



## **(I) Introduction**

University research is vital to the development of new medicines and health-technologies. Moreover, the core principles that guide universities – creating and disseminating knowledge for the public good – are well aligned with the goals of facilitating innovative research and ensuring global access to university-developed health technologies.

In the fall of 2006, the Philadelphia Consensus Statement on University Policies for Health-Related Innovations was launched and garnered the support of hundreds of luminaries in the fields of public health, science, law, and medicine. The statement calls on universities to ensure equal access to university research, promote research and development for neglected diseases, and measure research success according to impact on human welfare (Appendix I). The principles endorsed in the Philadelphia Consensus Statement guided our response to the Draft Global Strategy and Plan of Action.

## **(II) General Response**

The Draft Global Strategy and Plan of Action recognizes that there have been significant advances in biomedical science. To a large extent, these advances have been realized through research performed at universities and academic institutions. In order to effectively harness these advances so that they benefit the developing world, universities need to implement licensing strategies that ensure the unfettered transfer of university-developed innovations. The Draft Global Strategy and Plan of Action does not currently address the importance of these licensing strategies. Our response addresses this omission.

The Philadelphia Consensus Statement outlines three main intellectual property management strategies when university-owned intellectual property is necessary for the development of medicine or a health-related technology:

- Include licensing terms (1) in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in the developing world.
- Develop a transparent, case-by-case global access strategy to ensure access to health-related technologies (2). This is particularly important for biologicals, complex macromolecules and healthcare devices where generic production is not always possible.
- Carve out a type III disease research exemption for any patents held or licenses executed by the university.

We strongly recommend that all research universities adopt equitable access licensing strategies. In parallel, government funders of university research should move to condition grants on invoking these licensing strategies for publically funded technologies (3).

Below we respond to specific Elements with examples that may be used to move forward the Global Strategy and Plan of Action.

### **(III) Response to Element I: Prioritizing research and development needs**

- In reference to sub-element 1.2(a), universities must allow open-access to university-owned compound libraries to researchers from both the developed and developing world working on type II and type III diseases. Noting also sub-element 2.3(b), compounds from university libraries that are successfully developed into drugs must be made accessible through appropriate licensing mechanisms.
  - Pfizer, along with the Special Programme for Research and Training in Tropical Diseases of the WHO (WHO/TDR), has made a portion of its chemical compound library, the largest in the world, available to parasitologists in developing countries to identify novel anti-parasitics (4).
  - Universities can similarly make their chemical libraries available for high throughput screening for type II and III diseases, or at a minimum, work with pharmaceutical companies to broaden access to chemical libraries for specific diseases in a similar manner as described above.
- In response to sub-element 1.2(c), in order for developing country researchers to be active participants in the innovation process, it is essential that they have open-access to university research (5). We recommend that all research resulting from public funds, including scientific data and publications, be made freely available without delay.

### **Element 2: Promoting research and development**

- We recommend that developed country universities engage with nontraditional partners to create new opportunities for type II and III innovation and access.
  - To achieve this, 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 type II and III diseases.
  - Example interactions with nontraditional partners include: patent donation, dual-market licensing, and straightforward exclusive/non-exclusive licensing.
  - In order to maximize funding possibilities from nontraditional funders, universities should remove any barriers, such as intellectual property restrictions or excessive overhead costs, associated with non-government funding.
- In reference to sub-element 2.3(a), we emphasize the value and importance of "open source" research methods in drug development. Existing evidence suggests a significant role for free and open access to scientific literature and data in accelerating the research process. Rapid and effective dissemination of results helps the discovery process to "fail faster", with potential windfalls in time- and cost-efficiency.
  - Progress indicators, then, for "open source" research methods might seek to identify and enumerate the extent to which "open source" research is facilitated and undertaken.
- The progress indicators of "*No. of patents generated within developing countries*" and "*No. of patents held by developing country research and academic institution*" for sub-elements 1.3(c) and 2.3(c) respectively must go beyond just counting the number of patents and include access metrics. Access metrics are a set of

prescribed measurements or indicators that evaluate the technology transfer activities of universities by their global health impact (6). Impact can be quantified by secondary outcome measures defined by university policy and technology transfer licensing strategies. Current metrics evaluate academic institutions using economic indicators—the number of licenses and patents generated, the value of royalties and milestone fees, as well as the fiscal impact to the surrounding economy in the form of start up firms and equity. Such a framework encourages profits and patents over access-oriented licensing, resulting in licensing practices which are inconsistent with the public-service mission of public research institutions. Measuring and rewarding access-oriented licensing creates incentives for universities to pursue licensing mechanisms that promote global access to their technologies.

