

FOURTH NATIONAL CONFERENCE BRISBANE 1995

ST JOHN'S COLLEGE BRISBANE

MONDAY 25 SEPTEMBER 1995

BIOETHICS, THE HUMAN GENOME PROJECT & OUR FUTURE

The Hon Justice M D Kirby AC CMG *

President of the New South Wales Court of Appeal

Recently appointed member of the Ethical, Legal and Social Issues Working Group of the International Council of the Human Genome Organisation, Bethesda, USA

I remember a day vividly in about 1950 when two grey coated departmental officials came to the class room, handed us out little documents and in them we were asked, "what do you want to be when you grow up?" After deep thought at the age of 10 I write, "I wish to be either a Judge or a Bishop (one way or the other I was determined to spend my working day in fancy dress). Well, you've had a Bishop, indeed an Archbishop in this Lecture Series. Tonight I'm here as a Judge and citizen, yet I want to start in the manner of a Bishop with a number of texts. Let me start first of all with the following extract from The Australian which is headed, "Gene Debate Highjacked by Hysteria": "Illusionary fears of Frankenstein's laboratory have highjacked the debate over the use of genetic technology, clouding the positive aspects of gene therapy in the cure of disease, leading scientists told a technology forum this week". The Director of the Walter and Eliza Hall Institute of Medical Research and President of the Australian Academy of Science, Professor Sir Gustav Nossal said, "interference in genetic make up of humans existed only in the imagination". "It's all fiction, it's not reality, not in any lab in the world" Professor Nossal said. "Let's keep this debate on what is possible now and will be possible in the next 30 years. Let's not allow the debate to get highjacked by people raising illusory fears, much of which can't happen". "I believe the gene therapy era is going to be something of huge benefit to humankind and something not to be portrayed to the lay public as holding any terrors. I think there's a lot of mistrust in some sections of the community but I think it's misplaced, scientists have a lot of constraints on them. It's quite a regulated industry", he said. Professor Sir Gustav Nossal is President of the Australian Academy of Science. He is a most distinguished Australian. He is a friend.

Along the same lines have been comments in Nature by John Maddocks in an article, "New Genetics Means No New Ethics". Dr Maddocks in Nature in July 1983 expressed the view that there was no need to be alarmed. That there were no substantial dangers. That "it is usual for Hitler to be thrown into this debate". Yet he says at the end of his statement, "Geneticists are fond of saying, "it will never touch the germline"! But that is unwise.

in our own National Health and Medical Research Council Guidelines, which are part of the Statement on Human Experimentation, supplementary note number 7, Rule No. 2. It says all attempts to introduce pieces of DNA or RNA into human cells should be considered to be experimental and subject to the statement by the NHMRC, "Human Experimentation and Supplementary Notes". It further states in one of the instructions that as to the technique of insertion in the germline experiments in animals is a pre requisite. It is necessary in humans to confine the insertion of DNA and RNA into intended somatic cells without entry into germ cells. This is supplementary note No. 7 titled: "Somatic cell gene therapy and other forms of experimental introduction DNA and RNA into human subjects".

When I was in New York for the presentation of my report as the Special representative of the Secretary General for Human Rights in Cambodia I was sitting at breakfast one morning on the 22 November 1994 and opened my New York Times to find on the front page a story about a report which had been presented the day before to the American Academy of Sciences by a Dr Ralph Brinster, a Researcher at the University of Pennsylvania. Dr Brinster has focused on a group of early stage sperm cells called stem cells which arise in the testes and are the source of sperm that males produce. Sperm cells can divide to form more stem cells. They can then divide to perform more differentiated cells which will continue along a developmental path and will lead to the production of sperm. Dr Brinster is experimenting on mice. Since the stem cells are the genetic source of all sperm cells, genes inserted into the stem cells will appear in all the sperm derived from them and those genes in turn will appear in every cell of the animal's offspring, altering its lineage. Dr Brinster and his colleagues found that they could gather stem cells from the testes of mice, that had marker genes in all their cells. They could then inject the sperm stem cells into the testes of other animals and see the marker genes effects upon the next generation. The commentator who worked with Dr Brinster said that this could have far reaching clinical consequences for testing fertility and genetic disorders. I don't think he was considering only mice.

