

DNA FOR PEACE

Reconciling Biodevelopment and Biosecurity



Canadian Program
on Genomics and
Global Health

*Harnessing genomics to improve
global health equity*



University of Toronto
Joint Centre for Bioethics



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Executive Summary

Biodevelopment, the use of biological sciences and technology to fight disease, hunger, pollution and poverty, has enormous potential to help the world deliver on promises to improve living conditions for the poor.

Unfortunately, some of the technologies used to produce useful biological materials can also be used to produce bioweapons. The wave of terrorism in recent years has raised concerns of attacks using such deadly illnesses as anthrax, smallpox, botulism and plague. Even more dangerous weapons may be developed in the future.

As a result of these threats, there is a risk that attempts to increase biosecurity and prevent bioterrorism could sideswipe legitimate uses of biotechnologies to improve global health and living conditions.

Based on their expertise in biotechnology and ethics, the authors of this report call for international cooperation to ensure that the struggle against bioterrorism does not undermine biodevelopment, especially in the developing world. They say that promoting the good uses of biotechnology will actually help fight bioterrorism by building a global network of experts who can spot attempts to misuse the science. They call on world leaders at the G8 meeting this July to establish a global network help resolve potential conflicts between bioterrorism control and biotechnology development.

There is an urgent need to use modern biological sciences for global development goals. Inequities between industrialized and developing countries are among the greatest ethical challenges of our time. One-fifth of the world lives in poverty, without adequate housing, food, clean drinking water, sanitation and health care. Every year, millions die early as a result, many of them children.

Biotechnology has enormous potential to improve life for hundreds of millions of people, using such approaches as: molecular diagnostics, recombinant drugs, new drug and vaccine delivery systems, bioremediation to clean up pollution, sequencing pathogen genomes to find disease controls, female-controlled protection against sexually-transmitted diseases, bioinformatics, nutritionally enriched genetically modified crops and combinatorial chemistry. These technologies can also promote the UN Millennium Development Goals.

To help shape this report, the Canadian Program on Genomics and Global Health at the University of Toronto Joint Centre for Bioethics organized a two-day workshop, *The Global Bargain for Biosecurity*, at the New York Academy of Sciences in November 2005. This meeting brought together 28 international experts to explore links between biodevelopment and biosecurity from the viewpoint of human security in the fields of disease, hunger, environment, poverty and bioterrorism.

The authors of this report call on the world to move swiftly to find a suitable balance between biosecurity and biodevelopment. The authors make a number of key findings and recommendations:

- 1. The world must not let legitimate concerns about biosecurity undermine the promotion and use of biotechnologies for human development.**
- 2. We need to invest in positive applications of biological sciences in the developing world in order to protect against the misuse of these sciences for harmful purposes.**
- 3. We recommend a model of global governance that will achieve a balance between the potentially competing agendas of biosecurity and biodevelopment. This governance approach would consist of a network of experts, leaders and citizens from around the world.**
- 4. To catalyze action the G8 (group of eight industrial democracies) should begin the process of identifying an appropriate organization to serve as host for this initiative.**

1.0 Background and Objectives

Biotechnologies have allowed humans to change living organisms in ways that improve health and food production, fight pollution, and bring other benefits. These technologies can be used to help fight poverty, hunger and disease in a process that is called biodevelopment.

However, there are risks that biotechnologies can also be used to make bioweapons that can spread deadly diseases or even create new forms of illness. In addition to possible threats from terrorists or even countries, there is also the risk of harm from misuse of the life sciences and related technologies by individuals or groups that are simply careless or irresponsible.

If concerns regarding biosecurity are not to unduly undermine the application of bioscience for development, then we must align the potentially conflicting agendas of bioscience development and biosecurity in a synergistic manner, and create and identify policies and mechanisms to reconcile the trade-offs.

These are high-level issues. In 2004, the United Nations passed Security Council Resolution 1540, against the proliferation of nuclear, chemical or biological weapons and their delivery systems, and has a committee that is examining member states' approaches to biosecurity. The United States National Science Advisory Board for Biosecurity has an international subcommittee in this field. In December 2005, The InterAcademy Panel released a statement on biosecurity which addresses five fundamental issues facing scientists working in the biosciences: awareness; safety and security; education and information; accountability; and oversight¹. In January 2006, the U.S. National Academies issued a major report calling for global efforts to control the risks while still gaining the benefits from biomedical research and technologies².

Biodevelopment must be a priority. Arguably, the inequities in health between industrialized and developing countries count among the greatest ethical challenges of our time. Biotechnology holds great promise in meeting the UN Millennium Development Goals, which include reducing poverty, hunger and disease, and improving environmental sustainability. A study led by the University of Toronto's Joint Centre for Bioethics identified 10 genomic and other biotechnologies with the greatest promise of improving global health within a decade, particularly in the world's poorer countries. These include molecular technologies for disease diagnosis, recombinant technologies to develop vaccines, sequencing the genomes of diseases, and genetically modifying crops to increase nutrients.

Dealing with the agendas of biodevelopment and biosecurity requires a broad vision and a series of actions that seek to increase benefits to humanity from the biosciences while reducing the risks. The National Academies report made a number of recommendations for increasing biosecurity. It called for the strengthening of the scientific expertise of the national security community and the strengthening of public health capacity to deal with biological threats.

It also said that continuing advances in the life sciences and related technologies are essential not only to human welfare, but also to countering the future threat of bioterrorism. The report recommended the free and open exchange of information in fields of the life sciences and related technologies, noting that much information is already widely available, and attempts at suppression would simply drive work underground. It said that restrictive regulations and other constraints on the

¹InterAcademy Panel Statement accessed at: [http://www.interacademies.net/iap/iaphome.nsf/\(weblinks\)/MGLY-4VQVC7](http://www.interacademies.net/iap/iaphome.nsf/(weblinks)/MGLY-4VQVC7)

² U.S. National Academies Report accessed at: <http://www.nationalacademies.org/morenews/20060131.html>

free flow of information will not likely reduce the risks of the misuse of life sciences, but will make it more difficult for society to protect itself against such threats.

Given the global dispersion of life sciences knowledge and technological expertise, the Academy called for the global community of life scientists to adopt a common culture of awareness and a shared sense of responsibility, including specific actions that would promote such a culture. Restraints on the sciences would also limit the potential for life sciences and related technologies to improve health, provide food and contribute to economic development in poor nations.

This echoes concepts spelled out by a meeting of leaders in Africa last year. In October 2005, a conference in Kampala Uganda was held by the International Law Institute of Uganda of the African Centre of Legal Excellence, and the International Consortium on Law and Strategic Security. It developed the *Kampala Compact: The Global Bargain for Biosecurity and Bioscience*, referred to in the next section.

In November 2005, the Canadian Program on Genomics and Global Health at the University of Toronto Joint Centre for Bioethics organized a two-day workshop: *The Global Bargain for Biosecurity*, at the New York Academy of Sciences, which involved 28 experts in the fields of biosecurity and biodevelopment (Appendix 1).

The objectives of this workshop were to further explore the concept of a Global Bargain for Biosecurity through:

1. In-depth exploration of potential linkages between biodevelopment and biosecurity from the conceptual framework of human security.
2. Discussion on the governance aspects of this bargain, including the potential development of an equivalent to the IAEA (International Atomic Energy Agency) in the biological sciences, and possible steps towards formation of such a mechanism.

This report describes the proceedings of the workshop and, building upon these, offers recommendations from the Canadian Program on Genomics and Global Health on how to move forward to balance biosecurity and biodevelopment.

2.0 Method

The agenda of the workshop (Appendix 2) involved a set of five presentations, which set the stage for in-depth discussion around the highlighted issues.

The Global Bargain for Biosecurity and Health and the Kampala Compact Global Bargain; BWC and 1540 Committee

Professor Barry Kellman of the Consortium on Law and Strategic Security at DePaul University College of Law gave a presentation on Advancing a Global Strategy to Prevent Bio-Terrorism. Prof. Kellman emphasized the policy black hole and how there is a lack of a strategic agenda or international authoritative structure to guide the process. He separated the policy agenda into two parts, that of 'complication' policies (regulation of pathogens, lab security, law enforcement, etc.) and that of 'science transparency and integration' policies (overseeing potentially dangerous bioscience research, addressing challenges of new technologies, etc.). He went on to discuss the governance challenge and the need to address multiple agendas and disciplines. The advocacy of progress was discussed in three dimensions. These include authoritative specification of state requirements, high-level deliberations on integrating bioterrorism prevention with bioscience progress, and the idea of an international convention on prevention of bioterrorism. Current strategies and activities were summarized, and future planned activities were promoted.

OPPORTUNITY TO RECONFIGURE DISCUSSION OF BIO-TERRORISM PREVENTION POLICIES

- Two bio-diplomatic events of 2006
 - UNSCR 1540 re-authorization
 - BWC Review Conference
- Participation of previously-absent States
 - Rapidly accelerating focus on disease threats
 - Have expanding bio-science sectors
 - Aware of developed States' diplomatic failures
- Goal: 50 new States -- poor, disease-ridden & developing -- clamoring for biosecurity

This opening presentation gave rise to considerable discussion and set the stage for the rest of the workshop. Issues such as the significance of the Biological Weapons Convention (BWC) and Resolution 1540 were discussed, particularly to what effect the elements of the Global Bargain should have to conform in order to accord with these types of treaties, and if it is at all necessary to do so. Consensus on what the Global Bargain should emphasize was difficult to obtain however it was apparent that the Kampala Compact embodied tenets that were fundamentally agreed upon, including the desire to promote bioscience development, and not necessarily the development of legal regimes. We cannot cease the progress and discredit the benefits that science and technology offer, especially with regards to addressing global public health needs. This being said, participants noted that we need to monitor the rate of change regarding technology through adequate governance mechanisms. Inherent throughout these discussions was the need for different groups to work

together as a network of networks that could provide knowledge and different perspectives about biosecurity and bioscience development.

The Kampala Compact

Mr. Swithin Munyantwali's presentation provided a synopsis of the Kampala Conference on the Prevention of Bioproliferation, which took place in the first week of October 2005. He briefly outlined meetings in Uganda, Tanzania and Kenya, which were conducted prior to the Kampala Conference. Objectives and outcomes of these pre-conference meetings were outlined and include an overall objective to encourage Africa to play a more significant role on the global stage in the prevention of bioproliferation. Mr. Munyantwali's presentation also outlined outcomes of the Kampala conference, which included agreements on the need for an African leadership role, the need for a legal framework to prevent bioproliferation, and the need for a larger African conference. The *Kampala Compact: The Global Bargain for Biosecurity and Bioscience* was the main product from the Kampala Conference. This compact affirms agreed upon principles and the endorsement of a bargain. Health is Africa's priority and since prevention of bioproliferation is intricately linked to health, Africa must support all efforts to prevent bioproliferation.

KAMPALA COMPACT: THE GLOBAL BARGAIN FOR BIOSECURITY AND BIOSCIENCE

1 October, 2005

1. Promotion of biological sciences and biotechnology are fundamental to the advance of human well-being, development and security. The Millennium Development Goals call for the application of science and technology for development and emphasize the importance of collective efforts in this regard.
2. Biological science can also pose threats of misuse to develop biological weapons. These threats are inherently global. Because of the threats associated with biological weapons, biological science must be advanced along with a commitment to protect against its hostile applications.
3. Africans have played a major role in international negotiations resulting in the Convention on Biological Diversity and the Cartage Protocol on Biosafety. Africans are deeply committed to the strengthening of binding international law to avert development and use of biological weapons and can demonstrate global leadership in addressing these threats.
4. The potential devastation caused by biological weapons would be catastrophic for Africa where compromised immunity and poverty would magnify the impact of their use. Notably, Africa has witnessed recent genocide and conflict; biological weapons could have multiplied their horrible consequences. Africa is also potentially a fertile ground for obtaining lethal biological agents for producing and proliferating biological weapons.
5. At this time, Africans are grappling with enormous health crises in the form of HIV/AIDS, TB, malaria, emerging infectious diseases, poor health infrastructure, and food security. It is illegitimate to address threats of biological weapons without addressing these other health crises.
6. Biotechnology has great potential to improve health and agriculture, save lives, reverse environmental degradation, conserve biodiversity, and stimulate economic development. Notably, the African Union Commission's High Level African Biotechnology Panel is preparing recommendations on how best to harness this potential.
7. To promote human security and protect against misuse of biological science, States should adopt and implement preventive measures such as the following, taking into account but not limited by international commitments:
 - a. Measures for laboratory, pathogen, and transport safety and security, including relevant monitoring capabilities and training programs;
 - b. Measures to authorize, train and equip law enforcers to detect, interdict, and investigate wrongful activity involving biological agents;

- c. Measures to encourage national and local preparation and response capabilities, including strengthening public health systems, that can limit and mitigate the consequences of use of biological weapons;
 - d. National legislation to criminalize illicit biological science pursuits and enforcement mechanisms;
 - e. Partnerships among law enforcers with the biological science and public health communities;
 - f. Support reporting of suspicious activity and provide protection for those who report;
 - g. Measures to strengthen import/export, transit, and border controls;
 - h. Ethical codes for scientists with regard to risks associated with biological science; and
 - i. Definition of national jurisdiction and authority.
8. To promote human security and advance positive applications of biological science, targeted assistance and resources such as the following are essential:
- a. Promotion of biological science education and African centres of excellence in biological science;
 - b. Strengthening of African Universities, research institutions, Academies of Science and other scientific networks;
 - c. Establishment of joint research and development program for vaccines and other capabilities to protect against disease with special focus on HIV/AIDS, TB, and malaria;
 - d. Building of public health infrastructure and capacity, and development of preparedness and disease outbreak response assessment capabilities;
 - e. Disease monitoring, notification, and surveillance systems;
 - f. Development of public health communication systems within Africa and connected with global communication systems; and
 - g. Raising awareness and understanding of disease, whether deliberate or natural, through *inter alia* strengthening the capacity of civil society.
9. Measures to protect against the misuse of bioscience and assistance to promote human security must be inter-linked. There is a need for balance: Addressing biological weapons concerns inappropriately could undermine development of biological science and technology with catastrophic effects. Developing bioscience but failing to address biological weapons concerns could lead to catastrophe and undermine confidence in science. Addressing all these concerns in harmony is mandatory for human security in Africa and throughout the world.

Source: http://www.icsu-africa.org/Resource_centre/KampalaCompact05.pdf

The Kampala Compact was seen as a starting point from which we could explore and learn, pending its implementation. The presentation concluded with an emphasis on the need to gather resources in order to mobilize support across Africa, while raising funds to host a follow-up Africa-wide conference.

Exploring the Two Sides of the Bargain: Part 1 - Biotechnology for Development

Professor Abdallah Daar outlined some of the work being done at the Canadian Program on Genomics and Global Health involving biotechnology and biosciences for health development in developing countries, and its association with the Grand Challenges in Global Health, the United Nations Millennium Development Goals and the Helsinki Process Papers on Human Security. Prof. Daar emphasized the need to balance biosecurity concerns in order to ensure the appropriate development of biotechnology and biosciences for Africa. He highlighted the significant role of science and how scientific development is integral to the improvement of global public health. He went on to stress the dangers of highlighting biosecurity risks at the expense of promoting biosciences for development. Reflective of this are some of the newspaper headlines presented around the Kampala Conference: *African science policy 'must address bio-terror threat'* and *Biological terrorism a lethal possibility*. We must not over-endorse negative attributes of biosecurity

for the purposes of selling the point to the media. Rather we must balance the scales by using reasoned arguments to encourage the positive aspects of biotechnology and other related biosciences for addressing global health needs. It was suggested that we think more in terms of promoting a Global “Balance” rather than a Global “Bargain”.

Need To Strike A Balance

- Addressing biosecurity concerns **appropriately will allow** development of biological science and technology in Africa
- Addressing biosecurity concerns **inappropriately will undermine** development of biological science and technology in Africa

Some participants drew an analogy with the ‘hinge’ that holds together sections 7 and 8 of the Kampala Compact. Professor Daar was in agreement with the notion of a hinge and added that it is a matter of primacy. It is necessary to invest in the foundation as described in section 8, in order for the tenets of section 7 to be stable.

Prof. Daar concluded his presentation by pointing out the effectiveness of foresight and case studies in demonstrating the potential of biotechnology for improving global health, and the efforts in regions such as Africa in employing these strategies to address local health needs.

Exploring the Two Sides of the Bargain: Part 2 - Biosecurity

When considering issues surrounding biosecurity, it is apparent that scientific development and public health strengthening go hand in hand. Professor Nancy Connell explored the two main aspects of the Global Bargain: 1. the promotion of human security to protect against the misuse of biological sciences, and 2. the promotion of human security to advance the positive applications of biological sciences. Prof. Connell highlighted the need for national and local preparation and response measures, and stressed the need to build public health infrastructure and capacity to deal with disease outbreak.

The Single Overlapping Component

Biosecurity

Measures to encourage national and local preparation and response capabilities, including strengthening public health systems, that can limit and mitigate the consequences of use of biological weapons

Bioscience Development

Building of public health infrastructure and capacity, and development of preparedness and disease outbreak response assessment capabilities

Training individuals and teams to deal with a potential biological attack may be done through table-top exercises, which may help to identify the needs and gaps. In such an exercise, group discussion is guided by a simulated disaster. Professor Connell emphasized that the partnerships amongst policy makers, law enforcers, biological scientists, and public health communities is a necessity.

Global Governance and the Bargain: Global Governance, G8/L20

Professor Elizabeth Dowdeswell presented her views on the global bargain from a global governance perspective. Prof. Dowdeswell began by defining governance as how we make decisions, including processes, policies and institutions. She referred to the “language trap” involving distinctions between terms such as global vs. intergovernmental and governance vs. government. This highlights the appropriateness of considering a term such as global balance rather than global bargain. She identified the need for awareness raising, consensus building, agenda setting, norm setting and compliance as key determinants of institutional design. A fundamental question addressed was whether a governance approach is best designed and driven by governments or whether it is more effective to seek cross-sectoral consensus about an appropriate government approach. Newer, multidisciplinary networking models of governance, as opposed to traditional intergovernmental approaches, may be more appropriate in highlighting the innovation and assessing the risks that a global balance for biosecurity pose. The possibility of an emerging L20 (a group of 20 global leaders) was discussed. This initiative is the subject of current study in which a network of leaders from both developed and developing countries engage in a common cause while exchanging information and coordinating activities.

Governance Models

Traditional

Commissions – a catalyst for action through focused debate and discussion (e.g. UN Panel on Threats, Challenges and Change, The Weapons of Mass Destruction Commission and many others)

Treaties – legal mechanisms (e.g. Convention on Biodiversity, Biological and Toxin Weapons Convention and many others)

Emerging

Networks – diverse in purpose and approach, attempt to be inclusive, participatory and legitimate, complement the work of governments

The presentation concluded with an emphasis on the need to answer the question: Can we come together as a global community to harness significant technological development and minimize their risks for the benefit of all? If there is agreement on purpose, then “form follows function” should be the guide when choosing governance mechanisms.

3.0 Results and Discussion

Discussion was active, engaging and occasionally contentious. The presentations triggered a multitude of ideas and concerns, which played out in considering future initiatives. These ideas sorted themselves in three main clusters: Pressing Issues, Governance Mechanisms, and Action Steps. What major issues in the biosecurity/biodevelopment arena need to be addressed and in which priority? What type of governance mechanism is needed to guide resolution of these issues? What are the necessary steps in developing such a governance mechanism? Each of these questions was addressed and analyzed.

3.1 Pressing Issues

Throughout the workshop it became apparent that there was a need to determine which issues had to be addressed before the purpose and overarching mandate of a coalition or network of networks that would promote a global balance of the issues around biosecurity and biodevelopment could be defined. In order to provide a systematic approach to addressing the various concerns, we conducted a modified Delphi exercise to identify and rank the 10 most pressing issues in this area. Seventeen of the workshop participants were asked the open-ended question: *Are there any major issues in the biosecurity / biodevelopment arena that the creation of a new issues network could address and that would realistically advance the discourse and impact policy?* The responses were organized into common themes and a list of 13 issues was identified. Next, we asked the participants to rank their top ten choices from this list. By adding together the participants' individual scores (e.g., 1st ranked, 10 points; 2nd ranked, 9 points, and so on), we produced a summative point score for each application and generated a list of the top ten issues:

| RANK | ISSUE | SCORE |
|-------------|---|--------------|
| 1 | Standard Setting/Best Practices for Biosafety | 87 |
| 2 | Building Capacity for Biodevelopment and Biosecurity in Developing Countries | 84 |
| 3 | Raising Awareness of Biosecurity/Biodevelopment Issues | 67 |
| 4 | Training and Exercises | 61 |
| 5 | Gap Analysis After Studying and Comparing Current Biosecurity Regimes | 57 |
| 6 | Risk Evaluation Methods and Standards | 55 |
| 7 | Agenda and Priority Setting for Studies in Biodevelopment and Biosecurity | 52 |
| 8 | Evaluation of Potential Solutions | 41 |
| 9 | Implementation Research of Solutions | 40 |
| 10 | Design of an Authoritative Process to Execute These Issues | 36 |
| 11 | Information Sharing (Charter); Involvement Of Media And Industry | 32 |
| 12 | Defining Vocabulary | 25 |
| 13 | Building Capacity for Bioterror Preparedness | 7 |

3.2 Governance Mechanisms

The establishment of an effective governance mechanism was another reoccurring theme throughout the workshop. A newer type of governance mechanism, which includes a cross-sectoral consensus on the issues surrounding biosecurity and bioscience development, with a necessary connection to a

more traditional intergovernmental governance system, was desired. Methods to create such a mechanism could include a top-down approach that would establish overarching norms to encompass the shared desire for health development and human security. A bottom-up approach could also be considered, and most likely preferred, in which working groups would assess their individual capacities and strengths in moving the biosecurity and bioscience development agenda forward. Special consideration should be given to the formal processes inherent in the BWC, 1540, NSABB, etc., but the mechanism should not necessarily be governed by them. A web-based portal might be useful to maintain strong linkages and serve as a database from which to access information. In this regard, a network of networks could be created, which would ideally strengthen the capacity and intelligence needed to develop a capable authoritative mechanism. A platform that could support such a network may found be the International Council for the Life Sciences (ICLS), which is dedicated “to promot[ing] public health, safety, and security by safeguarding the opportunities offered by advances in the life sciences and their application.”



International Council for
The Life Sciences

International Council for The Life Sciences

Preamble

Extraordinary advances in the life sciences and their application have brought enormous benefits to public health, medicine, agriculture, and industrial processes. It is essential that the full humanitarian and economic benefits from these advances continue to be realized.

To do so, it is vital to develop a global mechanism that can serve as an authoritative source of objective consideration and analysis of the benefits of these advances and related risks. It is especially important that any such risks be first identified, understood, and effectively addressed. Any effort to do so must be international in nature and be led by the life sciences community, including private industry, academia, and other non-governmental institutions.

The speed of current life sciences developments often surpasses national and international governmental efforts to put in place legal and regulatory policy. Often the lack of international uniformity in the evaluation of these risks impedes the development of beneficial scientific advances. As the life sciences community is at the leading edge of these developments and their dissemination worldwide, it is well-placed to assist governments and the public by contributing directly to the international effort to deal effectively with the global identification and management of biological risks to public health, safety and security.

To promote this necessary culture of responsibility within the life sciences community, its leaders from around the world have agreed to create an international entity called the International Council for the Life Sciences (ICLS).

The Charter

An International Council for the Life Sciences (“the Council”) is hereby established that will:

- Create a self-sustaining global organization for the life sciences community to contribute to improved quality of life and enhanced public safety and security;
- Promote engagement of the life sciences community worldwide on issues of public safety and security;
- Facilitate effective partnerships between the various elements of the life sciences community, including private industry, academia, and government; and
- Serve as an authoritative source of objective consideration and analysis of global biological risks in relation to advances in the life sciences and their application.

Mission

The mission of the Council is to promote public health, safety, and security by safeguarding the opportunities offered by advances in the life sciences and their application.

What the Council will do:

To accomplish this mission the Council will facilitate essential and timely contributions to national and international policy development through a cooperative effort to reduce biological risks through their identification and management by:

Proactively engaging industry, academia, governments, and the public to enable accurate communication and understanding of the benefits and biological risks arising from advances in the life sciences;

Operating as an independent organization designed to cooperate closely with national governments and international inter-governmental organizations; and

Promoting the widest possible membership among the life sciences community.

*The complete Charter can be accessed at: <http://www.iiss.org/newsite/showdocument.php?docID=561>

There appeared to be great potential for achieving an effective and necessary balance between biosecurity and biodevelopment in the developed and especially in the developing world. However, there is a critical need to foster a sense of collaboration amongst individual groups that are each working on different yet related issues. A balance must be sought so that arguments supporting security against biological agents and weapons do not undermine or supersede the advancement of bioscience development for global public health.

3.3 Conclusions and recommendations

Considering the results of this workshop and a body of its own research activities, the Canadian Program on Genomics and Global Health finds and recommends the following:

1. The world must not let legitimate concerns about biosecurity undermine the promotion and use of biotechnologies for human development.

When viewed through the lens of human security, development and security are inextricably linked. Human security is compromised by disease, hunger, poverty, environmental degradation and physical threat. Biodevelopment, that is, harnessing biotechnologies to achieve human sustainable development, shows real promise. These developments may be denied should the inherent security risks assume preeminent importance.

2. We need to invest in positive applications of biological sciences in the developing world in order to protect against the misuse of these sciences for harmful purposes.

This is a question of reconciliation – safeguarding benefits and reducing risks. This balance is articulated in the Kampala Compact. Targeted assistance and resources to promote human security through positive applications of biological sciences is essential. As stated by the National Academies report, we need to support programs promoting beneficial uses of technology in developing countries. This provides the legitimacy and leverage for ensuring that nations, especially in the developing world, also adopt and implement preventive measures against the misuse of biological sciences. The first step on the road to biosecurity is support for biodevelopment.

3. We recommend a model of global governance that will achieve a balance between the potentially competing agendas of biosecurity and biodevelopment. This governance approach would consist of a network of experts, leaders and citizens from around the world.

An effective global governance mechanism is essential in aligning potentially competing agendas and reconciling tradeoffs among nations. By global governance, we mean the way in which the world community makes decisions. After a review of the more traditional models, including commissions and treaties as well as emerging experiences with networks, we conclude that a network of networks would be most appropriate. This would involve, as described by the National Academies report, globally distributed, decentralized and adaptive mechanisms with the capacity for surveillance and intervention in the event of malevolent applications of tools and technologies derived from the life sciences. The network would span the public and private sectors. A good metaphor – and one used by the National Academies report – is that this network would serve as a global immune system to detect, report, and ultimately interdict misuse of the biological sciences. We feel that this model could best address the complexity of ethical, social and legal issues involved and the rapid pace of evolution of the science and technology. It would recognize and seek synergy among the myriad institutions, activities, programs and policies already in existence.

4. To catalyze action the G8 (group of eight industrial democracies) should begin the process of identifying an appropriate organization to serve as host for this initiative.

The G8 has been developing an agenda to shape globalization to ensure that more of the world's people will enjoy the benefits of global public goods. In 2002, at the Kananaskis meeting, the G8 leaders launched the Global Partnership, which aims to prevent terrorists from acquiring or developing nuclear, chemical, radiological or biological weapons or related materials, equipment, technology and expertise. At its next meeting in Russia in July 2006, there is an opportunity, under the heading of infectious diseases, to give impetus to a coherent and timely discussion of the need for balance between biodevelopment and biosecurity. These discussions should include people from the developing world, where such diseases wreak great havoc.

This discussion should be used to start building a global network of experts on biodevelopment and biosecurity. It should result in the establishment and funding of an international panel of experts and engaged decision makers, and would give the project legitimacy. The panel should systematically spell out the issues and undertake a needs assessment building on the mini-Delphi exercise undertaken at the workshop. Concurrently, by raising awareness of the importance of the issue within the global community, the legitimacy and capacity of existing international agreements and organizations could be supported. The objective would be to lay the foundation for a model of global governance that would be inclusionary and worthy of support. A funders' forum could then influence the reallocation of resources or dedicate new funds to ensure a fair distribution of knowledge, time, infrastructural capacity and money be given for this dual agenda.

By focusing on this work, the group of leaders could help in achieving a reconciliation of two potentially competing agendas – biodevelopment and biosecurity.

Authors of the Report

The authors are responsible for the contents of this report.

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Abdallah Daar is Professor of Public Health Sciences and of Surgery at the University of Toronto, where he is also Director of the Program in Applied Ethics and Biotechnology, co-Director of the Canadian Program on Genomics and Global Health and Director of Ethics and Policy at the McLaughlin Centre for Molecular Medicine. He was a clinical lecturer in Oxford for several years before going to the Middle East to help start two medical schools. He took up the foundation Chair of Surgery in Oman in 1988, where he also headed the research labs. He has published/co-authored 5 books and has about 300 other publications in immunology, immunogenetics, transplantation, surgery, bioethics, science policy and global health issues. He has been an expert advisor to WHO and OECD, and is currently chair of the External Review Committee of the WHO/World Bank/UNDP/UNICEF Special Program on Tropical Diseases Research and Training. He was appointed by the African Union Commission to the high-level African Biotechnology Panel. He is a member of the Advisory Board for the International Council for the Life Sciences and the International Institute for Strategic Studies. He is a Fellow of the New York Academy of Sciences and is on the Ethics Committee of the (International) Transplantation Society and of the Human Genome. He is a member of the Canadian Bioethics Advisory Committee's Expert Working Party on Human Genetic Materials, Intellectual Property and the Health Sector; and Health Canada's Expert Advisory Committee on Cells, Tissues and Organ Regulation. He was awarded the Hunterian Professorship of the Royal College of Surgeons of England (1999), the Anthony Miller Prize for Research Excellence at the University of Toronto (2005) and the UNESCO Avicenna Prize for Ethics and Science (2005).

Elizabeth Dowdeswell

Elizabeth Dowdeswell is a Visiting Professor of the Joint Centre for Bioethics at the University of Toronto and the President and CEO of the Nuclear Waste Management Organization. She has served as an Under Secretary General of the United Nations and Executive Director of the United Nations Environment Programme from 1993 to 1998. She received a MSc in Behavioural Sciences and is the recipient of numerous honorary degrees and a Pierre Elliott Trudeau Foundation mentorship.

Dilnoor Panjwani

Dilnoor Panjwani is a Research Assistant for the Canadian Program on Genomics and Global Health at the University of Toronto Joint Centre for Bioethics. Dilnoor is a recent graduate of Queen's University with a dual degree in Honours Development Studies and Health Studies. She was the New York Workshop coordinator and is currently working on the human security project and potential links between bioscience and biosecurity. She is also researching potential Grand Challenges in Non-Communicable Disease in collaboration with the Oxford Health Alliance.

Deepa L. Persad

Deepa Persad is the Program Research Coordinator for the Canadian Program on Genomics and Global Health (CPGGH) at the University of Toronto Joint Centre for Bioethics. Deepa is a graduate from the University of Toronto specializing in Bioethics and has been working for the CPGGH on such projects as the Bill and Melinda Gates Foundation's Grand Challenges in Global Health and the Nanotechnology Developing Countries Top Ten study. Deepa was the coordinator for the Executive Course on Genomics and Public Health Policy which took place in Hong Kong, China in October 2004 and co-coordinator of the 2005 Global Bargain for Biosecurity conference which took place at the New York Academy of Sciences. Deepa has written several government grant reports and is currently working on identifying the Grand Challenges in Non-Communicable Diseases. Deepa is also a member of the Genomics and Nanotechnology Working Group of the UN Millennium Project Task Force on Science, Technology and Innovation.

Peter A. Singer

Dr. Peter A. Singer is Sun Life Financial Chair in Bioethics and Director of the University of Toronto Joint Centre for Bioethics and Professor of Medicine at the University of Toronto and University Health Network. He also directs the World Health Organization Collaborating Centre for Bioethics and the Canadian Program on Genomics and Global Health at the University of Toronto. He studied internal medicine at the University of Toronto, medical ethics at the University of Chicago, and clinical epidemiology at Yale University. Singer is the recipient of awards that include the CIHR Distinguished Investigator award, Senior Fellow at Massey College, the Award for Excellence from Yale University School of Public Health, and the University of Toronto Dales Award. He has published over 200 articles in journals including *Science*, *Nature Genetics*, *Nature Biotechnology*, *PLoS Medicine*, *International Affairs*, *BMJ*, *Lancet*, *New England Journal of Medicine*, *JAMA*, and others. He has held almost \$50 million in research grants, including three large grants from Genome Canada. He has trained over 50 graduate students and fellows, many of whom have leadership positions in bioethics around the world. He is a member of the Scientific Advisory Board of the Bill & Melinda Gates Foundation Grand Challenges for Global Health Initiative and the Committee on Advances in Technology and the

Prevention of Their Application to Next Generation Biowarfare Agents of the US National Academies. He is a Director of BIOTECCanada, and board chair of Branksome Hall School for Girls. His contributions have included improvements in quality end of life care, fair priority setting in healthcare organizations, and teaching bioethics. His current research focus is global health, in particular harnessing genomics and nanotechnology to improve health in developing countries.

Appendix 1 – Participants*

| Name | Affiliation |
|----------------------|---|
| Michael Allswede | University of Pittsburgh Medical Center |
| Linda T. Ambroso | University of Pittsburgh Medical Center |
| Nancy Connell | New Jersey Medical School |
| Abdallah S. Daar | University of Toronto |
| Elizabeth Dowdeswell | University of Toronto |
| Jonathan Granoff | Global Security Institute |
| Gigi Kwik Gronvall | University of Pittsburgh |
| Martiusz Handzlik | Mission of Poland to the United Nations |
| Elisa D. Harris | University of Maryland |
| David Heyman | Center for Strategic and International Studies |
| Swathi Kappagantula | Foreign Affairs Canada |
| Barry Kellman | DePaul University College of Law |
| Stephanie Loranger | Nuclear Threat Initiative |
| Samuel O. Manteaw | International Consortium for Law and Strategic Security |
| Stephen Morse | Columbia University |
| Swithin Munyantwali | International Law Institute- Uganda |
| Randall S. Murch | Virginia Polytechnic Institute and State University |
| Paula J. Olsiewski | Sloan Foundation |
| Dilnoor Panjwani | University of Toronto |
| Deepa L. Persad | University of Toronto |
| Roger Roffey | Swedish Defence Research Agency |
| Harvey Rubin | University of Pennsylvania |
| Cynthia P. Schneider | Georgetown University |
| Peter A. Singer | University of Toronto |
| Jerome A. Singh | University of KwaZulu-Natal- Durban |
| Mark S. Smolinski | Nuclear Threat Initiative |
| Eric Stephen | Defence R&D Canada |
| Terence Taylor | International Institute for Strategic Studies-US |

*The participants attended in their personal capacities. The authors are responsible for the content of this report, including the conclusions and recommendations.

Appendix 2 – Agenda

The Global Bargain for Biosecurity

Wednesday, November 16th

- 8:30am** Registration and continental breakfast
- 9:00-9:30am** Welcome and Introductions – *Dr. Peter Singer*
- 9:30-10:30am** Global Bargain for Biosecurity and Health and the Kampala Compact
Global Bargain; BWC and 1540 Committee – *Professor Barry Kellman*
Kampala Compact - *Swithin Munyantwali, Esq.*
Discussion
- 10:30-11:00am** Break
- 11:00-12:00pm** Exploring the Two Sides of the Bargain: Part 1
Biotechnology for development – *Dr. Abdallah Daar*
Discussion
- 12:00-1:00pm** Lunch
- 1:00-2:00pm** Exploring the Two Sides of the Bargain: Part 2 Biosecurity - *Professor Nancy Connell*
Discussion
- 2:00-2:30pm** Break
- 2:30 – 5:00pm** Global Governance and the Bargain Global Governance, G8/L20–
Professor Elizabeth Dowdeswell
Discussion

Thursday, November 17th

- 8:30am** Continental breakfast
- 9:00-10:30pm** Strategy to move forward, Next steps, Concrete actions
Discussion
- 10:30-10:45am** Break
- 10:45-12:00pm** Discussion (Continued)
- Noon** Lunch. Delegates depart.