

Opinion n° 78

Disparity in access to health care and participation in research on a global level – ethical issues

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“No exceedingly great genius is needed to accomplish great things: one must not be above men, but be with them”
(Montesquieu, Pensées)

Introduction

On May 7, 1999, Monsieur Bernard Kouchner, at the time *Secrétaire d'Etat à la Santé et à l'Action Sociale* (Health and Social Affairs) to the *Ministre de l'Emploi et de la Solidarité* (Employment and Solidarity), referred to CCNE on the subject of ethical issues connected to inequalities of treatment between countries of the North and of the South¹. More specifically, his query concerned the following:

“HIV contamination is only one example of the pathologies for which we are bound to note that there is disparity in access to healthcare on a global scale; I should like to have the recommendations of the National Consultative Ethics Committee in the light of this finding and their advice regarding possible remedies to a situation which, in ethical terms, is obviously a problem”.

The problem referred to above is undoubtedly ethical, but a response cannot be restricted to a purely medical or research framework. From the outset, it is tempting to give the subject more breadth to arrive at issues of morality to which a political response should be given. “The treatment for AIDS is politics” (Willy Rozenbaum). The President of the International Aids Society at the conference in Barcelona in 2002 said: “...of all the ills that kill the poor, none is as lethal as bad government ». In view of the blatant and shocking inequality between developed countries of the North, and poor countries of the South, indeed political decisions should express determination to take action rather than ethical choices based on possibly controversial cultural values.

Jonathan Mann² wrote that careful analysis of the principal causes of avoidable morbidity and mortality in the world, including cancer, cardiovascular diseases, wounds, infectious diseases, and violence, shows that these problems are inextricably connected to social discrimination and violation of fundamental human rights. The right to Health is one of the fundamental Human Rights. Access to healthcare continues to be a fundamental right. Health is the most potent objective of development.

Far from improving, the situation is worse than it ever was. Finding a cure is the purview of political morality. The situation therefore could be considered as beyond the competence of CCNE. The scope and the severity of the problem – of which awareness is as yet inadequate – do in fact transcend any attempt at analysis so that there is a risk of inertia which cannot be an acceptable conclusion without being guilty of indifference, or worse complicity, as a result. Therefore moral compulsion in this case reinforces and commands ethical preoccupations. The fact that these essential problems are encountered in countries of the South does not absolve us from caring nor exempt us from involvement. On the contrary, the very disparities between the North and South are frequently the cause of ethical tension, increasingly acute as time goes by, since certain scientific breakthroughs are of sole benefit to the countries of the North who can afford them, and health care options continue to increase in the North while the South is ignored.

We must therefore respond to this exacting moral requirement, since ethical values are universal, as we cannot fail to be aware, and they should point the way to elementary human solidarity rather than mere feelings of benevolence. Indeed, this is an obligation. In this Opinion, CCNE must attempt to increase public responsiveness, and to find and apply appropriate remedies.

¹ Recently, the tendency has been to no longer use the older terminology opposing « developed » and « developing » countries. The expression « countries of the South » in this document is a generic term for poor or so-called « emerging » countries.

² Founder and first director of the WHO Special Programme on AIDS

The fact that such remedies are so urgently required is in itself sufficient justification for this Opinion; all the more so because there are inevitable limits to what can be done and therefore priorities to be established with due regard for ethics.

In this connection, in 1993, CCNE had proposed in its Report n° 41 on the subject of "Cooperation in the field of biomedical research between French teams and teams from economically developing countries", that there was a need to establish for vulnerable people or populations, rules of good conduct for biomedical cooperation projects with developing countries. There was emphasis on the need for cooperation so as to arrive at genuine partnerships, and the Committee made some recommendations for further action.

This previous opinion only dealt with research, whereas the present referral is more extensive and covers health issues in general. Could these earlier recommendations be taken a step further? At the time, they had no effect, but have since been supported to some extent by more recent statements by various national or international bodies. One should mention, for instance, initiatives taken by the European Group on Ethics to the European Commission³, the Swiss Commission for Research Partnerships with Developing Countries (KFPE)⁴, the Institute for Development Research (IRD) on the ethics of "North-South" research⁵, the National Aids Council⁶, the ANRS⁷, Nuffield⁸, CIOMS⁹, NBAC¹⁰ ...

The preoccupation contained in the Minister's referral to CCNE, the intensification of inequality which it expresses, and the gradual increase of interest in countries of the North, as they have been called, could perhaps make it more likely that an opinion could now be taken into consideration and make a useful contribution to this battle which concerns the whole of humanity. To abstain from tackling the difficult ethical questions raised by economic disparity is to behave irresponsibly, and more so by the day. As treatment becomes more effective, to be deprived of access to it becomes even more unjust, as must be emphasised. Any recommendation in this respect must begin by recalling the absolute and urgent need for a universal political determination to refrain from - quoting the President of the French Republic at the 2002 conference in Barcelona - committing the crime of "failing to give assistance to populations in danger".

This Opinion seeks to provide some possible clues for future reflection and so facilitate attempts to reduce the inequalities which pervade the whole field of bioresearch.

I. The present situation

The magnitude inequality deserves mention, despite the fact that, fortunately, the media devote an increasing amount of space to the subject. HIV is a case in point. There are now more than 50 million people infected by the virus, of which 95% reside in developing

³ Opinion n° 17 "Ethical aspects of Clinical Research in Developing Countries", European Group on Ethics in Science and New Technologies to the European Commission, 4th February 2003. Available at : http://europa.eu.int/comm/european_group_ethics/avis3_fr.htm

⁴ Available at http://www.kfpe.ch/about/guidelines_f.html

⁵ Available at: <http://www.ird.fr/ccde/archives/index.htm>

⁶ Available at: <http://www.cns.sante.fr>

⁷ National Agency for Research on Aids (ANRS): Charter on Ethics for Research in Developing Countries.

⁸ Nuffield Council on Bioethics: Ethics of research related to healthcare in developing countries, 2002. Available at: <http://www.nuffieldbioethics.org>

⁹ The Council for International Organizations of Medical Sciences. Developed jointly by WHO and UNESCO. 1993: International Ethical Guidelines for Biomedical Research Involving Human Subjects.

¹⁰ National Bioethics Advisory Commission (USA): Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries, April 2001. Available at: <http://www.nbac.org>

countries (LDCs). Nearly 30 million deaths have been recorded, and there are 15000 new cases every day. Loss of life expectancy has risen to as much as 10 years in certain African countries. In South Africa, 20% of the population is affected, and in Botswana 36% of the young and active population with a large majority of women. The number of orphans and infected children totals more than several million.

