Human Freedom and the Human Genome

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HUMAN FREEDOM AND THE HUMAN GENOME

the *Ten Rules of Valencia*

The Hon Justice Michael Kirby AC CMG*

CELEBRATION OF FREEDOM

The recent celebration of the 50th anniversary of the adoption of the *Universal Declaration of Human Rights* affords us a context for reflections upon human freedoms.

There are a number of similarities between the moment in history when Mrs Eleanor Roosevelt and her colleagues proposed that *Declaration* and our time. Following the end of a major conflict, the world order had been changed. National borders had been rearranged. There was a great deal of uncertainty, doubt and exhaustion. Just like today. The world was caught in the grip of a most imaginative, dramatic and worrying technology. Then, it was nuclear fission. Today it is genetics. Then, as now, public attitudes were ambivalent: vacillating between pride in human creativity and dark fears about where that creativity might lead and whether it would endanger the very survival of humanity as we know it. Then, sombre evidence about the unethical experiments of the Nazi doctors was released, with the testimony of the War Crimes Tribunals. Now, the public is alarmed by reports on the proposals of Dr Richard Seed to raise funds to develop the capacity to clone human beings. Then, as now, a rift seemed to emerge between the attitudes of scientists and the fears of the public.

Back in 1949, scientists were reassuring the public about the safety of nuclear fission and how it would bring an endless supply of energy to humanity, releasing us to a new freedom from dependence on fossil and like fuels. Yet all that many members of the public could see was the mushroom cloud and the shattered dome at Hiroshima, left unrepaired as a symbol and

a reminder. Today, the dichotomy can be seen in the debate over cloning:

Fifty years ago, the world stood on the brink of globalism and did something about it. It created the United Nations Organisation. It developed the *Universal Declaration of Human Rights.* It set in train a truly international effort to search for, declare and uphold the fundamental norms of human freedom. It established institutions to translate the ideas in the *Universal Declaration* into effective action. Around the world, civil society organisations sprang up to assert and defend human freedoms and to stimulate national governments and international agencies (including the United Nations) into respect for freedom.

I saw this global machinery at work when I served as Special Representative of the Secretary-General for Human Rights in Cambodia. It is not perfect. But it represents an affirmation of human freedom and the realisation that it is a global imperative. Now, fifty years later, we are seeing the same tentative responses to contemporary problems by the international community. Relevantly, UNESCO has established its International Bioethics Committee. That body, of 36 persons chosen from around the world, has produced a new Universal Declaration - the *Universal Declaration on the Human Genome and Human Rights*. The new *Declaration* represents an endeavour to state the principles of human rights apt to the challenges presented by the Human Genome Project. The World Health Organisation (WHO), under its new Director-General, has also begun to adopt a more proactive stance in relation to human rights and the genome. Recently, at a summit of National Bioethics Commissions convened in Tokyo, WHO offered to provide a Secretariat to facilitate a permanent international network of such bodies. Joined by the Internet and served by this agency of the United Nations, the hope is that the brain power of humanity can be combined to come up, once again, with the defences to freedom which are needed if genomic developments are to be the servants, and not the masters, of humanity.

So at this moment, when we look back and look forward, we can take encouragement from the growing global debate about the implications of the genome project for freedom and for human dignity. It is the nature of science to present risks and challenges to humanity. It is the responsibility of humanity to produce the answers. Humanity has begun to do this. It has begun to consider who we human beings are, where genomic science is likely to take us and how we can interact effectively with the new environment in which we find ourselves. Undoubtedly, that environment presents risks:

As the work of UNESCO, and WHO, and also of the Ethics Committee of the Human Genome Organisation show, progress is being made. Responses are being offered to protect human freedoms in a context of genetic change and risk. By the same token, it is proper to remind ourselves of the warning given by Alrich Beck in his book *Risk Society*:

THE AGE OF THE GENOME

It was the explanation in 1953 by James Watson and Francis Crick of the structure of DNA

that provided a means of understanding the process of the transfer of genetic information between generations of the same organism. From the late 1970s it became possible to insert and remove genes in bacteria and to observe the results of doing so. This led to the possibility of sequencing and extracting genes from higher organisms and inserting them into bacteria which could then be grown, permitting analysis of the gene to take place.

