

BIOETHICS AND PUBLIC POLICY IN THE NEXT MILLENNIUM: PRESIDENTIAL ADDRESS

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Alastair Campbell, President of the Fifth World Congress of Bioethics, has described our mission as that of confronting major opportunities and challenges to be faced in a global context in the next millennium. We are bioethicists – philosophers, physicians, lawyers, nurses, theologians, social scientists, policy analysts, and other practitioners in our multidisciplinary field. To my knowledge, none of us is a fortuneteller, so we are unable to predict what fortunes or misfortunes the new millennium will bring. But we can look around us today and see what challenges face us here and now – challenges that are urgent and will not disappear unless public policy on a global scale rises to meet them.

I want to focus on two phenomena that are well described in the public health literature. The first is the gross inequalities in health and health care that exist between rich and poor classes within nations, as well as among industrialized countries and many developing countries. The second phenomenon that requires public policy remedies, most notably in developing countries, is the health status of women. Both of these are situations of grave injustice on a broad social scale.

Global inequalities go beyond health status and health care. They exist, as well, in access to such prerequisites for good health as clean water and adequate nutrition. Add to that the demographic picture of the burden of diseases such as HIV in sub-Saharan Africa, and we see that the problem cannot be solved by policies developed solely within nation states. In South Africa and Zimbabwe, 20 to 25% of the adult population is infected with HIV. In Botswana, about one in three adults is infected. Peter Piot, the executive director of the Joint United Nations Programme on

AIDS, recently noted that 'Because of AIDS, poverty is getting worse just as the need for more resources to curb the spread of HIV and alleviate the epidemic's impact on development is growing.'¹ But there is a need not only for drugs to treat people with HIV infection. Other diseases, such as malaria, wreak havoc in tropical countries. Malaria annually affects some 500 million people, and 90% of the cases are in Africa.² Countries with an annual healthcare budget of less than US \$10 per person can no more afford drugs to treat malaria in their populations than they can to treat HIV/AIDS. Without concerted efforts to forge public policies that address these international inequities, there is little hope for much improvement.

In early August of this year, the United States government made an offer of \$1 billion in annual loans to finance the purchase of anti-AIDS drugs in sub-Saharan Africa. By late August, South Africa and Namibia rejected the offer of the loan, and officials at the Southern Africa Development Community, which represents 12 other African countries, also expressed doubts about the proposal. They would prefer the United States to pressure American drug companies to reduce prices and to support countries that seek to produce generic drugs more cheaply.³ But that is a step the United States has so far been unwilling to take. Interest-bearing loans cannot be the answer to the problem. That is a market solution, not one that stems from considerations of justice.

Issues related to justice have attracted interest among some bioethicists in the past quarter century, but they have not taken center stage, and they have mostly focused on allocation of health care resources within nations. Only recently have bioethicists begun to explore inequalities in health and health care in the international sphere.⁴

¹ AIDS cases devastating hardest-hit countries, *The Nation's Health*, August 2000, p. 12.

² D. C. Jayasuriya. Health and Human Rights in the Third World. Paper delivered at the World Association of Medical Law Congress, Helsinki, Finland, August 8, 2000, published in Congress Proceedings, p. 516.

³ R. L. Swarns. Loans to Buy AIDS Drugs Are Rejected By Africans. *New York Times*, August 22, 2000.

⁴ N. Daniels, B. P. Kennedy, and I. Kawachi. Why Justice is Good for Our Health: The Social Determinants of Health Inequalities. *Daedalus* 1999; 128: 215–251; S. Marchand, D. Wikler, and B. Landesman. Class, Health, and Justice. *Milbank Quarterly* 1998; 76: 449–467; D. W. Brock. Broadening the Bioethics Agenda. *Kennedy Institute of Ethics Journal* 2000; 10: 21–38; S. R. Benatar. Global Disparities in Health and Human Rights: A Critical Commentary. *American Journal of Public Health* 1998; 88:295–300.

