Appendix B

McGill University Medical School
Response to the Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property

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Contributors:
Timothy Brewer, Director, Global Health Programs. McGill University
Grey Matlashewski, Chairman, Microbiology and Immunology, McGill University
Mark Wainberg, Director of the McGill University AIDS Centre
Brett Schrewe, Medical Resident in Pediatrics, McGill University
Sandeep Kishore, Weill Cornell / The Rockefeller University / Sloan-Kettering Cancer Institute
Caroline Gallant, McGill University
Ethan Guillen. Executive Director, Universities Allied for Essential Medicine (UAEM)
Reena Pattani, Medical Student, McGill University
Caroline Skolnik, Medical Student, McGill University
Nicole Saba, Research Assistant, Global Health Programs. McGill University

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Executive Summary

The World Health Organization (WHO) should be strongly supported in their efforts to develop a global strategy and plan of action on public health, innovation and intellectual property to address health priorities in developing countries. Canada, and Canadian universities, need to be active, full participants in the research and capacity building efforts described in the draft. The McGill University Faculty of Medicine is committed to the broad goals and actions outlined in the Draft Strategy, yet recognize that the Draft is occasionally vague concerning the specific actions to be undertaken and the methods by which these actions should be brought about. To that end, we support the following actions at the international, national and local level as crucial steps towards creating sustainable, needs-driven research and development to address diseases that disproportionately affect developing countries.

WHO

- Recognizing the critical need for new research and research capacity, place a high priority on expanding basic healthcare and educational infrastructure in developing countries while maximizing existing technologies and therapies, in particular promoting strategies to limit the emergence of drug-resistance in treatments for human immunodeficiency virus, tuberculosis and malaria
- In conjunction with funding agencies, develop a mechanism for coordinating research activities and support to maximize efficiency
- Encourage the establishment of focused, multidisciplinary teams of experts in target diseases from developing and developed countries to assist with the identification of research gaps, program goals, and program evaluation
- Encourage the establishment of long-term funding mechanisms in developing and developed countries to build and support research infrastructures, programs and careers to investigate neglected diseases
- Promote strategies to retain healthcare workers, scientists and public health officials within developing country settings

Canada

- Expand support for research in neglected diseases through traditional project-based grants, career awards and broad-based capacity-building partnerships between Canadian and developing country universities
- Establish ethical recruiting practices for Canadian organizations hiring developing country healthcare workers
- Revise the Canadian Access to Medicines Regime to establish a fast-tracked, streamlined process to insure that essential medicines reach those who really need them in developing countries

Canadian Universities

- Waive institutional overhead charges, or accept only the funding agency reimbursement, on research grants investigating type II/III diseases in developing countries
- 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 while having in place mechanisms to protect the intellectual property rights
- Develop mechanisms for patent donation, dual-market and exclusive/non-exclusive licensing or royalty waivers involving research products that address type II/II diseases in developing countries
- Undertake licensing, patent and royalty strategies that allow university-developed technology to be transferred to and utilized in developing countries

To the extent, that advances in biomedical sciences have been realized through research performed at universities and academic institutions, universities need to implement licensing strategies to insure that

these advances benefit the developing world. The Draft Global Strategy and Plan of Action does not currently address the importance of these licensing strategies. The Philadelphia Consensus Statement outlined three main intellectual property management strategies for university-owned intellectual property necessary for the development of medicine or a health-related technology:

- Include licensing terms 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 particularly 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.

The Draft Strategy should encourage research universities to adopt equitable access licensing strategies for research products from grants for type II/III diseases in developing countries; government funding agencies of these university research should move to condition grants on invoking these licensing strategies for publicly funded technologies.

While the above actions are likely to advance the Global Strategy's aims, the probable costs of building and maintaining compound libraries in developing countries seems likely to far outweigh any medium term benefits to public health in these regions. We would not recommend pursuing this objective at the present time.