It was in 1990 that "a fateful decision" was taken to sequence the entire human genome, ie the complete set of genes and chromosomes of the human organism. Thus began the Human Genome Project. It is the largest, boldest, most ambitious scientific research project ever undertaken. Its intention is to analyse the entire structure of human DNA, determining the location of the estimated 100,000 human genes. Already nearly 50,000 genes have been identified, although the function of most of them is still unknown. Although more than 95% of the human genome remains to be sequenced, new techniques and advances in that other contemporary technology, informatics, means that the 15 year time scale originally set for the finalisation of the project is far from unattainable.

This will produce a great mass of data which has been likened to "a very large encyclopaedia written in an unknown language". Then will begin the systematic search for the functions of each discovered gene. The hope is that these functions will provide knowledge which will help medical science to treat the more than 4,000 genetic diseases which presently afflict humanity, as well the multi-factorial diseases in which genetic pre-disposition plays an important role. Stated at that level, the prospect of genetic discovery seems utterly compatible with human freedom. In the long run, it will help particular humans, and perhaps their progeny, to be "free" from the actuality or the risks of exposure to genetic conditions that bring pain, suffering and often death to those whose biology is affected by them. But the challenge before the scientific and lay communities, is to use the mass of data now, for the first time, becoming available "in a way that fulfils scientific criteria and respects ethical as well as social concerns". Genetic disease, and its manifestation in human beings, is no laughing matter, either for the subject or the family or for the community:

So this is the fundamental challenge to man's freedom which we are witnessing. Scientists are generally "free" to research, to experiment and to push forward the frontiers of knowledge. Doctors are "free" to use the data produced for genetic testing and ultimately gene therapy, in the hope of discovering and treating genetically produced physiological or psychological misfortunes. But the community is also "free" to misuse the data so produced. It may thereby diminish the dignity of the subject of that data. It may invade the confidentiality and privacy of the person affected. It may discriminate against the person by reference solely to that data. It may add to the burdens of genetic difference and disadvantage new burdens of social discrimination. An inability to get or keep a job. An inability to secure insurance. An inability to be accepted as a migrant. And we are also "free" to burden the individual with knowledge that may blight his or her life because genetic testing and screening for inherited disorders is happening at a pace which far outstrips the availability of gene therapy or other treatments.

It is to respond to these and other challenges that the Director-General of UNESCO, Federico Mayor, asked the International Bioethics Committee to produce the *Universal Declaration on the Human Genome and Human Rights*. I shall annex the text of its chief provisions to my paper. But some of the central provisions need to be noted. They are crucial to the defence of human freedom in the context of contemporary genomic developments.

The opening provision declares that "the human genome underlies the fundamental unity of all members of the human family". It recognises the "inherent dignity and diversity" of every individual. There you have, at the outset, the assertion of a paradoxical reality that runs through the movement for universal statements of human freedom. They are global in their application. Yet they are individual in their focus.

The main substantive provisions of the new *Declaration* insist upon the requirement of rigorous and prior assessment of potential risks and benefits for any research, treatment or diagnosis affecting an individual's genome. In every case, the prior free and informed consent of the person concerned must be obtained. It is specifically recognised that each individual has the right to decide whether or not to be informed of the results of genetic examination. No one is to be subjected to discrimination based on genetic characteristics such as will infringe that person's human rights, fundamental freedoms and human dignity. Respect for the confidentiality of genetic data which can be linked with an identifiable person must be protected by law. Just reparation must be provided for any damage sustained as a result of an intervention affecting a person's genome. In order to protect human rights and fundamental freedoms, limitations on the principles of consent and confidentiality are only permitted where prescribed by law for compelling reasons which themselves conform to the international law of human rights. No research or application of research concerning the human genome may prevail over respect for human rights, fundamental freedoms and human dignity of the individual or groups of people.

Much of the new *Declaration* is addressed to the responsibilities devolving on researchers to conduct genomic research with meticulous care, caution, intellectual honesty and integrity and to share research outcomes in a way that fosters intellectual freedom, a prerequisite of scientific progress. States are urged to provide the framework for the free exercise of research on the human genome with regard to the principles established by the *Declaration* and so as to safeguard respect for human rights, fundamental freedoms and human dignity and also to protect public health. The *Declaration* urges the establishment in each country of independent multi-disciplinary and pluralistic ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications. There are many provisions for solidarity, international cooperation and promotion of the principles established by the *Declaration*. The International Bioethics Committee of UNESCO is given the task of disseminating those principles and promoting the acceptance of the *Declaration* throughout the world.