To refrain from going into too many figures, a single comparison established by UNAIDS could suffice:

- In Western countries: 500 000 people are under treatment, and AIDS is the cause of 25 000 deaths a year.
- In Africa, only 50 000 people get medication, but 2 million people a year die of AIDS.

More generally, according to UNDP's global report, 2.5 billion people have no access to basic health structures. Africa is the site of 90% of the world's cases of malaria (which kills 2 to 3 million people a year), and of 50% of the world's cases of tuberculosis.

Sustainable development cannot exist where health is not a priority. Public health expenditure is about 2 500 Euros per year and per person in the North, and 2.5 Euros in the poorest countries. Apart from purely humanitarian considerations, the economic consequences of such situations are momentous, as per capita incomes and human potential deteriorate.

Have economic inequalities between countries given rise to ethical deliberation beyond lamentation? So far, the approach has been fairly traditional, based on our own economic interests, on our assessment of needs, with no precise method of evaluation, and action seemingly focused on generosity and compassion, but neglecting the most elementary respect for human beings.

However, some signs of universal awareness are emerging, particularly since apart from the issue of elementary solidarity with the countries of the South, the North would also benefit if health disparities were to cease increasing. Can anyone suppose that if greater riches for some co-exist with the development of poverty for others, stable economic relationships could possibly develop on a global scale?

Independently of any doubt as to the appropriateness of the above referral to CCNE on this matter, the present situation alone is reason enough for CCNE to add its contribution to ongoing consideration of possible remedies to inequality. By its very dimensions it is in itself a genuine ethical issue, although rich countries seem only too often to find structural or cyclical reasons to justify their acceptance of it. However, oversimplification is also a danger. To speak blithely of universal righteousness, with no reference to reality; to accept as a pretext the existence of insurmountable cultural obstacles; to preach complacently to the unworthy, in both developed and developing worlds; to hold illusions about the equivalence of real needs and needs expressed; and finally to convince ourselves that our own contradictions are not those of the South, are so many blind alleys.

Economic, political, social, or cultural environments create real ethical tension, which calls not only for our awareness of the diversity, nature, and dimensions of the unsolved problems, but also on our commitment to action. In truth, what is required is nothing less than "turning the world upside down", as though to change its centre of gravity, and broach both research and access to healthcare problems, not any longer from the point of view of the

priorities which their economic and political power confer on countries of the North, but on the basis of the real needs of populations, which are clearly more affected by certain diseases in developing countries. Their poverty makes them so vulnerable that they sometimes express their needs with difficulty, resignation, or even mortification.

II. Examples of concrete situations

The following are examples, sometimes extreme, of the ethical issues involved.

The history of hepatitis B, for example, is emblematic. In the 70s, a French scientist was experimenting a vaccine on local volunteers in Senegal. The promise was made to them that, should the experiment be a success, their children would be vaccinated at birth in Dakar and Saint Louis in years to come. In this country in which the hepatitis B endemy is prevalent (almost a quarter of the population is contaminated), the promise was broken. Yet in 1994, vaccination against hepatitis B became general practice in France, and in a few years 2,500,000 children and more than thirty million people (75 million doses) were immunised, whatever their age or degree of exposure to risk, which was usually either low, or even infinitesimal.

This display of the principle of precaution before its time was abruptly reversed when rumours of a possible link between multiple sclerosis and the hepatitis B vaccine brought about a suspension of automatic vaccination in schools, in the name of this same principle of precaution. The impact on the media was considerable, the medical profession became alarmed, and vaccination arrested and not just in schools. Prison inmates, and drug users rejected its use. It was discontinued in French speaking countries of Africa and South East Asia where it was gradually being introduced.

And so, ill-chosen application of the principle of precaution can bring about situations where progress is reversed, of little consequence for us, Europeans, who get little exposure, but are dramatic for African countries, which in this case had been the subjects of experiment without any benefit to themselves, then stood by while the French population at large got immunised despite their lack of exposure - and the Africans did not - and finally suffered the backlash reaction which brought to a standstill the first attempts at mass vaccination in Africa.

A second example is vaccination against the HIV virus. We are all aware of the urgent worldwide need for the development of a vaccine. It would be difficult to evidence vaccine effectiveness in developed countries, and so it has to be done in countries where the endemy is widespread. In spite of the fact that existing candidate vaccines are unlikely to exempt from infection, tests are ongoing in Asia and Africa, even to the extent initially of using candidate vaccines which did not correspond to the viral strain prevalent in those countries. Is it likely that any country of the South would reject such attempts, taking into account that they could possibly share the benefits of a patent, that research teams could contribute financial resources, and above all, that there might be a glimmer of hope of effective prevention? The countries of the North seem almost unaware of the commitment they should be making to these people, i.e. provide adequate therapy in case of contamination.

A further example is the intrusion of medical teams in a population suffering from endemic malaria, with the aim of testing new molecules effective against the plasmodium. Some of the teams had no hesitation in reducing for a few weeks the presence of malaria in some small human groups, in particular children. However, when they left, the children and adults were recontaminated, and with augmented severity. The reason is that, although it is certainly not of excellent quality, there is a kind of immunity, called premunition immunity, in such populations which give children and adults some protection against recontamination.

In the absence of therapeutic monitoring after the radical treatment phase during the therapeutic test period, the health situation deteriorates paradoxically after the test, compared to the situation before, as a result of the loss of protection which was provided by the premunition immunity acquired through chronic contact with the parasite.

And so we find that the populations, thanks to whom new anti-malaria¹¹ molecules were tested, not only drew no benefit from the research, but also in fact ended up more vulnerable than they had been previously.

Finally, certain countries, such as India and Porto-Rico, have been selected as “natural” sites for experimenting contraceptive drugs, with no benefit to themselves.

III. Possible action

1) An appropriate method for evaluating requirements

Realistic evaluations of the needs of the countries of the South as regards research and health must be arrived at, since otherwise, any action would be inappropriate and therefore ineffective, or even harmful. This is in no way specific to the countries of the South. The difficulties encountered by countries of the North in defining their own priorities as regards research and healthcare are proof enough of the efforts which have to be made in this respect in developing countries.

Indeed, although we like to think in the countries of the North that we know how to assess our public health priorities, economic pressures, financial restrictions, or the fads that affect public opinion or even influence research activities, are all factors that contribute in no uncertain measure to warp an objective evaluation of healthcare requirements.