Finally, it should be recognized that even for type II/III diseases, substantial progress could be made through improvements in the health, public health, laboratory and educational infrastructures of developing countries and better utilization of existing technologies, treatments and expertise. There is often an overemphasis placed on seeking high technology solutions while neglecting basic infrastructure needs. A high priority should be placed on long-term funding to improve healthcare, public health and educational infrastructures in developing countries, and on increasing the availability of existing therapies, particularly for human immunodeficiency virus, tuberculosis and malaria while creating programs, policies and practices to prevent the emergence of drug-resistance.

(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, as well as the response from the Wellcome Trust (Appendix II), are included as references that guided our response to the Draft Global Strategy and Plan of Action.

(II) Specific Response

Element 1 - Prioritizing research and development needs

General Comment:

The aim of this proposed global strategy "is to provide a medium-term framework for an enhanced and sustainable basis for needs-driven, essential research and development relevant to diseases that disproportionately affect developing countries." However, it should be recognized that even for type II/III diseases, substantial progress could be made through improvements in the health, public health, laboratory and educational infrastructures of developing countries and with operations research to better utilize technologies, treatments and expertise that already exist. There is an overemphasis on seeking high technology solutions while neglecting basic infrastructure needs. For example, there is probably little public health or scientific value in establishing compound libraries in developing countries, as large compound libraries already exist and there are few data to support their role in leading to new treatments. A higher priority should be placed on increasing availability of existing therapies, particularly for human immunodeficiency virus, tuberculosis and malaria, while creating programs, policies and practices to prevent the emergence of drug-resistance. Another critical issue for both developed and developing countries is sustainability of researchers, public health officials, clinicians, microbiologists and others working in neglected areas, and long-term funding mechanisms to build and to support infrastructures, programs and careers to work in these areas need to be developed. Finally, it is essential that research priorities and development needs be identified and articulated by the populations most affected by these diseases, so that the programs address locally recognized issues of public health importance.

Specific Comments:

1.1 Identifying Gaps

WHO should support the development and ongoing interaction of multidisciplinary teams including epidemiologists, public health experts, clinicians, scientists social scientists and policy experts from developed and developing countries with intimate and complementary knowledge of priority diseases to identify gaps in knowledge. These teams also could play an important role in evaluating progress and reassessing goals over time.

1.2 Facilitating upstream research on new and existing products

Universities should 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 while having in place mechanisms to protect the intellectual property rights of individual researchers. It is essential that developing country researchers be active participants in the innovation process; however, their effective participation is dependent on having the intellectual and physical infrastructure in place to enable their

equal and active participation. Without sufficient infrastructure, it will not be possible for local communities to be the position to identify their own research priorities based on their own, independent needs assessments. In general, research results derived from public funding including publications should be made freely available with minimal or no delay.

1.3 Coordinating research activities between developed and developing countries

Given the limited resources, coordinating research activities between developing countries and developed countries and building local capacity are imperative. Increasing coordination and capacity building would be encouraged through the establishment of broadly based sustainable partnerships between universities (North-South, South-South and North-North).

Element 2 - Promoting research and development

General Comments:

WHO, the Canadian Government and McGill University should all undertake specific steps to promote research on neglected diseases. At the national level, the Canadian Government needs to maintain and expand support for research through such mechanisms as the Canadian Institutes of Health Research, the Canadian Foundation for Innovation and the Canadian Research Chairs programs. These programs have been very effective in building national research capacity, though past gains may be threatened by current levels of funding. Within these programs, more resources should be directed for type II/III diseases as well as type I diseases in developing country settings. Canada should honor its commitment to donate 0.7% of its GDP to poverty reduction, which may be done in part through support for research in developing countries.