Running through the principles of the new *Universal Declaration* are basic norms concerned with human freedom. There is a recognition of the intellectual freedom which is the environment in which scientific knowledge can alone move forward. But as with the original

Universal Declaration of 1948, most of the core provisions of the *Genome Declaration* are concerned with the freedom of the individual who may be affected by genetic research, testing or therapy. The dignity, privacy and integrity of that individual are to be upheld. In short, scientific progress should go ahead in the belief that its tendency is not to diminish human freedom but to enhance the benefits to humanity. But it should go ahead in an environment which respects the freedoms of the individuals affected and enhances the freedoms of people everywhere. All people have a right to share in the products of research and applications in biology, genetics and medicine which carry the promise of relieving human beings from suffering and improving the health of individuals and of humankind as a whole.

HUMAN CLONING

Possibly the most controversial provision in the new *Universal Declaration* is the one which makes reference to cloning. It states:

"11. Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organisations are invited to co-operate in identifying such practices and in taking, at national or international level, the measures necessary to ensure that the principles set out in this Declaration are respected".

The original draft prepared by the International Bioethics Committee did not contain a specific reference to human cloning. The purpose of the Committee was not to identify a particular scientific technique but to specify a general objective, relevant to all scientific practices, viz, the avoidance of infractions upon human dignity. It aimed to encourage later study and identification of what those infractions might be. The theme of human dignity runs through many of the provisions of the new *Universal Declaration*. In this sense, it draws upon the classic expression of Immanual Kant's second formulation of the categorical imperative:

Kant wrote:

This insistence upon respect for human dignity can be explained in historical terms by reference to the gross infractions of such dignity which have occurred in recent times. The terrible wars. The ghastly suffering of the Holocaust and other genocides. The fearful perils of the technological weapons of mass destruction. The assaults upon civil populations. The invention of new and ever more horrible means of delivering death and suffering to vast numbers of humanity. The blind intolerance of the grief of huge populations living with preventable diseases. The infliction of seemingly irremovable burdens of debt upon peoples who cannot find relief from it. The destruction of the earth's environment which builds up suffering and loss of freedom for future generations. In this context, the demand for the defence of human dignity from scientific practices which may wound that dignity in the course of advancing the new genetics, is scarcely surprising. It represents a clarion call for the defence of human freedom in the face of yet another potential challenge.

But what about cloning? The phrase "such as reproductive cloning of human beings" was included in the *Universal Declaration* of 1997 at the insistence of a meeting of governmental experts to whom the draft was presented by UNESCO. At least one member of the International Bioethics Committee has expressed his concerns about the final text of Article 11. Professor Michel Revel of Israel has observed:

A similar view was expressed to a conference in Adelaide in South Australia in November 1997 by Professor R V Short who wrote:

Professor Short points out that the growing of human embryo stem cells in culture in this way would be illegal in a number of the States of Australia and, doubtless, in many legal jurisdictions around the world. Many ordinary citizens would have a reaction of rejection, possibly even horror, at the notion of human cells being injected into the living cells of mice. Certainly, if such experiments were directed towards the banal object of producing a kind of genetic immortality in the subject, they might involve nothing more than a misguided "ego trip" of little scientific or social justification. But much more contentious is the suggestion that international principle and domestic legislation should intervene to prevent therapeutic experiments in the nature of cloning of human material. If experiments of that kind represent the next natural step in scientific discovery, should we permit intuitive reactions and feelings of revulsion on the part of communities and individuals to stand in the way? The challenge for the preservation of scientific freedom and the freedoms of the human species that protect its integrity, dignity and basic rights, is to permit (and even encourage) potentially beneficial science, whilst ensuring that this occurs in a context of expert ethical reflection and general public knowledge.