I have four capacities in which I have some relevance to speak to you tonight. The first is as a Judge. I was sitting in Court today dealing with the memo and articles and association of a shopping centre and I will be going back tomorrow to deal with three appeals in Sydney. Our legal system is a very interesting one. When I go to a country like Cambodia I see the great difference between a country like ours that can boast a continuous legal tradition of 800 years and a country that can't. In our country, in our legal system, the common law, there is never a gap. If ever there is no law it's left to people like me to develop the law by analogy from earlier cases. That's the doctrine of precedent: expanding and developing old cases to meet new circumstances. If in any of the problems that I mention tonight there is no law and Parliament doesn't make a law, then it's left to the Judges to develop the law by analogy to past principles of the common law. That is a way in which we have a fail-safe system in our sort of society against having gaps in the law and silences about important matters. So that is my first relevance to comment upon the issues of human genetic developments, human genetic research and the problems that it presents to our society and the law.

My second relevance arises out of my work for nearly ten years as Chairman of the Australian Law Reform Commission. That Commission had the task, on projects which were assigned to it by the Federal Attorney General, to develop the law in areas which were often at the frontier of law making. For example one of the first tasks which was given to the Law Reform Commission was to develop the law on tissue transplantation which was then becoming an important feature of medical science. The law on that subject had been pretty imperfect and often silent. Rather than leaving it to the chance that Judges would develop it and do it in a sensible and informed way, the Law Reform Commission was given the task to develop the principles. So it did. Those principles became the basis of the law on tissue transplants throughout our country.

The way in which the Law Reform Commission achieved that success in a country that really cannot boast many laws which are uniform I'll mention in a moment. It has quite important lessons, I think, for the way in which we have to tackle in this country the problems that are presented to us by human genetic developments.

The third relevant capacity relates to the fact that, at the moment, I am the Chairman of the Executive of the International Commission of Jurists (ICJ). The ICJ is based in Geneva. It's a worldwide body. Its commitment is to three things. Two of these are the protection of human rights and the rule of law. Both of those are very relevant to what I'm here to talk about tonight. So far as the rule of law is concerned, you can't have the rule of law if on important matters which touch essential features important to society, the law is silent. Although in theory the Judges can develop the law, if the law is silent because the democratic legislature hasn't attended to the development of the law then we don't really have the rule of law. We have the rule of silence. The International Commission of Jurists a year ago was looking into the next century and trying to decide what would be the important issues for human rights in the next century. One of the issues which it put on its agenda as one of the important questions for human rights in the century to come, was genetics, the Human Genome Project and its relevance to the human rights of people everywhere.

It is the fourth capacity which really brings me to speak to you tonight. It arises out of the fact that because of the three capacities that I earlier mentioned, I was invited exactly two years ago to attend a conference in Bilbao, Spain, on the subject of the Human Genome Project. I went there with the relative ignorance of the Human Genome Project that probably most lawyers have. In a sense, my eyes were opened to the tremendous importance of this project for humanity, for science, for medical research, for medical assistance, indeed for all of us. I was really rather alarmed at the lack of knowledge in my own profession, the law, and of the lack of debate in my own country about the implications of the Human Genome Project and the genetic research technology which it signals and which it facilitates.

At the conference there were four Nobel laureates, Carleton Gajdusek who is the Nobel laureate for 1976 in medicine, Jean Dausset, Nobel laureate in medicine, Sir Ervin Klug, Nobel laureate in chemistry, Dr. Hamilton Smith, Nobel laureate in medicine. There were other people from different legal traditions. Of course there were a lot of Spanish jurists and scientists. But one of the most important people there was a member of the French Constitutional Council, Madam Noelle Lenoir who is now, the Chair of the UNESCO Committee which is looking at the legal and ethical implications of the Human Genome Project and of genetic research.

