

Proceedings of
The Symposium on
International Health and Medical Ethics

—Harvard SPH Takemi Symposium—

December 1st and 2nd, 2000
Tokyo



Hosted by Japan Medical Association
Harvard School of Public Health



Supported by Japan Pharmaceutical Manufacturers Association
Japan International Cooperation Agency (JICA)

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The Symposium on International Health and Medical Ethics

Harvard SPH Takemi Symposium

December 1st and 2nd, 2000
Japan Medical Association Office, Tokyo

Main Theme

“International Health and Medical Ethics in the 21st Century”

*Hosted by Japan Medical Association (JMA)
Harvard School of Public Health (HSPH)*

*Supported by Japan Pharmaceutical Manufacturers Association
Japan International Cooperation Agency (JICA)*

December 1st (Friday), 2000 at the JMA Auditorium (1F)

Facilitator: Dr. Hokuto Hoshi (*Executive Board Member, JMA*)

—Special Address and Reception—

- 18:00~18:05 Greetings Dr. Eitaka Tsuboi (*President, JMA, WMA*)
18:05~18:45 Special Address Dr. Barry R. Bloom (*Dean, HSPH*)
 Chair: Dr. Akira Koizumi (*Vice-President, JMA*)
18:45~19:00 Q&A
19:00~ Reception at the JMA Hall (3F)

December 2nd (Saturday), 2000 at the JMA Auditorium (1F)

Facilitator: Dr. Hokuto Hoshi

First Session —Morning—

- 9:00~ 9:10 Opening Remarks Dr. Eitaka Tsuboi
9:10~ 9:20 Welcome Address Dr. Barry R. Bloom
9:20~10:00 Keynote Address Dr. Michael R. Reich (*Professor, HSPH*)
 Chair: Mr. Keizo Takemi (*Member, House of Councilors*)
10:00~11:00 Presentations Takemi Fellows
11:00~12:00 Discussion Takemi Fellows
 Chair: Dr. Akira Koizumi
12:00~13:00 **Lunch**

Second Session —Afternoon—

- 13:00~14:00 Presentations Takemi Fellows
14:00~15:00 Discussion Takemi Fellows
 Chair: Dr. Akira Koizumi
15:00~15:20 **Break**
15:20~15:40 Comments by Chair Dr. Akira Koizumi
15:40~16:00 Closing Remarks Dr. Michael R. Reich

Adjournment



Eitaka Tsuboi

*President, Japan Medical Association
President, World Medical Association*

On behalf of the Japan Medical Association, I would like to offer my heartfelt appreciation for the cooperation of the Harvard School of Public Health in organizing this important symposium on the problems of medical ethics in international health. I would also like to acknowledge the generous support for this conference offered by the Japan Pharmaceutical Manufacturers' Association and the Japan International Cooperation Agency.

Takemi Program in International Health was established in 1983 on the basis of an agreement between the late Dr. Taro Takemi and Professor Hiatt, former Dean of the Harvard School of Public Health. It was designed as an academic and practical program in the United States for specialists, primarily from developing countries, to conduct research activities on public health issues related to the development and distribution of scarce medical resources.

This symposium was planned with the grand goal of assembling former Takemi Fellows, many of whom have great influence in the field of international health, in a place where they can meet and exchange information about issues in the twenty-first century. I am aware that the role played in international society by the Program is already widely known. I hope that through this seminar, it will contribute greatly to international health on a global scale in the 21st century.

I also expect that the Takemi Program, which has a global impact, will be even more successful, under the excellent leadership of Dean Bloom and Professor Reich, and that the Japan Medical Association will continue its strong support for the Program.



Barry R. Bloom

Dean, Harvard School of Public Health

It is my pleasure, on behalf of the Harvard School of Public Health, to express my enormous appreciation to the Japan Medical Association for hosting this important meeting on ethics and international health, in collaboration with the Takemi Program in International Health. The Takemi Program represents an extraordinary partnership in providing a special educational and research experience for outstanding health professionals who have great potential for leadership in health around the world. At every international meeting on health that I attend, I meet former Takemi Fellows, who express their appreciation for their Takemi experience at the Harvard School of Public Health. It is gratifying that so many of them have achieved positions of leadership in their countries. As Dean of the Harvard School of Public Health, I wish to express my special appreciation for President Tsuboi and his colleagues at the JMA, who have been so dedicated in supporting the Takemi Program at Harvard. I am grateful for your generosity in hosting this meeting that brings together many Takemi Fellows to address a major issue in medicine and international health.

With the extraordinary advances in medical science, there are unprecedented opportunities for the development of new drugs, devices and procedures that will improve the health and quality of life of millions of people around the world. But to learn which of those advances is promising and safe, there will be a great need for clinical trials with many volunteers in countries around the world. For the medical community to maintain its respect and credibility, it is essential that the fundamental ethical principles expressed by the Declaration of Helsinki be honored and applied to our contemporary world. President Tsuboi is a world leader in placing ethical concerns at the top of the global health agenda, and this meeting sponsored by the JMA and the Takemi Program is an important one for all of us. Professor Michael Reich, Director of the Takemi Program, and I are most grateful for the opportunity for the Harvard School of Public Health to participate, and we look forward to a stimulating and important meeting.



Michael R. Reich

*Taro Takemi Professor of International Health Policy
Chair, Department of Population and International Health
Harvard School of Public Health*

As Director of the Takemi Program of International Health, I would like to express my appreciation to President Tsuboi and all members of the Japan Medical Association who have made possible this Symposium on International Health and Medical Ethics. The Takemi Program was established at the Harvard School of Public Health in 1983, and accepted its first group of Takemi Fellows in 1984–85. Since that time, 140 Takemi Fellows from 42 countries around the world have participated in the program, including 24 from Japan. The program was initiated with the vision of Dr. Taro Takemi about the importance of interdisciplinary research to improve the health of people around the world—through the idea of a partnership between Japan, the United States, and developing countries.

Remarkably, the Takemi Program has continued for these 17 years, through the dedicated efforts of many people in Japan. President Tsuboi, as Chairman of the Japan Committee for the Takemi Program, has provided important support to the Takemi Program and its Takemi Fellows. In addition, I would like to express my appreciation to Dr. Toshitsugu Oda of the Japan Foundation for the Promotion of International Medical Research Cooperation, and the other members of the Japan Committee for the Takemi Program. We are grateful for assistance provided by the Japan Pharmaceutical Manufacturers Association and by the Japanese Ministry of Health and Welfare, and by many individuals associated with these two organizations. The Honorable Keizo Takemi and his family have assisted our efforts to assure the continuity of the program named after his father. In addition, the Takemi Program and Takemi Fellows have received financial support from many international organizations, private foundations, and private corporations around the world.

This Symposium marks a special event in the history of the Takemi Program in International Health at Harvard. We are pleased that so many Takemi Fellows could attend the Symposium—through the generous contributions of the Japan Medical Association and the Japan International Cooperation Agency—to share their thoughts on international health and ethics. We would like to express our heartfelt appreciation to all who have made possible the existence and continuity of the Takemi Program.

Ethical Issues in Global Health Research

Barry R. Bloom

*Dean, Harvard School of Public Health
Boston, MA, USA*

It is an enormous privilege for me to present an opening speech at this very important symposium. I would like to say that part of the inspiration for the subject was the efforts of Dr. Tsuboi and the World Medical Association in reconsidering and revising the major ethical guidelines. And it seems like a very appropriate subject to consider at this time.

Let me begin with a brief history of ethical considerations in biomedical research. It is a sad fact that the first real codification of ethical principles occurred only after devastating experiments were done on human beings during the Second World War without their knowledge or permission. As a consequence, at the Nuremberg War Crimes Tribunal in 1947, it was not the medical profession, but the juridical profession—three judges, to be precise—that set up the first policies for medical research. The framework in which the ethical guidelines were developed is illustrated in Article 7 of the International Covenant on Civil and Political Rights, which states, “No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation.” By linking these two sentences, the foundational documents of medical ethics associated biomedical research with torture, degrading treatment and punishment. Thus we are left with the challenge of convincing the global public that our work is actually inspired by only the highest motivations.

The realization that this framework was inadequate began in 1964 with the Declaration of Helsinki which was designed by physicians and medical scientists, overseen by the World Medical Association, to try to set meaningful guidelines for the practice of medical research. There are several important principles that underlie all successive guidelines that were originally put

into the Declaration of Helsinki, and this, I think, is from the most current revision released earlier this year, in the year 2000, which states, “It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject.” And, “In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.” Thus, no matter how important a scientific question is, according to the current ethical guidelines, it has to be in the interest of humanity and individuals to justify putting human subjects at risk for any experimentation.

These guidelines were formulated initially in 1964, and I know through personal communication with members of that original committee that the possibility of conducting serious biomedical research in developing countries was never considered. Almost all of the original guidelines were relevant only to the industrialized countries of the time, although the world was rapidly changing and evolving. As the economies and educational status of people in developing countries have changed dramatically, the guidelines have been revealed to be inadequate to address all the critical issues faced by biomedical researchers working with human subjects. In 1982, together with the World Health Organization, the Council for International Organizations of Medical Science (CIOMS) convened to reinterpret or redefine the Helsinki Declaration guidelines for human experimentation done in developing countries. It should be noted that this was meant to be a clarification, not a replacement or amendment of the Declaration of Helsinki.

In these 15 guidelines and commentaries the aim is to indicate how ethical principles under the Helsinki Declaration could effectively be

applied to developing countries. While not the most important of the declarations or reports in considering biomedical research ethics, there is one from the United States that in a very succinct way defined the fundamental principles that are underlying all of the other reports and guidelines. Since they are so clear, I thought it might be useful simply to summarize those principles. The first is respect for persons, that is, respect for autonomy and self-determination. Individuals must have the power and the right to determine whether they will or will not be subjects for biomedical research. Secondly, research should adhere to the principle of beneficence, or having the purpose of doing good, maximizing benefits and minimizing potential harms experienced by the human subjects. And finally, the third principle in ethical experimentation in human subjects is that of justice, particularly with regard to products or knowledge that results from such biomedical research. There should be an equitable distribution of both the burdens and benefits of participation in research. People who do participate in research should be entitled to some benefits that derive from that and should not simply be used as experimental subjects to benefit some other group of people.

All of the existing guidelines in my judgment have had a fundamental limitation until this year. They are silent on the issue of the economic and technical capacity of either the trial population or the host country to implement the recommendations. Starting in 1998 the committee that I chair at the United Nations Joint Program on AIDS (UNAIDS), the Vaccine Advisory Committee, together with the UNAIDS Ethical Advisory Committee held a series of workshops and hearings in Geneva, Thailand, Uganda, Brazil, and Washington, sampling the views of 160 participants from 37 countries. At these meetings the participants were asked about the issues or problems that would be presented by the existing guidelines for ethical research if an AIDS vaccine were to undergo clinical trials. Given the assumption that no vaccine has ever worked perfectly in the first trial, there would have to be multiple trials of the vaccine. It would also mean that in the early trials it is almost certain that the vaccine would not protect some people until improvements were made.

The UNAIDS Committee considered five major issues, of which I will touch on only four: the issue of individual informed consent, the

issue of vulnerable populations, the issue of the best diagnostic and therapeutic method and the issue of reasonable availability in vulnerable populations. Until these discussions, the focus of concerns in most of the ethical guidelines was on ‘underdeveloped countries,’ the language used in the original Helsinki Declaration. Much of the recent dialogue has dealt with guidelines that would be more relevant to the realities and conditions in developing countries than those in developed countries. In our deliberations, however, we became much more aware that the term “developing countries” encompasses a very wide spectrum, ranging from extremely poor to middle-class or higher in socio-economic status, and, in fact, “developing countries” was not a single entity but a continuum. Thus, the aspect of research on developing country populations that the committee chose to emphasize was not on their being developing populations, but rather vulnerable populations; vulnerable to exploitation and vulnerable to harm.

Our discussions revealed that vulnerability is defined in a variety of ways. One apparent level of vulnerability is in the realm of economic capacity. To measure this we suggested using the United Nations Development Program’s Human Development Index, which ranks countries on their standards of education, development and economic status. Second is vulnerability in the context of lacking in community and cultural experience with scientific research. Third is lacking in local infrastructure and technical capacity for producing health care and treatment options even if AIDS vaccine trials were done. Finally, for conducting the proposed research, was there technical capability and ability to provide genuinely free informed consent. And finally, did a population have the capacity for conducting ethical and scientific review? And if the answer to any of those criteria was no, that suggested that the population was by definition a vulnerable one, and special care had to be taken to make sure that the research would be of the highest ethical standard.

On the issue of informed consent, we often consider it a certainty that every individual has the right and, in fact, necessity for autonomy and ability to give individual informed consent as it is in the most advanced industrialized countries. However, in many parts of the world individual informed consent is not only unimportant, but it could be harmful to individuals, for instance, in societies where village leaders are traditionally

the decision-makers and should not be undermined by individuals. As would be expected, we struggled with that criterion, and eventually came up with a useful recommendation. In some communities it is customary to require authorization of a third party, such as a community elder, to enter the community in order to invite its individual members to participate in research. We recommended that such authorization may not be used as a substitute for individual informed consent. What this says is that in those cultures where a village elder has great power, it would be inappropriate for research to be carried out on any individual without the consent of the elder. But if the elder does give consent, then the fundamental principle of Helsinki and all other ethical guidelines must be adhered to and all individuals must be free to choose whether or not to be subjects of research.

The most contentious issue in the Helsinki Declaration in its original formulation had to do with the standard of care of a subject who became ill during the course of the research. The original wording of Article 23 says that in every medical study, every patient, including those in a control group, if any, should be assured the best proven diagnostic and therapeutic method. When we considered this in the context of HIV/AIDS in a country in Africa, for example, like Uganda, the best proven treatment became a very huge problem. If one assumes that the seroprevalence was about 20%, and the per capita expenditure on health was about US\$6 per person per year, and the best proven treatment, which would be high activity anti-retroviral therapy combination chemotherapy, would cost US\$15,000 per person per year, there was no possibility that this country and many other developing countries around the world could afford the best proven treatment. This issue continues to inspire great debate among the medical and ethical communities all over the world.

In a recent draft of the U.S. National Bioethics Advisory Committee, “the best proven treatment” was removed and replaced with the words “established effective treatment” in order to best convey what is owed to research participants. The recommendations of the UNAIDS ethical advisory committee were inspired by the preamble to the World Health Organization Charter or Constitution which says “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being, without distinction of race, reli-

gion, political belief, economic or social conditions.” The concept of “the highest attainable standard” has also been enshrined in the Economic and Social Rights Convention, ascribing meaning to it that is important in the context of ethical biomedical research. As such, the final wording of the UNAIDS recommendations was “In the ideal case, one should try to provide the best proven therapy. Where that is not possible, the minimum would be to provide the highest level of care that is attainable in the host country.” In essence this means, some level of care better than common or routine care for those involved in the trial, but not necessarily the most expensive, best proven treatment anywhere in the world. In many respects, the simplest formulation of this concept, and perhaps the most useful, has been articulated in the recent revision of the Helsinki Declaration which says that “In every medical study every patient, including those of the control group, if any, should be assured of proven effective prophylactic, diagnostic and therapeutic methods.” The word “best” has been replaced with “proven” effective treatment for any aspect of the condition. This change is clearly a recognition, by all of the relevant bodies, of the importance of meeting the practical needs as well as the ideal needs of volunteers for human experimentation in developing countries.

The CIOMS guidelines have a very specific phrase that has been long ignored in biomedical research which says that “Externally-sponsored research must be responsive to the health needs of the host country. As a general rule, any product developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of successful testing.” This is very seldom done. A trial is carried out in a developing country, a product is either effective or not, and there is no provision for making that effective treatment available to the population that took the risks of volunteering for such a trial. I am very pleased that in the current revision of the Declaration of Helsinki, it says “At the conclusion of the study every patient entered into the study should be assured access to the best prophylactic diagnostic and therapeutic methods identified by the study.” So if there are multiple arms to a study, whichever one has the best results then has to be made available in an ethical way to the population that was involved in the study. Here I would just add a thought from the UNAIDS document

which says that “Plans should be developed at the initial stages of HIV vaccine” or, I would say any “clinical trial, to ensure such availability.” It is well known that if plans are not made at the beginning of a study, it is very difficult to guarantee availability at the end.

Thus the abiding question is: who is responsible for making those products available to the population? The current understanding is that the responsibility for providing access to the proven treatment or therapy lies on the manufacturer or the pharmaceutical company that carries out the trial. However, the world is changing. Very few trials are carried out by only one sponsor. Many trials are now being carried out by people who are not sponsors. These are contract research organizations that are hired by companies solely to design and carry out trials. The UNAIDS document said that traditionally the sponsor has been thought of as a single corporate entity such as a pharmaceutical company. In modern vaccine development programs there are commonly multiple sponsors, including one or more corporations, one or more national governments and one or more international agencies. It becomes clear then that pharmaceutical companies are not solely responsible for providing or ensuring the availability of successful products, rather, in contemporary medical research this is a responsibility shared among all the sponsors.

In that two-year period, I developed a perspective on the Helsinki and CIOMS ethical guidelines which I would like to share. The first is that Helsinki’s and CIOMS guidelines are universally respected and should not be changed lightly. But the documents must be living documents that evolve to encompass and provide guidance for changing realities and global health, like the problem of AIDS, and the necessity of carrying out trials in countries where AIDS is most prevalent. Also, the recognition that thoughtful people of good will may and often will disagree on ethical judgments. And finally, when those disagreements occur there is currently no forum anywhere in the world for reviewing independently and providing resolution for disputes about international ethical issues, and I believe such an international agreement on how to resolve disputes is urgently needed.

Now these are the kinds of ethical considerations that have been undertaken and some of the major issues of contention. But the context in which biomedical research for trials in develop-

ing countries is changing and worrisome. The income gap between the richest and poorest countries is ten times greater in the year 2000 than it was in 1970. There are a hundred million more people in the world living in poverty, defined as living on one dollar a day or less. The average salary in the wealthiest 20 countries is about US\$25,000 a year, and the average income in the 20 poorest countries is 50-fold less. The disparities are increasing. I have a thesis, and the thesis is stated simply as follows. There was a very famous politician, the Speaker of the House of Representatives from my state named Tip O’Neill, and his wonderful philosophical view of politics was that all politics is local. I tend to agree. I believe that all health care and health care systems are national, and that includes essential national health research. And that leads me to the view that all health research is global. What do I mean by health research and global health research? The first is that global health research is done by individuals and institutions, it is not done by nation-states and is not restricted within the boundaries of a nation-state. And global health issues are problems, issues and concerns that transcend national boundaries and may be best addressed by sharing knowledge and cooperative action. That is what I mean by global health research.