For my own part, I do not read Article 11 of the UNESCO *Declaration* as being addressed to *therapeutic* cloning of human material as distinct from *reproductive* cloning of an entire human being. But even the latter may need in due course to be reconsidered as we have more time to explore the constant interaction of scientific freedom and human freedom. Twenty-five years ago, when I was first involved in bioethical controversies in the Australian Law Reform Commission, there was an energetic debate about the ethical and legal acceptability of AIH (Artificial Insemination Husband). That soon gave way to the debates about AID (Artificial Insemination Donor). In due course, that too gave way to the general debates about HTT (Human Tissue Transplantation). Eventually, IVF (*In vitro* Fertilisation) came along and expelled all the earlier debates. Within Australia, legislation was enacted in the State of Victoria where considerable progress had been made in the scientific work on *in vitro* fertilisation. The result was that the scientists and technologists packed their bags and moved to mainland Asia. The scientific work went on; but not in Australia. Cloning is now, potentially, upon us. Many of the debates and controversies of the earlier time are being repeated. The lesson seems to be that notions of human dignity and of what is acceptable, or not, change in time. In part, the changes come about with increasing public familiarity with the scientific and technological developments, a perception of the benefits which they can

bring in identified cases and a realisation that the dangers to human dignity and freedom may be less than at first feared.

So can we defend human freedom in the age of the Human Genome Project? That is the fundamental question. I suggest that we can. But to do so we need to observe certain "rules". I am so bold as to call these rules *The Ten Rules of Valencia*. They concern an approach to the issues to be discussed here, such as genomics in the workplace; genetic data and the availability of insurance; genetic testing and therapy and medical practice; and the protection of individual rights to privacy and confidentiality. But the *Ten Rules of Valencia* also provide a framework for our approach to other topics; indeed all issues which now, or in the future, are presented as apparent challenges to human freedoms in consequence of the Human Genome Project. Let me therefore propound the *Ten Rules of Valencia*:

THE *TEN RULES OF VALENCIA*

1. *Foundation of good science:* The first rule is one which I learned in my work on the WHO Global Commission on AIDS. All laws, policies and strategies to deal with a new and puzzling challenge having a scientific dimension must be based on good science. Not ignorance, prejudice, unquestioned dogma or even instinctive reaction. Ethical judgments which cannot claim a thorough understanding of the applicable science rest on the shifting sands of ignorance. Alarmism, extravagance and pandering to fear of the new should have no place in the building of legal and ethical principles to respond to the developments of genomic science. Justice Stephen Breyer, of the Supreme Court of the United States, made this point in an address to the annual meeting of the American Association for the Advancement of Science reproduced in *Science*:

Only by knowing the true dimensions of the scientific issue will laws and policies be well targeted.

2. *Involve multi-disciplinary dialogue:* In furtherance of this idea, it is essential to encourage multi-disciplinary and multi-cultural dialogue. Multi-disciplinary, so that lawyers, ethicists and social policy makers can get their minds around the latest scientific developments and understand what they do, and do not, mean for present and future medical therapies and experimental endeavours. Multi-disciplinary because this will help representatives of the scientific community to perceive (and perhaps understand) the anxieties of lawyers, ethicists and others. The latter will tend to reflect the concerns of the general community. As past experience demonstrates, when science rushes ahead of community consensus alarm and political sensitivity can sometimes, at least in democratic societies, result in administrative policies which obstruct scientific work or even in laws that restrict it. Such was the agitation about the unknown dimensions of *in vitro* fertilisation, that laws were passed in several jurisdictions which had the effect of inhibiting activities of some scientists. The Director of the WHO Programme on Research in Human Reproduction has complained that widespread political opposition to cloning has resulted in rational debate on the topic falling victim to emotion and politics. The establishment, as the UNESCO *Universal Declaration* urges, of

national bioethics committees is one way of ensuring an institutional structure for the orderly exchange of information and the promotion of true public debate. The desirability of multicultural dialogue was instanced at the Summit of Bioethical Commissions held in Tokyo in November 1997. A handful of countries are at the cutting edge of genomic science. Most countries are potential clients of the pharmaceuticals and therapies which will result. They are venues for the experiments that will take place. Unless there is global dialogue and exchanges of knowledge and understanding, local pressure may build up to demand moratoriums and prohibitions which impede legitimate scientific experimentation.