At the university level, McGill needs to streamline and simplify administrative oversight of research projects overall and improve internal capacity to support investigators to apply for national and international funding. For grants involving type II/II diseases in developing countries, the University should waive the overhead costs or require only the overhead reimbursement provided by the funding organization. For example, McGill required a 40% overhead for a Drugs for Neglected Diseases Initiative grant awarded to fund a clinical leishmaniasis treatment trial in Peru that Prof. Matlashewski was the principal investigator on. The end result was that no funding came through McGill, and Prof. Matlashewski was unable to undertake studies for better diagnostics for this neglected disease. At the research results end, universities should develop mechanisms for patent donation, dual-market and exclusive/non-exclusive licensing or royalty waivers involving products to address type II/II diseases in developing countries. Universities need to be at forefront of promoting research and access to the benefits of research, not inhibiting them. McGill has the opportunity to take a national and international leadership role by revising it overhead and royalty rules.

WHO, Canada and universities need to promote novel ways and partners to identify funding for research and to promote innovation. At the country level, France has adopted a policy of using a small fee on airline tickets to support research and development in neglected tropical diseases. Universities should engage with nontraditional partners (e.g., public-private partnerships, grant making organizations, nonprofits, and developing-world companies or research institutions) to create new opportunities for type II and III research innovation and access. As novel funding and innovation mechanisms are developed, they should be publicized and promoted for others to emulate.

Specific Comments:

2.3 Promoting upstream research and product development in developing countries

It is important to support and expand "open source" research methods in drug development. Existing evidence suggests that free and open access to scientific literature may accelerate 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 for "open source" research methods could enumerate the extent to which "open source" research is facilitated and undertaken.

University compound libraries should be made available for high throughput screening for type II and III diseases through public-private partnerships or other mechanisms that insure that successfully identified drugs are made accessible in developing countries through appropriate licensing mechanisms. Besides promoting basic and applied research, it is necessary to recognize the need to expand allied humanities and social science research in developing countries.

It is important to understand what the correct outcome measures should be when evaluating the success of efforts to promote research and product development. The progress indicators must go beyond just counting the number of patents generated within developing countries or the number of patents held by developing country research and academic institutions to include measurements or indicators that evaluate the technology transfer activities of universities and their impact on global health. Metrics that rely on economic indicators—the number of licenses and patents generated, the value of royalties and milestone fees—may encourage profits and patents over access-oriented licensing, resulting in licensing practices that 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.

Element 3 - Building and improving innovative capacity

General Comments:

As mentioned, capacity-building needs to be both a high priority and a long-term investment. In building capacity, it is important to recognize and support local knowledge and expertise that already exist, and to find ways to bridge Western and Traditional health knowledge so that developing communities may more effectively harness their existing capacities and strengths and better understand the health-promoting behaviors of individuals and groups. It is not sufficient to train individuals in developing countries; strategies to retain healthcare workers, scientists and public health officials within developing country settings need to be established together with ethical recruiting practices by organizations within developed nations. Canada can have a leadership role to play in both of these aspects, by encouraging successful retention strategies in developing nations and by adopting ethical recruitment policies domestically. Mechanisms also need to be developed by governments, foundations and other funding agencies to support broad-based university North-South, South-South and North-North partnerships in addition to traditional, project-specific grants. The Canadian Teasdale-Corti program is an important example of the type of program support needed.

Element 4 - Transfer of technology

General Comments:

Existing international agreements and mechanisms need to be better utilized to improve the transfer of technology to developing countries. Because type I diseases account for substantial morbidity and mortality in developing as well as developed countries, technology transfers should not be limited to types II and III disease. Partnerships that lead to technology transfer, such as the recent announcement for the joint development of a *Haemophilus influenzae* type b vaccine between the Netherlands Vaccine Institute and the Serum Institute of India, should be encouraged. This approach should 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 undertake licensing, patent and royalty strategies that allow university-developed technology to be transferred to and utilized in developing countries. Access provisions included in university-issued licenses should 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.