Philosophers have argued that health care is a special form of social good, one not strictly commensurate with or replaceable by commodities in the marketplace. Following the concept introduced by Rawls⁵ and elaborated by Norman Daniels in his writings related to justice in health care,⁶ this line of reasoning adopts the premise that health is a 'primary good.' 'Primary goods' are things that every rational person would want because they are needed to carry out a personal life plan. Although health care and medications are not sufficient to guarantee good health, they are surely among the necessary conditions for attaining or restoring health in the case of treatable diseases. Daniels has made the compelling argument that access to basic health care is a requirement of justice. A goal of public health and medicine is to keep people as close as possible to the ideal of normal functioning, under reasonable resource constraints.⁷ The question is how can this goal be accomplished on a global scale, and what sorts of public policies are needed to make progress toward that goal?

The second injustice that requires public policy remedies – the health status of women – has several dimensions. Maternal mortality remains unacceptably high in many developing countries, a consequence of limited health infrastructure, poorly trained birth attendants, and women's inevitable recourse to illegal and unsafe abortions. In the past decade, the rate of maternal mortality remained highest in Africa, with 9.4 deaths per 1000 live births. The death rate for Southeast Asian women was 6.1. In contrast, the rate was 1.4 for North and South America taken together, 0.6 for Europe, and 0.1 for the United States.⁸ The platforms of the U.N.-sponsored international conferences in Cairo in 1994 and Beijing in 1995 called for increased access for women to appropriate, affordable and quality health, information, and related services throughout the life cycle; the strengthening of preventive programs that promote women's health; the undertaking of gender-sensitive initiatives that address sexually transmitted diseases, including HIV/AIDS, and sexual and reproductive health issues, among other goals. Yet a variety of factors continue to thwart progress toward these goals.

For at least the last ten years, scholars have documented a significant imbalance in the ratio of females to males in several

⁵ J. Rawls. 1971. *A Theory of Justice*. Cambridge, MA. The Belknap Press.

⁶ N. Daniels. 1985. *Just Health Care*. Cambridge. Cambridge University Press.

⁷ Daniels, Kennedy, and Kawachi, 1998, p. 228.

⁸ W. H. Helfand, J. Lazarus, and P. Theerman. Safe Motherhood Means: Social Equity for Women. *American Journal of Public Health* 2000; 90: 1382.

Asian countries. The most recent census in one Asian country reported about 900 women for every 1000 men, and in another, only 929 females for every 1000 males. The single most important cause of the excess mortality rate among females in these Asian countries is thought to be systematic neglect of the health and nutrition needs of girls and women, especially among girls from birth to 4 years of age.⁹ Other causes are high rates of maternal mortality, female infanticide, and abortion of female fetuses. This imbalance in the sex ratio has its roots in the low status of women in these cultures, which place a high priority on the health and education of male children to the exclusion of girl children in poor families.

A 1998 report of the World Health Organization revealed the role that attitudes toward sexuality and family planning play in contributing to unwanted pregnancy and sexually transmitted diseases, including HIV/AIDS, in women. In several African countries, condoms are associated with sex workers and premarital and extramarital sex, so many men are unwilling to use them within their marriage. The idea of using condoms with a marriage partner was rejected especially by men since 'condom use in marriage portends unfaithfulness which leads to mistrust.'¹⁰ Groups interviewed in one study agreed that a woman who feared infection by her partner should try to convince him to use a condom, but all also believed that this would not be easy, as women have to submit to male demands or face rejection or violence. Similar groups in another study also said that refusing sex or asking a man to use a condom was likely to lead to violence, rejection and separation.

Lest those of us from industrialized countries and long-established democracies be too complacent, I want to emphasize that inequalities in women's health status and access to health care are not confined to developing countries. An article entitled 'Human Rights Is a US Problem, Too'¹¹ documents the limited access to medical care of HIV-infected women in the United States, most of whom are poor. 81% of women recently

⁹ A. Cohen. Excess Female Mortality in India: The Case of Himachal Pradesh. *American Journal of Public Health* 2000; 90: 1369–1371, p. 1369.

¹⁰ E.K. Baoui, C.O. Garimoi, P. Maharaj, A.C.S. Mushingeh, S. Neema, E. Ngirwamungu, and P. Riwa. Attitudes to sexuality and family planning. *Progress in Human Reproduction Research* No. 48. 1998. UNDF/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. Geneva, Switzerland: 7.

¹¹ E. L. Gollub. Human Rights Is a US Problem, Too: The Case of Women and HIV. *American Journal of Public Health* 1999; 89: 1479–1482.

diagnosed with AIDS in the US are black or Hispanic. The article faults the public health prevention messages from the government as 'punitive and rigid' and the government's response generally as paternalistic and condescending. As an example, the article cites the US public health message insisting that women convince men to wear condoms 100% of the time or refuse sex. Yet, the author notes, most women at greatest risk of HIV infection fail to accomplish these preventive steps.