#### **(V) Response to Element 4: Transfer of technology**

- Transfer of technology that relates to type I disease should be prioritized at the same level as type II and III, as type I constitute a significant and growing disease burden (7).
- The recent announcement of technology transfer and joint development for a *Haemophilus influenzae* type b vaccine by the Netherlands Vaccine Institute with the Serum Institute of India should be seen as a model and encouraged to allow manufacturing of vaccines, medicines and health-related technologies in developing countries (8). This model could work especially well for university-developed innovations that have a market in both the developed and developing world. However, in order for such technology transfers to work without engaging in lengthy product-by-product negotiations, it is essential that universities include provisions in all licenses that allow university-developed technology to be transferred to and developed in developing countries. This model, featuring innovation and access provisions, constitutes a means to drive drug discoveries to pharmaceutical firms in the developing world.
- We support university participation in patent pools as an alternative licensing mechanism to ensure global affordable access to university-developed innovations.
- Access provisions included in university-issued licenses must be transparent and publicly available in order to monitor their impact and allow third-parties such as developing country research institutions and companies to take advantage of them.

For more information:

Universities Allied for Essential Medicine  
[www.essentialmedicine.org](http://www.essentialmedicine.org)

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## Notes

- (1) Access-minded provisions include, but are not limited to: (1) facilitation of generic competition by using for, example the Equitable Access License (Chaifetz S, Chokshi DA, Rajkumar R, Scales D and Benkler Y. Closing the access gap for health innovations: an open licensing proposal for universities. *Globalization and Health*. 2007; 3:1), (2) mandatory sublicensing clauses for low and middle-income markets, (3) specific access milestones, (4) agreements that reduce royalty payments from the licensee to the university in exchange for fair pricing or non-patenting in low- and middle-income markets on the part of the licensee.
- (2) Chokshi DA, Parker M, Kwiatkowski DP. Data sharing and intellectual property in a genomic epidemiology network: policies for large-scale research collaboration. *Bull World Health Organ*. 2006, 84(5): 382-7.
- (3) See recently introduced US legislation, *The Public Research in the Public Interest Act of 2006* (<http://thomas.loc.gov/cgi-bin/query/z?c109:S.4040>), as an example mechanism to condition public funding on the inclusion of equitable access provisions in licenses.
- (4) See [http://www.who.int/tdr/cd\\_publications/pdf/pfizer\\_release.pdf](http://www.who.int/tdr/cd_publications/pdf/pfizer_release.pdf).
- (5) A working definition of an open access publication can be found on the Public Library of Science website, <http://www.plos.org/oa/definition.html>.
- (6) For more information on access metrics, please contact the coordinators of the Access Metrics Initiative, Louis Fazen, Yale Medical School ([louis.fazen@yale.edu](mailto:louis.fazen@yale.edu)), or David Suk, University of Toronto ([david@dvsuk.net](mailto:david@dvsuk.net)).
- (7) See Disease Control Priorities Project, <http://www.dcp2.org/pubs/DCP>.
- (8) See Serum Institute of India obtains first ever Indian license for its Hib vaccine developed through technology transfer from the Netherlands Vaccine Institute, <http://hibaction.org/news/2007/05-03.php>.

## Appendix I

### 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

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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>.

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.

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**

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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>.

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>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.

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AIDS Law Project  
American Medical Student Association  
Canadian HIV/AIDS Legal Network  
Central and Eastern European Harm Reduction Network (CEEHRN)  
Community HIV/AIDS Mobilization Project (CHAMP)  
Development Research and Action Group (DRAG)  
Dignitas International  
Diverse Women For Diversity  
ENGAGE  
European AIDS Treatment Group, Brussels, Belgium  
Global AIDS Alliance  
Global Health Council  
Health GAP  
Initiative for Medicines, Access, and Knowledge (I-MAK)  
International Peoples Health Council (South Asia)  
Lawyers Collective HIV/AIDS Unit  
Oxfam International  
Partners in Health  
Research Foundation For Science Technology & Ecology  
Society for the Study of Social Problems  
Sociologists without Borders  
Southern Initiatives  
Stop HIV/AIDS in India Initiative  
Students Against Global AIDS  
Student Campaign for Child Survival  
Student Global AIDS Campaign