3. *Think positively:* It is natural to observers of the scene presented by the Human Genome Project to despair of the capacity of lawyers, ethicists and other social scientists to provide useful input to the regimes by which scientists actually work. In the face of the Internet, it may seem impossible, or at least virtually so, to devise an effective international regime that will safeguard agreed basic standards in information flows. Similarly, with the Human Genome Project. The interests, attitudes, religious beliefs and ethical perceptions are likely to be quite different from one country to another and certainly as between continents.

It is true that the achievement of effective global regulation of a pervasive scientific development is extremely difficult to attain. Quite apart from the different interests of different societies, there are often different starting points for the very idea of regulation. In some societies, the view is adopted that science carries risks and should not be permitted unless scientists can demonstrate affirmatively that there is no risk, or that the risks are negligible. In other societies, there is a presumption that science should be free to advance and will ultimately benefit humanity, as it has generally done in the past. Sometimes different approaches of this kind coincide with the differing investments which countries have in the products of scientific endeavour. Yet, despite the differences, regimes of general principle can still be established. The very achievement of the *Universal Declaration of Human Rights* in 1948, covering so many controversial issues, indicates that basic rules can sometimes be agreed globally. We have seen this happen in the development of the *Nuclear Non-Proliferation Treaty* which seeks to control the spread of nuclear weapons. Twenty years ago I worked on a committee of the OECD in Paris devising principles to govern the protection of privacy in the context of trans-border data flows. Those principles have profoundly affected the development of national law on privacy protection in the context of informatics. Now the UNESCO *Declaration* is before the international community. It promotes a small number of basic norms addressed to the rights of individuals and, the obligations of States and of the international community. In this way "core norms" can be laid down to promote local lawmaking and policy development. The very presentation and statement of international principles can help avoid unnecessary disparities of approach and inconsistency of laws.

4. *Choose manageable issues:* In dealing with the social consequences of the Human Genome Project, wisdom suggests that particular issues should be selected for early treatment. Some issues are more readily managed than others. Take for example the adoption of laws and policies to govern genetic testing. When it may be done? With whose consent? Where the data will go in identifiable form? Issues of this kind are susceptible to

regulation by protocols adopted by the medical profession supplemented, if necessary, by law. Similarly, with insurance. Whether insurers may demand, before accepting a proposal for life or health insurance, the provision of a report on genetic tests of a particular, limited or general character? Such issues may be decided (at least in the first instance) by a voluntary moratorium accepted by insurers, banning the demand for the disclosure of genetic test results in the case of a policy of a certain size; or excluding new genetic tests but requiring the disclosure of those already known to the proponent for insurance. In the long run, the rights of insurers and the obligations of the insured, to genetic data may be governed by law. So far as the results of tests already known are concerned, the universal principle that insurance is a contract of *uberrimae fides* may already require disclosure to the insurer of such information, if known by the insured.

Much more difficult of management by law or effective voluntary regulation are the deeper questions. Whether genetic data is relevant to the criminal responsibility of an accused convicted of a crime of violence allegedly attributable to genetic predisposition? Whether the protections of intellectual property law are apt to the patenting of mere fragments of human genes, such as those known as expressed sequence tags. Or whether laws can and should ban both therapeutic and reproductive experiments with cloning involving human biomaterial? In the first instance, at least, ethics committees and lawmakers will do well to concentrate on manageable, achievable tasks. The larger, more fundamental issues may require time until "the dust has settled and the emotions have been vented".

5. *Affirmative approach:* Whilst it is proper for ethicists, public policy makers and lawyers to be vigilant about the implications of genomic science, an attitude of suspicion, or even of antagonism, is unwarranted. Overwhelmingly, the Human Genome Project will be for the benefit of humanity. Needlessly living with a preventable serious genetic disorder is not ethical. Seeing children and other loved ones suffer debilitating and fatal illnesses beckons us to the promises which the ultimate development of gene therapy may hold out. Already, there have been significant achievements, despite the still primitive tools available to medical science:

In due course it will be possible by gene surgery, gene insertion and gene modification to provide relief to a patient with many (eventually, possibly, all) genetic disorders which cause death and serious incapacity. There is no beauty in needless death and painful suffering. Attitudes to such problems tend to vary sharply in accordance with one's proximity to their urgent demands. Although undoubted dilemmas are presented by genomic science, it is important to remind ourselves that the beginning of therapy is knowledge and that, already, simple genetic screening is providing to some patients the possibility of therapy which, until recently, did not exist.

