GLOBAL HEALTH COMMENTARY

The Global Access Initiative at The University of British Columbia (UBC): Availability of UBC Discoveries and Technologies to the Developing World

KISHOR M. WASAN,[1]* SHEILA J. THORNTON,[1] IAN BELL,[2] REBECCA E. GOULDING,[3] MICHAEL GRETES,[3] ANDREW P. GRAY,[3] ROBERT E.W. HANCOCK,[4] BARBARA CAMPBELL[5]

[1]The University of British Columbia, Faculty of Pharmaceutical Sciences, Division of Pharmaceutics and Biopharmaceutics, 2146 East Mall, Vancouver, B.C., Canada V6T 123

[2]The University of British Columbia, University Industrial Liaison Office, Vancouver, Canada V6T 123

[3]The University of British Columbia Universities Allied for Essential Medicines Chapter, Vancouver, Canada V6T 123

[4]The University of British Columbia, Department of Microbiology and Immunology, Vancouver, Canada V6T 123

[5]Dalhousie University, Halifax, NS, Canada

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ABSTRACT: The University of British Columbia (UBC) became the first university in Canada to develop a strategy for enhancing global access to its technologies. UBC's University-Industry Liaison Office, in collaboration with the UBC chapter of Universities Allied for Essential Medicines (UAEM), established a mandate and developed principles that provide the developing world with access to UBC technologies. This commentary will discuss these principles and provide examples of where they have been applied to several UBC technologies. © 2008 Wiley-Liss, Inc. and the American Pharmacists Association J Pharm Sci 98:791–794, 2009

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In 2007, The University of British Columbia (UBC) became the first university in Canada to develop a strategy for enhancing global access to its technologies.[1] UBC's University-Industry Liaison Office, in collaboration with the UBC chapter of the Universities Allied for Essential Medicines (UAEM)[2,3] established a mandate and developed principles that provide the developing world with access to UBC technologies.

In order for UBC to maximize the societal impact of its technologies within the ever-changing framework of licensing practices, legal concerns, business opportunities and time constraints, a practical set of strategies was required in order to retain the economic potential of University innovations to ensure their development while at the same time enhancing their social benefit by ensuring fair and affordable access for developing countries.

Broadening the societal impact and global availability of UBC technologies requires that these

*Distinguished University Scholar Professor & Chair.
Correspondence to: Kishor M. Wasan (Telephone: 604-822-4889; Fax: 604-822-3035; E-mail: kwasan@interchange.ubc.ca)

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concerns be addressed when novel UBC technologies are developed, patented and licensed. Thus, UBC established the following set of principles, which are consistent with the University's intellectual property policy regarding commercialization:

- Promote global access by entering public/private partnerships to develop new technologies to benefit the developing world;
- Prioritize environmentally friendly research and green alternatives, and take the lead in community sustainability;
- Respect biodiversity, ensuring value return to countries of origin;
- Endeavour to provide underprivileged populations with 'at cost' access to UBC research innovations through negotiated global access licensing terms whenever appropriate.
- Try to maintain the value of the technology and promote its development by permitting freedom to exploit it for profit in the wealthy industrialized nations.

As the understanding of issues relating to social licensing evolves, balancing ambitious objectives with legitimate business concerns requires patience, determination, and the willingness of all parties to be both pragmatic and flexible. To support its social licensing commitment, the newly adopted global access principles state that UBC will, wherever possible, employ the following strategies:[1]

- Build on the values of access and dissemination as demonstrated in the open source movement in the information technology sector;
- Promote the use of non-exclusive licensing of research tools;
- Consider field-of-use and jurisdictional limitations in exclusive licenses to retain rights for developing world countries;
- Negotiate developing world access 'at cost' to relevant technologies that are licensed on a world-wide exclusive basis (a common requirement for technology development);
- Continue to seek partnerships with not-for-profit and charitable organizations to provide much needed funding for neglected disease areas (i.e. Bill & Melinda Gates Foundation; Drugs for Neglected Diseases Institute (DNDi) etc.); and
- Design patent strategies with our development partners that ensure quality product delivery to those most in need, while promoting sustainable, local infrastructure.

Table 1. Universities Allied for Essential Medicines (UAEM)

Who is UAEM:
UAEM is a coalition of students and faculty at about 25 research universities across North America.
UAEM's goals is to improve access to medicines in poor countries through university action.
What UAEM Does:
UAEM's activities take place at both the chapter level and the international level.
At the chapter level, UAEM petition for changes in the policies and practices at its members' universities. An example of this is the initiative at UBC (www.uilo.ubc.ca/global.asp)
At the international level, UAEM convenes groups of students-in consultation with faculty members and other experts-to determine how best to improve access to medicines in poor countries through research and policy analysis. For example, a consensus UAEM Policy Statement was released in October 2005 after a meeting at Georgetown University (Washington, D.C., USA) that brought together more than 75 students representing 28 universities (see http://www.essentialmedicine.org/oct2005policystatement.pdf).
How You Can Get Involved:
Join UAEM through their web site (http://www.essentialmedicine.org)
Determine what steps your university currently is taking to ensure access to its innovations in poor countries by talking to faculty members, technology transfer officers, and administrators who set the university research agenda.
Learn more about the access and research gaps through organizations such as Medecins Sans Frontieres (http://www.accessmed.msf.org) and build awareness on your own campus.

Modified from Reference #2; Chokshi 2006.

In measuring the success of technology transfer activities at UBC, social impact has become a key metric alongside standard throughput, financial and economic measurements. Positive social impacts include improving human and animal health, supporting international biodiversity, protection of the environment, and promoting sustainable green alternatives.