The occasion was the 40th anniversary of the famous letter by Watson and Crick to Nature in April 1953. It was in April 1953 that they wrote their letter in which they indicated that genetic messages, important for our genetic composition, were to be found in the DNA. They defined the ways in which the DNA could be unravelled. They indicated its importance in terms of the future of life sciences. The human genes which Watson and Crick disclosed number approximately 100,000. Since their discovery the Human Genome Project has been developed as probably the most remarkable international cooperative scientific endeavour, certainly in the life sciences and probably of this century. Its purpose is to map the human genome. Many analogies were drawn between the great Spanish cartographers who had mapped the then known world and the cartographers of today who, turning inward upon the human genome, are mapping the whole of the human genome by a cooperative endeavour across the continents involving scientists in all parts of the world.

Genetic research is not only important for human beings. It is also important in animal husbandry in the development of pigs, chickens, super cows and the perfect lamb. However, in terms of the human genome and human genomic research, the research has already led to the discovery and identification of important markers for very serious human medical conditions. Huntingtons, muscular dystrophy, cystic fibrosis, sickle cell anaemia, "Fragile X" syndrome, various forms of melanoma, various forms of breast cancer, colon cancer, Alzheimers, Parkinsons. The search is on for that marker which identifies all such conditions. The issue which was examined at the conference in Bilbao was what implications this had for the legal system and for the principles of ethics which underlie the development of any legal system. What implications did it have for the development of the law. What should we, as lawyers, know about it? What should we do about it?

During the course of the debates by participants from various parts of the world and different legal traditions, a number of issues were identified as critically important. Over arching them all was the issue of democracy itself. How in a society of parliamentary democracy, do we ensure that our representatives in parliament face up to the growing number of problems and issues for the law which are presented by the Human Genome Project and the human genomic research technology that goes on around it. Various ways in which this should be done were identified and discussed. Various degrees to which it should be done or not done were discussed. Whether the development should be left entirely to self regulations, as Sir Gustav Nossal had suggested, was hotly debated. Whether, at least in certain areas, the law should step in and set the standards was a matter for anxious concern.

A second issue which was over arching was the question of human rights. How do we identify the human for the purpose of human rights. How do we ensure that the human rights respect the fundamental integrity of each human being and preserve and protect for each human being the right to knowledgeable informed consent about medical procedures which affect him or her. The whole principle of human rights is founded on the integrity of the individual. In the last month or so we've been seeing the shocking pictures of the opening up of the camps at Auchwitz and Dachau fifty years ago. We can see how sometimes in human history, evil people and gangsters get control even of civilised societies. They present a warning to us which we ignore at our peril.

Much of the time in the conference was addressed to issues which were specifically lawyers' issues, relevant to human genetics and new genetics. For example, the question of confidentiality. At the very time that privacy is becoming such an important issue in societies such as our own, along comes a means of intruding into the very being of individuals and finding out aspects of the individual's genetic make up which will provide markers which will provide accurate predictors as to the future medical history of the individual. Should the individual have an absolute right to prevent others having access to such information? What principle should govern the right of access to the information? Should a person for example, sometimes be under some legal obligation to provide it? Given that we can now get this data to inform a future spouse or partner of the data, as being relevant to the future development of the person and their children. What risks of genetic discrimination exist? What if a person doesn't want to know the genetic markers? Should such information only be provided to the individual at that individual's knowing informed request? Or are there some circumstances where at the request of others, for example members of the family, such information should be able to be obtained? What are the principles of consent and authority of law that should provide for access to such information? The importance of confidentiality was generally acknowledged. The importance of informed consent in undergoing genetic testing was also acknowledged. But the way in which these principles of a general character would be worked out in particular cases was accepted as presenting issues of great complexity and difficulty.

A second lawyers' question that was debated at considerable length was the issue of culpability. Our criminal law works very much on the principle of free will. That is to say that those who do antisocial acts have a free will to determine whether they will do an antisocial act or not do so. Yet in the face of genetic markers, for example a genetic marker which might identify some cause for aggression in a particular person is the notion of free will still a viable notion on which to build our criminal law? Can we really assume that people voluntarily, and with the evil intent that the criminal law postulates, commit crimes against society? Or at least in some cases will the individual be simply the victim of the genetic messages? I think nowadays we're noticing, especially with ADD, the Attention Deficit Disorder, that there are some children who by reason of this condition are committing antisocial conduct. Whether this is of a genetic origin or simply determined by their environment, I am not competent to say. But certainly some people, by predisposition, appear much more likely than others to commit antisocial conduct and to end up in courts before people like myself.

I suppose the hottest debate at the Bilbao conference and in much of the literature relates to patents. This is in patents that can be found the economic incentive for much of the research which is taking place. In the United States there are 35,000 applications for patents pending at the moment in respect of genetic research. In Europe 13,000 are at the European Patent Office in Munich. The development of the law of intellectual property has not kept pace with the development of genetic research. It's an interesting thing to reflect upon the fact that Watson, when he wrote his famous paper, took no steps, back in 1953, to seek any form of patent or any other protection for his discovery. He simply provided it as part of the common scientific information of humanity. At the conference in Bilbao there was a great deal of criticism, especially for developing countries, at the pressure that was in place in the United States of America, in particular, to secure patents. These were criticised as being an endeavour to introduce a form of neo-colonialism of a new variety whereby American corporations would have effective control over the development and access to much of the product from research upon genes which, it was said, were the common property of all humanity. Far from promoting access to such benefits it was likely, so many of the contributors from countries such as Argentina and the like felt, that these countries would not have ready access, nor would their scientists be able to pursue the research. If genetic discoveries were patented, they would be closed off from that form of research.

Insurance was also a matter which was extremely hotly contested because the conference came at a time when a report had just been produced in the United States of America on the relevant rules that should govern the insurance industry of that country. Whether there should be any limits upon access by insurers to genetic data was disputed. Some people said, "Of course there should be access to such information. We permit insurers to get raw data at the moment about whether a person smokes or doesn't smoke". Those of the contrary view pointed out that the whole object of insurance, was to spread the risk of health conditions and life threatening conditions, so that amongst the policy holders the policy holders were paying into a pool which would be provided to spread the risk in a way that was based on the best possible available information. There were many critics who said that if the principle of access were pushed into the field of genetic markers, people could be forced without proper genetic counselling into securing information on their health and on their markers which they didn't particularly want to know which would burden them with information that they didn't particularly need to get and which would prevent their getting access to insurance, or reduce their access or increase their premiums in a way which, in their former state of ignorance, would not have occurred. Is this something that should be permitted? Or is it something that should be restricted? What principles should govern access to such markers, information about markers and an obligation of the policy holder to undergo such tests? All of this was the subject of a very hot debate which was informed by the report of the United States committee.

There are many other issues that were discussed. They included the question of identification evidence, DNA evidence and the like. But the general feeling at the end of the conference was one of optimism. It was generally believed that we should look forward to the benefits of human genetic research. That we should remember the importance of diversity. That we should not seek to promote or even permit a monochrome uniformity. And that when issues of the future arose as to whether parents would be able to insist upon children of a particular height, or a particular skin colour, or eye colour, then that was something upon which the law could draw a line. The most telling moment came at the end of the conference when the four Nobel laureates made what for them was an impassioned plea. They said the one thing we must not do is to permit scientists to touch the germ cells because we don't know enough about this area of research now and we don't know enough to set into the future the unpredictable developments that would occur if we now permitted, with our present state of knowledge, the manipulation of human germ cells.

If we can believe the statement of the President of the Australian Academy of Scientists, then that is a problem which we don't have to worry about for 30 years. Yet if we can look at the research of Dr Ralph Brinster at the University of Pennsylvania where already he is dealing with the early stage sperm cells of mice and sending into future generations of mice, developments of a genetic character and tracing them through the progeny of the mice over future generations, I think the question is acutely posed, "Is this something that can be translated into the human species? There being no scientific reason or technological reason why it cannot, what is stopping it?"

Well, what is stopping it at the moment is self regulation instructions such as are produced in Australia by the National Health and Medical Research Council. It may be that there are also certain contractual obligations, in particular laboratories. It may be even that there are trust obligations. There may be employment duties. But society, at least in Australia, on this matter has not spoken. It has certainly not spoken through its Parliament. Therefore, the question is I think presented to us, whether or not it is safe "for 30 years" simply to allow this matter to proceed in laboratories around the world. Or whether there may not be many Ralph Brinsters who, looking at the development, are seeking to pursue their intellectual curiosity and not only their intellectual curiosity but their economic advantage or that of their institution? It's notable that Dr Brinster announced that steps had been taken by his laboratory to seek a patent on the development which he was pursuing. It was explained to me during my attendance at the conference in Bilbao, why so many American scientists are breaking with the traditions of the past and had pursued patents. The answer is really quite simple. About 10 years ago the Congress at the United States enacted a law that imposes a duty on institutions that receive Federal funds in the United States to protect, by intellectual property protections, the novel developments, the inventions that they make. If they don't, they run the risk of losing the Federal funding that they receive. Therefore, there is acute pressure upon those institutions to pursue the protection of the intellectual property. Of course once that pressure was applied and it was soon seen that there were very large profits to be made out of the commercial exploitation of the biotechnological developments, the pressure which was at first that of the Federal Act in the United States became a commercial pressure. It's the combination of these two things that has led to the 35,000 applications for patents in biotechnological developments in the United States which are pending at this time.

On the 4th March 1995 a development occurred in the European Parliament which is important to call to your notice. The European Parliament had before it a draft Directive from the Commission of the European Union, the organisation we used to call the European Economic Community. The Directive was the result of six years of work amongst the bureaucrats consulting the industry groups and consulting other bureaucrats. The matter went through the process of consultation which was laid down by the Maastricht Treaty. It went up to the European Parliament for formal ratification. But it was rejected by a vote of 240 to 186 with 23 abstentions.

The rejection was unexpected. It was the first time the European Parliament with new powers to reject Directives from the Commission of the European Union exercised its powers.

The pressure against adoption of the Directive came largely from the environmental groups, including the Greens. But ultimately they were joined by a large section of the socialists in the European Parliament. Contrary to all expectations the Directive was rejected. I think there's a lesson for us in Australia and in other Western countries of this development. It indicates that you can have the consensus of industry, the agreement of the bureaucrats, the wise nodding approbation of the lawyers, but ultimately, in a democratic society, you have to bring developments on the issue of the law as it touches genetic research, to the representatives of ordinary members of the community. That's as it should be. That is the rule of law. The Directive was concerned with a provision which would have permitted the patenting of life forms. The environmentalists said that that was an insult to humanity. That this was an offence to the common property of humanity. That you can patent a particular invention such as a particular drug, but you can't patent the actual markers. You can't patent part of the genome itself. That you can patent your invention that will affect the genetic makeup of the human being. But you shouldn't be able to actually patent the marker or the genome because that belongs to nature. It belongs to humanity. It doesn't belong to any particular scientist or any particular research institute. Still less does it belong to any particular corporation. That the corporations have a right to be protected for their investment in the inventions. But they don't have a right to patent part of the genome itself.

The Times newspaper made the point that I've just made to you. Without proper thorough public debate you're not going to be able to get legislatures, which are responsive to the anxieties of the kind that were mentioned in the European Parliament to agree to Directives of the kind that the bureaucrats and the experts in intellectual property law had developed. Not everybody took the absolutist stance that the environmentalists did. Some just didn't like the particular measure that had been developed. Others said that what was needed was some form of intellectual property protection which was different in quality from the patent. They felt that a patent was too complete a protection for too long and that you needed something which would not prevent other researchers getting at the basic core of the human genome for the development of research, for the benefit of humanity. But whatever the reason for the dispute, the Directive failed. It came as something of a surprise to a lot of bureaucrats after six years of work on it.

What can be done about that problem that is presented in microcosm by the experience of the European union, but which will, if we in Australia address issues of the kind that I've mentioned, present themselves to us as well? When I spoke at the conference in Bilbao I suggested that the answer was to be found in procedures such as the Australian Law Reform Commission had adopted in its work on the highly controversial issues of human tissue transplants back in 1977. Procedures included were not unlike this meeting tonight: the use of consultation with experts, with the community, the use of the media. But there is more. The use of the discussion papers, the crafting of legislation, thorough debate, carrying the community and identifying the controversial areas. Should we have an opt in or an opt out system for tissue donation? Should you have to actually volunteer that your organs will be available or should you be deemed to be a donor unless you have opted out of the system? Should there be a provision for somebody to give consent for children? Should there be access to cadaver body parts for use for the development of serum? Should there be a system of paying or not paying for body parts? All of these issues were identified, debated, discussed. Within the Law Reform Commission there are often disagreements. But they were presented clearly. The political process was helped to resolve many of the issues. We got, at the end of the day, a uniform law which is still in force in this country.

Since the work of the Law Reform Commission something that has come upon the world whilst we were dealing with issues such as corneas and kidneys and body parts. Since then we've had the development of IVF and the transplantation of life itself. This raises issues that are, in many ways, generically different from the issue of transplanting a cornea. The Canadians set up a Royal Commission in 1988 to look at the issues that were presented to the Canadian society by birth technology. The result was a tremendous disagreement within the initial Commission. Of the seven initial Commissioners four came to the conclusion that the Commission was not approaching the matter in a proper way. They went first of all to the Privy Council Office in Canada. They asked what they could do to stop the other Commissioners from reporting. The Privy Council Office said that there was no way the government could interfere with the running of the Commission and it would just have to be left to them. Subsequently, the government sacked four of the Commissioners. It appointed new Commissioners. The result was tremendous controversy in the Canadian community and the production of a report which has been very severely criticised. So I don't underestimate the difficulty, especially in a matter as controversial as genomic research, of consulting the community meaningfully and getting an informed opinion from the community as distinct from immediate reactions.

But not to take a step is to make a decision. Not to take a step is simply to leave it entirely to self regulation. This is to accept the fact that the Dr Ralph Brinsters of this world in their laboratories, working with their imagination and in the hope of the economic advantages that will come from the intellectual property protections that they can secure, will go ahead anyway. They will do what they think is right. Now there may be some who will say, "Well, that's something we have to tolerate", and that, in effect, genetic research is in the mind of human beings. It is simply the next stage of the development of science which is itself a product of the human species. In this sense the human species is itself not capable of stopping a dynamic process so important, so radical, so universal, so global. That may, in the end, be the conclusion that we reach. But if it is a conclusion let us reach it rationally after a full appreciation of its implications, both for individuals and for our society and for our species. That really is what I came to say to you tonight. Before I complete I would like to give you a little poem. It is by the great Australian Aboriginal poet, Oogeroo, Kath Walker. It's relevant to our topic:

*Let no-one say the past is dead
the past is all about us and within
haunted by tribal memories, I know this little now
this accidental present is not the all of me
whose long making is so much of the past.*

*No walls about me, the stars over me
the tall surrounding trees that stir the wind,
making their own music
Soft cries of the night coming to us there,
where we are one with all old nature's lives
known and unknown
A thousand thousand campfires in the forest are in my blood*

Let no-one tell me the past is wholly gone
now is so small a part of time
so small a part of all the race years
that have moulded me
Each individual, each one of us
is the product of all those race years
that have moulded us

951

The four Nobel laureates explained their opposition to interference with the germ line by saying that the way in which humanity had survived the many assaults on it, of pestilence and plague, was because of its variety. We just have to be very careful that we don't embark upon manipulation at least at the germ line without very great forethought. It would be prudent, said the four laureates, not to touch the germ line. I think that's an important lesson which we should reflect upon. It is one which I support.