How will developing countries fare?

Although there is agreement that, in order to arrive at a universal health policy, the starting point must be a realistic appraisal of the needs of populations, by means of an inventory, country by country, or even region by region, clearly the first mandatory step is to be assured that the inventory will not be based on concepts, self serving or otherwise, exclusive to countries of the North. Furthermore, the inventory must be the result of a method of evaluation which has to be checked, country by country, as regards the competence and independence of the bodies in charge of its definition and implementation.

Plans for making inventories should include a better definition of the needs of the population concerned, differentiating if needs be, between the needs (actual or expressed) of the population and its expectations. It can happen that a poor population (or its official representatives...) may wish to favour diagnosis and treatment of high technology pathologies to the detriment of those with a high medico-social component which are seen as “poverty diseases”. There is a feeling that the reality of the latter is humiliating and that it should be kept secret... Within this dichotomy, AIDS is at the intersection of these representations of the world, but makes it mandatory at all times to take account of the dimensions of the actual situation¹².

¹¹ New medications in fact for the use of people able to afford them...

¹² For example, to recommend an apparently rational encouragement to screen for HIV is very inadequate if treatment is not on offer, and can be the cause of severe stigmatisation by segregating those who are contaminated. The end result would be the opposite of the aim pursued.

These considerations apply, whatever the degree of prosperity of a country may be. Countries of the North must be aware of the hazards so that their assistance in the field can be effective; the object being neither charity, nor mechanical and unthinking imitation of medical facilities imported wholesale from the West. What is required is effective adjustment to the needs of the population, disregarding what we think seem to be their needs, and only considering their actual needs, in spite of the difficulty of making such an assessment.

Assistance given by rich countries is usually given in the name of generosity (religious, scientific, political...), or of our reading of the needs of the population, or based on our own interests (economic or strategic for instance), or because of a feeling of guilt. A response solely based on principles of charity in favour of people who are unaware of their condition and therefore “grateful” for that assistance, is no longer tenable if the right to health principle exists and becomes one of the new fundamental Human Rights, even if that right is still understood differently in different cultural, social, or geographic contexts.

The evaluation of the prevalence of diseases, function of the relative poverty of countries, also varies notably from country to country, because of deficient communication systems or total absence of information given to the population. The media attention devoted to AIDS (which affects predominantly the active part of the population, women of child-bearing age, and is connected to sexuality), so that it is presented as the absolute top priority, should not make us forget the devastation inflicted by tuberculosis, malaria, malnutrition, or measles. Is it not a fact, for example, that neonatal tetanus is one of the principal causes of mortality in poor countries, and that chronic diseases such as diabetes or hypertension are as much of a problem there as in countries of the North, and above all, that the birth of a child in countries of the South is attended by infant mortality at a level which has long been a thing of the past in the North.

Finally, any effective evaluation of needs must go hand in hand with an evaluation of means. All health policies come at a cost that cannot be ignored by the ethical bodies aiming to guide political choices. It is essential that populations concerned become aware of their real needs and the financial resources required to satisfy them. CCNE already emphasised this need for evaluation in its Report N° 57 in 1998¹³,

“ in the health sector, the economic and ethical approaches are complementary. Ethical considerations therefore suggest that when cost containment is the aim, the initial priority is to make whatever investment is needed immediately for the instruments of evaluation”.

2) Cooperation for research

The core issue in the North/South relationship as regards medical research is the huge divergence of interests. It is to the advantage of the North to perform inexpensive trials on large populations with no legal protection for research subjects that may have no connection whatsoever with the public health needs of the country concerned. The South has no leverage to prefer research strictly adjusted to its own requirements and does not have the financial resources to propose trials strictly adjusted to the local context.

¹³ CCNE Report N°57 (March 20, 1998): Technical Progress, Health And Societal Models : The Ethical Dimension Of Collective Choices.

In its Opinion of 1993¹⁴, CCNE emphasised particularly the need to guarantee the dignity and safety of persons consenting to participate in biomedical research studies of general interest, with cooperation between French teams and teams from economically developing countries. In order to guarantee the ethics of proposed research, the Report suggested the creation in France of a “*French consultative committee for the protection of persons consenting to biomedical research in developing countries, or CCPPVD*, which “*could be constituted under the aegis of ministerial departments responsible for Health, Research and Cooperation. This committee will be able to seek the advice of the National Consultative Ethics Committee*”. In parallel, CCNE proposed that projects “*also be studied independently by an ethics committee of the country or region where the proposed study is to take place*”. And, as a final recommendation, that “*a list of such local or regional ethics committees, as well as existing human rights defence committees, should be drawn up, published and brought up to date annually*”.

The need for partnership would have, in this way, been demonstrated between French Government authorities and those of the regions concerned, as regards preliminary studies or projects for submission to the specialised Committee to be created, and also the implementation of those projects. Quite obviously, the ethics committees that CCNE wanted the creation of, would need to show that they could guarantee their independence from political influence, or from national or international economic pressures, and also guarantee the competence of their members.

This Opinion included a report recalling the publication of the Nuremberg Code in 1947, article 10 of the Helsinki Declaration in 1964, and the 1981 Manila directives. Since it dealt with problems regarding research about communities rather than individuals, it referred particularly to procedures to be encouraged to make sure that consent was truly informed. The Opinion attempted to draw up rules of good conduct for the establishment of biomedical research projects with developing countries; unfortunately, at the time, the report met with no response ... However, it is to be noted that the ethics charter for research in developing countries adopted by ANRS in May, 2002¹⁵, closely follows the principles stated by CCNE at that earlier time.

Any cooperation agreement between government authorities must be the subject of prior evaluation, so that social, political, religious, or cultural characteristics can be identified. A possibility could be the creation of a French committee with special competence for the protection of individuals participating in a research project in the South, with the participation of WHO experts and representatives of the countries of the South. WHO has proposed some “Operational guidelines for ethics committees that review biomedical research”¹⁶. However, the concept of a specialised French committee may give the impression that problems are viewed from too narrow an angle, and protocols for countries of the South could be submitted to ethics committees in countries of the North, like any other project.

It is essential that an Ethics Committee from the country or region where research is to be done should examine projects. Its creation and composition may raise difficult training and control issues. Self-sufficiency and competence are pre-requisites for its legitimacy, and it must be representative. In all cases, the State itself must be involved.

¹⁴Cooperation in the field of biomedical research between French teams and teams from economically developing countries. Report n° 41, December 17, 1993.

