

GLOBALIZATION AND HEALTH

Challenges for Health Law and Bioethics

Edited By

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PREFACE

Within contemporary society, globalization has emerged as a key concern at the centre of ethical, legal and policy debates relating to health care. Conflicts between public interests and individual rights, the challenge of regulating health professionals and access to health services, and the effects of a global market all feature prominently in these discussions. As a result of globalization, these issues can no longer be understood solely within the political boundaries that define traditional notions of individuals and communities. Rather, solutions demand a global conception of rights and obligations, which in turn requires new approaches to health policy formulation and a reevaluation of existing ethical and legal frameworks. In essence, the impact of globalization on human health is testing the robustness of modern regulatory systems, legal doctrines and ethical paradigms.

PUBLIC HEALTH: DEVELOPING GLOBAL CONCERNS

The interconnectedness of the global economy presents new challenges in public health. While globalization has facilitated improvements in health care, it has also created new hazards and avenues for exploitation. It is becoming increasingly apparent that both national and international responses are required. Indeed, as the chapters in this section convey, public health is rightly a global concern.

Globalization has led to a sharing of both risks and responsibilities in public health. Belinda Bennett reminds us of the ease with which infectious diseases can spread within the global community, given the speed of modern travel and trade. Despite a long history of the impact of infectious diseases on human society, the SARS crisis in 2003 demonstrated the ongoing importance of having efficient public health infrastructures at national *and* international levels. However, as Bennett notes, “the huge disparities in health and health infrastructure that exist between countries continue to undermine the ability of countries to respond rapidly and effectively to outbreaks of infectious disease.”

Bennett’s critique of the SARS crisis also shows how concerns about public health become acute at the interface between the developed and the developing worlds, which raises important questions about the meanings of rights and obligations in an international context. The evolving field of bioethics would play a vital role in addressing such dilemmas. Udo Schüklenk and Braimoh Bello argue, however, that much of bioethics discourse has focused on high-tech issues such as stem cell research and nanotechnologies, and “traditional liberal bread-and-butter issues of informed consent and individual autonomy.” They argue that bioethics should instead focus on issues that affect many more people in the world – issues that address global inequities in health care between developed and developing

countries. To that end, they propose a range of topics that should receive greater attention by professional bioethicists: the 10/90 gap in health research, the transnational organ trade, access to essential medicines, health-based immigration restrictions, international research ethics and the flow of health information. According to Schüklenk and Bello, a refocusing of bioethics as a field of inquiry is essential if it is to have continued contemporary relevance.

The evolution of public health as a global concern invokes questions about global social justice. As argued by George F. Tomossy and Joylon Ford, the quest for cures exposes fundamental deficiencies in legal doctrines insofar as they may prevent access to justice. They examine the plight of developing world subjects who may become injured in the course of first-world sponsored clinical trials, and who face significant legal obstacles when seeking compensation from multinational pharmaceutical corporations. Concerns about distributive justice thus come into conflict with the corporate incentive to pursue profits within a global market. Tomossy and Ford argue that citizens of one jurisdiction should not be exposed to risks of harm in order to benefit others, and would call upon investigators, sponsors and regulators alike to protect developing world subjects. They advocate that access to justice by developing world plaintiffs should be facilitated in first-world courts, which will require correcting procedural and substantive legal impediments that are presently almost insurmountable.

Finally, concerns about global social justice and public health invite consideration of the ethical grounds upon which arguments for obligations on the part of individuals, corporations and governments in the developed world towards developing countries might be based. This theme is explored by Deborah Zion, who analyzes obligations in terms of a duty of beneficence, efficacy, justice and integrity. She proposes that setting up processes to analyze the effects, burdens and benefits of clinical research would be a vital starting point towards relieving global health care inequities.

THE GLOBAL BIO-ECONOMY: CONSENSUS AND INNOVATION

The viability of national regulatory systems is continually being confronted by a global market for health care that is driven by the forces of innovation and health care consumerism. The emergence of a global bio-economy has created the need for transnational regulation of biotechnology and medical products. While generating consensus in health care policy formulation has always been a challenge, it is particularly so against the backdrop of globalization where consensus needs to be located at both national and international levels. And, as in the previous section, ethical issues permeate these discussions.

Derek Morgan argues that “we stand on the threshold of what might be thought to be a new dimension in the relationship of human sciences to biotechnology.” He proposes that the emergent “bio-economy” is set to transform our lives in the same all-encompassing manner brought about by the industrial age and advent of the computer. With the key societal concerns for these stages having related to

environmental degradation and privacy respectively, he predicts that the central issue in the new economy will be ethics. In order to resolve some of the current debates in this regard (for example, cloning, genetic patenting and bio-engineered foods), Morgan argues that the development of international consensus will require the implementation of “biomedical diplomacy,” informed by traditional tools of “rhetoric, persuasion, negotiation, and economic and political leverage.” The rationale for this process, he maintains, must be based on “rethinking equity in health,” without which “all talk about human values, human dignity, human rights and democratic balance will be so much empty rhetoric.”

Our understandings of “the global” and of “risk” help to shape responses to innovative technologies in health. Drawing upon the example of regulatory debates surrounding genetically modified foods in the United Kingdom, Alan Irwin considers the relationship between internationalized patterns of innovation and the development of national policy processes. His analysis reveals how differing conceptualizations of “the global” can exist within public discourses about innovation, and how the interaction between “the global” and “the national” affects the construction of regulatory debates. Irwin argues that these debates present political challenges in the need to formulate “more open cultures of deliberation and reflection,” and that it is important “to move away from simply presenting globalization as an objective (and generally irresistible) force and towards an acknowledgement of its varied manifestations and social constructions.”

Thomas Faunce explores the link between innovation and corporate globalization by examining the intersection of international trade and domestic health policy. His critique addresses the impact of US-derived global intellectual property policies on government pricing of pharmaceuticals in Australia. He traces the evolution of these policies to their corporate origins in the United States and explores their enforcement through both international trade mechanisms and bilateral treaties. Faunce cautions that these policies represent “a significant, emerging problem for global public health,” and urges greater attention to principles in bioethics, public health and international human rights in order to ensure affordable access to essential medicines.

As with trade, advertising is being recognized as a critical force in the global economy. Its relevance is particularly significant in today’s consumer society where advertising plays a vital role in the development and expansion of markets for health products. Patricia Peppin analyzes the challenges associated with regulating advertising of pharmaceutical products through a comparative overview of the regulatory frameworks for advertising of medicines in the United States, Canada, the European Union, Australia and New Zealand. Drawing on semiotic theory, Peppin explores the construction of meanings through the information and images used in advertisements and the interpretation of those meanings by consumers. She warns of “significant public health consequences” associated with passing on advertising costs to health systems and with commodifying the doctor-patient relationship.

Globalization clearly presents significant difficulties for crafting consensus on regulatory policy in the area of biotechnology. This theme is explored by Timothy

Caulfield and Barbara von Tigerstrom. Using the examples of gene patents and laws designed to limit human cloning, they reveal the competing tensions that emerge from global debates surrounding these issues. As they note, the demand for extensive regulatory intervention exists; however, “differing cultural and socio-political positions magnify the policy-making challenge.” The authors acknowledge the difficulties inherent in reaching consensus on contentious issues and the potential for international agreements to limit the scope of national policy making. Their analysis thus yields an important lesson: “there can be no simple template for understanding and addressing the implications of globalization for biotechnology policy.”

GLOBALIZATION AND HEALTH CARE

Having canvassed the implications of globalization for health care on a macro-level, this last section turns to the nexus between health care professionals and consumers. Globalization has had a fundamental effect on rights and obligations at the micro-level through its impact on national policies and legal systems. As these chapters show, the effects of globalization filter through to shape the rights of individuals and practices of the health professions.

Kerry Petersen’s examination of the rights of children conceived using donated gametes to access identifying information about their biological (donor) parent provides a case for the study of individual rights in health care in a global setting. Despite the absence of consistent national or international patterns governing assisted reproductive technologies, common themes and regulatory approaches emerge from international comparisons. Petersen’s critique thus reveals that incremental changes in regulatory reforms in this area favouring openness and disclosure of donor identity demonstrate the influence of human rights discourse on national health policy formulation.

John Harrington analyzes the impact of global market forces on national health systems, and signals the threat to national regulatory systems posed by health tourism and the commodification of human organs. Patients are increasingly travelling abroad in order to access health procedures. He argues that “consumption of health care, just like its provision, is no longer confined by national borders,” with the global trade in human organs continuing to defy attempts to curtail it. Indeed, Harrington notes that the taboo against commodification has started to erode, with the consensus against commodification coming apart “under pressure of the actually-existing market.”

In the final chapter in this collection, Ian Freckelton charts the emerging landscape in the global regulation of health care practitioners. Drawing on the experience of the United Kingdom, Canada, Australia and New Zealand, Freckelton maps the common regulatory trends that are emerging against the backdrop of this changing regulatory environment. He examines the changes caused by increasing consumerism and availability of health information in the age of the Internet, as well as the issues that arise from increased global movement of health professionals, and

the ethical issues arising from the recruitment of developing world health professionals to meet the needs of health systems in developed countries.

CONCLUSION

Across the three themes of this volume, globalization has emerged as a fundamental force shaping ethical, legal and policy debates in health. The authors in this volume have shown that all aspects of health care, whether one is speaking of individual rights, professional obligations or governmental policy, are invariably influenced by transnational factors. As has been observed in globalization discourse more generally, these effects have been both positive and negative. The obvious challenge facing all countries, developing or developed, is to embrace the benefits of a global bio-economy while avoiding its harms. As is increasingly evident from attempts to govern innovation in biotechnology and access to health care, however, legal and regulatory mechanisms can only go so far towards achieving this goal. From the collective efforts of our colleagues in this volume, we would therefore derive the conclusion that a sound ethical base is needed upon which to ground policy initiatives, whether at national or international levels, and regardless of the difficulties obtaining political consensus might present. Such a base, we suggest, must ultimately be grounded in global considerations about equity and respect for human rights.