The continued subordinate status of women in so many parts of the world is a gross injustice, one that stems from a conception of justice different from that of the maldistribution of health and health care in the world. The form of injustice that results in the poor health status of women is gender discrimination, plain and simple. Women and girls are disvalued, treated as inferior to men and boys, and in some countries, both married and unmarried women are limited by law and custom in the exercise of their autonomy. Given these phenomena with deep cultural roots, what role can public policy play in seeking to change the fundamental cultural values?

As we reflect on past institutions and episodes from history, some quite recent or even still current, we cannot help but wonder how intelligent and otherwise morally upstanding human beings could have tolerated and endorsed them. To name only a few: the hideous human experiments conducted by otherwise reputable German doctors during the Nazi era; the infamous Tuskegee syphilis study sponsored by the United States Public Health Service; the forced sterilization of women in government-sponsored programs to control population. It is an interesting thought experiment to imagine what ethical judgments will be made 100 or 1,000 years from now regarding the current global inequities in health status and health care. Might future generations judge wealthy nations to have been unconscionably remiss in failing to make genuine efforts to close the gap? Might bioethicists 200 years from now ask why public policy at the turn of the 21st century was not directed more forcefully at eliminating violence against women and addressing the problem of excess female mortality in countries where that demographic situation exists?

Perhaps most striking of all, will bioethicists in future generations be flabbergasted by the situation in the super-rich and powerful United States of America, where 44 million people are without health insurance – that is 18.4 percent of the population – and necessary medications are beyond the reach even of many people who have a minimal form of health insurance?

Will they be even more amazed to learn that in 1999, when the US economy was booming, 31 million people in the country grappled with hunger or often could not afford to eat balanced meals? And that number is tiny in comparison with those who are starving or near starvation in the developing world. When bioethicists of the future read the mainstream literature of our field from the last three decades of the 20th century, they may very well wonder about us: Why was only a very small percentage of the literature in our field devoted to the injustice in health status, access to health care and adequate nutrition, and morbidity and mortality of women over these decades as bioethics has come to maturity?

If the hope for rectifying at least some of these injustices lies in developing responsive public policies, several key questions need to be addressed. One of the most vexing is: Whose responsibility is it to develop and implement such public policies? If politicians in the wealthy United States cannot see fit to ensure universal health care and adequate food to all citizens of their own nation, what hope is there for resource-poor countries that cannot begin to afford comprehensive health care for their citizens? Is it reasonable to expect wealthy countries to devote a substantial portion of their own resources to helping the poorest countries to improve the health status of their citizens? Is it plausible to hold that considerations of justice give rise to such obligations?

One place to begin is in the vast and growing international research enterprise. Professor Coovadia from South Africa has written:

A major consideration in research among third world populations is the application of the basic ethical principle of distributive justice. No intervention is supportable unless it is made widely available to the affected population. This principle requires that studies should benefit, not only participants in a trial, but also the class of persons they represent.¹²

This sentiment is echoed in international ethical guidelines for research, such as those issued by the Council of International Organizations of Medical Sciences (CIOMS):

As a general rule, the sponsoring agency should agree in advance of the research that any product developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of

¹² H. M. Coovadia. The Expectations of Resource-poor Countries in Clinical Research. *Good Clinical Practice Journal* 1999; 6: 16–17, p. 16.

successful testing. Exceptions to this general requirement should be justified and agreed to by all concerned parties before the research begins.¹³

Yet concurrence with this viewpoint is by no means universal. Speaking from my own experience, I witnessed disagreement among participants at a meeting sponsored by the Nuffield Council in London in 1999. One researcher from a developing country argued that the clause in the CIOMS guidelines that seeks to ensure that products are made 'reasonably available' is too weak, since it does not promise enough. Yet another participant, a researcher from the UK, contended that a requirement to make a product reasonably available to inhabitants of a poor country is too strong, since the country or industry sponsoring the research would never want to undertake such an obligation and the result would be that research simply could not be done in those countries.