6. *Be realistic:* Another requirement is to be realistic in appreciating the proper limits of legal administrative or other controls upon scientific endeavour. Rules of professional conduct or legal regulation may simply chase a scientist from one legal jurisdiction to another, when there is no relevant inhibition on the research in the latter. In times of economic uncertainty,

different countries vie with each other to attract investment, particularly in potentially lucrative and futuristic activities such as are involved in gene therapy. In the past, there have always been tax havens. In the future, it seems likely that there may be regulation-free zones for that genetic research which promises large investments and speedy economic rewards. At last report, Dr Richard Seed, facing legal prohibitions in the United States forbidding human reproductive cloning, was said to be offering to bring a large capital investment to Japan if there were no similar restrictions there. The attraction of agreeing to his bid is not only the suggested market for reproductive cloning as a solution to infertility where IVF, say, has failed. It is also the other suspected benefits of cloning as a means, ultimately, for producing compatible organs and tissues for transplantation. Professor Michel Revel observes:

7. *Engage the public:* One of the problems of late twentieth century science is that it has gone beyond the ready understanding of even an informed layman. How many well educated people understand Einstein's relativity theory? The notion of the atom? How computers actually work? What a gene really does? In their enthusiasm for advances in their own disciplines, scientists and technologists are not always skilled, or even concerned, to engage the general community about what they are doing and where it may lead. Yet, unless the community is informed, at least in a general way, there is a danger of over reaction, prohibition and restrictive laws. In my own work on bioethics, I have always insisted upon the need to express the rules in language which an intelligent lay person could understand if he or she chose. Yet I have sometimes found difficulty in securing the agreement of scientists to define their terms. What is the use, for example, of issuing a statement on the ethics of cloning which is expressed in terms of "somatic cells nuclear transfer" and "mitochondrial disease" without defining such terms? This is one reason for supporting the establishment of national bioethics commissions - so that they can continue, or begin, the process of informative scientific dialogue with the community. Only this will allay irrational fears, sometimes fuelled by media stories more concerned with entertainment than with true scientific possibilities.

8. *Absolute limits:* Allowing fully for the difficulty of restraining the inquisitive minds of scientists and prohibiting in every country the particular kinds of experimentation with human material that evokes global repulsion and legal prohibition, in particular places, there are some scientific activities which would be likely to evoke universal condemnation. They would stand a good chance of producing a global consensus for prohibition, regulation or at least moratorium just as nuclear proliferation has done. An instance would be work towards the creation of a human/animal hybrid. Such an idea is presently a matter of science fiction. However, rapid developments in bio-engineering have already led to experiments with animal hybrids, including the zebra/horse, tiger/lion, sheep/goat. One reported example of human/animal hybridisation has been the fertilisation with human sperm of polecat eggs in research concerned with male infertility. The *in vitro* fertilisation of chimpanzee eggs with human spermatozoids is not only possible but, reportedly, it has been the subject of experiments in a number of laboratories although usually interrupted at the early stages. If such experiments were limited to observation of early responses during fertilisation, as

adjunct to serious scientific work of potential benefit, views would doubtless differ.

To some extent, opinions on such subjects depend upon notions of when human life begins. The view held by some Christians that it begins from the moment of fertilisation could attract condemnation to any such hybrid experiments. But the difficulty for global prohibitions is that Judaism and Islam consider that the embryo does not acquire human characteristics until after 40 days. Some lay opinions, unaffected by religious belief, would doubtless allow an even greater interval, say before the foetus was viable or otherwise takes on characteristics apt for legal protection. The point is that different religions and philosophies respond in different ways to these problems. This makes universal prohibitions, regulation or moratoriums difficult to achieve.

