DEPARTMENT OF SCIENCE AND TECHNOLOGY

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HYATT KINGSGATE HOTEL, SYDNEY, 20 NOVEMBER 1981

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The Hon. Mr. Justice M.D. Kirby
Chairman of the Australian Law Reform Commission

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THREE CONCERNS

It is clear that genetic engineering is an important new technology which will have implications for the Australian legal system. Indeed, the implications can already be seen in Australian Federal legislation such as the Crimes (Biological Weapons) Act 1976 and the Health Acts Amendment Act 1981, which made amendments to the Therapeutic Goods Act 1963. The first-named Act is addressed to prohibiting, in the circumstances outlined, the development, production, stockpiling, acquisition or retention of 'microbial or other biological agents'. The more recent legislation is designed to permit controls, particularly over imports, by imposed standards promulgated under s.11 and 13 of the Act. The era of legislation dealing with genetic engineering in Australia has already arrived.

Very great profits can be expected as a result of the industrial application of genetic engineering technology. These profits will merely reflect the 'great utility to society' which has already been established by scientific manipulation of the 'most basic forms of life'. Essentially, the new technology raised three issues of interest to me that will require early attention:

1. Identification of the point at which the potential of catastrophic damage (however small the risk) warrants the community's taking preventive action of a mandatory and not simply a voluntary kind.

2. Early consideration of the ways in which national regulation could be secured, because of the lack of clear constitutional power for Federal regulation of all aspects of genetic engineering.

3. Recognition of the need to include 'a full spectrum of relevant voices' in 'watchdog' committees established to monitor genetic engineering research and development in Australia.

So far as the first point is concerned, there is a disturbing comment in a recent essay by Professor Max Charlesworth of Deakin University in Victoria titled 'Biology and Ethics'. He cites a paper by J. Hopson in which it was claimed:

> Half the researchers follow the guidelines [voluntarily imposed by the NIH in the United States] fastidiously : others seem to care little ... Among the young graduate students and post-doctorates it (seems) almost chic not to know the NIH rules.

So far as the second point is concerned, Australia cannot boast of a large catalogue of uniform laws achieved by negotiation among the States. Such uniformity as we have achieved tends to have been secured by the operation of Federal legislation. Unfortunately, in the area with which we are dealing, there is no clear Federal constitutional power for national regulation of genetic engineering on a comprehensive basis. We face the spectre of the development of differing regulations in different parts of the country to deal with a problem that is not merely national but international in dimension.

So far as the third point is concerned, there is another unhappy comment in Professor Charlesworth's essay 'Biology and Ethics':

> However, since the UNESCO conference in 1975 I think it is true to say that almost nothing has been done at the practical level to make the team approach (involving both moralist, jurist and biological scientist) recommended by the Varna meeting, an effective reality. There has been some attempt at the academic level in the US to set up so-called 'Science, Technology and Society' courses at MIT and other institutions, and there has been some interest elsewhere in the new discipline of bioethics (see, for example, the Bibliography of Bioethics, 1975— ; and the Bibliography of Social Ethics and Life Sciences, 1076-). But, by and large, the opinion leaders in the biological sciences do not see any real need to involve moralists and jurists in assessing the social import of their work. Indeed, in my view there has been a notable retreat from the concern expressed in the mid 1970s by scientists and others about the social implications of the new discoveries in biology.

DANGER INSTANCES

The extent to which industrial application of genetic engineering techniques pose dangers to Australian society is the subject of dispute and controversy. A number of instances have arisen overseas which indicate that close attention would be needed for scientific developments of this kind. Although some of the instances (previously cited by me) are said to be controversial, I cannot resolve the controversy, for I am not a scientist. Though some of them do not relate specifically to genetic engineering as such, they are sufficiently closely associated in kind to provide an illustration of the type of problem to which the law may have to address its attention and provide remedies and solutions when things go wrong, as well as guidance for the legitimate operator and punishment of the illegitimate enthusiast, unrestrained by voluntary codes:

. In England in 1966 a disease research institute imported a virus from Africa. The virus escaped, causing foot and mouth disease in a district. In a legal decision, it was held that some businesses who lost profits as a result were not legally entitled to recover.