A key factor in the development and acceptance of these principles was the establishment of a Universities Allied for Essential Medicines (UAEM) chapter at UBC in 2005. UAEM (Tab. 1) is an alliance of students and faculty

from universities around the globe that advocate for an increase in both access to existing medicines and research on neglected diseases at academic research institutions.[2] UAEM works with student and faculty groups across North America and Europe in a coordinated effort to improve the research, licensing and patenting decisions of universities. They assemble teams of experts in matters of pharmaceutical research and development, intellectual property, technology transfer, and healthcare delivery in resource-poor settings, in order to construct creative new approaches to improve the development and delivery of public health goods. UAEM has convened several teams of experts to develop licensing language and policy documents that universities can use to enhance their efficacy in improving global public health. The UBC chapter is actively campaigning along two lines;[3] (a) to push universities to ensure that biomedical end products, such as drugs, developed in campus labs are mode accessible and affordable in developing countries, and (b) to facilitate and promote research on neglected diseases, which are diseases predominantly affecting people who are too poor to constitute a market attractive to private-sector research and development investment.

One example of a current global access project at UBC is in the laboratory of Dr. Kishor M. Wasan. The development of a lipid-based amphotericin B formulation for oral administration is currently underway, and has significant implications for treatment of a number of disease states, including systemic fungal infections and kinetoplastid parasitic infections.[4–6] The traditional formulation of Amphotericin B (Fungizone®, a colloidal suspension) requires a treatment regime of parenteral administration ranging from 5 to 40 days, and is associated with infusion and drug-related side-effects (infection of the indwelling catheter, patient chills and shaking due to RBC haemolysis, dose-dependent renal toxicity, fever, bone pain, thrombophlebitis).[7] Although lipid-based second-generation formulations (Abelcet® and AmBisome®) already exist and permit a shorter course of therapy (3–5 days), are highly effective and exhibit lower toxicity when compared to Fungizone®, the cost of these formulations is a barrier to widespread use.[7,8]

Initial data from both cell lines and *in vivo* research indicate that the oral formulation is highly efficacious and exhibits low toxicity within the dosage range required in order to treat diseases such as disseminated fungal infections

Figure 1. Worldwide distribution of visceral leishmaniasis. World Health Organization, Special Programme for Research and Training in Tropical Diseases (WHO/TDR) 2004.

and leishmaniasis.[4–6] This has significant implications in developed nations, where the rates of opportunistic fungal infections such as candidiasis, histoplasmosis and aspergillosis are climbing, particularly within patient populations affected by cancer, organ transplant recipients, diabetics and HIV/AIDS.

In developing countries, access to an oral formulation of Amphotericin B could dramatically increase patient access to treatment and significantly reduce mortality associated with visceral leishmaniasis, a deadly parasitic disease that claims over 60,000 lives annually[7–10] (Fig. 1). Each year in the Indian subcontinent alone, over 500,000 individuals play host to *Leishmania donovani*, an insidious parasite that invades macrophages, rapidly infiltrates the vital organs and ultimately leads to severe infection of the visceral reticuloendothelial system. Visceral leishmaniasis, also known as Kala-azar, is most prevalent in the weak and the young within a population.[7,9,10] Left untreated, almost all infected individuals will die.[8–10] Visceral leishmaniasis is transmitted by the bite of an infected sand fly and affects over 200 million people from 62 countries. The current therapeutic arsenal against *Leishmania* is limited to a small number of parenterally administered agents, with daily injections of pentavalent antimony compound for 28 days being the usual course of action.[7] Due to increasing resistance, antimonial drugs can no longer be used in many areas, including north-eastern India where the incidence of Kala-azar is highest. Amphotericin B is the current secondary treatment of choice against leishmaniasis and has a 97% cure rate with no reported resistance.[8]

However, the parenteral route of administration and significant renal toxicity are considered significant barriers to treatment.

The development of an effective, safe and inexpensive oral formulation of amphotericin B would have significant applications for the treatment of disseminated fungal infections in developed countries and, if made affordable, would dramatically expand access to treatment of visceral leishmaniasis by introducing a readily available highly tolerated oral formulation of a drug with known efficacy.

In May 2008, UBC announced its first technology licensing agreement using its newly implemented global access principles. Vancouver-based iCo Therapeutics Inc. was granted the exclusive right to commercialize the Wasan laboratory's oral formulation of the drug Amphotericin B. In return for the worldwide right to develop and sell this oral amphotericin B formulation in the developed world as a treatment for blood-borne fungal infections, iCo Therapeutics has agreed to ensure the availability and accessibility of a suitable formulation to countries in the developing world to treat leishmaniasis.

Examples of two global access initiatives at UBC, one of which is led by Dr. Brett Finlay and both of which include as a key participant, Dr. Robert Hancock, for which UBC received Grand Challenges in Global Health grants from the Foundation for National Institutes of Health and the Bill and Melinda Gates Foundation.[1] Projects receiving these grants have pre-defined global access strategies in place, with the aim of developing essential medicines for the developing world. The UBC-led project explores ways in which the body can boost its own immune system to fight infection, particularly in relation to drug-resistant superbugs. As part of this global project a UBC spin-off company, Inimex pharmaceutical, agreed to provide one of its candidate drugs under the terms of the global access strategy.

In addition, UBC has an agreement with the University of Papua New Guinea to share revenues from discoveries made using Papuan New Guinean marine products, relating to Earth and Ocean Sciences Professor Ray Andersen's research into new therapies from natural products. Revenues will support the country's exchange and education programs and marine conservation activities.

As we close the gap between accessiblity and affordablity of existing medicines to the developed and developing world, universities are well positioned to make a difference. University scientists are major contributors to the drug development pipeline. At the same time, universities have a fundamental commitment and moral responsibility to advancing the public good. As members of the university community, it is our responsibility to hold them to this commitment.

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