Yet I doubt that anyone would support the notion (if it should become scientifically possible) of creating a true animal/human hybrid, such as the mule. There could possibly be other restrictions which could be agreed as an international norm given the present state of knowledge. For example, in the currently available techniques of gene therapy, experiments with the human germline may well be inadvisable and properly the subject of moratorium, regulation, if not prohibition. Without effective norms to restrain such activities, there will be no reason why they should not proceed. Difficult though it is to find consensus which will extend beyond a nation or countries which share a common ethical tradition, what is at stake here is the human species. A species belongs to no nation and no single religious or ethical tradition. The commonality of humanity's interest in the future of the species affords the proper basis for a search for the forbidden territory which should be strictly regulated.

9. *Developing global institutions:* Without global institutions, talk about prohibitions, regulations and moratoriums will be just that: talk. The absence of effective inhibitions amounts to a permit for science to go where any individual researcher chooses. Even if, in a free world of scientific inquiry, that may be appropriate as a general rule, if we accept that some activities should be forbidden and other principles promoted, we need to go beyond talk. Ultimately, we require effective institutions of regulation and lawmaking which render the genomic scientist and the technologist, like everyone else, answerable to the law. Modern science presents, by its complexity and the speed of its changes, a significant challenge to the capacity of civil institutions to respond effectively. This is not the fault of scientists. They cannot be blamed for the inefficiencies of the lawmaking process or the delays of ethical reflection. By the same token, those inefficiencies and delays take on a new significance in the age of the Human Genome Project, the Internet and nuclear fission. One of the biggest challenges to the freedom of humanity in the coming century will be to build more effective national and international institutions which can respond with appropriate speed and expertise to the challenges of science and technology.

10. *A step in evolution:* Finally, it is necessary to approach the developments which spring from the Human Genome Project with a full appreciation that it is not something alien to humanity. The human genome was always there, long before Watson and Crick provided the key to find it. Human beings have been manipulating plants and animals to serve their purposes for generations. Responses to potential developments must avoid either the

simplicities of uninformed intuition or the mental prison of genetic determinism.

In terms of evolution, it is perfectly possible that the discovery of the means eventually of eliminating serious genetic disorders may be seen as a qualitative change in the human species itself. Yet past experience has demonstrated the importance of diversity in the human gene pool, particularly in terms of epidemics. It also suggests the unwisdom of eliminating those who manifest genetic conditions which are only one aspect of the subject's personality. What is a "defect" may itself sometimes be a real matter for debate and change of opinion. The elimination of every birth which manifested the gene(s) for Huntington's Disease would not be justified. If it should ever become possible, the elimination of every birth manifesting a genetic propensity to homosexuality would be an outrage. The freedom of humanity does not extend to a freedom to eliminate every element of genetic variety that does not find favour with particular people. Even if that should become scientifically possible, it will be necessary for human freedom to recognise and to respect the diversity of our species. In a sense, diversity is the protector of freedom. Whilst we should see the Human Genome Project as a new step on humanity's evolutionary path, evolving as it does from human intelligence, the challenge before us is to ensure that we have the wisdom and the strength and the courage to render this science the servant of mankind. Science must not, uncontrolled, become our master.

CONCLUSIONS

If we observe the *Ten Rules of Valencia*, we will approach the legal, ethical and social quandaries presented by the Human Genome Project with fresh enthusiasm and a new optimism. This is not a time for despair. Fifty years ago, Eleanor Roosevelt and her colleagues tackled the task of finding the basic rules of universal human rights and expressing them in a single document. That document has had a profound influence on history. It continues to do so. Human beings are moral beings. It is part of their humanness to be concerned with ethical choices. Puzzling although the choices are which are presented by genetics, it is not beyond our skill to defend human freedom in the age of the human genome. The opportunity presented by meetings such as this is vital in the furtherance of the dialogue. The Human Genome Project sprang from the mind of human beings. Ethical rules, and eventually laws, will come from the same source.

We need as much energy, optimism, and determination in our ethical reflections as can be found in the scientific endeavour. This is no time for despair, resignation or pessimism. It is an exciting time for science. But it is, equally, an exciting time for bioethics and law.

ABSTRACT

In this paper the author outlines the challenges and risks to freedom presented by developments in genetics. He describes the approach to and main provisions of the Universal Declaration on the Human Genome and Human Rights adopted by UNESCO in 1997. He discusses the sensitive issue of reproductive cloning. He then propounds ten general "rules"

to guide our approach to the resolution of bioethical quandries in the field of genomics: