The following article is an updated version of a poster presented at the HUGO Human Genome Meeting, held in Cancun, Mexico, April 27-30, 2003.

Abstract

It appears that large-scale population genetic studies are the necessary next step in genomics research. Such studies promise to provide correlative data to permit researchers to understand the etiology of a vast array of complex human diseases. Simultaneously, such studies are increasingly seen as yet another mechanism for the developed world to benefit at the expense of the developing world. In fact, a recent World Health Organization Report suggests that “without explicit attention at the international level, the initial technological fruits of genomics are likely to consist primarily of therapeutic and diagnostic applications for conditions affecting large populations in rich countries.” (World Health Organization, Genomics and World Health, 2002). In developed and developing countries alike, there are concerns that the pharmaceutical industry stands to gain at the expense of the population(s) from which population genetic data are derived. In light of the current interest concerning ongoing population genetic studies and an increasing interest by many countries, Canada included, in embarking on large-scale population genetic research, it is appropriate to consider the concept of benefit-sharing as a potential mechanism to assuage these concerns. It is this author’s position that by virtue of common law equitable principles and developing norms in international law, including the Human Genome Organization Statement on Benefit-Sharing, that there are principled legal and ethical reasons to compel the sharing of benefits that accrue from the commercialization of the resulting data. Using the United Nations Convention on Biological Diversity and the Bonn Guidelines as a model, I suggest that appropriate benefit-sharing mechanisms have been considered in the context of non-human biological materials and that these same mechanisms may be applicable in the context of international and intra-national population genetic studies.

Healthcare: An International Concern

- The International Community can no longer ignore the human health needs of the developing world.
- Increasingly, obligations are seen to be owed by the developed world to the developing world.
- Global pharma industry and HIV/AIDS crisis in Africa.

“Benefit” Defined

- A good that contributes to the well-being of an individual or a community
- It is more than the avoidance of harm and is not identical with economic profit
- Dependant on needs, values, priorities, and cultural expectations of society

Benefit-Sharing Mechanisms may Include:

“[A]greements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or of information infrastructures, reimbursement of costs, or the possible use of a percentage of any royalties for humanitarian purposes.” (HUGO, 2000)
“Common Heritage of Mankind” Defined

- International law concept
- Based on the notion that Humanity has vital interest in certain natural resources
- The benefits and burdens associated with exploitation or preservation of such resources ought to be shared by all
- See, for example, conventions on air & sea. (Kemal Baslar, *The Concept of the Common Heritage of Mankind*, 1998.)

A Legal and Ethical Requirement for Benefit-Sharing?

Relevant international instruments include:

- International Convention on Economic, Social and Cultural Rights (ICESCR)
- UN, Convention on Biological Diversity (CBD) & Bonn Guidelines on Benefit-Sharing
- UNESCO, Universal Declaration on the Human Genome and Human Rights
- HUGO Ethics Committee, Statement on Benefit-Sharing
- WTO, Declaration on the TRIPS Agreement & Public Health
- WTO Agreement on Generic Medicine
- UNESCO International Declaration on Human Genetic Data

ICESCR, Article 1(2)

“All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic co-operation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.”

UN Convention on Biological Diversity (CBD)

- Biological diversity is a “common concern of humankind” (preamble)
- Not applicable to human genetic material (see, Bonn Guidelines, para 9)
- State sovereignty over genetic resources is recognized
- Members are obliged to facilitate access to genetic resources for environmentally sound uses
- Prior informed consent required

CBD, Article 15(7)

- Results of research and development and the benefits arising from the commercial and other utilization of genetic resources must be shared with the source party
- Agreement re benefit-sharing on “mutually agreed terms”
- Bonn Guidelines expand on this nascent requirement of benefit-sharing

The Bonn Guidelines

Purpose

- to assist states in developing overall access and benefit-sharing strategies to promote the conservation and sustainable use of biological diversity, and
- to identify the steps involved in the process of obtaining access to genetic resources and the sharing of benefits

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<tr>
<th>Monetary Benefits</th>
<th>Non-Monetary Benefits</th>
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<td>Royalties</td>
<td>Capacity building</td>
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<td>License fees</td>
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Mixed-type Benefits

- Research funding
- Joint ventures
- Joint ownership of IPRs

Universal Declaration on the Human Genome and Human Rights

- Article 1: The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.
- Article 12: Benefits from biomedical research shall be made available to all, with due regard to the dignity and human rights of each individual.

HUGO Statement on Benefit Sharing

Recommends that:

- All humanity share in, and have access to, the benefits of genetic research
- Benefits not be limited to those individuals who participated in such research
- Even in the absence of monetary profit, immediate health benefits, as determined by community needs, could be provided
At a minimum, all research participants should receive information about general research outcomes and an indication of appreciation.

Profit making entities dedicate a percentage (e.g. 1-3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

**UNESCO International Declaration on Human Genetic Data**

> “Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared by the society as a whole and the international community.”

### WTO: DOHA Statement on the TRIPs Agreement and Public Health

- The TRIPS Agreement does not and should not prevent members from taking measures to protect public health.
- 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.

(WTO Declaration on the TRIPS Agreement & Public Health, November 14, 2001.)

### WTO Agreement on Generic Medicine

- The WTO Member States reached a historic agreement that will make it easier for poorer countries to access generic drugs made under compulsory licenses.

(WTO Declaration on the Implementation of Paragraph 6 of the DOHA Declaration, 30 August 2002.)

### Conclusions

- There is a well-formed ethical imperative to share the benefits of population genetic research with the populations from whom the samples are obtained; there is evidence of an emerging legal requirement to do the same. The field of genomics can and should be the exemplar to highlight the potential benefits of globalization.
- In the words of Herold Varmus “science is both possible and valuable in all economies and that science can be a means to help unify the world’s population under a banner of enlightenment, demonstrating a virtue of globalization.” (H. Varmus, “Genomic empowerment, the importance of public databases,” Nature Genetics, suppl., September 2002.)

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**Articles for Submission**

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**Deadlines:**
- February 15, August 15, October 15, 2004
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