Though mentioned earlier, it is important to consider the role of open-source mechanisms as a means of promoting technology transfer. These mechanisms can play an integral role in promoting knowledge parity between the developed and developing worlds, especially at the university level, and should be mentioned explicitly. Finally, non-profit pharmaceutical partnerships can be important ways by which to promote innovation and technology transfer particularly for neglected diseases.

Element 5 - Management of Intellectual Property

General Comments

Expanding the capacity of developing countries to recognize and protect the intellectual property of their researchers is a clear need. National databases of patent status also would be valuable. There is a need for innovative incentives for pharmaceutical research and development in treatment for neglected diseases; however, incentive schemes must be created in such a way as to promote access to technologies, information and products in developing countries at affordable prices. As well, in order for these schemes to be sustainable and effective, they cannot simply rely on donations or future commitments. Advance-market commitments may be a viable strategy of encouraging needed research and development in neglected diseases, but need to be developed in ways that protect an investigator's intellectual property while providing equitable and expedient access in developing countries to the technologies and medicines developed under such schemes. Strategies that reinforce the existing patent system may potentially be counterproductive to making research and research products accessible in developing countries. Developed countries with well-established generic drug industries should take a more proactive role in producing and procuring generic drugs for use in the developing world. WHO and universities should partner with legal experts in intellectual property and trade to identify better ways to procure generic drugs and differential pricing for Type II / III diseases in developing countries.

Element 6 - Improving Delivery and Access

General Comments

Drug pricing in developing countries should be structured to accurately reflect a government's ability to provide medications to its citizens, and governments should not be dissuaded from implementing sound public health policies because of pricing systems that disproportionately disfavor the developing world. While all countries should have the capacity to monitor quality, safety and efficacy of healthcare products within their jurisdictions, it is not clear that all countries need to be able to produce some or most essential drugs. Making new technologies, particularly vaccines and life-saving treatments, affordable in high-burden developing countries remains a substantial public health challenge. WHO should lead the global response to specifically address this issue.

Specific Comments

6.3d Promoting competition and ensuring that pricing of medicines is consistent with public health policies

Canada can be a leader in encouraging the compulsory licensing legislation mentioned in this section. Canada has already passed the Canadian Access to Medicines Regime (CAMR); however, it remains to be seen if the legislation will be effective. Canada must prioritize making CAMR work. Ensuring the effectiveness of CAMR is a simple and immediate contribution that Canada can make to contribute to achieving progress in this area. However, it is not enough for legislation to be enacted. The Canadian experience has shown that for such legislation to be effective, developing countries must know that they can make use of its provisions. Furthermore, the mechanisms for making essential medicines available must have a fast-tracked, streamlined process. Success should be measured by the numbers of drugs that reach people who need those drugs via the legislation.

Legislation enabling access to essential medicines by other countries is consistent with the Doha Declaration on the TRIPS Agreement and public health. The Agreement states that a country may make a notification to import drugs in cases of: "a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." WTO members have the right to determine what constitutes "national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency". More importantly, the declaration provides that "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the fullest, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."

Element 7 - Sustainable Financing Mechanisms

General Comments

Sustainable financing of research and development for the health needs of developing countries are crucial to the success of any of the objects listed in this WHO Draft Strategy. Public-private partnerships should be actively pursued, but not to the exclusion of other approaches. It is not clear that public-private partnerships are the only or most cost-effective mechanism for developing and delivering needed healthcare products to developing country populations.

Element 8 - Establishing monitoring and reporting systems.

General Comments

A monitoring system is needed, though action places lack sufficient details to know what the appropriate system should be. There is also a need for clearly-expressed guidelines on creating structures to promote effective and accountable administrative structures; this point could be added to sub-element 8.1.

Appendix I
Philadelphia Consensus Statement On University Policies for Health-Related Innovations

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.[1] 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.

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

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)[2] is one example of a model license promoting access to university intellectual property in which all qualified entities[3] are permitted to supply the product to public and private sector markets in low- and middle-income (LMI) countries.[4]

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,

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[1] See Article 25, Universal Declaration of Human Rights.
[2] See http://www.essentialmedicine.org/EAL.pdf.
[3] Qualified entities include, but are not limited to, public or private generic manufacturers registered in the country of production.
[4] 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.

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

Adopt policies promoting in-house ND research. Universities should (a) adopt a classification system defining and prioritizing neglected diseases[5]; (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.

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.[6] 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.

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

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

[5] For example, the United States Orphan Drug Act could provide a legal basis for defining a set of neglected diseases.
[6] See http://www.essentialmedicine.org/EAL.pdf.

known the number of licensing agreements that include access-minded provisions[7] as well as details of nontraditional partnerships for ND research and development.

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.

[7] 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.

Appendix II
Response by the Wellcome Trust

wellcome trust

WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property: Draft Global Strategy and Plan of Action

Comments by the Wellcome Trust

September 2007

Introduction

1. The Wellcome Trust is pleased to have this opportunity to comment on the WHO Intergovernmental Working Group's (IGWG) Draft Global Strategy and Plan of Action on public health, innovation and intellectual property. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.

2. The Trust devotes a substantial portion of its funding to research on health problems that disproportionately affect developing countries. We agree that there is an urgent need for global cooperation to enhance the development of, and access to, health products for these countries. We commend the WHO and the IGWG for taking on the task of creating a strategy to achieve this. However, the current draft must be made more focused and more specific if it is to provide a workable framework for action. Below we have elaborated on four issues that we consider essential for the IGWG to address:
   - Sustainable funding for product development public private partnerships (PDPs);
   - Coordination and increased funding for health research capacity strengthening;
   - Prioritising global R&D needs for neglected health products and sharing information on who is filling those needs; and
   - Management of publicly funded IP to promote its application to developing country needs.

Sustainable funding for product development public private partnerships (PDPs)

3. The strategy and plan of action needs to include long-term commitments from national and multilateral donors to increase funding for PDPs. The PDP model has proven very effective at combining the strengths of R&D capacity in the public and private sectors, in the North and the South.[1] A strong array of PDPs will be one of the best ways of taking forward the development of new products for low income markets.

4. There is now a real deficit in funding the PDPs as they move into large-scale clinical trials. Furthermore, with about half of PDP funding coming from just one source (the Gates Foundation) there is an urgent need to diversify their funding base. Ideally, national and multilateral donors who currently do not play a major role in this area could commit during the IGWG negotiation process to provide more funding.

[1] As demonstrated in Mary Moran et. al. (2005) "The New Landscape of Neglected Disease Drug Development" http://www.wellcome.ac.uk/assets/wtx026592.pdf

5. Some pharmaceutical companies are to be applauded for their in-kind support to PDPs but it is important to foster strong commitments from more companies. WHO may be able to catalyse this through more engagement with the industry leaders and industry associations, and by convening pharmaceutical companies, funders and PDPs.

6. To deliver top quality PDP clinical trials in developing countries, more training of individuals and more funding for developing country clinical trial sites must be provided. The INDEPTH network currently provides an important base for malaria trials but more clinical trials infrastructure is required. There is also a crucial need to provide career pathways for key individuals involved in clinical trials – including between trials – otherwise teams are lost and expertise dissipates. Personnel exchanges between PDPs and pharmaceutical companies could be key tools in this type of capacity building.