*Belinda Bennett and George F. Tomossy
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CHAPTER TWO

UDO SCHÜKLENK & BRAIMOH BELLO

GLOBALIZATION AND HEALTH

A developing world perspective on ethical and policy issues

Globalization in the context of health may be viewed as a concerted global effort towards prevention, elimination and eradication of diseases, and the promotion of human health worldwide. This brings a lot of issues to mind: from the ever-growing mobility of people and the public health consequences of such a change in peoples' movement patterns, to concerns about ethical standards in international health research, as well as ethical analyses critiquing the continuing existence of the 10/90 gap in health research. Intellectual property rights and affordable access of the world's poor to patent-protected essential AIDS drugs, as well as immigration ethics, have been high on international agendas. What is significant, perhaps, is that most of the critical contributions to any of these ongoing concerns have not actually come from professional bioethicists but from other professionals (Farmer and Gasteau 2004). Bioethicists, true to the traditions of their relatively young field, have continued their focus on high-tech issues such as stem cell research and nanotechnologies (Dhai et al. 2004; Boyle and Savulescu 2001; Daar et al. 2004). Some bioethicists have criticized this preoccupation with "high-tech" issues as "following the money" (Elliot 2004).

The argument advanced here is, basically, that funding for bioethics research is to a large extent controlled by the pharmaceutical industry and government organizations, such as the US National Institutes of Health, or wealthy private funders, such as the Wellcome Trust in the UK. Because all of those funders are mainly concerned about "hi-tech" issues as opposed to developing world issues, not much bioethical research is undertaken in those areas. Considering that many more lives are affected by the existence of intellectual property rights and the frequent resultant lack of affordable access to essential drugs, this in itself is worthy of critical reflection about the field and its researchers' priorities. This contribution aims to sketch an overview of issues that should take priority within bioethics over the traditional liberal bread-and-butter issues of informed consent and individual autonomy. By necessity, such an overview cannot at the same time provide in-depth

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analyses of each of the issues mentioned. Rather, it should be read as a proposal for a different kind of research agenda for bioethics to what is the field's current status quo.

THE 10/90 GAP

According to the Global Forum for Health Research (2002, 3):

Every year, more than US\$70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is what is called the 10/90 gap.

The issue of neglected diseases research is obviously of central importance to people living in developing countries (Médecins Sans Frontières 2001). However, even if the current commercial research agendas of the pharmaceutical industry were directed at diseases according to the world's needs and not necessarily according to commercial considerations, another problem would inevitably arise. It was brought to the world's attention by Edwin Cameron, an HIV-positive South African judge. In his address to the delegates attending the International AIDS Conference in Durban in 2000 he stated:

Nearly 34 million people in our world are at this moment dying [of AIDS]. And they are dying because they don't have the privilege that I have, of purchasing my health and life...Now why should I have the privilege of purchasing my life and health when 34 million people in the resource poor world are falling ill, feeling sick to death, and are dying? That to me...seems a moral inequity of such fundamental proportions that no one can look at it and fail to be spurred to thought and action about it. That is something, which we in Africa cannot accept. It is something that the developed world also cannot accept.
(Cameron 2000)

In other words, people in developing countries will face two major challenges in their attempts to access lifesaving medication. The first challenge is that the medication in question might not exist, because the necessary research was not considered commercially sufficiently attractive by pharmaceutical multinationals to justify substantial investment (Schüklenk and Ashcroft 2002; Sterckx 2004). The second challenge is that the medication available is likely to be too expensive to permit affordable access. This has been the case in many African countries like South Africa and Uganda, where the majority of people suffering from HIV/AIDS have no access to treatment drugs because of their extreme cost. In Uganda, for example, where more than two million people are infected with the virus, it is estimated by UNAIDS that not more than 2,000 people have access to drugs (Schüklenk and Ashcroft 2002; Cochrane 2000). A team of researchers from Doctors Without Borders (Médecins Sans Frontières) reviewed the situation in a 2002 *Lancet* publication and concluded that "despite an ever-increasing need for safe, effective, and affordable medicines for the treatment of these [tropical] diseases, drug development has virtually stopped" (Trouiller et al. 2002).

International discussions about how to address these challenges in a just manner have been going on for some time but without any satisfactory solutions at the time

of writing (Hubbard and Love 2004). New trade frameworks for health care research and development (R&D) have, for instance, been proposed by the US-based Consumer Project on Technology.¹ Love (2003, 1) argues that “trade agreements should be reframed to focus on standards for sharing the costs of R&D” and that we “need business models for financing R&D that do not depend on marketing monopolies for approved products.” An ethical allocation of research resources that takes into account global health needs would help to bridge this gap and reduce the consequences of such misallocation. This would not only be of benefit to the researchers involved, but also to their countries and the global community in general.

ORGAN “DONATION”

Unprecedented numbers of people move across borders (sometimes illegally), but so do human organs destined for organ transplantation. Ethical issues discussed in this context have to do with the fundamental concern of exploitation of impoverished organ donors in the developing world. Commercial organ sales resulting in organ transfers (for payment) from developing world sources to developed world recipients clearly are of concern, because of the economic power differential between the parties to the contract. Similarly, doctors’ participation in such contracts has been criticized as incompatible with their professional obligations.