In that sense, global health research is a public good. To economists a public good means a good that is not owned by the place or the inventor, but is useful for many other people other than those who produced the product or knowledge. And that is the essence of the knowledge derived from biomedical research. That research is done in a changing world with increasing globalization, multinational corporations, international pharmaceutical and vaccine companies, contract research organizations hired to do trials and health management organizations spreading around the world to control the costs of health care and to deliver health care in a different way than traditionally. There are new infectious diseases and reemerging infections. There is global transfer of toxins, of poisons, of environmental risks, and the net result is that the gap between the rich and the poor at the level of health and science and technology is increasing. All of that is the context, then, to look at the new advances and new approaches in biomedical science.

The pinnacle of those new approaches is the Human Genome Project, probably the most exciting project in the history of modern biology.

But if one looks at the focus of the Human Genome Project, it is mostly dealing with problems of the rich countries, it deals primarily with non-communicable diseases—cancer, cardiovascular disease and psychiatric disease. On this I would make two points. The first is, there is a portion of the Human Genome Project that is devoted to pathogen genomes, and there have been 22 pathogen genomes completely sequenced, many of which are pathogens like the tubercle bacillus, other bacterial pathogens that primarily afflict people in developing countries through such illnesses as cholera, typhoid fever and leprosy. The second point would be while there are big differences between the diseases of developing countries and industrialized countries, there is a tendency towards convergence, so that 20 years from now chronic diseases will be the major problem in both sets of countries. The Genome Project is of extraordinary interest because if epidemiology has defined the external risks to health, the Genome Project is going to define intrinsic risks that each of us has, unique risks for disease. And it will do so using unbelievably sophisticated technologies, such as gene expression and micro-arrays, and DNA chips. The amount of information is so complex that the human mind and the eye simply cannot put them together intuitively or practically. Therefore, one needs a whole new discipline of bio-informatics, and one needs large populations to look at subtle differences between individuals that control the degree of susceptibility.

A DNA chip is smaller than my wristwatch and holds 8,000 genes. A slightly larger chip containing 16,000 genes was used to study patterns of genes turned on and off in human cancers. By using complex informatics and computer analysis, it is possible to group individual tumors and demonstrate that all the tumors of melanomas have a very consistent pattern, quite different than the pattern for lymphomas. And from this kind of analysis it is possible by using purely molecular technology to take even a single tumor cell and define the nature of the tumor and distinguish at a molecular level between a melanoma, a lymphoma, colon cancer, etc. More importantly, it is now possible to look at the gene expression patterns, for example, of breast cancers, and predict which will survive current treatment for more than five years and which individuals will die in short times, even with the best current treatment. And that enables us to determine which individuals will not succeed in

treatment and should try new and experimental treatments. And this is at a level, in the breast cancer case, that no pathologist is able to distinguish between these two types of tumors.

The possibilities are immense. There will be many positive outcomes from the Human Genome Project. There will be the development of bio-markers, markers, genes, color tests, enzymes, that indicate the kind of tumor or the kind of circumstance or the kind of disease that will lead to a great deal more opportunities for diagnosis earlier and more definitively. The definition of the structure of the gene predicts the structure, to an extent, of the protein and will enable the development of many new drug targets. A new kind of chemistry is capable of producing in a small laboratory 50,000 new compounds a week, more than a major drug company would have been able to produce in a year just five years ago.

The first two vaccines derived solely from the Genome Project have been developed, where the DNA sequence was read, inferences were made about what would be antigenic fragments, peptides were synthesized and shown to be protective in mice against *Neisseria meningitidis* and against *streptococcus pneumoniae*, two major diseases in desperate need of vaccines.

I'm very optimistic about stem cell therapy, where it is possible to take early stem cells from embryos—but five years from now probably from blood or bone marrow without the need for embryos—and to replace damaged tissue, as in the case of myocardial-infarcted tissue or damaged tissues in other organs, for example, in the case of multiple sclerosis, and produce new cells that function in the exact environment. Gene therapies will be developed, they will be developed primarily for single gene defect diseases, inborn errors of metabolism. It will be harder to get them to work than stem cells because the gene will be more difficult to regulate up and down as it would in a normal cell, but it will be a major advance. And from this, great numbers of new drugs will be developed so that one could imagine the day a child is born in a rich country, their DNA would be put on a chip and it would be possible in a matter of hours to predict all the intrinsic risks for susceptibility to disease—cancer, heart disease, Alzheimer's disease, and then at day five of life provide a cocktail of drugs to prevent those risks from developing. And one has the nightmare of every child for the rest of its entire life taking between 50 and a hundred

pills a day to prevent against all of the intrinsic risks. Whatever that is, that will not be the life envisioned by a child that grows up in a developing country.

But even the power of the genome causes really extraordinarily interesting problems. For example, estimates are that there are about 80,000 genes in the human genome. Perhaps all of them or only half of them are functional. At the present time, if one looks at all the drugs in the world for which we know the target of the drug, there are only 479 defined targets for all the existing drugs. And we know that 40% of the new molecular entities or drugs are 'me-too' drugs that actually work on one of those already existing targets. So if one assumes that maybe 10% of the human genome will represent new targets for drugs, how will the pharmaceutical industry be able to make ten to twenty thousand new compounds? It is not clear. And if drug costs are the major cost to the health systems, both in Japan and the United States, where drug costs are rising at the rate of 18% a year, what do we do if we have 10,000 new drugs and how will we control the costs and ration access to new drugs?

Finally, the genome is going to be helpful perhaps in predicting risks for adverse effects. Many of you know that the only drug for treating inflammatory bowel disease recently has been removed from the market because three people died. When hundreds of thousands of people receive a drug and only three people die, it may be that those three people have a special genetic predisposition for adverse effects. The Genome Project may make it possible for the pharmaceutical industry to predict those people who have the greatest risk for adverse effects, as well as predicting who will respond well and who will not to new drugs.

The Genome Project has predictable risks, however, that have ethical implications. One is that, as I suggested, with many new targets for drugs and many new drugs, drugs will be tailored to the individual, not to populations. And this will lead to what I call "boutique" medicine, individually-tailored pharmaceutical and other medical interventions. There will be an exploitation of populations in developing countries for research and clinical trials who may not benefit from that research when it is carried out on contract. There is a danger when the risks for disease are made available that insurance companies will adjust their risks and exclude people from the day they're born because they may have

some genetic predisposition for one disease or another. There may be discrimination, again based on genetic risks, in jobs, marriage and housing. And all of the information on anyone's genome poses great threats to privacy and confidentiality. And finally, with all the good that the Genome Project will do, it is almost certain to increase the gap between the rich and the poor countries. And it is a major responsibility, I believe, of the medical and scientific communities to seek population-based treatments like vaccines, like drugs such as aspirin that could be given to people no matter what their economic status is, that would have wide application. But that is not the current trend.

The next revolution in parallel and succeeding the genetic revolution will be in behavioral research and the brain itself. We now can show a man thinking, with a positron emission tomograph (PET) scan. From the point of public health we have an awareness now in the U.S. that 50% of all the annual debts are due to behavioral problems, that is tobacco, poor diet, lack of exercise and preventable injuries. Fifty percent of people who die in the U.S., were they to change their behavior, would not die in this given year.

We have also learned that while we believe that behavior is one's individual responsibility, it is really not. The advertising industry is very well aware of that fact. Behavior is socially patterned. In the health business, one cannot simply target only high-risk individuals. One has to target the society and the culture. And there's a need to engage better than we do with the media and the communications people who know how to reach the public and have a major role in increasing tobacco, poor diet and lack of exercise.

Now with the new biology and the new genetic therapy, what is the best we could hope for countries that cannot now provide even existing vaccines and essential drugs to their populations? My hope is that it will be possible from the Genome Project to provide better and cheaper tools for prevention and treatment, particularly at the population level. But we have to think at that level to make it happen. I would hope that it would stimulate local and regional research and industry in developing countries themselves. If there are 10,000 new drug targets, seven or eight major pharmaceutical companies cannot make drugs for all of those targets. It opens new opportunities for biotechnology and the pharmaceutical industry in many countries.

Finally, I would hope when the opportunities become available and the gap between their use and the opportunities become clear, it will create a demand and mobilize resources for a global responsibility. All of us should take some responsibility to see that the advances of science become available to the poorest people in the world. To do that is going to be a great challenge. In my view, the way that we have to begin to think about that is not on the basis of national health, but on global health. And that is to create partnerships on the basis of mutual collaboration without exploitation and without imperialism. And reciprocally, those partners, developing country partners, must be, as we must be, accountable for the use of public funds in the research and to see that it is used in a way that fosters the health of the most people possible. We have a responsibility to learn from the best and from the worst practices in partnerships. What makes partnerships succeed and why do they fail, even though it would be in everybody's interest to succeed. And the hardest part of any type of collaboration is to sustain it and to make it long lasting and long active.

I want to conclude with a small diversion of a subject that is intrinsic to everything we worry about, which is the cost of health care and the need for cost effectiveness and saving money. There's a debate at Harvard, and perhaps elsewhere in the world, that is very clear between people who really care about health and who really care about development. And the debate is between people who believe that health is instrumental for economic development. And I think there is a coming consensus that it is very hard to get economic development in poor countries unless one invests in health and in education. And I think that's clear. But there is another view articulated by the Nobel laureate of last year, Amartya Sen, who believes that health has an intrinsic value, and it is essential for allowing human beings to fulfill their potential and their capability. And I would remind you that the enjoyment of the highest attainable standard of health is in the Charter of the World Health Organization.

And as we worry about cost effectiveness, let me remind you that there was a very striking example of cost effectiveness. It was in 1348 when the Black Death devastated Europe. It killed 50 to 70% of the urban population of Europe. But from an economic point of view, it reduced marginal labor, it increased wages, it

opened guilds to wider membership, it stimulated technology, because they had to feed more people with fewer resources. And they had to create the printing press when the scribes died and were no longer able to copy the bible, it created great universities when there was great disillusionment with the religious orders who could not protect the population from the disease. In essence, from an economic point of view, it was the Black Death that transformed Europe from the medieval to a modern state. It only killed 50 to 70% of the urban population of Europe. Be careful of making all judgments based solely on economic considerations.

Finally, if I were to state my vision for where we would like to go or I would like to see the relationship between biomedical research in an ethical way and developing industrialized partnerships, it is with partnerships. There's a tendency for pluralism, a thousand organizations each doing their own good thing. I feel that is not nearly as effective as bringing them together in areas of common interest, in partnerships in which the whole is greater than the sum of the individual parts. The point of these collaborations should not just be to produce new knowledge, but to use research to create knowledge that will contribute to global equity, knowledge that will improve rather than increase the disparities between rich and poor in the world. I think that can only be done if we understand that everyone has an interest, a self-interest and a moral interest in taking responsibility for health research and generating knowledge that benefits everyone in the world. I would argue each of my visions for essential global health research is epitomized and exemplified by the Takemi Program, which is a true partnership between Harvard University and the Harvard School of Public Health and our colleagues at the Japan Medical Association and the generous sponsorship of the Japan Pharmaceutical Manufacturers Association. This symposium has been a wonderful experience for so many distinguished people who are now gathering here together in Tokyo and with great pride watching the success of the Takemi Program, which has been sustained over the years. As you will see, responsibility has been global because the Takemi Fellows have worked in various countries in the world but maintained a network. And I would say this program has been an inspiration for me; if it could be generalized, think of how we could change the face of the earth.

Ethical Analysis in Public Health

Michael R. Reich

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I would like to begin with two citations from Dr. Taro Takemi on ethics. First, in 1977, he wrote, "According to a new medical ethics I have in mind, the protection of the life of an individual is the responsibility of society as a whole, and it is in such a society that the physician offers his technology and spiritual service." Then in 1981 he wrote, "Medical ethics of the future must be based on a global and human viewpoint. It must be one in which there is a meaningful relationship between each individual human being and the physician at all times. I believe that we must clearly recognize that the concept of medical ethics today is expanding to a global scale." That was nearly 20 years ago. And today I think we are witnessing the value of Dr. Takemi's ideas as we sit here today to talk about ethics and its implications globally for physicians, for public health, for Japan, for the United States, for the developing world and for all of us.

I would like in my presentation to cover three points. First, I would like to speak with you about a conceptual approach to ethics. Second, I will discuss three main categories of ethical

argument. And then third, I will present some implications for international health policy.

Let me begin with some of the broad conceptual approaches. Why do we need ethical analysis for health policy? First, public health problems are not just technical problems. Technical analysis alone will not give us answers to the most important public health problems of today. Second, how do we decide which problems to address? We have limited resources. It's not possible to address all problems at once. We need to set priorities. And third, once we've defined a problem, once we have a set of solutions, how do we decide which solution is the best one? All of these issues drive us to the need for ethical analysis. In this symposium today we'll be talking about many specific cases that require ethical analysis. We'll talk about smoking and tobacco, we'll talk about how the end of life is dealt with, we'll speak about AIDS treatment in developing countries, pharmaceutical policy in various aspects and we'll talk about dietary supplements. Each of the public health problems here requires ethical analysis and reflection.

Dr. Taro Takemi on Ethics

"According to a new medical ethics I have in mind, the protection of the life of an individual is the responsibility of society as a whole and it is in such a society that the physician offers his technology and spiritual service."

Taro Takemi, 1977

Harvard SPH Takemi Symposium 

Fig. 1

"Medical ethics of the future must be based on a global, panhuman viewpoint. It must be one in which there is a meaningful relationship between each individual human being and the physician at all times. I believe that we must clearly recognize that the concept of medical ethics today is expanding to a global scale."

Taro Takemi, 1981

Harvard SPH Takemi Symposium 

Fig. 2

At the Harvard School of Public Health we have had a required course in ethical analysis and public health for the past 10 years. Ethical analysis is considered a core competency for anyone who wants to be a public health professional. Indeed, I taught that course, along with Professor Marc Roberts, and in order to attend this symposium I had to ask Dr. Roberts to teach two of my classes. The course at Harvard provides the basis for my talk today. I would like to give you a synopsis of some of the main ideas that we present in the course.

If we think about ethical analysis in public health it moves us beyond the doctor-patient relationship, which is typically considered the basis for medical ethics. If we think about public health we have to think about how individuals and societies confront patterns of illness in the world. And we have to think about how individuals and societies confront the determinants and the consequences of those patterns. I think that, as reflected in the quotations from Dr. Takemi, he was in many ways expressing the importance of considering public health. In doing this, however, ethical theory alone is not sufficient. Why? First of all, philosophical terms often are not clearly defined. Secondly, if you want to use ethical analysis to make real decisions about policy it requires practice in applying ethical theory. And thirdly, in our approach, we believe that you have to go back and forth between ethical theory and practical cases to understand how to use ethical theory in guiding decisions about allocating resources for public health policy.

There are three main categories that we use in ethical analysis. First is to say the best decision is defined by the consequences of a policy on society. That is typically considered utilitarianism. The second approach says that the right decision depends on rights and opportunities for people, not on consequences. This is typically the basis for liberalism, for rights-based thinking. The third says the right decision is defined by the virtues of a community, by the values held in a particular community, and this is called communitarianism. I'd like to give you some examples for these three categories of ethical thinking. They all believe that moral truth exists, and that there is a right way to do things. They have very different ideas about what that right way is.

In addition, each perspective has problems. Each perspective has questions that are not answered. For utilitarians the question is how do

you measure consequences? Which consequences should you be concerned about? For liberals the question is which rights do citizens have? Which rights take priority? And for communitarians the question is who defines the community and how are the virtues defined in the community?

I think these three perspectives are all relevant to Japan for several reasons. Japan is becoming increasingly internationalized. Japan is in the process of constructing policies for international health, as part of its policies for international assistance. And Japanese organizations, including the Japan Medical Association, including the Japan Pharmaceutical Manufacturers Association, including non-governmental organizations, are all increasingly involved in international health.

What are the key principles for these three perspectives? Remember, utilitarians are concerned about consequences. The right policy is the policy that does the most good. What matters is well being of people. In seeking to increase well being, each individual counts equally, and the best action is decided by adding up the gains and the losses in well-being for the different people. There are two broad ways to measure utility. The first says the best way to measure consequences is to let each person decide on their preferences about well-being. So each person in the audience would say, I think that what matters most to me is X. This is called subjective utilitarianism. The second approach says we need some experts to devise a scale and an index to measure everyone's well-being, these are called objective utilitarians, and then decide on what the best policy is according to consequences. So a health policy for a subjective utilitarian would ask consumers about their willingness to pay to avoid death or disability, and then use the data to calculate the costs and the benefits and the policy that has the greatest benefits and the least costs is the one to follow. An example from the presentations today might be if the costs of smoking outweigh the benefits, then health professionals should try to help people to avoid or stop smoking. Dr. Prakash Gupta will talk about this in his presentation.

Objective utilitarians might construct an index or a scale. One of these scales is called disability-adjusted life years (DALYs) to measure health, and it is used to calculate the impact of different policies on health. This measure is used to calculate which policy has the greatest

impact in saving a certain amount of health, and priorities are then based on the cost effectiveness of different interventions. An example in the presentations today is if certain pharmaceutical products will improve health at low cost, then national policy measures are justified to assure access to those drugs. This issue will be discussed by Dr. Sauwakon in her presentation on intellectual property and public health.

Liberalism takes a totally different approach. It says each individual has the capacity to make moral choices about life. Each individual, therefore, is entitled to respect and each individual has a right to certain preconditions to make the best choices in life. This perspective emphasizes rights. And again, there are two approaches to rights. One approach says the only rights that matter are the rights to be left alone, to be free to choose, to be able to speak, to be able to buy and sell. This is typically called libertarianism, represented by national leaders like Ronald Reagan and Margaret Thatcher. The second approach says that people have rights to those resources needed for a reasonable range of opportunity. People have rights to a minimum standard of living, which is similar to the notion of the welfare state. So a libertarian would say, for example, that people have the right to buy and sell human organs for transplants. People have the right to suicide and euthanasia, the right to abortion. The priority is given to the market and to the individual to decide what constitutes the best life, with minimal intervention by the state. So an example here from the presentations today is to what extent should governments intervene in the private market of dietary supplements? This is the presentation by Dr. Geok Lin Khor. And a libertarian would say keep the state out and let the market work. An egalitarian liberal concerned with positive rights would have a very different perspective. They would say each individual has a right to a basic package of health services for all citizens. The government's responsibility is to assure that everyone has universal access to a minimum standard of packages of health. So, for example, they would say there's a right to drugs for treatment of AIDS for the worst-off citizens of society. The role of the state here is totally different. The role of the state is to redistribute resources to assure fairness and to assure justice. An example from the presentations today is an analysis of the rights that exist to pharmaceutical products, and how the state can assure access

without excessive expenditure. Dr. Bong-min Yang from Korea will talk about efforts to change the drug distribution system in Korea and its implications for different kinds of rights.

The third main category of ethical thinking is communitarianism. This approach says people live in a society not in isolation. If you focus on rights too much you will disrupt social cohesion. A good society requires citizens with virtuous character, and the role of society and the role of government is to instill the right virtues and preserve a desirable social order. The question here is, who decides on what is virtuous? And again, two approaches exist. Relative communitarians say each society, each community should decide for itself what the true virtues are, and there will necessarily be different virtues for different communities. The universal communitarians say no, there is one right definition, one right set of values that apply to all people in the world, and we can use coercion to get people to accept our notion of the good. So, a relative communitarian would say local culture determines local practice, even if the practice hurts health. So, for example, in Japan you could say the rules for organ transplants are decided by the Japanese community's cultural beliefs, and if those practices differ from the United States, so be it. Dr. Eiji Marui will discuss these issues in his presentation on where to die in Japan. How does a country shape its values on the place to die, and what's the role of the community and the role of community medicine in shaping the right policy? A universal communitarian would say there is a single set of international norms for healthy behavior, regardless of local culture. This approach does not tolerate health practices rooted in local culture. It says there is one right way. Similar issues are raised in the presentation by Dr. William Pick on South Africa and AIDS treatment. To what extent should international norms constrain national policy on access to drugs for AIDS in South Africa?

Now let's turn to the implications of this approach to ethical analysis for international health policy. Senator Keizo Takemi told me earlier today that the role of an academic is to talk about complicated theory and the role of a politician is to talk about simple choices and matters that people can understand. I hope that some of these complicated ideas can be connected to real decisions and real questions in the last part of this presentation.

The first implication is that you cannot do

international health without ethics. Indeed, you cannot do public health without ethics. Values are implicit in all health policy decisions, and in all policies for international health. In addition, we believe that it is important to address those value choices explicitly.

The second is that conflicts in values often occur in debates about the right policy. It's not only that values are part of decisions, but there are conflicts in values. These conflicts occur within a single category as well as between categories. Does local culture take precedence over rights? What happens if trying to maximize health violates certain rights? When do you ignore the consequences to certain groups in trying to maximize the consequence for an entire society?

The third point is that ethical analysis can help to resolve these conflicts. We believe that ethical analysis is just as important as epidemiological analysis, economic analysis, and political analysis. It is a core training for both public health and medicine.

I wanted to conclude with three questions

that I think will be discussed in the papers that are presented today. The first question is what is the appropriate role for the market in health? When is it appropriate to use the market? When and how should the market be regulated? Which products is it appropriate to sell? Which products should the government provide? The second question is how can we respect local culture as globalization makes the world smaller and more connected? Sometimes local culture conflicts with global efforts to improve welfare. Who decides when local culture takes precedence and how? The third question concerns the obligations of the rich to the poor. When there are so many gaps in welfare and health between the rich countries and the poor countries what are the obligations of the rich countries like Japan and the United States to poor countries, and how can those obligations best be met?

I hope that these questions will be relevant to the presentations and commentaries we hear today on the role of ethical analysis in public health and international health.

Ethical Issues Raised by Smoking



Prakash C. Gupta (Takemi Fellow 1984–85, India)

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I have chosen the topic of smoking because globally we know that adult deaths are increasing largely due to two causes, HIV and smoking. Just about a week ago the World Health Organization estimated that this year there are going to be three million deaths from HIV, and four million deaths from smoking. And by 2030 on the basis of current patterns of smoking, the number of deaths is going to be 10 million. So we are dealing with a very serious public health problem. We understand quite well that smoking is the most preventable cause of serious disease and death among adults in the world today. And this is something that is no longer disputed by anyone, not even by cigarette companies. For instance, on the Phillip Morris web site we find the statement: "We agree with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer, heart disease, emphysema and other serious diseases in smokers. Smokers are far more likely to develop serious diseases like lung cancer than non-smokers." Similarly, on the British-American Tobacco website we find: "With cigarette smoking come real risks of serious diseases such as lung disease, respiratory disease and heart disease. Also for many people it is difficult to stop smoking." These statements are not from any medical association but from two of the largest tobacco companies in the world.

So there is no disagreement today about the health consequences of smoking. But it was not always like this. In advertisements from the 1950s, you can read that "Dentist Ed Wise smokes Lucky Strikes," "Leading doctors still smoke Lucky Strikes," "Eminent doctors prove Philip Morris to be less irritating," and one very famous advertisement, "More doctors smoke Camels than any other cigarettes." So this was

the way in which cigarettes were advertised. Since then, of course, we have progressed quite a bit, and such advertisements are not allowed anywhere, even if cigarette advertisements are allowed.

So we have made a lot of progress. But there are also many points where we need to make more progress. I will, in my presentation, contrast the two situations. For example, in the 1940s or 50s it would not have been uncommon in a hospital for a doctor to offer a cigarette to a patient. But today it would be a completely unacceptable behavior. Smoking in front of a patient might have been the norm 40 or 50 years back, but it is a completely unacceptable behavior today. We all understand that smoking by health professionals is something that is highly undesirable. We also understand that smoke-free health care facilities are highly desirable. And we also know that doctors themselves have led anti-smoking campaigns, and they were the first groups to drastically reduce their own smoking. And we have data on these trends.

For example, during the late 40s and early 50s the smoking prevalence among physicians in the U.S.A. was the same or slightly more than in the general population. But by the time the first Surgeon General's report came out, it was down to 30%. By the early 1980s it was less than 10%, and in the early 1990s, only 6% were classified as daily smokers. Many of them had smoked at some point, but most have given up their tobacco habits. Unfortunately, this decrease is not matched by other categories of health professionals, nurses and staff at medical colleges or in all countries. What about the initiation of smoking? For that we should look at the medical college students.

These data are available from studies at

Johns Hopkins University where they have been monitoring the smoking habits of medical college students (Fig. 1). In the late 1940s and early 1950s smoking prevalence among medical students was 65%, the same as, or slightly higher than, in the general population. But again by the 60s it decreased to 40%, and during the 1980s it was less than 3%. So the initiation of smoking in medical college students, at least in the United States, has gone down tremendously. Unfortunately, this has not happened everywhere. For example, I looked at some studies in India. Smoking and tobacco use among medical college students in India is still very high. I am not aware of much data from other countries.

Considering this extensive knowledge about smoking, it should be logical that all the medical and health conferences that take place around the world ought to be smoke-free. There should be no smoking in those conferences. But as far as

I know the only agency that has qualified and provided guidelines for a smoke-free conference is the International Union Against Cancer based in Geneva. They have provided mandatory and desirable guidelines for declaring a non-smoking event, including all venues that are attached to the conference, and applying to all attendees, whether they are delegates, advertisers or volunteers. Further, the guidelines stipulate that the conference should not have any association with any tobacco company. Among desirable conditions, there should be smoke-free facilities for all attendees, such as hotels, restaurants, transport, shopping. If this is not feasible, there should at least be a separation of smoking and non-smoking areas. The executive committee of the International Union Against Cancer accepted these guidelines, which I wrote, and now, in order to have the sponsorship of the International Union Against Cancer it is a require-

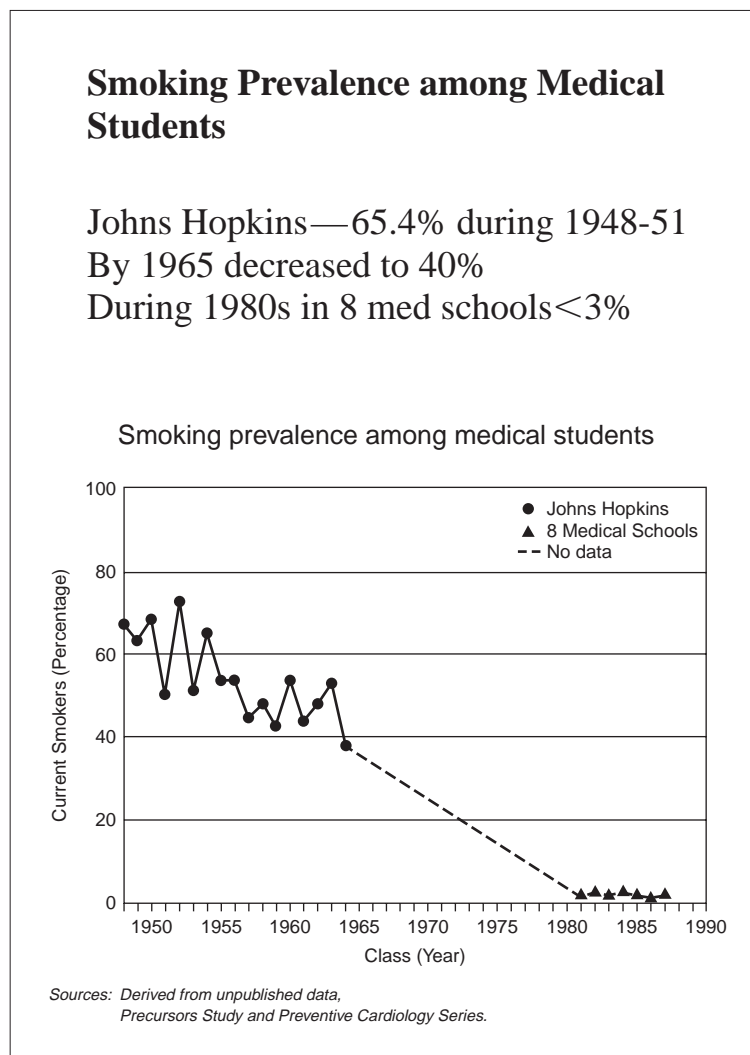


Fig. 1

ment to follow them.

Also, we understand that in any health care facility the direct advertising and the promotion of smoking would be unacceptable. I suppose no one would actually do that but it should be noted that there is a lot of indirect advertising and promotion that is still tolerated. For example, there are magazines that are left around in patient waiting areas. These magazines often contain many cigarette and tobacco advertisements. There is one suggestion from an organiza-

tion called "Doctors Ought to Care" in the United States to tackle this problem. They suggest crossing out every tobacco advertisement with a thick black marker and displaying the following notice: "Many of the ads in this publication are misleading and are a rip-off. For example, Smoking does not make one glamorous, macho, successful or athletic. It does make one sick, poor and dead. We care about you and your health."

Physicians should be expected to inquire about every patient's tobacco habit and offer

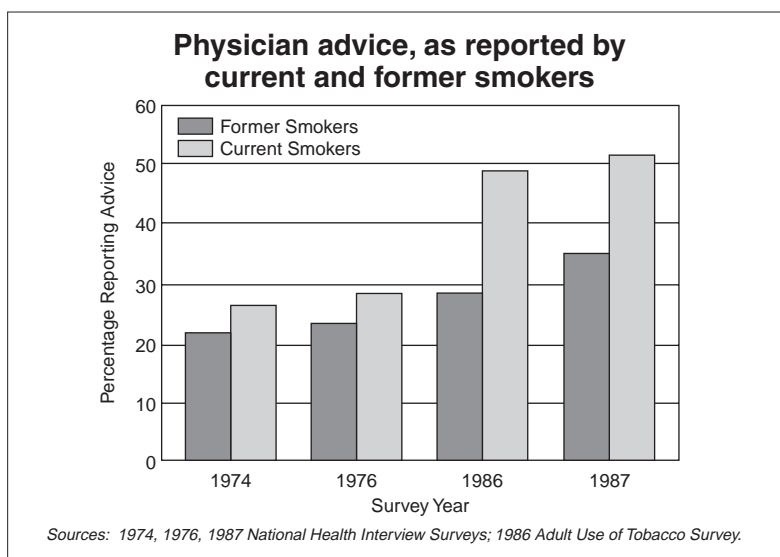


Fig. 2

Current smokers advised to quit, by time period and demographic characteristics

	1974 to 1976 (n = 16,033)	1986 to 1987 (n = 10,403)	Ratio
	Percentage (Standard Error)		
Overall	27.3% (0.4)	49.7% (0.5)	1.8
Sex			
Male	25.8 (0.5)	45.8 (0.7)	1.8
Female	28.9 (0.5)	53.3 (0.7)	1.8
Age			
20 to 29 yr	19.4 (0.7)	41.9 (1.1)	2.2
30 to 44	26.7 (0.6)	49.6 (0.8)	1.9
45 to 64	33.0 (0.9)	55.1 (1.1)	1.7
≥65	33.4 (1.2)	54.5 (1.4)	1.6
Race			
White	28.5 (0.4)	51.5 (0.5)	1.8
Black	18.4 (0.9)	39.4 (1.3)	2.1
Other	15.9 (3.1)	44.1 (3.0)	2.8
Education			
<12 yr	27.2 (0.6)	47.9 (1.0)	1.8
12	25.2 (0.6)	48.5 (0.8)	1.9
13 to 15	28.5 (0.6)	52.1 (0.9)	1.8
≥16	30.8 (1.3)	53.4 (1.5)	1.7

Sources: 1976, 1984, 1987 National Health Interview Surveys, 1986 Adult Use of Tobacco Survey.

Fig. 3

cessation advice where necessary, as it is the largest determinant of adult ill health. In fact, there have been several randomized clinical trials which show that a three-minute counseling session with a patient can substantially increase cessation rates and lead to improvements in public health. Clearly, not every patient would end their tobacco habit or quit smoking, but a substantially high percentage would, which would lead to a significant improvement in public health. The clinical test guidelines in relation to tobacco use are available from various sources; the most recent one is from the U.S. Department of Health and Human Services, which came out in June 2000.

But how far is this advice followed by the physicians? Again, we have data from the United States (Fig. 2). In the mid 1970s about 25% of the current smokers were advised about their tobacco habit. In the 1980s it has gone up to 50%. So there is progress. Again, one does not know about other parts of the world, and the progress is not uniform if you look at the data (Fig. 3). More women than men are advised, younger persons are advised less, non-whites are advised

less compared to whites and, less educated are advised less than highly educated. So there are these kind of demographic differences.

It is also well-established that one of the consequences of smoking during pregnancy is low birth weight, and other adverse outcomes. This is a well-known fact to attending physicians and all attending physicians and obstetrics/gynecology specialists do inquire about smoking to pregnant women and offer cessation advice, particularly where smoking among women is common. But another fact is that exposure of children to environmental tobacco smoke causes specific diseases like middle ear infection and it exacerbates asthma. And there is a recent exhaustive review and many background papers that were commissioned by the World Health Organization. All of the background papers and consensus statements are available at the WHO web site. Yet, it has not become a common practice for physicians who are attending parents of children to inquire about smoking habits of parents and offer cessation advice and warning them that this is injurious to the children.

— Comment for the Presentation —

Ethical Issues Raised by Smoking



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I would congratulate Dr. Gupta for his exceptional presentation about one of the most important problems in public health, with a lot of interest to the discussion on international health and medical ethics.

In my comments I want to emphasize two aspects, the smoking habits among children when they start, when people start to smoke, and the role of the health professional in the campaign against smoking. In Brazil the anti-tobacco campaign is advancing positively. For the first time we have a federal law regulating the smoking advertisements in TV and other media. However, cigarette smoking remains a serious public health problem, and the attitudes of health professionals are very important to change this problem. The prevalence is declining only in more affluent population groups, remaining around 40% among the workers and the poorer. Furthermore, the smoking prevalence is increasing among women and teens, and it's also a problem among children, especially if they work. In a study of around 5,000 children between 6 and 17 years old in more than 3,000 households in Pelotas in southern Brazil, a mid-sized city with 300,000 inhabitants, I have found a close relationship between child labor and smoking. The smoking prevalence was 12% among the workers and 3.3% among the non-workers. To calculate this prevalence, the WHO criteria for adults were used, that is, if the respondent was smoking on the day of the interview and had at least one cigarette per day during the past six months or more. Controlling for age, the prevalence was significantly higher among workers than non-

workers. From 6 to 9 years old, 3.3% of the smokers among workers and 0.1% among non-workers. From 10 to 14 years old, 4.1% among workers and 1.5% among non-workers. And from 15 to 17 years old, 18% among workers and 13% among non-workers. These findings call attention to two interactive problems, work and smoking. In a common perception the kids think that if they can work they can smoke. Many papers call attention to some family and social characteristics that increase the smoking prevalence in kids of parents and friends who are smokers. And the adults' behavior is also a strong influence in the work environment.

Further, access to money and the possibility to buy cigarettes freely are concurrent problems. In many countries around the world, another relationship between child labor and tobacco is the significant presence of children working on tobacco plantations and selling tobacco in the streets. In Brazil we also find health professionals smoking in public buildings like the headquarters of the Health Department in Pelotas or in the classroom or in the health centers. To change this attitude will be one of my priorities in my mandate as Secretary of Health for the city of Pelotas, which starts on January 1, 2001. We need more campaigns, collaborative studies, restrictive policies and well-designed education programs to carry out at schools, work environments, health centers and communities. But we need also strong leadership against smoking from health professionals, politicians and decision-makers. Tobacco control needs to reach all children, workers and health professionals.

Health and Medical Ethics in Taiwan: New Century, New Challenges and New Thinking



Chung-Fu Lan (Takemi Fellow 1986–87, Taiwan)

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Today my talk will address health and medical ethics in Taiwan. My approach is to give you a brief introduction about recent developments in Taiwan, and then to provide some strategic thinking about the future of health care in Taiwan.

Taiwan is now the only nation in the world that is not a member of the United Nations and is also not affiliated with the WHO. But people in Taiwan, particularly in the medical society, are still working very hard trying to catch up. We are under great pressure from China, but we try to help China too. There is a drastic change in Taiwan. Since 1995 our national health insurance program has been implemented. Since then the changes have reached every sector of health care, particularly the medical society and the hospital sectors. For example, there's a great change in the health care environment in hospitals. The hospital is now getting larger and larger. Some hospitals now reach 7,000 beds in one system, and they can see the patients, the number of out-patients, reach 18,000 patients per day just in one hospital. The demand for health care professionals, particularly physicians, is under very great financial pressure, particularly from market-driven health care reforms. The public expectation is much higher than before, and the relationships between doctors and patients, hospitals and insurers are quite poor now. As for the medical schools or academic medical centers there's also a trade-off between the academic duties and their relationship with the communities and how to achieve clinical excellence.

So, there are many examples of ethical dilemmas happening in Taiwan now, specific to each sector of the health care system. For example, at

some community hospitals they have birthday parties or anniversary parties for the test tube babies. One single community hospital delivered 2,000 test tube babies in the last few years. And Caesarean sections are also quite prevalent. This kind of overuse of diagnostic tests or examinations or therapeutic care is quite common in Taiwan's medical practice now. Some other ethical dilemmas we are faced with include a very high hemodialysis rate and teen pregnancy, and it also quite common for teen mothers to have abortions. In terms of end of life care such as sustaining life using high-tech equipment and the use of hospice care, we have some debate over whether we should just give them care and continue to sustain their life or just end their life. Although, by law, the Medical Care Act is quite strict about organ transplantation after brain death, there is some doubt in general practice. In human subject experimentation, because of pressure for faculty to get promotions or for hospitals to be accredited, clinical research gets more funding but they are also quite loose in the regulation on human subject experimentation. Now we are just trying to strengthen this kind of regulation.

I think there is some major force and influence for health and medical ethics in Taiwan. First I think there is a value change with regard to life and society. The whole culture, particularly the Chinese, Confucius-based culture, has changed a lot. Also, people are living longer and there is a change in the population structure. The younger generation, they do not always obey or follow all the rules and their thinking has changed a lot too. Even the expanding of the government, the law of the government through financing and regulation has had a great impact

on health care. And, of course, the technical advancement in medicine and information technology has also had a great impact. With the involvement of the financial industry and even religious organizations, medicine is being run just like a business now.

The public is now more knowledgeable and questioning about the practice of medicine. They challenge the traditional medical care practitioners and their interests. And there is also conflict over the difference in thinking about medical practice and health care reform.

In Taiwan traditional medicine still has some impact and now almost have 4,000 students study Chinese medicine in China today. Japan's influence is gradually reducing, but the American influence is increasing. And Taiwan just tries to balance that. We now send more physicians out of Taiwan to study in Europe.

Now I would like to mention a little bit about the change of Taiwan's health care system, particularly physicians' behavior and hospitals'

behavior. Currently in Taiwan, the government run national health insurance scheme dominates almost everything in health care. So the highly regulated situation under the government encouraged managed competition. There are too many physicians, but some medical specialties seem to be fading now. For example, some surgical specialties cannot find any new residents to enter the surgical training program now. Also, continuing medical education is now compulsory, and the government just tried to enforce a policy that physicians have to renew their license every five years. Clinical practice guidelines are like a fever and everybody, every physician, is talking about evidence-based medicine, the clinical path, case management, and so on. Post-graduate training in health policy and management and law is also available for physicians now. Many medical graduates who are already working as the director of the hospital or in some other administrative position, try to get into a school of public health or law school to get



Fig. 1

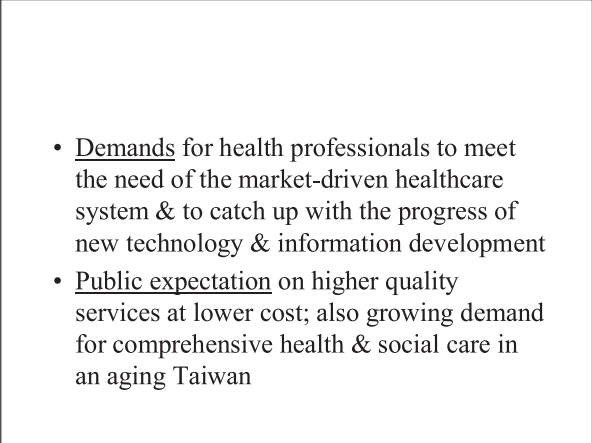


Fig. 2

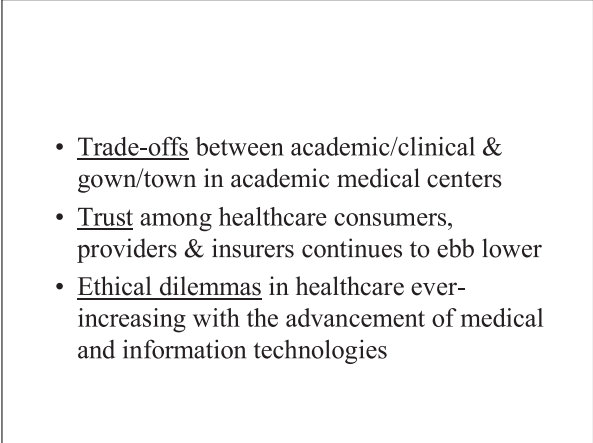


Fig. 3

another degree. Strengthening the law of the medical society is also being debated now, particularly the law of the medical association. Now they are divided between the private hospitals and the public hospitals as well as between the primary care physician and tertiary care physician.

Hospital behavior is also changing a lot now. They are talking about appropriate size, because as the hospitals are getting larger and larger, the smaller or medium-sized hospitals are phasing out. And they use all kinds of management strategies such as diversification, integration or strategic alliance. Capital investment is also coming into the health care system. Very few hospitals are doing Total Quality Management or Total Quality Improvement, and when they do, they try to do cost containment and quality improvement at the same time. In addition, hospital accreditation has gotten tighter and tighter, and the National Health Insurance Bureau is changing both physician and hospital payments.

So in just a month we are going into the 21st century, and I would like to predict some scenarios for the future. First, the medicine of health care will start to change from personalized medicine or socialized medicine; maybe to concentrate more on population based care, such as focusing on a specific disease and then considering the nation as a whole before doing something about it. The second scenario perhaps will start from conventional medicine, such as primary or specialty-based medicine or hospital-based medicine, and then expand that or integrate it into more IDS or IDN such as horizontally and vertically integrated systems. So from prevention to medical care to rehabilitation of social services we are linked together. And now Taiwan is also running the system just like the United States. We try to copy everything from the United States now. In the third scenario, I think that medicine in Taiwan will be organized so that the manager will be running the hospital or the system, keeping professional autonomy

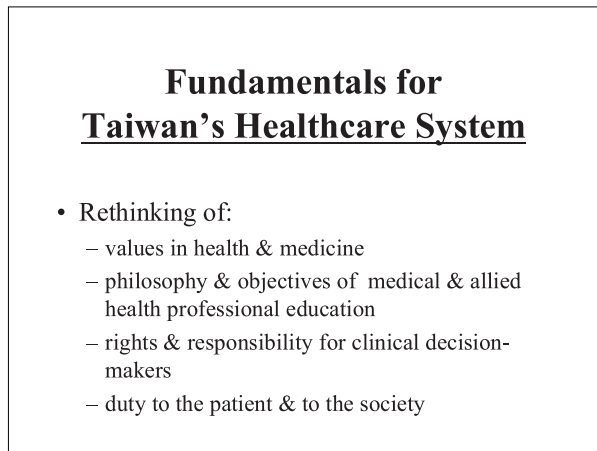


Fig. 4

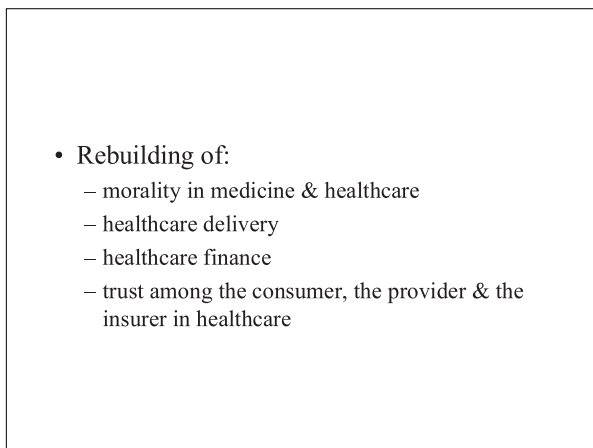


Fig. 5

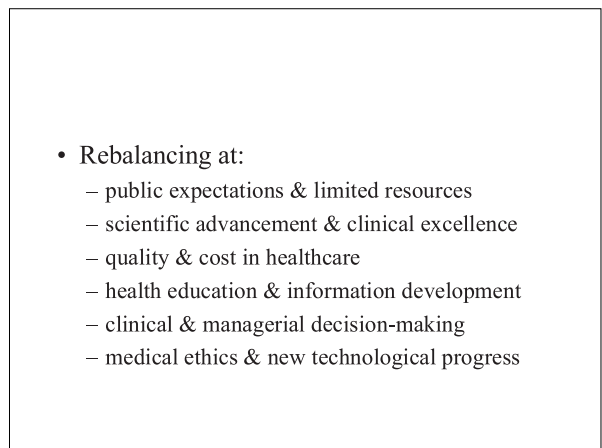


Fig. 6

down and raising manager's capabilities. The fourth scenario I predict is for the fee-for-service system to gradually change to case payment and perhaps next year Taiwan's physicians and hospitals will fall under the global budget due to the constraints of the NHI budget. In this scenario, everyone, including the physicians, will have a huge database in Taiwan, because all medical care or insurance claims will be recorded and there will be profiles of hospitals, physicians and patients. With this kind of huge database or data bank they can achieve evidence-based reimbursement together. And this might be a huge data bank for the public health professional, but it will affect all the physicians and the hospitals and even the citizens. We might concentrate more on the future based on the advancement of the Genome Project. Yesterday Dean Bloom told us of the profound impact of the Genome Project. I also predict this will be a genomic medicine, and there are also several groups in Taiwan trying to work on that now. And the last scenario I predict will be e-medicine because Taiwan is now quite good in information technology. As you all know, we provide a lot of computers to the world, and we also try to use that technology in the hospital information system through hospital automation, using the chip to do medical records and insurance cards. So everyone will hold a chip just to record his or her medical care. In fact, this kind of e-medicine is already quite prevalent in Taiwan's medical system now.

So finally I would like to offer some options or fundamental thinking about Taiwan's health care system. I personally believe rethinking of the values in health and medicine is very important. Every medical student is now required to take a course called "Medical Ethics." And not only for medical students, but dental, nursing and other allied health professional education all require it. And the philosophy of objective and

medical and allied health professional education must be rethought as well. The rights and responsibilities of clinical decision-makers are also very important. Now when the physicians see the patient, it's not judged by them only, the insurer will interfere. And the management in the hospital also has some word to say about their clinical decision-making. So physicians are very dissatisfied with the current system in Taiwan. The duty to the patients and to the society also needs to be reevaluated. I personally also think to review the morality in medicine and health care is very important. If the doctor is not happy, I don't think anyone else will be happy with his or her treatment. So the health care delivery and finance is a very important topic now, and in Taiwan we have just a five-year history with national health insurance, but we are already talking about the health care reform. As we are trying to reform or rethink delivery and finance systems, the trust among the consumer and provider and the insurer in health care must also be rebuilt.

Finally, I personally think the balance between public expectations and limited resources is very important. The balance between scientific advancement and clinical excellence is also very important as well as the balance in quality and cost in health care. Almost every physician or hospital administrator likes to go to seminars or take courses or workshops to try to learn about the specific techniques to manage this imbalance. The health education and information dilemma is also very important, and we must try to take advantage of new areas in information technology. So clinical and managerial decision-making must be rebalanced. The role of the doctor and the role of this new health care manager have to reach some kind of new balance, and medical ethics has to catch up with the new technology progress.

— *Comment for the Presentation* —

Health and Medical Ethics in Taiwan: New Century, New Challenges and New Thinking



Bimo (Takemi Fellow 1991–92, Indonesia)

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In his presentation, Dr. Lan made an excellent description of the changes that Taiwan has faced and the challenges that they have to deal with in the future. In my comments, I would like to mention that Indonesia is also facing similar changes in the health care environment. But there are some differences because of different systems and culture. For example, the dominance of the health insurance program is not so prominent yet in Indonesia, because Indonesia is still in the very early stage of developing its insurance system, and managed care works as the model now. But I would like to mention one challenge that we face in Indonesia that was not mentioned by Dr. Lan. That is the challenge of globalization, and the prospect of having a free-trade agreement in a few years. The impact of that in Indonesia would be a large influx of foreign physicians to work in the health care services in Indonesia. It poses a major challenge to the medical profession in Indonesia, that is, how to ensure the quality of services provided throughout the country. The Medical Association in Indonesia now has the big task of preparing

the necessary infrastructure in meeting the global standard for that.

I would like to point out here that changes are happening not just in Indonesia or Taiwan, but also in other countries as well. The changes and the challenges would be unique and specific to each country. And each country has to find its own way how to deal with the challenges posed by the changes. Unfortunately, there are no comprehensive models that exist to which a country can refer on how to deal with those situations. I would like to raise a challenge for all of us here for further discussion in the symposium. Are there some common themes of issues that cut across countries, despite the differences, that we could collectively find a solution for? I am sure there are lessons learned in one country that would be useful for other countries in dealing with those challenges. And also there is a challenge for all of us as members of the international health community to foster the development of a network of communication between countries to share the lessons learned and to work together for a common arena.

Where Shall We Die, In the Hospital or At Home? —Past, Present and Future Perspectives of Community Medicine in Japan



Eiji Marui (Takemi Fellow 1986–87, Japan)

Department of Public Health
Juntendo University School of Medicine, Professor
JAPAN

Today I will talk about where we die in Japan. After 50 years of so-called “progress” of the medical sciences in Japan, what has happened? This is in some senses a natural experiment in Japan; I can say it is before and after the experiment. Usually we think about “when shall we die?” That is a very important thing. How long can we live? Length of life is our concern. And then our concern changes to, “how we die,” and in that sense, the cause of death is very important: acute death or chronic death. In some areas we will die with medical care and in others without any medical care. And then today, finally, we come to, “where shall we die?” It is just the beginning, but it leads to further issues. For example, the quality of life for each patient and,

at the same time, we have to think about the quality of medical care. But still, today, I will just touch upon the major issues.

In 1951 just around 15 or 16 percent of all deaths occurred at hospitals or clinics, and more than 80 percent at home (Fig. 1). But after 50 years, less than 20 percent happened at home, and more than 80 percent of deaths occurred in hospitals or clinics, in medical facilities. So, dramatic changes have happened in the last 50 years. For example, in 1961 in Japan we completed universal health insurance, but that did not influence this pattern. Fifty years ago our belief was that if we have better medical care, that we will get a better death, or that modern technologies mean good care, or the people

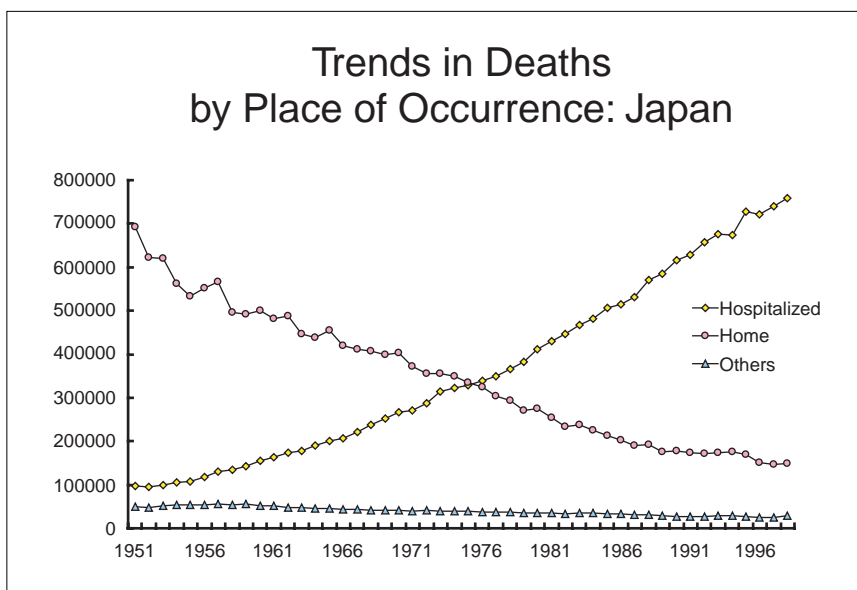


Fig. 1

wanted to stay and die in hospitals with more medical instruments or facilities. And especially the earlier stage in the last 50 years the reality was that poor people had to die at home. And at that time, fewer physicians, but many medical practitioners worked in the community. And then after the 50 years experiment of “progress” of medical science in Japan, we consider more medicalized care to be associated with less quality of life. Or many people believe that poor people have to die in the hospital and others feel the need for more humanistic medical care. As a background, fewer medical practitioners are working in the community, and some people feel that we need more home care seriously. And some rich people are willing to pay for death at home.

At first I felt that ‘where to die’ might not be the best ethical issue to discuss, but I believe it is a good example of ethical issues in Japan because death is one of the ultimate forms of our health. And quality of life in the final stage of life is very important. The right to decide where to die is very important. Many people have pointed out the “spaghetti syndrome” in hospital. That’s quite a miserable picture. We have the very well-known folklore in Japan called the oba-suteyama story that says at some stage of old age, family members take the elderly deep into the mountain and leave them there. So it’s a kind of natural nursing home. We have to make the effort to seek a better solution, and that should

be a solution that is socially acceptable. There are many problems—what is the role of hospitals, what is the role of medical care, and, of course, the background changes of family situation are there, and finally, who decides the place of death.

The number of hospitals increased, but in the last 10 years it has been decreasing. The number of total beds is the same, while the number of physicians and nurses is still increasing and the medical expenditure, it’s greatly increasing now. In the last 25 years single households and nuclear families have been increasing, so the household composition has changed. And especially the households with members over 65

Survey on Death of the Aged

- In September 1995, MOHW
- Subject: 5,454 caregivers of elderly people who died in April 1995
- Nation wide survey (13 prefectures)

Fig. 2

Deceased subjects preferred places to die and actual places of death

actual place of death	total	deceased subjects who expressed a preference of a place to die (preferred places to die)			deceased subjects who expressed no preference of place to die	unknown	
		own home	Hospital· clinic	other			
number of deceased subjects	4755	1473	1313	121	39	2713	569
Percentage distribution (%)							
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
own home	20.0	30.1	33.1	5.8	7.7	15.9	13.5
hospital· clinic	78.7	69.1	66.3	94.2	84.6	82.9	83.3
other	1.3	0.7	0.6		7.7	1.1	3.2

Fig. 3

years old has increased lately, and especially single elderly people and elderly couples. This makes it very difficult for one to stay at home with a bad physical situation.

Next, I will introduce the survey on the death of the aged from 1995 (Fig. 2). This shows that of 1,473 people surveyed, nearly 90 percent of the aged people wanted to die in their own home, and less than 10 percent wanted to die at hospital (Figs. 3 & 4). But actually, only one-third of the people die at home, and two-thirds of the people who wanted to die at home ended up dying in the hospital (Fig. 5). People who wanted to die in the hospital could actually die there (Fig. 6). So where is the good place to die? Our own home, hospital, clinic, or nursing home, hospice or maybe some other place? So, finally I think that we cannot go back to the good old days because the medical environment has changed, family structure has changed, so even if all the

people wanted to die at home, the family structure has changed so much that they have no place to die at home. So the places will be quite diversified. Some people try to go home to die, community physicians try to set up a home care hospice, so that maybe we may have more options. We will set up facilities for dying people in nursing home or some other kind of place. And how can the preference be realized? If you want to die somewhere in particular, how could that wish be realized? And, of course, we need to change the attitudes of patients and physicians. And the role of medical practitioner in community is very important and could be the key. Many medical professionals are trying to change hospital and clinical settings for death. And so, we have to seek new ways in the 21st century. That is my report on the 50 years of natural experiment in Japan.

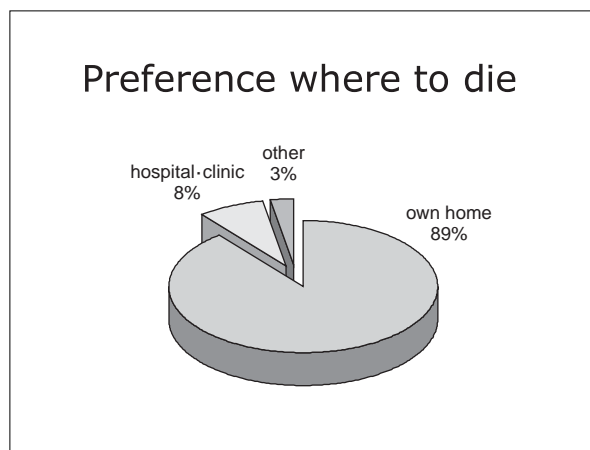


Fig. 4

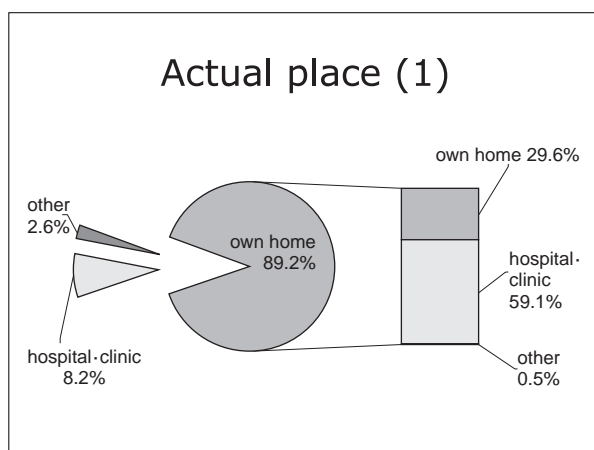


Fig. 5

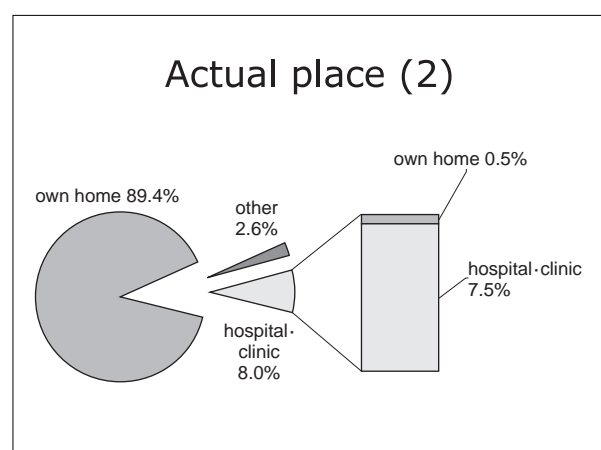


Fig. 6

— Comment for the Presentation —

Where Shall We Die, In the Hospital or At Home? —Past, Present and Future Perspectives of Community Medicine in Japan



Lola Dare (Takemi Fellow 1999–2000, Nigeria)

*Chief Executive Officer, Centre for Health Sciences Training
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NIGERIA*

Dr. Marui's paper has raised several issues related to quality of care and quality of life at death in Japan. This includes the fact that most Japanese are not dying where they wish to die, death has become medicalized as technology is interpreted as good care, and there exists an ethical dilemma in relation to quality of care, quality of life and access to health care services. This reversal in place of death is also observed in many developing countries, including Nigeria where I live and work. Besides the changing epidemiology of diseases from communicable diseases to non-communicable diseases, we have also observed other reasons for this reversal in place of death. In the first place hospitals, on account of poor patient satisfaction, lack of equipment and poor provider attitudes, are perceived as places not to be cured but to die. So people just don't go there anymore. In addition, the increasing cost of health care services means that people can't afford the care anyway, so they wait at home until they are terminal, and then they seek health care services for technology that can no longer help them. There is a huge emphasis in public health policy on technology and curative care at the expense of simple home-based care that can improve health. And so people do not have access to care.

Culturally, dying at home in Nigeria implies old age, peaceful, painless death. And most people, even the educated, want to die at home. When you die at the hospital, which implies that you have a disease, you've had trauma, and there's discomfort associated with that kind of

death. This, of course, raises several issues in ethics and public health. I would like to raise some of these issues, not because I have answers to them, but for continuing the dialogue. In the first place, place of death has implications for quality of care and public health practice.

Secondly, the ethical analysis presented by Professor Michael Reich needs to be considered in defining packages of quality of care. Whose reality counts, the reality of the physician, the reality of the politician or the reality of the end user of the health service? Thirdly, there are very big ethical issues in terms of access to health care and the distribution of health resources—the number of beds, what kind of manpower is needed. Do we train more specialists or more community-based providers? Finally, if you look at the principles of utilitarianism, liberalism and communitarianism that Professor Reich has talked about, and you look at the various practices of both public health, international health and private practice in many parts of the world, including Nigeria, you would find that this concept of ethics often does not come into defining care for many communities that we work in.

Finally, I would like to thank Dr. Taro Takemi for his foresight in supporting the Takemi Program, the contribution the Program has made to broadening my own perspective of international and public health, Professor Reich for his commitment and professional development of all Fellows and the opportunity to be here provided by JICA.

Ethical Concerns in the Dietary Supplements Business



Khor Geok Lin (Takemi Fellow 1988–89, Malaysia)

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University Putra
MALAYSIA*

As a nutritionist I have chosen to speak on some ethical concerns in the dietary supplements business. The dietary supplements business involves many billions of dollars. According to the *Nutrition Business Journal*, in 1998 the dietary supplements industry involved 23 billion dollars in the United States alone. And it includes a wide array of nutrition products, natural foods like the nutraceuticals, functional foods, dietary supplements and also nutrition supplements used in cosmetics. I will be focusing on the dietary supplements.

What is a dietary supplement is actually well-defined by the FDA, according to the Dietary Supplements Health and Education Act of 1994: "A dietary supplement is taken by mouth, intended to supplement the diet, it contains one or more of the following dietary ingredients: vitamins, minerals, etc., and the dietary supplements can be the form of pills, tablets and so on, and its label must clearly state that it is a dietary supplement." Now there is increasing demand for dietary supplements worldwide. I would like to propose some reasons that people are getting greater access to this complementary and alternative medicine, including traditional medicine and dietary supplements. Also people are getting perhaps more disenchanted with the conventional health care, including its increasing cost. There is a worldwide epidemiological shift from infectious to non-communicable chronic diseases, which requires consumers to seek alternative medicine. The demographic shift increases proportions of all segments of the population, but it is the middle-aged and the older population that create demand for more of these alternative medicines. It is very important to note the aggressive and effective distribution

and sales channels for dietary supplements. And if you look at the last point, in the United States they are sold in retail stores, in the mass markets, including supermarkets, and also direct sales. And this is the scenario in many Third World countries, too.

Now I will address some ethical concerns, starting with the regulatory issues, specifically the lack of legal control regulations even in countries like mine, Malaysia. We have regulations for the use of nutrients to be included in foods, but there are no regulations for dietary supplements. Even in countries where there are regulations there may be poor enforcement of these regulations. And there are loopholes and ambiguity in relations. For this I can show the United States itself as an example. And now in the age of e-commerce we can order nutrients and dietary supplements over the Internet. So who is regulating these sales? I take the example of United States because data are more easily available. Now with regard to the regulation of dietary supplements in United States, there is a specific act of 1994 that provides the legal framework for dietary supplements. And yet there are ambiguities, as I highlight here, a regulatory dilemma. Under the DSHEA (Dietary Supplements and Health and Education Act), no claim can be made for a dietary supplement to treat, cure or mitigate a disease. However, a dietary supplement can make claims that it affects or maintains the structure or function of the body. And you know the dietary supplement industry, they're very clever and skirt this issue, and you get all kinds of claims on the products. So are these health claims or are they structure function claims? Well, it depends. For instance, 'helps mood disorders' is allowed, and if you're feeling

depressed, that becomes a health claim perhaps. Or ‘helps to rejuvenate and repair cartilage’ so if you have arthritis, perhaps you look at it as a health claim. And so on. So there’s ambiguity in this regulation.

The second ethical concern is misleading and unsubstantiated health claims. That is very prevalent despite the fact that a health claim is actually well defined, again by the FDA: “A health claim characterizes the relationship of any food, nutrient or substance to a disease or health-related condition.” However, again, you have loopholes and misleading claims. And I take with you here a very specific example. A very important dietary supplement that is used worldwide is Omega 3 Fatty Acids. It is advertised widely that Omega 3 Fatty Acids can help to reduce the risk of coronary heart disease. However, the FDA, having critically reviewed the evidence from studies, including clinical studies, as recent as October 2000, has taken a stand that there is no significant scientific agreement among experts that such evidence supported a health claim for Omega 3 Fatty Acids and coronary heart disease. Thus the health claim stating that Omega 3 Fatty Acids may reduce the risk of CHD is misleading. However, there are studies to show that if you take less than three grams of Omega 3 Fatty Acids a day it may be helpful. And so, FDA does allow labeling that says not more than two grams per day of Omega 3 Fatty Acids can be taken. This will provide an added safety margin for consumers to remain below the three grams per day safety level. This is for the United States, but I assure you, in countries like Malaysia what you get is advertisement that you have more Omega 3 in every capsule you buy, so the more the better. And this is allowed.

The third ethical concern that I would like to address here is, of course, very important, and that relates to safety. The emergence of herbs or botanicals worldwide is becoming an issue of concern from the safety perspective. The World Health Organization estimates that 65 to 80% of the world’s population use traditional medicine—Chinese medicine or botanical medicine, as their primary form of health care. And the use of herbal medicine, the dominant form of medical treatment in developing countries, has been increasing and in developed countries in recent years as well. And the regulations vary even

among the developed countries. For example, in Britain certain specific forms of herbal medicine are exempt from medicine’s license, and in France it’s different; in Germany, Denmark, Holland and Sweden herbal remedies are sold as food supplements. And in Australia herbal medicine accounts for 26% of the complementary and alternative medicine, and it involved one billion dollars in 1999; 57% of Australians are using this form of alternative medicine. I can give one example of a herbal product that was in use worldwide, and then, recently, it was found to be unsafe, and that aristolochic acids were found to be potent carcinogenics and nephrotoxins, and over a hundred cases of nephropathy reported in U.S., Canada and Europe in this year alone. Although small amounts ingested may have no adverse symptoms for years, this has chronic implications, for example, leading to renal failure. There are over 600 species of plants that contain this toxin, and many originate from China, and are used widely in Chinese medicine.

So, should more control be introduced? Well, if you take the case of Australia, under the Therapeutic Goods Act of 1989, “Alternative medicines can be listed for a small fee without evaluation provided that no specific claim is made for efficacy and there is no available evidence of problems with quality or safety.” So many of these alternative medicines are listed for a small fee without scientific evaluation, even in a country like Australia. And, in fact, there are more than 4,500 herbal preparations on this list and less than five are registered as a result of full evaluation of safety and efficacy. Again, I use models from the U.S. and Australia to show that, despite the developed status in these countries, despite regulations that they have in these countries, there are problems, and these are also problems in the Third World countries where there are no regulations at all.

The fourth concern that I would like to address in this forum is health care providers’ conflict of interest. Here is a citation from David Kessler, former FDA commissioner: “Don’t these pharmacists look and see what you are selling? Maybe they are no longer in control of the store. Maybe they are just behind the counter and anything in front of the counter goes.” But it’s time for that profession to take responsibility for what it is selling, while the same goes for other medical and health professionals—dietitians,

nutritionists, even doctors who are involved in the sale of dietary supplements and herbal products. I think they need to be sensitive to this need to control and take an ethical stand. The American Dietary Association recently took the position that ensuring consumer access to safe dietary supplements that are truthful and not misleading, fully-labeled, should be the over-

arching goal of FDA's dietary supplement strategy. This should apply to other countries, with separate categories for dietary supplements, which are vitamins and minerals, which are established for a long time, separate them from the botanicals, the herbals. The latter will require more scrutiny or limits.

— Comment for the Presentation —

Ethical Concerns in the Dietary Supplements Business



Prakasamma Mallavarapu (Takemi Fellow 1992–93, India)

*Director, Academy for Nursing Studies
INDIA*

I congratulate Dr. Geok Lin Khor for a very succinct presentation. I would like to concentrate on two aspects of this presentation related to dietary supplements. One is from the international public health point of view, where dietary supplementation is done on a large scale as part of public health programs in several developing countries, where it is thought to be an essential requirement as part of public health. And secondly, I would like to concentrate on the wide marketing of dietary supplements and the related public health implications and ethical issues.

Firstly, dietary supplements as public health programs. We are aware that in different developing countries dietary supplementation is taken up as a large-scale public health program. We have examples of dietary supplementation of iron and folic acid for pregnant women, of dietary supplementation of vitamin A for children under five, of iodized salts, of various examples across several countries where dietary supplementation is a national program, where is it done, where millions of dollars are poured into these public health initiatives, where research goes on to see how many micrograms are required to correct the imbalance and to make it safe for the pregnant woman, for the child, or for those living in areas where iodine is to be made as a supplement. For those risk groups where, without the supplementation, it would lead to lifelong disability or even death, these programs are usually taken up as campaigns on a war footing, as national programs and missions, and a lot of the national budget is allocated to this. And we also see international agencies involved. We have the example of rich countries pouring money into poor developing countries where this

food supplementation becomes a major program. One example is the USAID-sponsored program of food supplementation in several countries.

On one side we know that this is necessary. It is an essential requirement. And there are public health programs for this. But who regulates the programs? Who regulates and sees whether the amount of input, if we see from the utilitarian point of view, the costs incurred, do they really lead to gains? And what are the implications of such large-scale programs? Across nations we have seen examples where iron supplementation or world food programs have not really improved the nutritional status of people over the years. They would have improved the status at that point of time for those small groups who benefited from the program, but have not really brought about a lasting impact. And for this we have to look into the ethical issues, was this the best program for that country at that point of time? Did it not lead to complacency? Did it not divert resources and block the problem? And was it not only a short-term strategy where long-term impact is clouded? Would it not have been much more cost effective to give information to make food accessible and available? In the words of Hippocrates: "If they had made food be the medicine, maybe it would have been a much more long-term strategy." And therefore we come to the issue of who regulates these national programs, and how does ethics and how do public health professionals get into the decisions about who regulates international food aid programs or food supplementation programs?

My second point is about the market and the availability and marketing of vitamins, minerals, herbs, medical cures, alternative remedies. I would like to quote one or two examples of herbs,

which are widely used in several countries for diabetes treatment, that people really believe will reduce their blood sugar levels. I have one concrete example of a fish medicine for asthma in India where millions of people come on one particular day in a year, and this fish medicine is given only one day in the entire year. And now we have many people from other countries, South Asian countries and even from the West coming to take this fish medicine, really believing that it cures them of asthma if they take it on that day. The medicine is put into the mouth of a little fish, and the fish is put into the mouth of the patient. And recently we had even our chief minister lining up for this medicine on that day. So the messages that we give to people are that these are effective, and this is a medicine to be taken up by those who have the problem.

In a society with a well-informed public maybe choices can be made, because regulation and information on the packets and on the brochures would say how effective it is. But in a

society with scarce information, with poor literacy, what is the role of the government or health professionals in providing such information? We see public health issues, for example, where there are vitamins and minerals which are sold over the counter are taken up by people with very low income levels, and I can put the example of injections taken as shots to feel better by poor people all over the world. I can put the example of IV fluids when a person is feeling weak, obviously because he worked hard and would like to take a bottle of IV fluid to feel better. And so this is where we cannot stop the public with marketing and say, it's a free market. It is there for people to choose and use. Somewhere public health ethics has to come in and public health professionals have to take the lead in making information available and ensuring that adequate research, systematic research goes into these unsubstantiated claims of drugs and vitamins and minerals.



Nii Ayite Coleman (Takemi Fellow 1996–97, Ghana)

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I'm very honored to have this opportunity to make a few comments. This morning I have listened to four very good presentations and their respective comments on cases that illustrate some of the ethical issues in public health practice and medicine. The wide variation in the cases that we've listened to illustrates the complexity of international health issues. I would like to make comments that are global. I will not take the individual cases. I would like to make three points.

The first point is that the conception and embodiment of medical ethics, as shown in the presentations, are inadequate to deal with issues of public health and international health practice. The second point is that I would like to look at some of the approaches for developing a new framework for international health ethics. And finally, I would like to raise a few issues for consideration in developing this framework for international ethics.

Why am I saying that medical ethics are inadequate to deal with the challenges of international health? The second presenter alluded to the changing health care environment. This changing health care environment has made it increasingly difficult for the concept and embodiment of medical ethics to deal with the challenges that are arising. We have heard of calls from several medical quarters for a new medical ethic. In fact, the American Medical Association has come up with a draft medical ethic that was published in 1999 for discussion. So even within the field of medical practice there's clearly inadequacy in the code as we know it. Again, changes in the health care environment, such as managed care, have shifted decision-making from the physician to other people. And so it is not only the physician who ought to be held accountable now, but we have to find ways of holding organizations accountable. This fact has also been acknowledged by the American Medical Associa-

tion, and there is a committee to look at how to make organizations accountable. So I think these points clearly illustrate the inadequacy of medical ethics in dealing with these issues.

When we talk about international health then it becomes obvious that the model of medical ethics has broken down completely. That model, which relates to actors, the physician and the patient, breaks down because in international health we are talking about so many actors, so that model definitely cannot work. So I believe that it is clear and one would not doubt that medical ethics as we know it cannot really be adequate in dealing with the complex issues that happen, as analyzed in the presentations this morning.

As a call is made for the development of a new medical ethic, I think that it is also appropriate to call for the development of an ethical framework for international health practice. I would like to say that there are two ways one can look at the development of this new framework. We can decide to have analogues of the principles in medical ethics as we know it, or we can decide to develop a new framework altogether. I think that the analysis that I made about the inadequacy of medical ethics and the model breaking down makes it obvious that developing a new framework based on analogues from the old medical ethics will not be very suitable. And therefore the call will be for a *de novo* development of a framework for ethics and international health practice. This assumes that international health is clearly defined, but obviously this is not so. In the past decades we have witnessed an evolving definition of international health. Many centuries ago, it started with the quarantine movement, and then it went on to the treatment of tropical diseases, and we have areas in which international health has been thought of as dealing with problems or health issues of poor people all over the world. Quite recently it has been

viewed as sort of a north-south dialogue. I think that Dean Bloom's speech yesterday clearly illustrates the new dimensions of this collaboration. We should move from thinking of resources being moved from north to south and rather into partnership between north and south, between developing countries and developed countries.

So if we want to develop this new framework what are some of the issues we should consider? I would like to mention just four of them. I would like us to remember the motivation for international health all along. What motivates us to engage in the practice of international health? I think we will remind ourselves that throughout the changing phases of definition of international health, humanitarian service has been a key issue. The second point I would like us to

consider in developing a new framework is the 1948 Universal Declaration of Human Rights. The third one is about globalization, the phenomenon of globalization. Several people have referred to it here. And the last one is one of a new concept of human security that is evolving. If we consider these four points in developing a new framework, then I think we will all agree that a good guiding principle is one offered by the American philosopher John Rawls who stated that such decisions should be made based on principles derived under a "veil of ignorance." So that just in case we happen to be the ones who are less fortunate or the least fortunate, we are at least cared for by a certain minimum standard.

The Ethics of HIV/AIDS: A South African Case Study



William M. Pick (Takemi Fellow 1990–91, South Africa)

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SOUTH AFRICA*

I will start by thanking the organizers of the symposium for making it possible for me to be here and to address you on a subject which is of great importance to South Africa. I want to talk to you today about the dilemma we face in South Africa as we try to address one of the biggest catastrophes that has struck mankind for a long time.

By way of introduction, I would like to remind you that South Africa is a country on the southernmost tip of the African continent. It has a population of 40 million people, and a population growth rate of 1.8 percent, which is low for African countries. It has a GDP per capita of two and a half thousand U.S. dollars per annum, which is reasonable for an African country. But it does have a very unequal society, as reflected by the GINI coefficient of 0.62. The infant mortality rate is high, and the country spends about 8.5% of its GDP on health care, most of it in the private sector. The AIDS epidemic in South Africa has been explosive. Evidence from blood samples taken at antenatal clinics reflect a dramatic increase in seroprevalence from 0.8% in 1990 to 24% in 1999, which means that every fourth woman presenting for antenatal care in the public sector is HIV-infected. The government does have an AIDS plan which is led by the President, premised on a multi-faceted approach involving both private and public sectors. And the President's involvement in HIV/AIDS in South Africa stems from the fact that while he was Deputy he led the Partnerships Against AIDS Initiative in our country. This has been a mixed blessing, and those of you who have read the media will be aware that there is considerable controversy in our country at the present time. After many years of apathy the new government has been quite desperate in trying to do something about

the AIDS epidemic, and in so doing inevitably encountered a range of ethical dilemmas. Some of these dilemmas were, in fact, addressed very eloquently yesterday by Dean Bloom, the issue of informed consent, particularly in the ethical context where the definition of individual is captured in the ethical philosophy of *buntu*, which says the individual is a person through other people. And so, the issue of community consent becomes a major consideration in our context.

I'd like to focus on two areas, the area of vaccine development and the area of reduction of transmission from mother to child. In 1998 it was decided that South Africa would in fact develop her own vaccine. One might ask whether a country that faces a lot of poverty can justifiably invest resources in developing its own vaccine. This clearly is a dilemma which was confronting scientists and government two years ago. And if South Africa were to develop its own vaccine, which clade subtype was it going to be developing it against? The decision was then to develop a vaccine against clade C, and given the fact that we suspect that there is some cross-protection between clade C and B, that decision was quite a critical one. What it meant was that any vaccine development in South Africa would take two to three years longer than if she had adopted the clade D vaccine which had been developed in many other parts of the world. And the reason for the clade C preference was, of course, 90% of infections in poor countries are caused by this clade.

The question we ask ourselves is should we go to vaccine trials? Are we able to ameliorate the physical risks that are involved? Can South Africa really overcome or reduce the psychosocial risks of those who would participate in this vaccine trial? The issue of stigma is a major

consideration. And just to illustrate the point, I want to share with you a story of a young person, whose name was Gugu Dlamini. As part of a national campaign to de-stigmatize HIV/AIDS, she declared her seropositive status to her community. But a week later she was killed by villagers who felt that she had brought shame upon the village. That is the nature of the stigma. And it's in that context that we face enormous dilemmas as we try to address the problem of HIV/AIDS.

Other issues are the desire or the need for government to compensate people for the social and economic harm they might suffer as a consequence of participation in the HIV/AIDS trials. For example, a person that's come to their trial HIV-negative gets the vaccine, becomes positive, and then finds him or herself unable to get insurance. Does South Africa have the capacity to really involve communities at all levels of research given the complexity of our country, the vastness of the terrain, and the lack of literacy in many parts of the population?

As you know, anybody participating in a vaccine trial that does become positive, that does become infected, in the arm of non-intervention, needs to have access to treatment. The big debate is how intensely do we treat? Do we continue to treat way beyond the duration of the vaccine trial? And is it not true that if one does treat, one is producing some inducement for people to participate in a new trial?

The other major challenge is in the area of reduction of mother-to-child transmission of the virus. We anticipate that South Africa will have 70,000 HIV-infected births per year. And the evidence is overwhelming that using short-course anti-retroviral therapy is cost-effective and does reduce mortality. Government policy, on the other hand, says that we will not provide any of these drugs to mothers who are pregnant with HIV. And so, we are condemning thousands of children to death. The argument used there was the equity argument. Is it reasonable to provide

anti-retroviral therapy to pregnant mothers with HIV when they only account for 10% of all the HIV infections we will have in our country? In other words, we are excluding 90% of the HIV-infected population, mainly adults, from access to the drugs.

I think underlying Africa's reluctance to commit itself to providing these drugs is a larger ethical dilemma that I think faces most countries in the world today. And that is the issue of intellectual property rights. The World Trade Organization, as you know, has some ruling on trade-related intellectual property and protection of those rights, which does allow countries under circumstances of emergency to parallel import cheaper drugs and to have compulsory registration. A lot of pressure has been put on South Africa currently not to go that route. In fact, there is an act of Parliament that is now at the high court being challenged which would enable government to do parallel importing and register drugs compulsorily. The pressure has taken a range of forms. South Africa is on a watch-list in the United States as a potential property rights violator. And shortly after this watch-list two months later, preferential tariff treatment was withdrawn for four imports from South Africa to the United States. And so there's a real challenge here to understand globally what are the ethics, how are they going to ensure that poor people have access to cheaper drugs in the presence of these kind of pressures?

Let me conclude by saying I've tried to demonstrate that the ethical issues around the HIV/AIDS epidemic are of global importance. I've also tried to show that there is a real potential for conflict between researchers, individuals, communities, health care workers, patients, pharmaceutical companies and governments. And it is my hope that as we confront these ethical dilemmas we will not only begin to understand them better, but we will, in fact, be able to mount a global response to what is indeed a human tragedy.

— *Comment for the Presentation* —

The Ethics of HIV/AIDS: A South African Case Study



Maha El-Adaway (Takemi Fellow 1997–98, Egypt)

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I would like to thank Professor William Pick for the excellent presentation, which tackled many of the issues that we are dealing with in Africa, especially the epidemic of AIDS and its explosion.

Although I come from the other side of Africa, where the epidemic takes a different picture, we are in touch with what is happening, because we want also to know and to learn from what's happening in the sub-Saharan part of the continent, because it is going to affect us in the future. We have to learn from the experiences.

Professor Pick tackled a number of subjects, including confidentiality and consent, ethical issues related to vaccine development in a developing country where finances should be allocated to other areas, such as in treatment, and the ethics of treating pregnant mothers who are HIV-positive and may transmit the infection to their children. When looking at all of this, it raises many questions about how priorities are set. Is it more important to develop a vaccine when other countries are developing it, or is it more important to treat patients with HIV-positive in general, or to treat mothers because their unborn children are still free of infection and we can really save them? So it raises not only ethical issues, mainly in the form of equity, but also about affordability and financial resource allocation. And more importantly, it shows us how the political environment can shape the agenda for HIV/AIDS and treatment in the country.

One of the ideas that Professor Pick discussed which seems to be particularly relevant to me in Egypt was whether we should focus our

efforts on preventing HIV/AIDS or on treatment. And what would be the role of donors and foreign funders in shaping this interest? If I talk about the experience in Egypt, we are now in the beginning of the health sector reform process where a basic benefits package is being developed. And, unfortunately, HIV/AIDS is not part of it, not even as a preventive measure. And when we ask why this is not part of it, we say, well, we are a low-prevalence country where HIV is not really a serious matter. But, unfortunately, our Ministry of Health is not giving any attention to HIV/AIDS. All the cases that are taken care of are actually done through foreign-funded projects. Even though it is called the National AIDS Control Program, the fact is it is only funded through UNICEF and other international agencies.

So what can we do? What can we do for prevention purposes? And what can be our issues? How can we set our priorities? I thought when I was listening to Dr. Pick maybe it would be nice for South Africa to produce a vaccine or produce a drug that can be used in countries like Egypt and in other countries, because surely they would provide it at a better price. But looking at the intellectual property rights, would it be possible? And when would that be possible? I know that many of us would not have an answer or would be confused to give an answer to this. Is it yes or no? Should we look at affordability and our resources and how we allocate them, or should we look another way on what is fair and what's equitable? I had most difficulty with the case about the children, the unborn babies. Is it really not fair that we do not give treatment for

the mothers, especially in other developing countries? In Thailand like you showed us, the short courses proved to be useful and to prevent the infection from going to children. We can save children who have are infected for no reason, it was not their fault that they are getting sick or they are becoming HIV-positive. And I actually discussed this with Professor Pick, and he told me that some studies were done, on a very small scale, but these studies showed that giving treatment to mothers and preventing the infection

from going to children is actually very cost-effective. So why don't we take the argument and at least treat the mothers? But it also is not fair to treat the mothers and not give the drugs to the other people who are sick in the community. But look at it from the viewpoint of the children who are born without an infection if their mothers are treated. For children to be sick or not to be sick should be their own choice, and surely they would not want to be born into this world with this infection.

Protection of Intellectual Property Vs. Protection of Public Health: Ethics and Politics



Sauwakon Ratawijitrasin (Takemi Fellow 1995–96, Thailand)

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I would like to discuss issues surrounding two contradictory pharmaceutical policies. One is when a drug is considered a public health tool, then we want the policy goal to be to make it available and affordable to the entire population. So we want to increase access. Now, if a drug is considered a different object, as an object which is intellectual property, then the policy argument is that it is the property of someone, then the right to the property needs to be protected and then monopoly is given. So, these two are contradictory in terms of policy decisions on a specific case. I will present two cases in Thailand to show the dilemma surrounding these two policies.

But first let me discuss the Trade-Related Aspect of Intellectual Property Rights Agreement (TRIPS). Basically, the main point of TRIPS is that it requires member states to set up a system for patents that will protect intellectual property rights which would be valid protection for 20 years. But TRIPS also allows some exceptions. In the case of necessity for public health and nutrition in a country, the government can adopt some measures to stop patents for a while, to address the public health concern. One of these measures is compulsory licensing, which is the authorization of someone else, a third party, to be able to manufacture and sell, in the case of pharmaceuticals, the product without the consent of the patent holder.

In Thailand in the past decade there have been two big controversies surrounding patents. The first one was the revision of our earlier patent law to adopt product patents. Earlier we had only process patents. In 1992, Thailand decided to adopt product patents, even though TRIPS allows a transition period for developing countries, and we are a developing country. So

we actually can adopt it this year, or maybe in five more years. However, Thailand did it very early. It wasn't because we were very quick, but because we were pressured to be quick, because at that time the United States and European countries pressured Thailand to adopt patents, to revise our patent law in exchange for some increase in export quota. The increase in export quotas was temporary, but the change in the law is more permanent. Although it did not seem to be smart to do it, the Thai government did it anyway.

A new case happened last year and continued until the earlier part of this year, which had to do with a drug called DDI or didanosine. This is a drug to treat HIV/AIDS, and there was a process patent issued for this drug in January 1998. The patent holder is Bristol-Myers Squibb. The issue arose last year when NGOs discovered that affordability is a problem, because each tablet of DDI costs about a dollar or a little bit more, and you have to take four tablets a day. So the cost per day is about 178 baht. It's quite difficult for a large number of low-income people with HIV/AIDS who need this drug. Their minimum wage, which is the legal minimum wage, per day is 120 baht. They go without food and other things just to buy drugs and still find themselves without enough money to buy just this one kind of drug. So affordability is clearly a big problem here.

Thailand has a strong AIDS group led by one of the new senators; and health NGOs for the local people; and some international NGOs, such as Doctors Without Borders, MSF. All these groups participated in the campaign to request that the government do something about DDI. What they proposed was compulsory licensing to authorize a government pharmaceutical organi-

zation to manufacture this product. However, the Ministry of Health chose to do two things. First, they negotiated with the drug company to reduce the price. After several months of negotiation and campaign, the result was that the company agreed to reduce the price about 30%, and then the government allowed the Government Pharmaceutical Organization, the GPO, to produce the drug, not in tablet form, but in powder form. The powder is added to antacid and then you mix it with water and you take it. It is more inconvenient, but it doesn't have anything to do with the patent because the patent is a process patent. So the patent is intact, and the right is intact. There are some other means, although more inconvenient, but some other means to reduce the price and increase affordability, and the Government Pharmaceutical Organization product costs about 50% of the original price of the tablet.

For these two cases there are dilemmas on ethical principles or political concerns that can be raised. First, there is something about private incentive or private reward to promote protection of intellectual property rights for innovation in the future, versus public interest that will help to increase access for health needs immediately. So there is something about private and future versus public and now that must be weighted in making a policy decision. The second issue is to what extent will multi-national corporations and governments from other countries be able to charge high prices in developing countries. How much do developing countries' poor people need to pay for the price of innovation in

another country, which may be excessive in terms of cost of living, which is very different?

However, from the observation of these two cases we may ask whether ethical issues were debated at all during the decision to adopt product patents or during the decision not to do compulsory licensing. Apparently the answer is no. Ethical issues were not considered when the policy-makers or the government made decisions on these two particular cases. It was political concerns that led them to make such a decision. And I think the reason is probably very simple, because the benefit of public health is basically dispersed and accrued to the powerless. However, the profit of trade is concentrated and awarded to the powerful. So it's very clear for policy-makers. When there was pressure from outside, other governments, it's the pressure of the real power and lobby from the pharmaceutical textile and other industries, which allowed sacrificing health and pharmaceutical patents, in exchange for increased export rights. Then in the second case there are two pressures, so the government adopted compromise measures.

So, I think in conclusion I would like to say that ethical analysis needs to be made very clear in every policy debate. Price negotiations between governments and pharmaceutical companies may be practical, but it's very difficult for the public to really understand or accept. In addition, in order to make ethical analysis clear there needs to be political analysis and political strategies to implement the analysis, so that the conclusions from the ethical analysis can really work in the real work.

— *Comment for the Presentation* —

Protection of Intellectual Property Vs. Protection of Public Health: Ethics and Politics



Jin Hyun Kim (Takemi Fellow 1996–97, Korea)

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Dr. Sauwakon pointed out the public choice problem between an innovator's private profits and the public health. But I would like to see this issue from a slightly different point of view. In other words, I'd like to touch on trade imbalance between advanced countries and developing countries in the pharmaceutical industry. In an international perspective the point is: who gets the benefits from the protection of intellectual property rights? And who bears the burden? Most drugs, including essential drugs widely used in developing countries, are developed by multi-national drug companies. Most of them are based in the U.S. or European countries, not much in Japan. It is very interesting that, as far as I know, Japanese pharmaceutical companies are mostly focused on domestic markets. They don't export as much as the U.S. or European countries. I don't know why exactly.

Multi-national drug companies in the U.S. or Europe have comparative advantage in technology, research and development and worldwide distribution channels in the pharmaceutical industry. As a result, there are few original brands in developing countries, which means that developing countries have to pay many royalties for

the use of intellectual property rights. But the dilemma that developing countries have is that they cannot afford to pay for it. The prices of brand drugs are usually very high in developing countries compared with production costs. This implies that the enforcement of intellectual property protection will give a strong economic incentive to make multiple imitations of original brands in developing countries. In this situation developing countries will be reluctant to sign the TRIPS agreement. This may bring about legal, political and ethical problems among major stakeholders, both in developing countries and advanced countries. In this regard, the TRIPS agreement in the WTO system should be reconsidered, I think, in such a way that the protection of intellectual property rights does not jeopardize the public health in developing countries. For example, the protection periods applied to developing countries could be reduced to, say, 10 or 15 years from the current 20 years. And the price should be flexible. Otherwise, essential drugs, as well as new effective drugs, will not be available in developing countries under the TRIPS agreement.

Antimalarial Drugs: Attractive Innovations, Tough Choices



Allan Schapira (Takemi Fellow 1987–88, Denmark)

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This presentation follows very much on what has already been said about the ethical issues related to drugs in developing countries. Although we always hear that the malaria situation has gotten worse, the number of malaria deaths has actually gone down overall, but gone up again in the last two decades (Fig. 1). The decline in malaria deaths is due to improvements in the situation in Asia, with access to drugs and destruction of forests probably being the two major factors. In recent years China has been one of the countries most impressive in reducing the malaria burden. North America and Europe, of course, have been very low for many years. In Central and South America, the figures are relatively low. The reason for the increase during the last two decades, then, is that the situation has not improved in Africa. In fact, the situation has become worse in Africa, and one of the major factors in making the situation worse in Africa is worsening drug resistance, particularly chloroquine resistance.

We have chloroquine resistance practically everywhere now (Fig. 2), and fansidar resistance is spreading and has during the last five years become quite important in some parts of Africa. We have had resistance to the more recent drug mefloquine for the last 10 years in Thailand and neighboring countries. And there is also mefloquine resistance in some areas in South America.

The traditional view about antimalarial drug policies has been that you get resistance to one drug, then you change to another one. Countries have changed from chloroquine, to amodiaquine, which is only a little bit more expensive, to sulfadoxin-pyrimethamine, better known as fansidar, which is also quite inexpensive. But then, the logical choice after that in terms of ease of use and effectiveness, mefloquine, becomes quite expensive. And then if mefloquine resistance occurs, as has been the case in Thailand, you will use something like quinine and tetracycline combined, somewhat expensive, but with

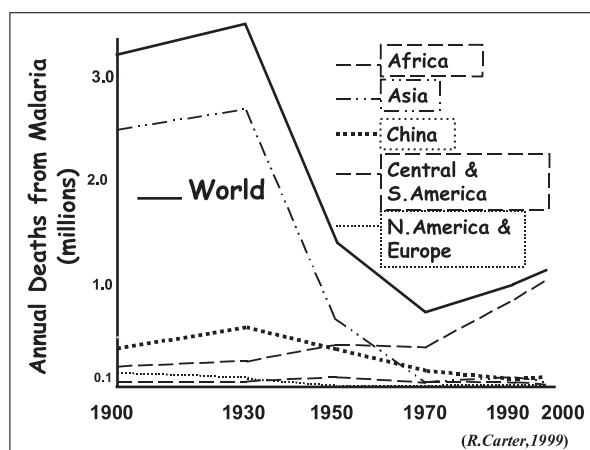


Fig. 1

the much worse problem than the price which is that the regimen usually lasts for one week. And it's very unpleasant to take quinine three times a day. Actually nobody does it because it doesn't really work. People don't get cured by quinine tetracycline.

Then in the 1980s the world realized that there was a treasure in China that was being rediscovered, so-called qing hao-su, traditional

medicine going back several thousand years, used for treatment of fever, possibly also used for treatment of malaria in China. Data were worked up in China during the 1980s. Effectiveness and efficacy were shown, and safety was also shown in China. And there are a lot of derivatives in the first generation which are rather similar. There are small price variations that make it interesting to play around between

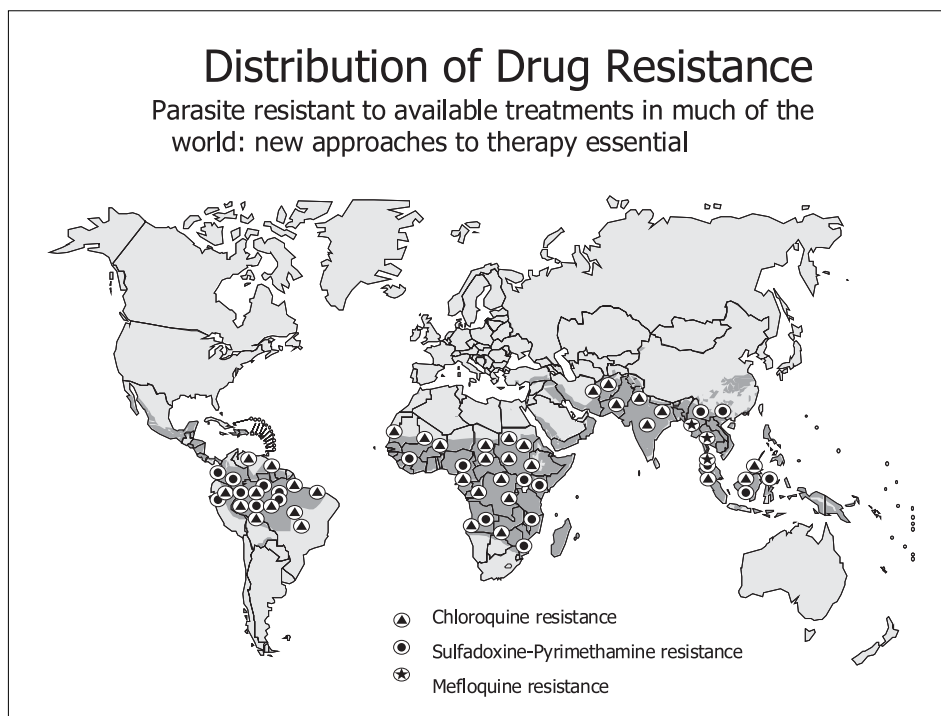


Fig. 2

Options for 1st and 2nd treatment of malaria

Options	Effective against strains resistant to	Regimen (daily doses × days)	Cost range (US\$) [°] (adult RX course)
Chloroquine (CQ)	None	1 × 3	0.06–0.22
Amodiaquine	CQ	1 × 3	0.17
Sulfa-pyrimethamine	CQ	1 × 1	0.06–0.10
Mefloquine (15mg/kg)	CQ, SP	1 × 1	1.55–3.18
Mefloquine (25mg/kg)	CQ, SP	1 × 2	2.33–4.77
Artesunate-Mefloquine (15mg/kg)	CQ, SP, Q, M	(1 × 3) + 1	2.25–3.85
Quinine 7	CQ, SP	3 × 7	1.22–1.63
Quinine 3-Tetracycline 5	CQ, SP	(3 × 3) + (4 × 5)	0.66–1.16
Quinine 3-SP	CQ, SP	(3 × 3) + 1	0.58–0.8
Quinine 7-Tetracycline 7	CQ, SP, Q	(3 × 7) + (4 × 7)	1.42–2.27
Chloroquine-SP	CQ, SP ?	1 + (1 × 3)	0.12–0.32

[°] -International Drug Price Indicator Guide 1999 (except artesunate)

Fig. 3

these derivatives. And then there's a second generation of semi-synthetic compounds, which are compounded with fluorine that are considerably more expensive and are all still in the developing stages.

What is so special about these artemisinin drugs? One, the action is very rapid, more rapid than any anti-malarial drugs. Two, the mechanism of action, although it is not completely understood, seems to be different from the mechanism of action of other classes of anti-malarial drugs, and by and large it seems that there is no cross-resistance between these compounds and other antimalarial drugs. Safety so far is excellent. The disadvantage is that if you use these drugs as monotherapy to be fully effective they must be given for seven days. Vietnam adopted the use of artemisinin derivatives around 1990. There was a terrible malaria situation in Vietnam during the 1980s, and deaths went up, malaria cases went up, the Slide Positivity Rate went up, all of this due to social degradation. The economy was going terribly, and the Soviet Union was withdrawing the DDT that they had provided for the country. But when things go bad quickly then they can also improve quickly. There was a really dramatic improvement in the malaria situation in Vietnam, and since the mid 1990s the number of malaria deaths per year have been lower than ever before in Vietnam when reasonably good data have been collected (Fig. 4).

It was at this time that the artemisinin drugs

were introduced. Some people have made a lot of the association between artemisinin drugs and the reduction of mortality. We've tried to do a very careful evaluation district by district, seeing how vector control was introduced, how the artemisinin drugs were introduced, how the health services improved, and how people stopped migrating so much. The conclusion of this very careful evaluation was that these factors were all so interrelated that no clear conclusions could be drawn. But probably the artemisinin drugs played a role in obtaining the very low mortality that we have now.

We can move to a country not so far from Vietnam, which is Thailand, which has not had these fluctuations in its malaria situation, but it's famous for very good monitoring of resistance to antimalarial drugs. Many years ago chloroquine just went down and become useless, and SP fansidar went up very quickly. Then they started using quinine, but that went down slowly. Since people don't take quinine they adopted mefloquine, but after a few years mefloquine also started going down. Things in Thailand looked extremely bad about seven years ago. Then in came the artemisinin, which in Thailand from the beginning was combined with mefloquine, in contrast to Vietnam and China where they used these drugs as monotherapy. And what was detected in Thailand was that when combining artemisinin and mefloquine the efficacy of this treatment was preserved to an extent which has not been seen with

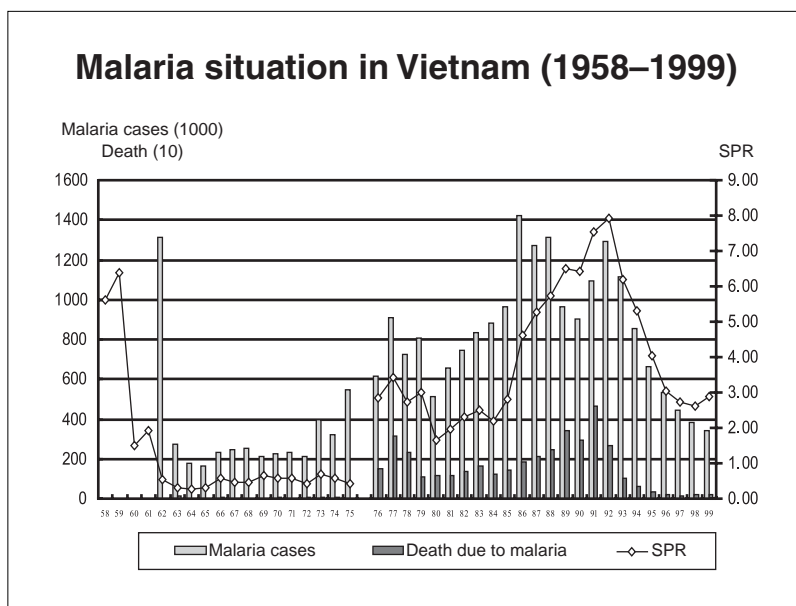


Fig. 4

any other antimalarial treatment before. Furthermore, the susceptibility of parasites to mefloquine has started to improve in the areas where the combination was used systematically. So, it looks very much as if the principle of applying a combination to stop drug resistance is working in that particular situation in Thailand.

Since this was discovered a lot of theoretical work has been done. The theory behind combination treatment is that if you give two treatments, then you kill all the parasites, so there are no survivors. This would then lead to a delay in the emergence of resistance. I have to say that there is a raging debate about the validity of these models and these theories, and there are various ways of looking at it. From a theoretical viewpoint, it is not very well proven that the combination therapy principle will lead to delay of resistance, but empirically the observation in Thailand does suggest that it works. Now, in practice people who are working with malaria chemotherapy are advocating combination therapy more and more these days, including artemisinin drugs. Why? These regimens last for only three days, which is reasonably acceptable from a compliance viewpoint. One or two days would be better. But some empirical studies have shown that many patients can, when they are properly educated, comply with a three-day regimen. These regimens are well-tolerated. Therefore, we can expect to see high compliance, not only in Thailand, where people are very discipline in taking the right treatment. If we have high compliance with high efficacy we will have high effectiveness. The high effectiveness means that patients will be satisfied because the treatment works. They will go on accepting the treat-

ment and take it correctly, which means again that in practice, more for these practical reasons, we could expect the principle of combination therapy to work in the sense that a given country can for a relatively long period, 10 to 15 years, have only one antimalarial standard treatment that will remain effective. This will relieve countries of these frequent changes that they have to make. Especially African countries now have to do like Asian countries did 10 years ago—move from chloroquine to fansidar, from fansidar to amodiaquine. This will bring enormous difficulty, confusion and frustration on the parts of patients, and enormous costs for the public health systems to make these changes.

Cambodia is one of the countries with a very difficult drug-resistance situation. Cambodia is a country where people get antimalarial treatment almost anywhere. They get it from drug sellers in the market, which is completely different from the neighboring country Thailand. We have tried to work with the Cambodians to develop a drug policy which differentiated three strata in the country. Where it was worst people would get mefloquine, in other areas quinine tetroccline, and up in the northeast, which is very backward and still chloroquine sensitive, they would get chloroquine. This has now been changed to one regimen, combination of mefloquine and artesunate, given for three days. Since it works universally, training and public education is much easier. Since we do not have malaria clinics like in Thailand that can give the drug to the people, we have worked with the Cambodians in developing pre-packaged formulations so that people can get one package based on their age group, take this one for three days and that's

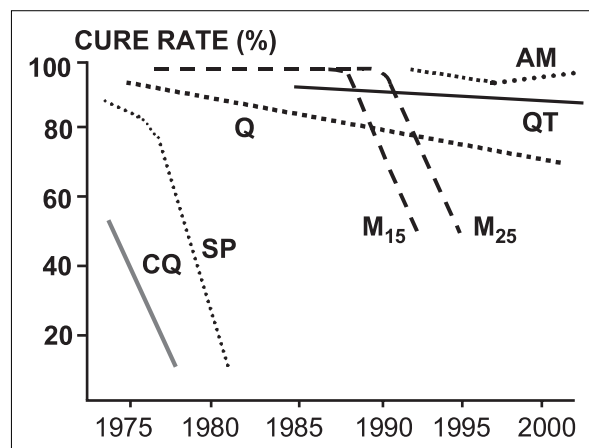


Fig. 5

it. Operational studies so far indicate that it works, but it's on a pilot basis so far.

In the meantime, Vietnam, which is much less dependent than Cambodia on foreign aid, has adopted similar principles. It has had a similar situation of differentiated drug policy in the whole country according to drug-resistance patterns, and is now moving in the direction of one combination treatment, which is a completely new treatment, developed by Chinese and Vietnamese scientists somehow out of the purview of international cooperation from other countries. It is a very exciting development that there is something developed very empirically between China and Vietnam, not with the same requirements for clinical testing as in other countries, but the results so far look very promising, and this combination is cheaper.

There was a review done recently on what a combination treatment would cost if used in African countries (Fig. 6). There's a dramatic difference between the classical treatments, chloroquine, amodiaquine, fansidar, and so on, and what it is expected that a combination treatment would cost per adult dose. Even the cheapest combination treatment, which is fansidar artesunate, is estimated to cost more than two dollars per adult treatment. It can probably be cut down to something like 1.5 dollars. But because artesunate is not a synthetic drug, because the farmers in China and Vietnam where it's grown want a certain minimum for growing their plants, and the extraction costs something, these

combination treatments will cost more than one and a half dollars per adult dose, even in the best of circumstances, even if there are no multinational drug companies making profits from them.

Even in Asia, for some combinations that are expensive, the question of whether we should do trials does come up in the decision-making. What has to be said in this respect is that until now in Thailand and Vietnam, when trials were done it was very difficult to project what the actual costs of the treatments would be. And the scientists, who have been quite daring in some cases from China, Vietnam, and Thailand, who have tested different drugs and combinations, they have done the international community a great service. The knowledge that has been gained by going ahead and doing clinical trials in the face of uncertainty is now benefiting these countries and is benefiting the international community.

Can we use non-GMP drugs when GMP is not available? If you stand with your back against the wall, what else can you do? We have to. There are Chinese and Vietnamese artemisinin formulations available. They have been checked for quality and they have been used to good effect. But what about when European and American companies pick up and produce the same drugs at GMP standards? Here, now suddenly the decision-making process is getting more complicated because there are choices. How much is quality worth? Some people take an absolutist viewpoint and say there that quality is essential,

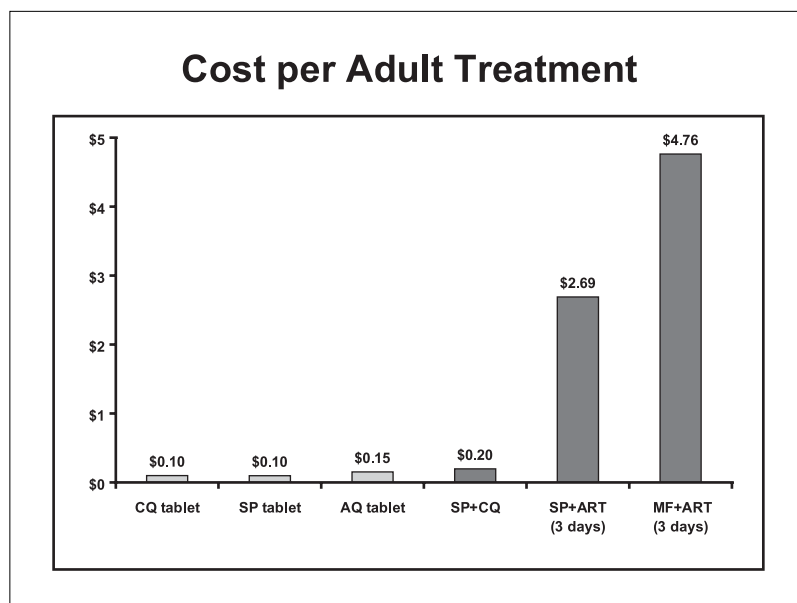


Fig. 6

absolute, but if it costs too much, then it's too much, because the affordability may not be there.

What about treatments that have not undergone Phase IV clinical trials? This is a very important question. And I think here we have to be very careful, because there is now commercial pressure from some producers that have combinations that have been well-validated by clinical trials. But if we are talking about release as first-line treatment in Asian or African countries with many hundreds of thousands of malaria cases per year, millions of malaria cases per year, then I think we need to be very careful not just to go ahead and say this is the standard treatment because it has been gone through clinical trials. We need phase four safety testing before releasing drugs on a very large scale.

The situation in Africa is far more dramatic than in Asia, because, by and large, in tropical African countries we can assess that there is up to one fever episode per person per year that needs an antimalarial treatment. Combination treatment costs more than one U.S. dollar per adult. There is no reason to expect that the pure production costs are going to get below the one dollar threshold ever. Can the governments pay? When we ask them they say no. If they have to, can they? I think it will be very difficult. And I think one has to be realistic, not beat the drum or talk about morality or weapons and so on. I think one has to accept that it's a reality. It's very unlikely that African governments can raise the revenue, in most cases, to pay for such treatments. Can the patients afford it? Patients can probably often afford much more than we think they can afford.

The Asian experience with these drugs is that if the patients have to pay for treatment that they can just afford, then they are not going to pay, because there are cheaper alternatives. A

cheaper alternative is to take just half the treatment or to mix with something that's cheaper or to use something that's cheaper. And if things go in that direction, the patients are allowed the choice between cheaper and not so good, versus more expensive and better, too many patients are going to take cheaper and not so good. And we are not going to get anywhere in the drug-resistance problem. We're going to continue in the same morass of rapidly developing drug resistance, need for changing treatment, and confusion about what is effective and not effective.

If combination treatment at this cost is going to do the job of securing highly effective treatment for people in Asia, Africa and South America, then there have to be subsidies so that price-wise it becomes a very attractive alternative to monotherapies which are less effective. Public-private partnerships may be very interesting, but may also have drawbacks. And I think there is no way to avoid the decision on the part of the international community. There will have to be enormous public investments by the international community or we are not going to make substantial progress in this field.

It should also be said that combination treatments are not "the" final solution to the problem of malaria treatment. They will make things much better for a long period. We still need new drugs, and I would like again to say that the public investments which we are seeing now in the various initiatives for discovery of new antimalarial drugs are needed, because in 10 to 15, maybe 20, years, we will need new antimalarial drugs. There are international initiatives, there's a special initiative between Japan's Ministry of Health, the Japanese Pharmaceutical Industry, and the WHO TDR Program for discovery of new drugs. We need these initiatives to be certain of having effective treatments in 10 to 20 years.

— Comment for the Presentation —

Antimalarial Drugs: Attractive Innovations, Tough Choices



Siripen Supakankunti (Takemi Fellow 1996–97, Thailand)

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I would like to congratulate Dr. Schapira for his wonderful presentation on antimalarial drugs, attractive innovations, and top choices. Dr. Schapira illustrated the dynamic problems of antimalarial drug resistance, drug availability, quality of drugs, prices and market competition, drug resistance problems and drug use patterns in Asia and Africa. I would like to make two additional points for our common understanding on this issue.

First, the problem of drug resistance due to quality of drugs and quality of drug producers versus market competition and price. Second, what choices are available for policy makers, especially in the poor countries. The problem of drug resistance has a long history in anti-malarial drug development. There are various factors related to this problem. For example, quality of drug on producer's side and proper use of drug on patient's side.

Dr. Schapira did illustrate well the problems of drug quality, including the problem of drug resistance. What choices do we have or in other words, what choices do we not have, especially for the poor countries in Asia and Africa. If good manufacturing practice (GMP), which is a western concept, needs to be inexpensive and as Dr. Schapira discussed in his paper, the increased price of GMP products is offset by the necessary quality control of non-GMP products we are faced with a hard choice and need for further clarity. All drug producers in both developing countries, like Thailand, and developed countries, like Japan, need to have quality control processes. However, each country has its own

system. GMP lays out the minimum requirements for quality assurance and again, each country has its own ethical guidelines. For example, in Thailand, GMP is for private producers only. Why does the GPO (Government Pharmaceutical Organization) in Thailand have its own guidelines? We need to reinforce the importance of quality assurance, but the question is how. Quality assurance is especially important for international drug markets, when we face the problem of drug resistance due to poor quality of drug. Therefore, we should agree upon criteria or guidelines that every country can accept. Moreover, we need to reinforce these guidelines with a good monitoring system in the country.

The second point is the choices for policy makers to assure affordability of drugs. This is a serious problem in making choices for various combination treatments. Each country has its own health care financing system. Some might offer what we call a benefit package. Again, should antimalarial drugs be included in the package or not. In other words, who pays for drugs: the patient or the government? This concerns the ethical issues that Dr. Michael Reich addressed in the morning. There should be sufficient evidence to show the cost effectiveness of each alternative treatment. However, this is not an easy thing, since there are problems between efficacy and effectiveness. Therefore, comparative studies among countries are essential. We need to consider the methodology of each study carefully, especially studies done in one country with different situations than other countries, such as studies on drug availability,

patient behavior, preventive policy such as coverage or vector control and improvement of health system. We still have the conflict between donor and recipient countries policy on antimalarial drugs, and the problems of price setting. To

create an information base is important, and it can be shared among countries to make a better choice for the poor patients who have no choice at all.

Policy on Drug Distribution in Korea — A Challenge to the Welfare State —



Bong-min Yang, Ph.D. (Takemi Fellow 1989–90, 95–96, Korea)

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There have been two major health care reforms in Korea in the last five years. One is the health insurance reform that has changed our system from a multiple fund system like Japan's to a single payer system. That change is now complete and presently we are in the process of going through a second reform, which is on the drug distribution system.

The new drug policy started implementation from July 2000. This means that we already have a new policy in effect. But now there are problems that have arisen as a result of this new policy implementation. And so, let me go into details of this new policy. I will tell you what the current state is and what we can expect from this new policy.

There are a few interesting features attached to this new drug policy. The first is that we had unprecedented physician strikes four times in the last six months. The second interesting feature is that this drug reform policy is driven by consumer organizations. It is not driven by the government, not by the medical groups, not by the pharmacists, it is driven by consumer groups. Although we need further refinement of this new policy, fortunately the physicians are back to work fully, 100% now. The physicians came back to clinics and hospitals, and the consumers, although they have some inconveniences because of this new policy, they go along with this new rule. So, in a word, the new policy is in place.

Now, there are many ways to look at this new policy. I'm trying to look at this policy in terms of changed economic incentives. And I would like to tell you why we needed this policy change and

what we expect from this new policy.

In Korea, we have assured quality drugs. They are available, we can afford them, but they are not used rationally. This is the problem we had. It is the typical middle-high income country problem of drug consumption. And another problem we had is we did not have adequate regulatory capacity in drug dispensing. It is a dual distribution system, so all drugs are sold either by pharmacists without prescriptions or by physicians in their own clinics and hospitals. So there is no division of roles between physicians and pharmacists. On top of that, if you sell drugs you have, on average, 50% profit margins. So if you sell drugs worth of \$1,000 per month, you gain \$500 as profit margins. Because of this strong profit incentive, and since there is no division of roles between physicians and pharmacists, both physicians and pharmacists have a very strong incentive to prescribe, to dispense more drugs than necessary. That was the problem we had. Under this situation there is no way that consumers can use drugs rationally.

In summary, I could say that Korea had a lack of safety monitoring in dispensing, which means that there is no cross-checking in drug dispensing. Physician and pharmacist drug dispensing and prescriptions are not checked by other agencies. The result is the misuse and excessive use of drugs. Another result is excessive expenditure on pharmaceuticals. I think the total level of expenditure in total health care expenditure is slightly higher than the case of Japan.

Another problem we had was that since the pharmaceutical companies spent a lot of money

for product promotion, we have very little money left for research and development. That means Korean pharmaceutical companies did not have a competitive edge in the international market. So, we introduced a reform where, prescribing and dispensing of drugs are done in a linear way. I call it a separation policy in that under this policy, physicians only prescribe, pharmacists only dispense based on prescriptions, and separation is mandatory for all outpatient services. Outpatients in general hospitals, hospitals, university hospitals are all subject to this new policy. You have to give the prescription to the patient, and the patient takes the prescription to a pharmacist outside the hospital. It's mandatory. There is no way you can buy a drug within a hospital. That is what I mean by separation policy.

Because of this new system, physicians have little margins left by selling drugs. And for pharmacists, the margins from arbitrarily dispensing has diminished as a result of this new policy. And so, both physicians and the pharmacists have less incentive for excessive prescription and dispensing. From this changed situation, we expect improvement in public health and that misuse and excessive use of drugs will be reduced. We also expect an improvement in drug safety. It means that pharmacists now review the physicians' prescriptions, and medication errors can be reduced as a result of this new single system. The financial implications are the following. Although in the short run we expect an increased financial burden on consumers, in the long run as consumption on drugs falls, we expect people to spend less on drugs.

Another benefit we expect is consumer rights. In the past consumers did not know anything about the drugs they consumed. On prescription charts the language the physician used were only between physician and the dispenser within the clinics, who were generally nurses, including some part-time nurses. But that language should now be common to everybody, a language that's known. So consumers now know what they consume to treat the health problems they have.

There is also an enhanced transparency in health delivery. In the past 20 years or so, fraudulent claims by physicians, pharmacists and Oriental medicine doctors had been a very big problem for health insurance financing. But now those false claims can be reduced a lot.

Fraudulent claims can now be reduced because now for a single patient who gets a prescription from a physician and gives this prescription to the outside pharmacist, both the pharmacist and the physician claim for reimbursement separately. So if these two claims are compared, you can check whether the claims made are true or not. So we expect a significant reduction in insurance reimbursements. That is what the government says is an important benefit of this new policy.

Another benefit that we could expect from this new policy is that we can enhance the efficiency of the pharmaceutical industry. As I mentioned, Korean pharmaceutical firms are spending a lot of money on product promotion. Now with generic substitution possible under the new system, that product promotion by pharmaceutical firms can be much less. The saved money can now be used for research and development for these pharmaceutical firms so that they can have a competitive edge in international and domestic markets.

The new policy has caused controversy, such as the physicians striking four times. But now, they have come back to work and the new policy is fully in force. But still, there are some unresolved issues that are under negotiation such as the extent of generic substitution, and the limitations on pharmacists' arbitrary dispensing. Twice in the last six months there has been an increase in the insurance fee, which is the main reason physicians came back to work. And the government has promised another increase in January of next year, which is just a month away. But that is another issue still under negotiation because consumer groups, labor unions and the farmers now challenge this government fee increase. And in the last four weeks these consumer groups and labor unions are refusing to pay those fee increases that already happened. So it is a problem for the government to handle. They already promised provider groups to increase fees, but consumers refuse to pay those increases.

Finally, I would like to make the conclusion that both retrospectively and prospectively, the reform policy was the right choice. We have had a lot of problems and controversies so far, which I believe are due to a government that was not prepared in time. Right before I came to Japan I met a top decision-maker in government, and I

told him that now you're facing problems, challenges from consumer groups, challenges from physician groups, challenges from pharmacists. The only way you can solve this complex problem is to have your own position fixed based on public health ethics. That is what I meant by philosophy. Otherwise, the problems will continue.

I am asking the government to have the right ethics, at least from now on. I told them that is the only way to restore consumer trust. The

problem is that the providers—the physicians and the pharmacists—as well as the consumers do not trust the government. That's a big problem for them. The government is moving backward, forward, right, left. They are drifting. I told the government to decide on its position according to clearly stated public health ethics. I keep asking what is your ethics, what is your philosophy about public health?

— *Comment for the Presentation* —

Policy on Drug Distribution in Korea —A Challenge to the Welfare State—



Kanchanasak Phonboon (Takemi Fellow 1986–87, Thailand)

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First of all I would like to thank Dr. Yang for the very useful and valuable lessons for Thailand, because we plan in the near future to undertake the same policy reform. The lessons from Korea would provide a very good example on how to plan in such a case. Along the spectrum that Professor Michael Reich talked about this morning, I think I am in the utilitarian camp, and a little in the communitarian camp, so my point of discussion will be based on such positions.

From the excellent presentation by Dr. Yang, we can look at many dimensions. Because Dr. Sauwakon has presented her very useful ethical dilemma on drugs, I will focus instead on the role of physicians. I would like to focus on two points after Dr. Yang. First, the personal freedom and market incentive versus patients' and public interest. If the medical professional has personal freedom to do anything, I believe that he or she must do the best that one can do to serve the best interest of the patient and the public. In this case, I think it would be best for the interests of the patients and the public to have a separate role between physicians and the pharmacists in dispensing drugs to the patient, because without a separate check and balance system it would be

very hard to see whether a doctor might try to encourage patients to take some kind of treatment that maximize his or her benefit or income instead of maximize the patient's benefit at the end.

The second point is about prevention versus curative care. In this case also substantial resources might be spent for curative care instead of prevention to improve overall health of the community. There are already many approaches for prevention that Dean Barry Bloom presented which encouraged people to change or maintain what they have. One aspect of prevention that I think is very important is on risk management, because in most middle and high-income countries most of the health problems are chronic diseases. And clinical decisions for both patients and doctors are complex, and there are many trade-offs, for example, in decisions about whether one should take aspirin to prevent heart disease or whether a woman should take estrogen therapy after menopause. These decisions need more time to discuss and communicate between doctors and patients. And this also would be better to spend time with, instead of focusing only on the curative aspect.



John Bertie Mendis (Takemi Fellow 1991–92, Sri Lanka)

Representative: Yangon, UNICEF
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The four papers presented this afternoon and the respective commentaries that followed highlighted a number of ethical dilemmas faced by policy-makers and decision-makers. These dilemmas emerge when they are confronted with the need to ensure both the protection of intellectual property rights and human rights of individuals to survival and enjoyment of the highest attainable standard of health and for the treatment of illness and rehabilitation. If ethics can be viewed as a set of principles that guide moral decision-making and behavior, the papers demonstrate that the principles to guide decision-making, to defend intellectual property rights are not only well-formulated but are also backed solidly by political, legislative and administrative means, for example, the WTO arrangements. However, the principles to defend individual rights to health care, though equally well formulated, in human rights instruments, suffer from a lack of or weak political, legislative, and administrative commitment for their effective implementation. What needs to be done to level this playing field? How many more million lives must be lost due to malaria and HIV/AIDS, for example, before acceptable compromises are found to protect both intellectual property rights as well as the rights of individuals to the highest attainable standard of health?

The authors suggested a number of solutions this afternoon—long-term purchase agreements to seek price reductions for essential drugs, subsidies for essential drugs through international

financing, and generating public pressure to leverage political commitments and actions, as possible strategies to level this playing field. These are pragmatic solutions. But are they adequate? I doubt it. But we who believe in equity and social justice must continue the search for the compromises that will truly level the playing field for the benefit of all.

Professor Reich, if I may paraphrase, said that there is a right way to do things out there. The idea of a global forum suggested by my colleague, Dr. Coleman, possibly organized by the Harvard School of Public Health and JMA, to help further clarify the understanding of international health and contribute towards the development of processes and methods that could be applied at national and international levels to resolve ethical conflicts, deserve serious consideration. As a U.S. multilateralist, Harlan Cleveland once wrote in an essay on human rights, “We may be living, even if we are not noticing and articulating, through one of the profound shifts in human values that comes along once in a millennium. The idea of human rights, the notion that societies should be managed as if people mattered is so fundamental, so natural, so obvious once revealed that it may be just the first revolution to achieve global reach.”

Finally, I wish to thank the Takemi Program and the Harvard School of Public Health for my own professional growth and the Japan Medical Association for making it possible for me to be here today.

Michael R. Reich

*Taro Takemi Professor of International Health Policy
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I would like to begin by expressing my appreciation to all of the Takemi Fellows who have made presentations and comments at this Symposium. From my heart, I want to express my appreciation that you are here and for your contributions. I would like to finish today with three thoughts about ethics and public health, and to illustrate those thoughts with some statements from the presentations.

The first point is that ethical issues are everywhere in public health. You cannot approach a public health question without confronting ethical questions. We know that there are limited resources, we know that there are life and death questions, we know that you have to make difficult decisions, especially in poor countries. One thing I was reminded of today is that a basic problem is that there are technological changes, new technologies and organizational changes happening in our health systems faster than changes in our ethics. The ethical codes can't keep up with the changes in the health systems. As Dr. Nishida said, "What kinds of ethics do we need for managed care?" As Dr. Marui said, "Where do we die?" This is a question that is relevant not just for Japan but for many countries. How do we assure the quality of life while we are dying? What is a good death and who decides what a good death is? And in Taiwan, as the health system is changing, a series of ethical problems are arising—conflicts among different schools of medicine, conflicts in an aging society and health reform efforts that have put values at the center of the political agenda. Ethical questions were also raised in the presentation about dietary supplements by Geok Lin Khor. How do we regulate sales of dietary supplements on the Internet? What should we be regulating? Should we be regulating misleading claims? Should we be regulating health claims? How do we deal with the question of should we limit what people want? So, ethical issues appear throughout public health, and medicine, almost everywhere we

look.

The second point is there are no simple or single ethical answers. This relates to a broader set of questions in philosophy which says there is no moral truth out there, that the utilitarians, the liberals, and the communitarians, are all looking for something that doesn't exist. This position argues that moral truth is not discovered, it is created. This is the school of thought known as post-modernism. They say that you can't find moral truth the way that you find scientific truth, because moral truth doesn't exist, we have to create moral truth, that there is no single moral truth, there are multiple ideas about what is good and what is right, and that we need to combine these in new ways that make sense for us. I was reminded of this point in Dr. Lan's presentation on Taiwan. He said, "We need to rethink values in health and medicine, and we need to rebuild trust in new health systems." In Thailand how do we balance the protection of public health with the protection of intellectual property, and how do we know it's in balance? As Dr. Bimo said about health reform, "There is no single comprehensive health reform that will work everywhere. There is no one model. It has to be constructed within the realities of each country." Similar issues arose in Prakasamma's comments about people who believe that asthma can be treated if on a certain day you take a medicine in a fish and swallow it. Should we be regulating this? Are these beliefs wrong? How do we decide?

My third point is that we need to construct new moral agreements. If moral truths are created, then we have to be better at learning how to construct moral truths, moral agreements that will work, that will be effective. The papers presented today showed that this can be done. Dr. Gupta talked about the ways in which doctors have become agents of change on tobacco. Lola Dare asked a pointed question, "Whose reality counts?" The point is that we have the

potential to shape the answer. We have the potential to shape whose reality does count.

Dr. Sauwakon, in talking about Thailand, said, “Ethical issues have not been raised effectively. It’s all been based on politics.” And then she said, “We need to find political strategies that can introduce ethical questions more effectively into policy decisions.” She stated that this has happened with tobacco in Thailand. Senator Takemi is trying to do the same here in Japan, to introduce ethical issues through the tax code on tobacco.

Two last examples come from Allan Schapira’s presentation on malaria. He argued that there is a need for a commitment from rich countries both to make available existing therapies for malaria and to invest in new technologies for malaria. To make this happen effectively requires a new moral agreement which recognizes the connection between rich countries and poor countries and puts significant resources into making that happen.

Finally there is an example from Korea. The question of separating prescribing from dispens-

ing is a very sensitive issue in many countries in Asia, including Japan. Korea is a case of “big bang” policy reform. They’ve done a sudden separation, mandatory, and it has had all sorts of consequences. What Dr. Yang did not tell you, in his modesty, is that not only has he been studying this process, he has been participating, facilitating and leading this process. He has been instrumental in helping to create a new moral agreement about how pharmaceuticals will be used, dispensed and paid for in Korea. He’s not just an observer, but very much someone who has crafted and constructed the new moral agreement.

I think this leaves us on a positive note that it is possible to construct ethical arguments and moral agreements for public health reforms. Indeed, it is something that we must do in each of our own societies and globally to realize the potential that exists for improving the health of everyone, for making societies more just and fair, and for giving people a sense of real substantive participation in improving the quality of their lives.



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