¹⁵ National Agency for Research on Aids (ANRS): Charter on Ethics for Research in Developing Countries.

¹⁶ Available at: <http://www.who.int/tdr/publications/publications/pdf/ethicsfr.pdf>

Some kind of external mediation structure, with no interests to defend in either the North or the South, should be given a voice. This body could provide fully independent arbitration regarding evaluated needs. Independent committees for the monitoring of a research protocol, composed of experts from both the North and the South, could be a useful adjunct for advice, appeal, or conciliation.

As in the North, increasing the level of responsibility and information of prospective partners contributes to the respect and advancement of ethical principles. An individual is not the object of research; he or she participates in research. The interests of research can never take precedence over those of the person consenting to it or of that person's community.

No research which does not lead to benefit for the population concerned should be considered; this is the case for instance for genetic population studies. Plans must include some kind of benefit in return for these populations, and the North should not have exclusive rights to the gain from possible patents. Genetic data drawn exclusively from countries of the South must be classified as potential resources for these same countries. Furthermore, the absence of risk cannot be taken as fair compensation in the event of absence of benefit.

Structures created locally for research purposes, and which are well suited to local conditions, must continue to be available to the country concerned once a project is completed. Resources for financing the research should be, at least to some extent, managed by a responsible body in the country concerned.

Once research is completed and has demonstrated that a treatment is effective, it must be at least made available to the people who participated in the medical trial. Distributing the drug or drugs to a larger section of the population concerned often raises insuperable problems.

One of the major problems with medical trials in countries of the South and which has led to fervent discussion is the evaluation of "best available treatment" or of treatment best suited to local resources, and even more disputed is the possible use of a placebo for the control group.

A notable example are the trials on transmission of the AIDS virus from mother to child, which has been significantly lessened in the countries of the North by giving prolonged antiretroviral treatment to the mother and then to the neonate. This optimal strategy is difficult to implement on a grand scale in countries of the South for both practical and economic reasons, so that investigators have been of the opinion that tests should be carried out with shorter and simpler protocols, better suited to local conditions. This view was disputed in some quarters. However, and principally in order to be able to judge the degree of efficacy of an "intermediate" effect with these strategies, the ethical discussion considered whether the control group should get the best treatment available in the North or a placebo, because the rate of transmission in the absence of treatment varies considerably from one region to another (in practice with differentials of as much as 17 to 32%).

Some people consider that this practice is not unethical because it is necessary in order to obtain valid conclusions and tangible collective benefit in countries where no treatment is the rule. In fact, these shorter treatments that are easier to implement in Africa, do not hope to reduce the rate of transmission as drastically as the therapeutic protocols used for both mother and child in countries of the North. However, the intermediate efficacy can only be assessed in comparison to the rate of transmission observed in the absence of treatment.

The latest version of the Helsinki Declaration¹⁷, paragraph 29, modifies the text regarding the use of placebos in clinical trials:

“The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current¹⁸ prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists”.

The potential difference between “best treatment available” and “best current treatment” for the control group, which was hotly disputed in WHO, strikes a singular note for a developing country since it would hardly be cynical to comment that the “best current treatment” is, alas, often no treatment at all...

On this matter in particular, CCNE concurs with recommendations recently published by the European Group on Ethics¹⁹, which stated:

“The use of placebos should be regulated in developing countries in principle by the same rules as in European countries. Any exception must be justified and this justification must be clearly demonstrated in the research protocol submitted to the ethical committees and especially approved by the local committee”.

There are therefore two radically opposed viewpoints as regards clinical research and treatment:

- respecting standards for care and research according to the scientific development in a country of the North;
- or “adapting” research to the demands of the actual situation and those of local conditions.

Both of these positions are open to criticism. The first scorns the principle of ethical universality, but strives for standards that can be counter-productive for poor countries, whereas the utilitarian, economic, and pragmatic approach of the alternative spurns the Kantian philosophy of the respect of ends, and favours the means to achieve them. Ethical reflection should incite us to go beyond such discord and seek as our major objective the respect of the rights of people and of their communities, leaving aside dogmatism and cultural relativism leading to excesses.

The central objective should be to adopt similar criteria for decision in both the North and the South.

To facilitate this “equalitarian” enterprise, it may be necessary to pass laws for the protection of those who agree to participate in biomedical research. Encouraging independent authorities that are required to guarantee the respect of ethical principles, should be compatible with preservation of the social models of the country concerned. Discussing the respective legitimacy of the various authorities, of the elite, of the population, and their relationships with the representatives and the guarantors of the country’s authority represent a significant part of the ethical issues to be dealt with.

It may not be utopian to make protocols that provide mutual benefit the rule, by reinstating, through ethical action and political determination, equality between partners who are

¹⁷ Adopted in October 2000 in Edinburgh, available at: http://www.wma.net/f/policy/17-c_f.html

¹⁸ Our underlining.

¹⁹ Opinion n° 17 “Ethical aspects of clinical research in developing countries” European Group on Ethics in Science and New Technologies to the European Commission, February 4 2003, available at: http://europa.eu.int/comm/european_group_ethics/avis3_fr.htm

vulnerable populations on one side, and on the other, research laboratories whose economic weight is sometimes considerable. What is needed is to progress from cooperation to collaboration and partnership, by creating a climate of respect and mutual tolerance which will guarantee long-term stability. Seeking such a partnership would encourage the emergence of a “virtuous circle” and could perhaps also be prescribed in higher education so that PhD students could choose to benefit from university courses pertinent for both actors.

This kind of “ethical commitment” as regards training could set an example for equitable sharing and just reward for other precious resources such as the ecology, agronomy, or the preservation of biodiversity.

In conclusion, a research protocol that includes neither the monitoring of a trial, nor more importantly the long-term availability of treatment validated by the trial for those who participated, is a fundamentally unethical trial. Short term therapeutic testing for a chronic disease is abusive.

3) A policy for access to medication and vaccines; the problem of patents

The Porto Alegre forum evidenced the following: 72% of the world’s population lives in developing countries corresponding to 7% of sales of medicines; 1/3 of humanity has no access to medication, and in certain countries of Africa and Asia, the figure is more than 50%. The policies of the major pharmaceutical companies whose research programmes ignore diseases in these countries²⁰ are puzzling. The Porto Alegre conference emphasised the obstacles which the World Trade Organization puts in the way of producing generic drugs, since it obliges countries who wish to take that course, to agree to the ratification of a treaty on intellectual property rights that includes patents, whereas 99% of the world’s patents belong to individuals or companies in rich countries.

At the WTO summit in Doha (Qatar), the possibility of “breaking” a patent in the case of health emergencies such as the AIDS pandemic in Africa was recognised. On this subject, a representative of a Brazilian association fighting AIDS said that the object of the operation was not to gain a medicine, but to gain the basic right to continue living.

In this respect, one should refer to a list produced by WHO, and which it conveniently updates every two years, to define those drugs that are necessary for the preservation of life, and make access to them a fundamental right. This might prevent some molecules from being patented without specific right of access for countries of the South (compulsory licences). The principle of compulsory licences is included in the Trade-related aspects of intellectual property rights (TRIPS) Agreement of WTO. This allows the government of a country to grant a licence for making a proprietary drug, to a manufacturer of generic drugs, if it considers that this action serves public health, particularly in the case of an emergency, like the AIDS epidemic.

That the United States’ economic pressure on the Government of South Africa, which had announced its intention of producing generic drugs to treat AIDS, is to be suspended, is very good news. However, it is surprising, and worrying, that Kenya which had been one of the first countries to pass a law authorising the import of generic drugs to fight AIDS, is now blocking the entry of generics which can no longer be imported except by the holders of the patent and with their explicit consent. In view of the well-known hostility of the major pharmaceutical companies to this system, one can hardly deny that the condition is unlikely

²⁰ Between 1979 and 2002, only 1 % of new molecules generating medications concerned tropical diseases.

to be satisfied. Let us simply underline that the decision to amend the law authorising the import of generic drugs was taken to the detriment of 2.5 million sick Kenyan citizens.

It is to be hoped, however, that the outcome of litigation in Pretoria initiated by 39 pharmaceutical companies against the South African government, who have decided to simply drop their lawsuit, could be a sign of a more responsible attitude on the part of the pharmaceutical companies. It is true that there was some speculation that renunciation on their part was due to a more realistic appraisal of their own interests. They would have run the risk in the course of such litigation, of having to explain their tariff policies, which they preferred to keep secret, since they are negotiated on a country-by-country basis depending on international market forces. There was also the prospect of explaining the financing sources of AIDS research. They could also find that, for instance, the considerable part of research that takes place in public institutions becomes apparent, whereas many of the molecules for sale are developed by public institutions and then passed on to companies under exclusive licensing agreements...

In any event, because of the global health crisis, what was described as a breakthrough has taken place in Pretoria. But this is only the first step: the problem of non-infectious diseases is intact.

The problem of access to medicines has been put on the agenda of the recent G8 conference, and this is a good thing. However, there is every reason to deplore that the G8 Health Action Plan is undeniably a setback and has dropped any reference to the Doha agreement.

Recent agreements arrived at in Cancun on August 30, 2003, are obviously a step forward in the liberalisation of the circulation of generics, but it remains to be seen whether the implementation procedures do not obstruct irrevocably the agreements' effectiveness.

Intellectual property rights could be reviewed so as to defend a country's right to protect public health. The Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) signed in 1994, under the aegis of WTO, states "*according to WHO rules no country should be prevented from taking measures for the protection of human life or health*". Seeking some form of compromise between the demands generated by health crises and those governing the financing of research, the European Union has recently proposed cooperation between WHO and WTO. Such joint action, associating medical expertise and economic realities could help to put an end to individual obstruction²¹.

This is the only possible path to the general adoption of concerted and effective practices for the use of compulsory licenses and procurement of generics.

As regards patents, European jurisprudence tends to begin by judging the apparent validity of a claim, and therefore to investigate its pertinence. On the contrary, the United States Patent Office essentially guarantees the originality of the work of invention, i.e. the non-existence of anterior work, but makes no assertion on the validity or the extent of the claims based upon it, so that possible arbitrations are left to the competence of courts if the patent is challenged. As a result, there is a frequent inflation of claims, since inventors seek to protect *a priori* (and randomly) inventions that could *possibly* be derived from the primary invention at a later date (exclusive rights to subsequent use). The interpretation of patentability criteria for

²¹ "Accès aux médicaments : l'Europe en première ligne" (*Access to medication: Europe on the front line*) ; Pascal Lamy : Le Monde January 23,2003.

DNA sequences for example is generally weighted heavily in favour of the inventor, and may lead to situations which are counterproductive for innovation and the cost of health care²².

Traditional values in European countries and the interests of emerging countries argue in favour of a more critical preliminary examination of the legitimacy of such claims, in order to avoid a situation where challenges in court become the only weapon, generally an expensive one, against abusive patents. Therefore, CCNE recommends that the government takes the matter up with the UE and the European Patent Office with a view to reinforcing traditional European practices for the granting of patents, and should the case arise, applying the existing legal procedures for discoveries with an impact on public health, (setting affordable prices, or compulsory licensing).

An initiative launched by some French scientists with a view to negotiating with professional associations for the right to use orphan medicines or conventional medicines to treat orphan diseases, should also be encouraged.

IV Principal obstacles (real or presumed) to change.

1) Infrastructure deficiencies in the countries of the South.

Most importantly, research must not be allowed to serve as a substitute for public health deficiencies.

Is it realistic to approach the central issue of access to sophisticated therapies before tackling basic public health problems? In particular, should the obvious problem of insufficient infrastructure be solved before discussing access to sophisticated medication? The scant resources devoted to healthcare are usually accompanied by excessive centralisation of infrastructure, so that this shortcoming is compounded by the remoteness of certain populated areas and difficult communications.

In the same way as policies for safeguarding the environment and improving hygiene help to enhance the state of health of a given population, policies for improving communications and the development of appropriate local health structures are also essential. Extending ultra sophisticated means of diagnosis and treatment to cover every location is obviously not a realistic option. A partial response to the problems generated by centralisation and isolation is telemedicine, and this is beginning to be on offer. However, there is a need for sufficient and appropriate training for those who will be transmitting from the outpost.

In any event, the fact that infrastructure is lacking must never stand in the way of offering access to appropriate care. A proliferation of infrastructure is not the real key to solving the problem. Rather, improving the quality of existing facilities, the quality of healthcare, of management and respect of individuals, and above all promoting a system of integrated healthcare attenuating any excessive division between primary care and hospital structures, are ways of improving access to healthcare.

2) Difficulties in transferring technology

Technological progress only increases inequality of access to treatment to the detriment of the countries of the South.

²² See in particular «*The ethics of patenting DNA – The Nuffield Council of Bioethics*». Available at <http://www.nuffieldbioethics.org>

The increased cost of maintenance of medical equipment requires highly trained specialists and this is increasingly difficult to finance; traditional equipment tends to be replaced by single-use devices because this is how manufacturers can respond both to the laws of the market and those of profit making. Sometimes, this new equipment complies with extreme versions of the principle of precaution and the question arises of whether it is really necessary to cease using altogether cheaper traditional equipment, which is more accessible to countries of the South.

Medical imagery expertise and know-how are infinitely more difficult to transfer than clinical medicine. Echographers are increasingly expensive to train, and sophisticated training of doctors from countries of the South in countries of the North means that they cannot work efficiently when they return to their country of origin. This is so for activities as commonplace as transfusion; the safety precautions demanded in our country are such that they are almost inapplicable in countries of the South, and therefore they are not appropriate when training specialists from these countries in the blood transfusion centres of the North.

In any event, the need to transfer technology that is suited to local conditions and corresponds to both needs and possibilities, and to promote training of users of such equipment, should be stressed. French speaking countries of the South want a more amenable visa policy which could help to develop training courses in countries of the French speaking North. More systematic policies for twinning healthcare centres in the North to healthcare centres in developing countries should be encouraged to develop the transfer of technology and the training of the medical and technical personnel who would benefit from such transfers.

One final point is the growing “verticality” of aid programmes. Excessive vertical segmentation does not take into account the need to care for all the needs of an individual. An AIDS programme for pregnant women that ignores the circumstances of childbirth and delivery ends up wide of the mark.

3) Precaiousness

Ambiguity about access to any particular medication in a generally precarious context is a real stumbling block in countries of the South. Even in the North, possibilities open to the more poverty stricken are not representative of the amount of investment in medical research and public health.

Furthermore, health depends on satisfying elementary needs such as access to water and sufficient food²³. A useful contribution to an efficient health system could be taking such simple measures, but specific health policies are required because of the political and psychological impact of the “right to healthcare” (recognised as a Fundamental right).

In fact, one of the ways of overcoming precariousness would be to promote equitable (not just hypothetical “equality”) access to healthcare. We are seeing the political emergence of a

²³ In this respect for instance, it is particularly worrying to observe the regression or even the disappearance of breast-feeding in countries where HIV contamination is rampant.

new paradigm, it being understood that sustainable development implies giving priority to health²⁴.

4) Compliance

Poor compliance to treatment on the part of patients in countries of the South is a frequent claim. In fact, this is due to a lack of information. A striking finding in recent studies is that as regards treatment for AIDS, patients in Africa are exactly as compliant if not more so than their counterparts in the North. One should be careful not to overstress contrasting behaviours in the North and the South. For example, it is a known fact that in the North, compliance for medication treating hypertension or diabetes is only 60%!

5) Problems related to chronic diseases

Recent and laudable European or global initiatives sought to reduce inequality of access to healthcare for transmissible diseases, particularly AIDS, tuberculosis, and malaria²⁵. This should not, however, be reason for neglecting chronic diseases such as diabetes or hypertension, which are a bane on countries of the South, and for which the necessary long-term treatment is more often than not somewhat alien to local custom and thinking.

The obstacles listed above must never become an alibi for inaction, nor a reason to focus exclusively or predominantly on problems of access to care and prevention. Although in the initial stages, there is clearly a need to adjust healthcare to limited resources in developing countries, this can only be a passing phase in a process aspiring to universal ethical principles.

Furthermore, adapting research to the limited resources of emerging countries could lead to *a priori* judgment criteria for these countries that differ from those applied to countries of the North. This is hardly acceptable.

V Problems related to cultural particularities

1) Preliminary comment

Although cultural environment deserves to be given more consideration in this context, because it may lead to different but nevertheless appropriate solutions in different countries or continents, proper attention to the dignity of individuals or groups is still just as important. This is the philosophy that must guide any reflection regarding healthcare disparities in different parts of the world.

²⁴ "La coopération dans le secteur de la santé avec les pays en voie de développement" (*Cooperation with developing countries in the health sector*): Report of the Haut Conseil de la Coopération Internationale to the Prime Minister.

Available at: http://www.ladocumentationfrancaise.fr/cgibin/brp/telestats.cgi?brp_ref=024000459&brp_file=0000.pdf

²⁵ For example, the 6th Framework Programme of the European Commission is supporting a long-term partnership with developing countries to combat these three pathologies, grouped under the name of "poverty-related diseases". This "European and Developing Countries Clinical Trials Partnership, EDCTP" will have a total financial volume of 600 million Euros, with equal contributions from the European Community, participating countries, and industry.

With reference to its usual means of communication, (Art, Science, or Prayer), culture has been accused of not furthering integration. "...culture does not unite. It identifies, therefore it divides as much as it assembles. The word is ambiguous"²⁶. Taking into account cultural specificities should possibly lead, when these specificities are compatible with effective healthcare, to variations on the more generally accepted solutions. In fact, if they are correctly understood and used, specificities are in no way obstacles in the path of access to care, and can become allies for the success of any health campaign.

An alternative view of the meaning of family, effects on the individual behaviour of a group or a village, must be taken into consideration in the same way as respect for the role of traditional or religious authorities, or of any other natural and recognised authority, since they are all factors for social stability.

2) Informed consent

All research protocols obviously entail informed consent from anyone participating, on an individual basis or within a group of populations.

However, the notion of free and informed consent must be appreciated in the context of the populations concerned by the research. The degree of literacy or autonomy of decision within a family, a group, or a clan, or even a village, must be taken into consideration. Research protocols must always take account of these factual situations and therefore require prior study and sociological investigation (human sciences) before any medical or scientific steps are taken.

The burden of economic disparity and lack of previous training may be considerable and, in this context, it would be reprehensible not to take remedial action. To obtain consent in exchange for monetary compensation, however modest, or in exchange for free healthcare of another description, is not exceptional, but remains blameworthy.

How can one verify that informed consent has in fact been given? The limitations of informed consent in countries of the North for the more vulnerable sectors of the population are well known, and one can hardly demand more of the South than it is possible to achieve in the North...

In this case also, referral to Ethics Committees in the countries or regions concerned is essential.

More than informed consent, which has a faintly fictitious quality, there should be a requirement that volunteers for a clinical trial be given information through a process of communication which fits in with their local customs and traditions, neither too much, nor too little, but aiming above all at freedom of choice.

More than formal consent, respect of individuals signifies full information on the true significance of placebos and randomisation. In this matter, there is no unambiguous opposition between individual and community or collective consent.

²⁶ "Ce sera une autre Europe - Introduction à la Convention européenne" (*There will be another Europe – Introduction to the European Convention*), Alain Lamassoure, Notes of the Robert Schuman Foundation, February 2003.

For this procedure, it has been suggested that a system of tutoring could be used. With the agreement of those concerned, the tutor would help them to understand their situation and the options open to them. This tutor could be someone with special moral authority, such as a religious or secular local figure. However since medical information would have to be made known to the tutor, the principle of medical confidentiality would be violated. There is no reason to accept this violation in the name of cultural dissimilarity.

3) The possibility of broadening the concept of privileged information

The issue is whether the circumstances governing the notion of privileged information as it is generally accepted in the North could be viewed in a different light in developing countries, because of cultural particularities.

Assisting patients through a tutoring system, the important role played by the family, the local group, or religion in certain areas could enhance the flow of information and contribute to better understanding of health issues and treatments required.

That being so, would it not be appropriate to work on broadening the concept of privileged information, moving in the direction of shared secrecy? This debate is not really the business of the countries of the North.

Keeping this in mind, and to illustrate with an extreme case the particular problems which may arise as regards protecting privileged information, reference can be made to the situation arising out of practices widespread in West Africa, called Levirat and Sororat²⁷.

Should future spouses be left in ignorance of the risk they incur in their new marriage if the deceased partner died of a sexually transmitted disease, which the surviving spouse could be carrying?

What of the situation of spouses who could not “benefit” from the Levirat or the Sororat custom because their contamination would be made known to their future partner?

A contaminated woman to whom a doctor reveals the risks if she were to remarry, might well be afraid that this information would be passed on to her intended future spouse. If so, and as a result, the woman does not marry her deceased husband’s brother, the community to which both of them belong will wonder why the practice of the Levirat was not followed. It will be obvious to one and all that there was some kind of health related problem and her group may reject the widow who has not remarried to the extent that she has to leave her neighbourhood or her village. The fact she did not remarry becomes a mark of shame.

This kind of situation must obviously be dealt with in the same way as it is dealt with elsewhere. The problem of rejection is not specific to developing countries. The remedy is to educate public opinion to understand that condemnation of contaminated people is not acceptable behaviour.

There is a clear requirement here to approach the problem by collective reflection with women’s associations, male groups, youth organisations, and sports’ clubs. There is a particular need for educational programmes in schools. The notion of medical confidentiality cannot of course be dropped. It should be universally accepted and be part of the basic values

²⁷ Levirat is a practice whereby widows are required to marry the brother of their deceased husband; Sororat is a practice whereby a widowed husband is required to marry the sister of his deceased spouse.

underpinning diagnosis and healthcare. The primary task is to fight incomprehension and intolerance of the sick.

4) Regarding the status of women

In some developing countries, women have a special status that generates a situation of inequality in the gender relationship, which quite obviously must be the subject of special attention since it could well compromise a realistic understanding of health problems.

In certain countries, women sometimes benefit from a form of social organisation based on a matrilineal system that gives women an important role, within the home only, but more generally giving women an inferior status.

For instance, there are customs whereby if a woman is asked in marriage, she marries for the sole reason that this is the path to social recognition, and no attention is given to the state of health of her future spouse. Cultural specificity does not make this acceptable any more than in any other context in which the dignity of women is denied. However, in the very same countries, an exemplary role is played by women's associations to improve matters and move in the direction of true equality of status between men and women.

Nevertheless, the "housewife's" special role will probably persist for some time to come. That being so, this role should be used as a vector for information on health and hygiene, knowledge about disease and elementary diagnosis, followed by treatment, so that women can become the first line of medical assistance to their families, and more than that, if you add the women's traditional role of education.

Where there are women's associations, they should actively lend a hand in that direction. When no such associations exist, they should be vigorously encouraged; the fight against AIDS, in particular, functions primarily through women's associations. The level of education of women is an essential factor for a real public health policy to gain ground in a country. Conditions for giving birth safely remain a number one priority for women's rights.

5) On the role of associations generally

Problems specific to developing countries can be summed up, as we have seen, as regards treatment, as being problems of information, training (for the young particularly), and knowledge. Any action must rely on complete awareness of the dimensions of the problems and on assistance to sustain efforts to confront them.

The usefulness of any form of association cannot be emphasised too strongly, be it for health problems or for entirely different purposes of a cultural or social nature. Just as much importance should be given to religious groups.

General policies cannot function efficiently if information is not delivered down to the smallest social unit through successive agents so that the chain of awareness of shared responsibility is never broken.

6) For a better approach of the common good?

Information (and therefore education) is the first requirement of modern ethics. Women, the earliest doctors and teachers, must get just recognition for their role in the transmission and sharing of knowledge. So they can fill this role, the first priority is better access to formal

education. A significant fact is that a population's life expectancy is considerably impaired by illiteracy.

To fully develop this positive effect on health, it is essential that knowledge be shared. It is also important to recognise the federating role that healthcare plays in the midst of convergent efforts to make life more humane (healthcare and medication are more potent when the medical community also provides attention and counsel), to pull together (health carers and patients face adversity as a team), and to empower (health policies as a result of joint democratic decisions).

In the context of medical and social cooperation, several kinds of exploitation have to be discussed:

- Inequitable exploitation of results obtained in countries of the South; this can be intellectual exploitation without any recognition of the South's physical or intellectual contribution. For example, it is entirely unethical to identify or patent a gene using a collection of data from the South if there is no intellectual or economic benefit for the country concerned. Rules of good conduct as regards publicity or partnership should always be included in the protocol.
- Industrial exploitation of traditional local resources without any return for the country of the South. There are examples of patents for certain prescription drugs that do not recognise the debt owed to the traditional lore at the origin of the research.
- Exploitation of the results of research carried out in the South for the exclusive benefit of the North.

It is clear that such processes, far from representing ethological idiosyncrasies here or there, relate to a much more "fundamental" examination of what unites humankind. Countries of the South can contribute significantly to ethical reflection (at a national or universal level) so as to help define the future of the world and of humanity.

Although numerous international organisations seek to promote political dialogue, security, trade, culture and mutual assistance between countries, ethics seem to be still in the process of construction, or even of definition²⁸. At a time when there are countless demands for ethical guidance, research for the foundations of "universal ethics" is obstructed by the risk of disregarding dissimilar opinions, or at the opposite extreme of only agreeing on the very broadest principles. Skirting the dangers of "moral fundamentalism" or of "cultural relativism", intercultural dialogue and open minds are the way to a broader view and the identification of consensual elements through "negotiated" pluralism²⁹.

It should be possible, if such dialogue is encouraged, to find a meeting ground for two dissimilar sensitivities. Seen from the South, traditional thinking determines the moral periphery of a group. In this kind of culture, self-identification and social integration are facilitated. To present, discuss, and appraise it³⁰ is a truly ethical undertaking. In this way, it is to be hoped that ancestral belief, released from the constraints of colonisation, but

²⁸ Jean M'Barga: Contribution de l'Afrique au questionnement éthique. (*Contribution of Africa to ethical reflection*). Symposium "L'Afrique et la bioéthique" (*Africa and bioethics*), Yaounde, January 9, 2001

²⁹ European Group on Ethics in Science and New Technologies to the European Commission, Round-table debate on the "ethical aspects of clinical research in developing countries" Brussels, October 1, 2002. Available at : http://europa.eu.int/comm/european_group_ethics

³⁰ For example, to condemn female genital mutilation and recognise it as "bad" in the name of reason can reinforce the pertinence of the cultures and traditions of the populations considered.

confronted by the rules of a world where frontiers are vanishing, can enrich the global heritage of humanity.

Possible recommendations?

While setting out recommendations inspired by the present Opinion, CCNE cannot ignore the fact that health problems are part of a more general policy of sustainable development – as it is now called - that comprises the environment, hygiene, nutrition, education or fighting illiteracy. Sustainable development must help everyone, including the most deprived (and therefore the most vulnerable) sections of the population in the countries concerned.

Furthermore, as is the case for other areas, and possibly more so as regards health, there is a need to reach out to other cultures. Although health has been much improved by medical advances, the aspiration to find global solutions to health problems must respect (or even guarantee?) cultural singularity when it contributes to social equilibrium and therefore individual fulfilment.

Different cultures may see certain situations in a different light. The choices that these specificities determine as regards healthcare policies must be respected, as long as they ensure, differently perhaps but effectively, personal dignity. The following recommendations seek to have due regard for ethical universality.

1. In the presence of conflict and contradictions, ethical reflection is an incitation to action because we cannot remain indifferent, and in doing so, we serve not only our conscience but also our interest.
2. Care should be taken to ensure that whatever authorities exist in the South are constituted in such a way that they are better able to define their true priorities. These views would then have to be accepted, even though our Northern viewpoint might have us prefer to give priority to diseases which unfavourable social and environmental factors encourage, rather than chronic diseases or those with a substantial biological component.
3. Although initially, care and treatment must of necessity be scaled to fit available resources, universal ethical criteria of pertinence must govern that process.
4. Authentic partnerships must be worked out for healthcare activities (twinning) and research protocols. They must be integrated into regional planning, and promote effective cooperation between countries of the South. For example, the *Agence Internationale de Francophonie* could well serve as a framework for such partnerships by helping coordination between French agencies (such as the Ministries for Health, Research, Sustainable Development, Industry, or Foreign Affairs) and their relations with multi-national organisations.
5. Cultural singularities must not be a pretext for inaction or for taking advantage of the most vulnerable.
6. Medical confidentiality cannot be discarded for the benefit of the community. There is no reason why inhabitants of the South should be less sensitive to infringement than their counterparts in the North. On the contrary, cultural singularities point in the direction of increased importance to be attached to the notion of confidentiality.
7. Paramedical professionals, who need to be trained and appreciated, and associations – particularly of women – are ideal partners.
8. Although medical research in countries of the South is vital, it should always be initiated by expressions of interest from the South, instead of originating from the North for more or less self-serving reasons.

As regards research partnerships with emerging countries, financial participation by public institutions should be subordinated to respect of accepted international rules of ethical conduct, by both partners. Important points are mutual respect of intellectual

property rights belonging to either party, and the right for the emerging country's team to enjoy the status of full partner and not be simply seen as a provider of services. This latter point concerns, inter alia, feedback of information to the partner team and to the patients involved, in particular as regards results of genetic studies which have an impact on health.

9. Access to healthcare and research must aim to be sustainable.
10. Criteria for research must comply with universal standards. Ethical conflict arises precisely out of vacillation between local cultural specificity and universal requisites.
11. Access to treatment should be self-evident whenever individuals or groups have participated in therapeutic research.
12. The existence of independent, competent, and representative ethics committees or committees for the protection of individuals should be highly encouraged in countries of the South. Some mediating body could make sure that the relationship itself between committees of the North and those of the South is ethical.
13. The issue of consent to healthcare and research is more related to the respect of individuals and to fighting indifference as regards those who are ailing, than to an excessively legalistic attitude about recording such consent.

Conclusion

One of CCNE's key roles as regards this subject is to put persistent emphasis on the frailty of the world order. Inequality among men, which used to be accepted as being part of "Nature" or of the natural order of things, becomes unbearable once the world is aware of the inequity of situations which modern globalisation highlights glaringly.

Recognition of the right to Health is necessarily one of the most essential Human rights; Jonathan Mann spoke of the "inextricable connection between health and human rights".

CCNE therefore firmly recommends that, without delay, public authorities in countries concerned – as they are all – and international institutions, should take whatever steps are required to further increase public awareness that inequality of access to health and care between countries of the North and those of the South generate problems of the utmost urgency.

Recognition of the fundamental right to health must lead without delay to the implementation of coherent and determined policies to respond to that urgency.

The object of North-South cooperation is to make optimal use of available resources that can be mobilised in the service of human dignity.

It is probably true that growing economic and scientific interdependence, more than ethical considerations, will stimulate States into thinking about the ways and means of achieving ethical, and not just economic, globalisation. The path to mutual recognition must steer clear of two illusions – sovereignty as a remedy to globalisation of practices, and ethical autonomy in the presence of economic interests. The example of North/South relations demonstrates the need for global, but adaptable, regulation: unified, but also harmonised to regulate medical practices and research. The aim should be to render ethical considerations opposable to political and economic forces, and therefore to States and transnational corporations. Such an objective supposes coordination between essential rights (UNO), including the right to health (WHO), and the rules applicable to trade (WTO) and intellectual property rights (WIPO). Ongoing debate within WTO shows the dimensions of the problem. This, however, will be the necessary condition for ethics to become more than brave words.

September 18, 2003