In another personal experience, I spent the last year serving as a consultant to the National Bioethics Advisory Commission in the United States, working on its forthcoming report on international collaborative research. When the Commission tackled the question, 'What obligations do industry and industrialized country sponsors of research have to the population in resource-poor countries *after* the research is completed?' they found it most difficult to reach agreement. Individual commissioners reversed their positions from one meeting to the next, and often disagreed with one another. The Commission readily agreed that sponsors of research should provide successful products of the research to the individuals who participated in a study if they still need those products after the study has ended, and also that sponsors should assist in capacity building in those countries. A final version of the Commission's report is just now being prepared, so we will soon learn what was the consensus on making products available to the host country or community after research is concluded.

Several prominent bioethicists from the United States have stated a clear and persuasive position on what is owed to developing countries in international collaborative research, as follows:

If the research only has the potential to benefit the limited number of individuals who participate in the study, it cannot offer the benefit to the underdeveloped country that

¹³ Council of International Organizations of Medical Sciences. 1993. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: 45, Guideline 15.

legitimizes the use of its citizens as research subjects. It should be emphasized that research whose goal is to prevent or treat large populations is fundamentally public health research, and public health research makes no sense (and thus should not be done) if its benefits are limited to the small population of research subjects.¹⁴

In recent years, some promising activities have been taking place on the international scene. We can see the beginnings of efforts to address the overwhelming health needs of resource-poor countries in several initiatives to make the successful products of research available to developing countries where experimental products are tested. The use of prior agreements – outlining a realistic plan for making the proposed research product available after a study is completed – is a relatively new phenomenon, and appears to be growing.

The World Health Organization (WHO), the International Aids Vaccine Initiative (IAVI), a non-profit organization founded in 1996, and UNAIDS, the Joint United Nations Programme on HIV/AIDS, have all entered into some types of agreement in advance of beginning research. WHO collaborates with industry to promote the development of health-related products and technologies stemming from agreements aimed at ensuring that successful products will be made widely available at low cost to both the public sector and developing countries. IAVI has managed to broker novel pricing and intellectual property agreements with industrial partners, designed to increase global access to AIDS vaccines developed with IAVI support. And UNAIDS has succeeded in getting certain manufacturers to agree to preferential pricing agreements for developing countries prior to the initiation of research.¹⁵ These efforts demonstrate that arriving at prior agreements is indeed possible. Yet these efforts are just bare beginnings. Granted, a shift from marketplace values to those of distributive justice cannot and will not take place all at once. The challenge for the next decades is to expand such agreements, and to create and implement broader public policies that have a good likelihood of diminishing the inequities in health and health care that exist within nations and throughout the world. Expressed in the language of the

¹⁴ L. Glantz, G. J. Annas, M. Grodin, and W. Mariner. Research in Developing Countries: Taking 'Benefit' Seriously. *Hastings Center Report* 1998: 41.

¹⁵ For additional details, see the draft report of the National Bioethics Advisory Commission, Chapter 4, at www.bioethics.gov

international human rights framework, we need to work toward a 'progressive realization' of this goal.

As for the injustices related to discrimination against women and the resulting morbidity and excess mortality of women in many countries, there is a role for human rights activists and watchdog organizations to play. The campaign launched by the late Jonathan Mann to join public health and human rights had already begun in attention to women's health in the United Nations conferences in Cairo and Beijing in the mid-1990s. A summit meeting of world leaders at the United Nations in New York that concluded on September 8, 2000 resulted in a Millennium Declaration from the General Assembly. The Declaration included the following fundamental values as essential in international relations in the 21st century:

Under the heading of *equality*: 'The equal rights of women and men must be assured'.

Under the heading of *solidarity*: 'Those who suffer, or who benefit least, deserve help from those who benefit most.'

The United Nations Millennium Declaration also included the following resolutions: 'By the year 2015, to have reduced maternal mortality by three-quarters, and under-5 child mortality by two-thirds, of their current rates'; and further, 'To encourage the pharmaceutical industry to make essential drugs more widely available and affordable by all who need them in developing countries.'¹⁶

In conclusion: if these United Nations resolutions are to be more than aspirational ideals, governments, nongovernmental organizations, and the private sector need to work together on an international scale to establish public policies that take meaningful steps to implement these goals. It is my sincere hope that we, as bioethicists, will do our part.

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¹⁶ B. Crossette. U.N. Meeting Ends with Declaration of Common Values. *New York Times*, September 9, 2000, A4.