector response. In order to advance the development of therapies for neglected diseases (ND), universities should:

### **PROMOTE RESEARCH AND DEVELOPMENT FOR NEGLECTED DISEASES**

- 1. Adopt policies promoting in-house ND research.** Universities should (a) adopt a classification system defining and prioritizing neglected diseases<sup>5</sup>; (b) support existing researchers engaged in ND work; (c) recruit talented ND researchers by establishing proper incentives and marketing their ND research programs; and (d) formalize annual review practices aimed at identifying new or currently shelved technologies with promising potential for application to ND end product development.
- 2. Engage with nontraditional partners to create new opportunities for ND drug development.** Universities should actively seek out nontraditional partners (e.g., public-private partnerships, grantmaking organizations, nonprofits, and developing-world companies or research institutions) to facilitate development of technologies applicable to neglected diseases. Example interactions include: patent donation, dual-market licensing, and straightforward exclusive/non-exclusive licensing. In order to access novel funding sources for neglected diseases, universities should remove any barriers, such as intellectual property restrictions, to accepting research grants from nontraditional funders.
- 3. Carve out an ND research exemption for any patents held or licenses executed.** Licensing terms should allow other non-profit institutions to conduct research for neglected diseases using the university's patented innovation.<sup>6</sup> Similarly, for any out-licensed technologies, universities should retain the right to non-exclusively license use of its intellectual property for neglected disease research and for distribution of any resulting products in developing countries.

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Given their avowed commitment to the public good, universities should measure success in technology transfer by impact on global human welfare rather than simply by financial return. The positive social impact from university innovations—particularly in poor countries—would go largely unnoticed if technology transfer were to be measured in dollars alone. In order to develop transparent criteria measuring access to health technologies and innovation in neglected-disease research, universities should:

### **MEASURE RESEARCH SUCCESS ACCORDING TO IMPACT ON HUMAN WELFARE**

- 1. Collect and make public statistics on university intellectual property practices related to global health access.** To further elucidate how university patenting and licensing strategies affect access to the end products of academic research in developing countries, each university should disclose all healthcare-related end products in which it holds any intellectual property. Data should also be published on patents applied for or granted in all low- and middle-income countries. Conversely, universities should make known the number of licensing agreements that include access-minded provisions<sup>7</sup> as well as details of nontraditional partnerships for ND research and development.
- 2. Collaborate with other universities and consortia to develop more robust technology transfer metrics that better gauge access to public health goods and innovation in neglected-disease research.**

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<sup>5</sup> For example, the United States Orphan Drug Act could provide a legal basis for defining a set of neglected diseases.

<sup>6</sup> See <http://www.essentialmedicine.org/EAL.pdf>.

<sup>7</sup> Access-minded provisions include, but are not limited to: (1) facilitation of generic competition, (2) mandatory sublicensing clauses for LMI markets, (3) specific access milestones, and (4) agreements that reduce royalty payments from the licensee to the university in exchange for fair pricing in LMI markets on the part of the licensee.