Coordination and increased funding for health research capacity strengthening

7. Donors and research institutions in the South and North should coordinate their efforts to strengthen health research capacity. We believe that there is a particular need to strengthen the ability of African research institutions to build their capacity. In April 2007, the Trust sponsored a meeting in Kilifi, Kenya to convene leaders of African research institutions and funders to discuss how the groups could better collaborate to achieve this aim. Some recommendations that came out of the meeting were:

   - Health *service* capacity strengthening is often a prerequisite to health *research* capacity strengthening, because academic medical centres can otherwise be overwhelmed by the need to provide health services and be unable to find time for research;
   - In supporting health research capacity in the UK and developing countries, the Trust takes the approach of developing people and supporting them throughout their careers. This is no less important in building and sustaining research capacity in developing countries. It needs to start early, with well-trained school teachers, strong school science education and research experience opportunities for undergraduates. For those who go on to a PhD, there must be job opportunities at different levels of seniority, with some degree of competition but not to the extent that good scientists are forced to abandon a research career due to lack of job opportunities. To avoid "brain drain", internationally competitive researchers must be given adequate opportunities and incentives to remain in, or to return to, their home countries. Girls and women need to be recruited and encouraged into this pipeline from the beginning.
   - Supporting senior scientists should be a priority, in order to strengthen the cadre of leaders and role models. This can be done by nurturing junior researchers, attracting senior scientists back from abroad, and nurturing those already in post.
   - Research institutions need support for organisational and management processes.
   - Northern institutions should be encouraged to establish long-term partnerships with institutions in the South, rather than short term projects or visits. South-South partnerships should also be encouraged and supported. Southern institutions need support to build negotiation skills so that they can more effectively negotiate with funders and Northern partners.

Prioritising global R&D needs for neglected health products and sharing information on who is filling those needs

8. The WHO should convene health experts from the South and North to prioritise health problems of developing countries that are in need of better technical solutions. The 14 conditions identified in the draft strategy are a good starting point – we are especially pleased to see the attention to type I, type II and type III diseases – but the prioritisation of health

problems must be explicitly supported by evidence, and must be able to change according to the evolving understanding of global needs. For example, the need for developing country-specific research on chronic diseases has been recognised only relatively recently, and new infectious agents are continually evolving. Likewise, research priorities must be able to change based on the progress of R&D for specific health conditions: as the basic understanding of diseases advances, R&D priorities must be able to take advantage of new opportunities, or abandon dead ends.

9. The WHO should also provide a forum for research sponsors in the public sector and the private sector to share information on what R&D they are supporting that has relevance to priority health problems. Even within the public sectors in individual countries, research funders are still working out the best ways to coordinate their activities to achieve common goals. In the UK, the newly established UK Collaborative on Development Sciences is bringing together the key government and philanthropic research funders, including the Wellcome Trust, to coordinate support for research that directly or indirectly relates to international development. Progress on coordinating public sector activity on a global scale is still far behind where it needs to be.

10. Engaging the private sector in this process will be more of a challenge, due to the need to protect commercially sensitive information. Information sharing arrangements for industry partners will need to be designed to respect these requirements.

Management of publicly funded IP to promote its application to developing country needs

11. Universities and public sector research institutes, with encouragement from public and charitable research funders, should take IP management decisions with a view to maximising opportunities for the inventions to be used to benefit poor populations in developing countries. When licensing IP to commercial partners, this may mean including terms that preserve access to the technologies to address needs of developing countries, particularly if the primary licensee does not intend to serve those markets. The IGWG strategy should encourage these practices.

12. Oftentimes, IP that could be developed to serve neglected health conditions does not attract interest from commercial licensees or investors. Therefore, what is required is a commitment from technology transfer offices at universities or public research institutes to invest time and effort to seek other translation opportunities for these inventions. This may involve making contact with PDPs or other non-commercial partners, or identifying public or charitable sources of translational funding to further develop the technology. Doing this requires university leaders and technology transfer offices to be committed to translating research results to produce global public benefit, rather than narrowly focusing on translation as a means to achieve financial returns.

13. In some countries, including the UK, there is currently a lack of clarity on whether the driving force of a university technology transfer should be making money for the university, or exploiting technology for societal benefit in line with the university's charitable mission. Governments and research funders need to make it clear that the function of technology transfer in public institutions is to deliver the benefits of technology to the global public.

ADDITIONAL REFERENCES

(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.

(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), or David Suk, University of Toronto (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.