. In 1973 there was an accidental release of a smallpox virus from a laboratory in London. It resulted in two deaths before the outbreak was contained and a full report was made to the English Parliament.

. More recently, a researcher at the Government Research Laboratory at Porton Down in the United Kingdom had been infected with a viral haemorrhagic fever when protective gloves were accidentally penetrated by the virus.

. In New Zealand an experiment to improve the nitrogen-fixing capacity of a fungus commonly found on the roots of pine trees involved genetically engineered strains of the fungus being introduced to pine seedlings at a research station. Within a few weeks all the seedlings had died. The risk of spread of such a fungus required attention.

. In 1981 in the United States Dr. Martin Cline injected bone marrow containing genetically engineered DNA into two patients without first getting permission under 'voluntary guidelines'. Although the doctor had been reprimanded, some commentators had criticised this as being 'too lenient'.

VOLUNTARY REGULATION

One of the issues posed for society by the scientific harnessing of genetic manipulation is the point at which compulsory legal regulation becomes appropriate : the point at which the potential of catastrophic damage (however small the risk) warrants the community's taking preventive action of a mandatory and not simply a voluntary kind. Licensing, an inspectorate and the paraphernalia of state supervision of scientific research and activity have many disadvantages. They are expensive to establish and maintain. They tend to be slow and cautious in decision-making. Often they are ineffective. Moreover, where new industrial techniques are concerned, there is a need to ensure complete confidentiality to business secrets. On the other hand, the adoption of voluntary guidelines and the establishment of monitoring bodies in Australia and overseas does appear to acknowledge that there are risks of a certain order. The profit motive and market forces, however socially useful in normal circumstances, may need to be reinforced as the risk to society increases. Though instances of accidents and mistakes in the course of genetic engineering so far are relatively few, they are sufficiently worrying in kind, if not in number, to indicate that there is a potential social problem of great complexity and importance. The self-same profit motive may, without mandatory requirements enforced by the law, sometimes tempt smaller operators in particular (or the enthusiastic researchers of this world) to 'go it alone' for fear of disclosure of their secrets to competitors or the irritating dull hand of bureaucracy insisting on a pause to reflect.

NEED FOR A COMMUNITY VOICE

I welcome the announcement by the Minister of the appointment of a distinguished committee of scientists and businessmen to monitor genetic engineering developments in Australia. However, a greater community voice may be necessary in committees of this kind, if the government is to receive a full range of community opinion and if the community is to be reassured that its legitimate interests and fears (however irrational they may seem to some scientists) are given due and careful consideration. A committee without a full spectrum of relevant voices may deprive the Minister and the government of the range of community opinion necessary on topics such as this. Just as war is too important to be left to the generals and law and law reform too vital to be left with the lawyers alone so, I believe, the future problems of genetic engineering are too intricate and sensitive to be left to scientists and businessmen alone, however dedicated and intelligent. It would be my hope that in due course the membership of the committee may be expanded to include those who can represent a completely disinterested community viewpoint. Such a committee could alert the scientists to problems which they do not perhaps perceive or, though they perceive them, may sometimes be inclined to dismiss too lightly.

Certainly lawyers should be associated with the committee, especially if it turns to genetic engineering involving the human species. Research on genetic manipulation involving higher life forms, including the cloning of mammals and the correction of genetic defects in mammals (including humans) raise very serious moral and legal dilemmas. It is my opinion that it would be positively dangerous both to the committee and to the lawmaking process in general for such issues to be turned over to bodies predominantly made up of scientists and businessmen. Nothing less than a thorough and disinterested presentation of these issues to the community and to its political representatives will be satisfactory if we are to preserve the rule of law in the face of even such dramatic and potentially beneficial developments as genetic engineering and recombinant-DNA technology.

The Law Reform Commission, in all of its tasks, seeks to open up a dialogue between the relevant experts, the lawmakers and the whole community. If I can say so, this is the model that should be considered in dealing with the community's legitimate interest in the development of a genetic engineering industry in Australia.