Professionalism, in its historic religious derivation, means essentially to profess publicly to serve the public good (Koehn 1994). Arguably, access to lifesaving organs based exclusively on a given prospective patients’ capacity to pay is incompatible with professional duties so understood. Equitable access as a fundamental requirement of the principle of distributive justice is not guaranteed under such circumstances, despite frequently equal needs on the part of those requiring transplant organs. The material principle of justice requires the equal treatment of equal needs. Medical professionalism traditionally required impartiality in the treatment of patients competing for scarce resources. If recipients of donor organs are allowed to jump the queue based on their capacity to pay, as opposed to being prioritised based on clinical need, medical professionalism ceases to operate as it should.

Evidence has begun to accumulate that at least some “donors” had no substantial understanding of the implications of their decision, or were not even aware of their “donation.” It has also been reported that organs have been stolen from deceased patients as well as from impoverished patients. The latter had gone to hospitals for care and left them with less than their full set of organs (*Associated Press* 1999). Reportedly, the Turkish Interior Ministry warned after the major 1999 earthquake that groups were roaming the country in search of children orphaned by the earthquake to kidnap them and remove organs for sale (*Bloomberg* 1999). Many reports have also been accumulated by University of California at Berkeley-based Professor of Anthropology, Nancy Scheper-Hughes, who noted that:

The rapid transfer of organ transplant technologies to countries in the East (China, Taiwan, and India) and the South (especially Argentina, Chile, and Brazil) has created a global scarcity of viable organs that has initiated a movement of sick bodies in one direction and of healthy organs – transported by commercial airlines in ordinary Styrofoam picnic coolers conveniently stored in overhead luggage compartments – often in the reverse direction, creating a kind of “kula ring” of bodies and body parts.
(Scheper-Hughes 2000, 193)

IMMIGRATION ISSUES

People from developing countries face ever-growing hurdles in their attempts to migrate to developed countries. A variety of means have been introduced to prevent sick migrants from entering developed countries. For instance, in California, regulations require that health care providers who rely on “public funds” not care for illegal immigrants. In Canada, the identification of potential immigrants who might cause costs to taxpayers has become one of the main purposes of the country’s immigration medical procedures. In the United Kingdom, prospective immigrants have to undergo a medical examination designed to determine whether they might be unable to support themselves or their dependents or require medical treatment.

The United Kingdom Home Office can grant immigrants permanent leave of stay for compassionate reasons. One would expect that a serious, even life-threatening illness of a person from a developing country should be sufficient to grant permanent leave of stay on compassionate grounds. Yet the opposite is the case. Medical doctors can be called in to prevent immigration. Among the reasons they could offer to justify the refusal are contagious diseases such as pulmonary tuberculosis, but also senility, mental disorders, sexual aberration, physical disability (including bodily deformity), and other conditions that might prevent persons from supporting themselves or their dependents. In other words, vulnerable people from countries that can reasonably be assumed to have insufficient health care facilities are most likely to be denied entry into developed countries and denied access to their health care facilities.

Medical professionals across the Western world are continuously involved in medical examinations designed to prevent the most vulnerable of potential immigrants from entering societies with fully functional medical systems. Indeed, doctors within the public health care system have been encouraged to report sick, illegal immigrants to the authorities to help them deport such people. Recently, Pollard and Savulescu (2004, 349) proposed changing the eligibility criteria for overseas’ visitors (to the United Kingdom) and people of uncertain residential status access to National Health Service treatment to “urgent medical treatment.” They provide the following definition of “urgent medical treatment”: “treatment to prevent either risk to the public (in the case of infectious disease) or serious harm to the individual (now or in the future).”

An international organization of medical doctors, Physicians for Human Rights, has noted that fundamental challenges to the notion of medical professionalism are posed by what it describes as “dual loyalties” conflicts. These conflicts occur

whenever doctors find themselves in a situation where they have to decide whether they should prioritize the health of their patients over government regulations, policies of managed care organizations and the like (Physicians for Human Rights 2002). The obvious question is whether health care professionals have moral obligations to their patients that preclude participation in such practices. Unsurprisingly, immigrants' organizations have suggested that doctors should have the health of their patients in mind, and support their attempts to immigrate into a country that has a functioning health care system. At least some immigrants have been reported to immigration authorities after having sought medical assistance. It has been argued in the *British Medical Journal* by leading UK bioethicists that it is up to immigration authorities, not doctors, to enforce immigration policies (Pollard and Savulescu 2004).

The participation of medical professionals in immigration control measures is ethically problematic and deserves closer scrutiny by medical ethicists as well as national medical associations. In addition, an inquiry is called for into the professional ethics of doctors who join forces with immigration authorities in order to track down illegal migrants. Clearly, this issue needs to be situated within the context of distributive justice. After all, it is western pharmaceutical companies that charge prices for their drugs that make lifesaving medications effectively inaccessible to people in the developing world. Is it so unreasonable, then, to suggest that there is a moral obligation to support sick migrants from such societies who seek medical support in the developed world?

IPR AND ACCESS TO ESSENTIAL DRUGS

Bioethicists and political philosophers have joined in an international debate centering on the relationship of intellectual property rights (IPR), patent protection, drug prices and access to essential drugs for the poor in developing countries. At issue is the fact that pharmaceutical multinationals charge prices for patented drugs that prevent the overwhelming majority of people in developing countries from access to their products (Sterckx 2004). The primary reason for the protection of intellectual property rights and patents is, interestingly, a public interest-based argument. It states that in order for such companies to be able to achieve a desirable public objective, that is to research and produce new drugs, they must be able to reap or anticipate a profit from their products sufficiently high to support a significant research effort (Schull 2000). Precisely this reason, however, provides a possible justification for overriding some patents in some countries. If patents are protected to ensure that the public has continuing access to privately developed drugs, something is going wrong when the public cannot actually afford access to those drugs at all. This is not to say that private companies that spend enormous amounts of money on research should not recoup their investment from patented drugs. However, if the owners of those patents price their drugs out of the reach of the majority of those in need, so goes the argument, there is very little point in protecting those patents any longer (Schüklenk and Ashcroft 2002).

Of course, the issues are more complicated than this. For a start, in developed countries, many people in need of expensive, patented AIDS drugs are able to access those drugs. The same, however, cannot be said for developing countries. Here the argument in favor of setting aside patents seems to succeed. Indeed, the World Trade Organization's *Trade-Related Aspects of Intellectual Property Agreement* (TRIPS) expressly permits developing countries to override the patents for drugs that could be utilized in public health emergencies such as AIDS, TB and malaria. The problem with TRIPS-related policies is, as argued by the pharmaceutical companies, that without such internationally recognized patent rights, there would be no funds and incentives for further R&D (Schull 2000).

Currently, patent owners already battle for market share for their existing products. The argument is that financial incentives to engage in R&D investment may not necessarily jeopardize drug research, as they do not tamper with the patent rights in place in the developed world. Furthermore, it is worth noting that the profits for which industry is clamoring have never been generated in the developing world. What is interesting with regard to this debate is that bioethicists have moved on from arguments suggesting that pharmaceutical multinationals should provide some donations to worthy projects, and engaged in argument at a policy level. The discussion, in other words, is no longer operating on the usual ethics level of "please do the right thing," and investigating "what is the right thing to do," rather it has moved on to proactive policy development (Cohen and Illingworth 2003). It certainly helps that legal frameworks exist to actually execute this strategy. Of course, bioethical analyses mirror in many ways the ideologies commonly found in public discourse. Not surprisingly, neo-liberal philosophers have argued in favor of patent protection, and suggested that developing countries do more to support important drug research on their soil (Resnik 2001).

It is worth asking the following questions: who should invest in R&D in poorer countries? How feasible will it be to generate R&D funding outside pharmaceutical companies? If this was feasible, drug patents may begin to fade away from the center of international ethical debate. It is already being argued that

taxpayers, not shareholders, have borne most of the cost. Publicly funded research organizations have contributed hundreds of millions of taxpayers' dollars to AIDS drug research. Indeed, the Pharmaceutical Research and Manufacturers of America, an industry lobby group, estimates that private industry finances only about 43% of drug development. Five commonly used drugs against AIDS – didanosine, lamivudine, nevirapine, stavudine, and zidovudine – were developed largely as a result of public funds. (Schull 2000)

As Tina Piper (2004, 475) argues:

There is a growing recognition in the international and domestic context that the patent system may not function well for the equitable and affordable delivery of healthcare goods, and its strict operation may have to be altered by enacting accompanying regulation or changing patent laws themselves.

RESEARCH ETHICS

Most major pharmaceutical companies have transformed into global corporations. Their research no longer takes place exclusively in developed countries. An ever-growing number of clinical trials are undertaken in developing countries capable of hosting such investigations (Concar 2004, 28). On the positive side, this globalization of research activities results in the desirable strengthening of research capacities in developing countries. It is also undoubtedly cheaper to run some trials in developing countries than it would be to run them in a developed country. This certainly is one of the reasons why research has become a global enterprise. To a large extent this is what globalization is all about. Producing certain outcomes or products as cost effectively as is feasible remains the primary objective. Achieving this objective is conceptualized and operationalized not any longer in a particular country but on a global scale.

Concerns about the exploitation of research participants in developing countries focus on two distinct issues: the standards of clinical care provided during such trials and the question of what care or benefits are ethically required after the trial has concluded.

An acrimonious and lengthy international debate on the ethically appropriate standards of care provided in clinical trials in developing countries was triggered by an AIDS trial that took place in South Africa, among other countries. At the heart of this debate is whether the standard of care is universal or local (determined by the levels of a given country's infrastructure and wealth).

The trial in question was responding to a perceived need in developing countries to investigate a potentially affordable medication that might reduce the transmission of HIV from a pregnant infected woman to her offspring. Before the trial started, a trial undertaken only in developed countries had established that 25 percent of HIV-infected pregnant women who use no antiretroviral medication transmit the virus to their offspring, but less than 8 percent of those who used a particular regime of the drug zidovudine do. This trial regime soon became the gold standard for mother-to-child-transmission (MTCT) prevention in the developed world. Unfortunately, this drug regime proved to be unaffordable for the majority of infected women in developing countries. The developing world trial aimed at testing a cheaper yet effective MTCT regime. In order to do so, the investigators sought to establish not whether a lower dosage was as efficient as the higher one provided in the developed world, but whether it was more efficient than doing nothing. In other words, the test regime was matched against a placebo control.

The trial regime was quickly denounced in international medical as well as bioethics journals, because it violated a standard provision of the world's pivotal research ethics guideline, the World Medical Association's *Declaration of Helsinki* (Lurie and Wolfe 1997; Schüklenk and Ashcroft 2000). The Helsinki Declaration would have required the developing world investigators to compare their trial regime against the existing gold standard of HIV MTCT prevention, i.e. the locally unaffordable regime.

Defenders of the trial in question argued that the Helsinki Declaration was not a particularly useful ethical yardstick to hold against the developing world-based trial. They proposed that the Declaration be adjusted to reflect the realities of developing world health care (Levine 1999). At the heart of their analysis were two ethical arguments. The first argument was that women in the trials in question were no worse off by virtue of their trial participation. The participating pregnant women would not have had access to antiretrovirals at all, in the public health care sector of their countries. Hence, those in the placebo arm were not in any way worse off, while those in the active agent arm were almost certainly better off. The second argument states, in a nutshell, that the Helsinki requirement to test a new experimental agent always against the best-proven diagnostic and therapeutic method of treatment is preventing useful research in developing countries. If one always has to test a new agent against the best medication that exists somewhere in the world, no matter whether people in a given location can access or afford it, one would not be able to investigate cheaper treatment regimes that could actually make a difference in a developing country.

The counter arguments employed questioned the need to develop cheaper drugs, asking whether or not there is such a thing as a natural (in the sense of: not subjected to human choices) price for any given medication. Proponents of this point of view argue that the prices people pay for essential drugs are the result of pricing decisions made by major multinational pharmaceutical corporations (Schüklenk 2000). Solutions to the matter of drug pricing then could be sought in internationally accepted regulations such as the TRIPS Agreement, which allows for compulsory licensing and parallel importation of essential drugs in cases of public health emergencies. This obviously would eliminate a lot of the persuasive power of the position we have just described. If it is possible to remove the patent protection of essential AIDS drugs, and as a corollary of this their high price tag, the need to develop cheaper AIDS drugs for developing countries may well all but disappear. Arguably, however, this does not in itself solve other issues such as lacking systems for the delivery of antiretroviral drugs in many developing countries. The successful provision of such treatment regimes relies on regular counts of certain blood cells, satisfactory levels of nutrition and so on and so forth. Still, it is widely accepted that the drug price is one of the primary hindrances of poor peoples' access to essential AIDS drugs. One might even argue that prices for diagnostic instruments could be subjected to a critique similar to that deployed against high prices for patented drugs. The point of this argument being is that diagnostic instruments' prices are also kept artificially high because of the patents held by the developer and producers of such products.

Two other interrelated issues need to be looked at. Both have to do with standards of care. One such issue is what standards of care participants can reasonably expect after a trial has concluded; the other question is what standards of care are ethically required for people who contract HIV during preventative vaccine or microbicide trials? Preventative vaccine or microbicide trials are designed to test whether a vaccine candidate or a microbicide is capable of reducing the number of

HIV infections transmitted in a given cohort of patients. As no preventative agent currently exists it is legitimate to compare the candidate agents against a placebo control. Invariably, in any given clinical trial, there are a number of participants who labor under a therapeutic misconception. They believe, despite the genuinely best efforts of the investigators, that they are receiving a working preventative agent against HIV. If such a participant becomes infected as a consequence of risk-taking triggered or influenced by the therapeutic misconception, such a participant's situation has worsened as a consequence of his or her trial participation. UNAIDS holds the view that an infection acquired under such circumstances does not constitute a trial-related injury. While it might be politically and financially opportune, we doubt that this view withstands critical scrutiny (Schüklenk 2004).

The policy implications of this question obviously go far beyond AIDS research and affect all prevention trials. In South Africa two pivotal research ethics committees withdrew approval for upcoming preventative HIV vaccine trials because the committees considered the investigators' intention not to provide essential AIDS drugs to trial participants who become infected unethical (Schüklenk 2004). The ethical evaluation of this question is once again strongly influenced by economic factors. If a given investigator has to find the additional funds to guarantee life-long treatment (or, as South African ethics committees suggested, while there is a therapeutic benefit to be gained) with essential AIDS drugs, he or she may well decide not to proceed with the trial at all. In turn, this could severely increase the time it takes to develop a preventative HIV vaccine. More lives might be lost in the medium to long-term if this was a consequence of demands pertaining to standards of care to be provided to failures in preventative trials.

FLOW OF HEALTH INFORMATION

The concept of globalization is embedded in the speedy development of technologies that have enhanced communication and interconnectedness, and have led to the rise of claims that the world has become a global village. Though it is often said to bring new opportunities for sharing ideas and technologies, it is uncertain how far this has been realized in terms of global health. What is presently apparent is that even though these technologies have been around for decades, their potential to transform the health of the global community through a fluid health information system has not been harnessed. The resource constraints in developing countries do not promote the development or acquisition of these technologies. However, information is one of the pillars on which an efficient health information system is built. This has severely hampered capacity development in these regions. As at 1998, less than 0.2 percent (one million people of the 700 million people in Africa) has access to the Internet, and 80 percent of these were in South Africa. Of the remaining 20 percent, the ratio of Internet subscribers to those who are not is 1:5000, a figure that is quite alarming when compared to the 1:5 ratio obtainable in the US or Europe (Edejer 2000). Recent statistics show that the digital divide is still very severe: as at 2004, only 1.4 percent of Africans and 7.1 percent of Asians have

access to the Internet compared to 68.3 percent in America and 45.1 percent in the European Union. In Nigeria and Ethiopia, only 0.5 percent and 0.1 percent respectively use the Internet as compared to the 75 percent and 69 percent for Sweden and America respectively (Internet World Statistics 2005). As Edejer (2000, 798) observes: “That the digital divide is more dramatic than any other inequities in health or income is depressing because information and communication technologies have been hailed as one of the potential solutions to these inequities.”

Efforts are being made to reduce if not eliminate these inequalities, but as more people have access to Internet-delivered information in the developing world another problem (that really constitutes an extension of the IPR discussion above) lies in the fact that vital health information needs subscriptions in order to be accessed. Subscription fees charged by some publishers are too high for the average researcher, and frequently even institutions in developing countries cannot afford them. A look at the references of the published work of young scholars reveals that the bulk of them have come from freely accessed journals, some of which are beginning to cancel their current free-access policy. The *British Medical Journal* will in 2005 revert to a subscribers-only access policy plus free online access for readers in least developed countries. Ironically readers in least developed countries are also least likely to have Internet access. South Africa, for example, is quite rightly not listed among this group of “least developed countries”; hence, free online access to the *British Medical Journal* will cease to exist. The predicament for such countries is that as they get their infrastructure sufficiently developed to acquire the relevant information and to utilize it, they are denied access to valuable information because they are not considered poor enough any longer to be given the concession of a free subscription. Yet they are not rich enough to continually afford the subscription fees and/or they must choose which of a range of essential journals will be provided.

Other journals have proposed a different model: they offer free subscription but require that authors pay for their work to be published. This makes it difficult for young researchers to publish their research findings, and is therefore disrupting the flow of vital information that such journals are supposed to serve. This lack of equitable access to health information is undoubtedly one of the reasons why very few works from researchers in developing countries are published in internationally recognized journals. Of about 3,000 journals indexed by international services like Medline and Science Citation, only 2 percent are from the developing world while the other 98 percent come from the developed countries. The reasons for this are not so clear. According to Edejer (2000, 798):

possible explanations range from the difficulties encountered by researchers in developing countries in gaining funding for research – only 10% of funding is spent studying problems relevant to developing countries – to the existence of ethnocentrism at its worst in biomedical publishing circles.

Although, global health problems due to inequalities in health information flow are plenty, some movement towards more equitable access to health information could be achieved through concerted efforts from developed and developing world

leaders. The latter have, through bad governance and corruption, plunged many developing nations into abject poverty. Developed countries, which are the main custodians of novel ideas and technologies, should formulate information dissemination policies in the spirit of globalization as this will improve global public health.

CONCLUSION

Globalization in its own right is not necessarily a bad development for both developed countries and the developing world as it has helped to break down barriers between regions, eliminate monopolies, increase markets for pharmaceutical companies and promote access to drugs and health care for developing countries. The international flow of research funds has undoubtedly assisted in building up research infrastructure and competencies in developing countries. Global efforts have been largely successful in eradicating smallpox, eliminating polio, which is likely to be eradicated in the near future, and controlling many other diseases like onchocerciasis and tuberculosis (Global Forum for Health Research 2002).

Readers, we hope, will agree with us, that professional bioethics could benefit from efforts to refocus its research agenda by way of taking into account the number of people affected by a particular concern. Our overview, as indicated in our introductory remarks, makes no pretense to analyze the issues and answer the problems mentioned in this article. Rather we suggest that the mentioned areas of inquiry are worthy of serious bioethical analysis and arguably that they are of greater significance than the areas that are preoccupying bioethicists' research time at the time of writing. We further suggest that bioethics cannot avoid addressing economic inequalities as well as international policies if it wishes to have anything of relevance to contribute to these issues. No doubt, this would have negative implications for bioethics' funding, seeing that major funders of bioethical research are not interested in offering resources to undertake this necessary work. Arguably the integrity of the field itself could be at stake, depending on how mainstream bioethics responds to this challenge.

NOTES

- 1 See the wealth of documents at Consumer Project on Technology, available at: <<http://www.cptech.org>> (Last accessed: 24 January 2005).

REFERENCES

- Associated Press*. 1999. Officials probe Turkish organ theft, 17 September.
- Bloomberg*. 1999. Turkish officials say quake children stolen for their organs, 1 September.
- Boyle, R.J., and J. Savulescu. 2001. Ethics of using preimplantation genetic diagnosis to select a stem cell donor for an existing person. *British Medical Journal* 323: 1240-3.
- Cameron, E. 2000. Press Conference, XII International AIDS Conference, Durban, South Africa, 10 July.

- Cochrane, J. 2000. Narrowing the gap: Access to HIV treatments in developing countries. A pharmaceutical company's perspective. *Journal of Medical Ethics* 26: 47-50.
- Cohen, J.C., and P. Illingworth. 2003. The dilemma of intellectual property rights for pharmaceuticals: The tension between ensuring access of the poor to medicines and committing to international agreements. *Developing World Bioethics* 3: 27-48.
- Concar, D. 2003. Trials and errors: With drug companies now testing new medicines in all parts of the globe, are ethical standards being compromised? *New Scientist* 178(2400): 28.
- Daar, A.S., A. Bhatt, E. Court, and P.A. Singer. 2004. Stem cell research and transplantation: Science leading ethics. *Transplant Proceedings* 36(8): 2504-6.
- Dhai, A., J. Moodley, D.J. McQuoid, and C. Rodeck. 2004. Ethical and legal controversies in cloning for biomedical research: A South African perspective. *South African Medical Journal* 94: 906-9.
- Edejer, T.T. 2000. Disseminating health information in developing countries: The role of the Internet. *British Medical Journal* 321: 797-800.
- Elliott, C. 2004. Six problems with pharma-funded bioethics. *Studies in History and Philosophy of Biological and Biomedical Sciences* 35: 125-9.
- Farmer, P., and N. Gastineau. 2004. Rethinking medical ethics: A view from below. *Developing World Bioethics* 4: 17-41.
- Global Forum for Health Research. 2002. *10-90 Report on Health Research 2001-2002*. Available at: <<http://www.globalforumhealth.org/FilesUpld/36.pdf>> (Last Accessed: 28 April 2004).
- Hubbard, T., and J. Love. 2004. A new trade framework for global healthcare R&D. *Public Library of Science Biology* 2(2): 147-50.
- Internet World Statistics. 2005. Internet Usage in Europe. Available at: <<http://www.Internetworldstats.com/stats4.htm>> (Last Accessed: 5 January 2005).
- Koehn, D. 1994. *The ground of professional ethics*. London: Routledge.
- Levine, R.J. 1999. The need to revise the Declaration of Helsinki. *New England Journal of Medicine* 341: 531-4.
- Love, J. 2003. A new framework for healthcare R&D. Available at: <http://www.earthinstitute.columbia.edu/cgsd/documents/love_000.pdf> (Last accessed: 30 April 2004).
- Lurie, P., and S.M. Wolfe. 1997. Unethical trials of interventions to reduce perinatal transmission of HIV in developing countries. *New England Journal of Medicine* 337: 853-6.
- Médecins Sans Frontières, Drugs for Neglected Diseases Working Group. 2001. *Fatal imbalance: The crisis in research and development for drugs in neglected diseases*. Geneva: Médecins Sans Frontières.
- Physicians for Human Rights. 2002. *Dual loyalties and human rights*. Boston: Physicians for Human Rights.
- Piper, T. 2004. Commentary. *Journal of Medical Ethics* 30: 475-7.
- Pollard, A.J., and J. Savulescu. 2004. Eligibility of overseas visitors and people of uncertain residential status for NHS treatment. *British Medical Journal* 329: 346-9.
- Resnik, D.B. 2001. Developing drugs for the developing world: An economic, legal, moral and political dilemma. *Developing World Bioethics* 1: 12-32.
- Schüklenk, U. 2000. Protecting the vulnerable: Testing times for clinical research ethics. *Social Science and Medicine* 51: 969-77.
- . 2004. The standard of care debate: Against the myth of an "international consensus opinion." *Journal of Medical Ethics* 30: 194-7.
- Schüklenk, U., and R.E. Ashcroft. 2000. International research ethics. *Bioethics* 14: 158-72.
- . 2002. Affordable access to essential medication in developing countries: Conflicts between ethical and economic imperatives. *Journal of Medicine and Philosophy* 27: 179-95.
- Schull, M. 2000. Effect of drug patents in developing countries. *British Medical Journal* 321: 833.
- Scheper-Hughes, N. 2000. The global traffic in human organs. *Current Anthropology* 41(2): 191-211.
- Sterckx, S. 2004. Patents and access to drugs in developing countries: An ethical analysis. *Developing World Bioethics* 4(1): 58-75.
- Trouiller, P., P. Olliaro, E. Torrelle, J. Orinski, R. Laing, and N. Ford. 2002. Drug development for neglected diseases: A deficient market and a public-health policy failure. *The Lancet* (22 June 2002).

Available at: <http://www.doctorswithoutborders.org/publications/other/miltefosine_06-2002.shtml>
(Last Accessed: 13 March 2004).

World Health Organization, Commission for Macroeconomics and Health. 2001. *Macroeconomics and health: Investing in health for economic development*. Available at: <<http://www.un.org/esa/coordination/ecosoc/docs/RT.K.MacroeconomicsHealth.pdf>> (Last accessed: 30 March 2005).