

New Technology Ethic

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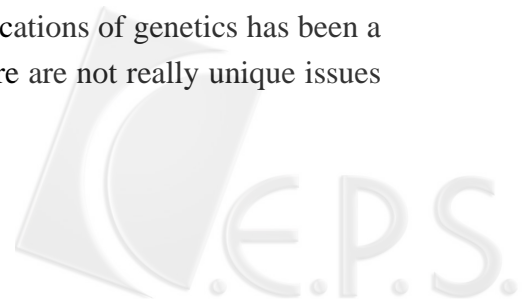
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The ethical principle of beneficence, which we could say means loving good, requires us to develop ways to help others in the world. One of these ways to help others is science and technology. I have a basic belief that human beings have a right to exercise their mind and ingenuity to create alternative solutions to problems which they see to be important. As long as this creativity does not harm someone else, this right to think and then apply this thinking to innovations, is recognized on this planet as a fundamental human right.

If we think about it this exercise of creativity is central to what we call human dignity. Although some critics of genetic engineering use human dignity as a restriction upon human ingenuity, human dignity is insulted by those who seek to inhibit the exercise of human invention. I want my child, and her children, to be able to exercise this freedom of inquiry that I have enjoyed. I want my child to be able to enjoy the fruits of other's ingenuity, the same as I have. The future technology in several decades is impossible to predict.

Bioethics is both a word and a concept. The word comes to us only from 1970 yet the concept comes from human heritage thousands of years old (Macer, 1994). Bioethics is love of life (Macer, 1998), balancing benefits and risks of choices and decisions. This heritage can be seen in all cultures, religions, and in ancient writings from around the world. We in fact cannot trace the origin of bioethics back to their beginning, as the relationships between human beings within their society, within the biological community, and with nature and God, are formed at an earlier stage than our history would tell us.

There is no inherent clash between genetics and human values as some books, including one under the title "Genethics" (Suzuki & Knudtson, 1989) would like to have us believe. What is needed is a revival and renewed discussion of ethical values as society interacts with technology, and reassurance that scientists are responsible. Applications of genetics has been a useful catalyst for this process, but detailed analysis suggests there are not really unique issues (Macer, 1993).



What I work at is to try to make people think carefully before using new technology because the speed of technological change seems to increase. This may be one of the principles of new technology ethics. In the past change was not so rapid, so there was time to go back and time for other societies to pause and reject a social or technological experiment that was tried in another country. Though generally no technology has been socially rejected, except perhaps, for nuclear power, and biological and chemical weapons.

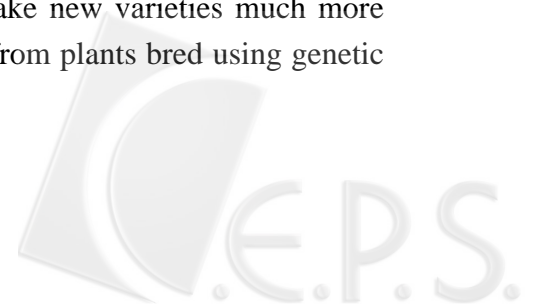
Related to this idea is the emergence of something called the precautionary principle. Simply stated it suggests if the risks cannot be quantified and shown to be negligible, we should not embark on a new technology. It is an extension of the ideal, or principle, of do no harm, into something which is an absolute law. It is commonly used by opponents of genetically modified organisms (GMOs) and genetically modified food (GM food), as a reason for not starting to use these. I will come back to these issues later, however, as has been pointed out, the precautionary principle if applied to our past would not have allowed innovation that we have enjoyed. Rather we have to use some form of technology assessment balancing risks and benefits.

Still we do need to have some precaution when introducing new technology, because the modern global society will rapidly copy a technology so that there is little time for other societies to watch if the society trying it first has a problem or not. Perhaps this is a difference in the ethics we need for new and old technology. Giving society time to think was one of the goals for us when working in the UNESCO Bioethics Committee from 1993 to 1998 we developed the Declaration on the Human Genome and Human Rights. The Declaration was unanimously accepted by 178 member countries of UNESCO, and by the UN General Assembly in 1998. This Declaration to celebrate 50 years of the Declaration of Human Rights, is designed to make people think carefully.

New technology is very broad, and I will have to focus on several examples, namely, modern biotechnology, GM food, and human genetics. Other major issues such as reproductive technology, life sustaining technology, organ transplantation, use of stem cells, and computer technology, are also facing us, but the same principles may be applied.

Modern biotechnology and ethics

Bioethics considers the ethical issues raised in biology and medicine, and especially those raised by human activity in society and the environment using biotechnology. The word "biotechnology" simply means using living organisms, or parts of them, to provide goods or services. All civilizations were formed needing food, clothes, and medicines, and in that sense biotechnology is not new. What is new is that we can now make new varieties much more quickly, and with greater variation - and many foodstuffs made from plants bred using genetic engineering are already being sold in parts of the world.



In the 1980s medicines started to be made using genetic engineering. Today, as the first patents on genetically engineered insulin and human growth hormone expire, they are regular products with generics. GM medicines save people's lives, and no one has a right to say someone cannot have access to medicine that is made without any harm to anyone.

There is a serious ethical issue of equity of access, as discussed in medical ethics. Some new medicines are expensive, the same as some medical procedures. While we can call for universal access to all medicines, if we live in a society where you can buy a one million dollar house, I do not think I can stop someone spending one hundred thousand dollars on saving their life or the life of their loved one. Neither can someone inhibit research into finding cures, providing it does not hurt others. Scientifically and ethically I am against genetic reductionism, and think the broad dismissal of anything that is genetically modified is wrong.

GMOs and GM food

The genetic engineering debate since 1997 has been historically interesting. The focus has been on environmental release of GMOs and marketing of GM food. The debate at the end of the 1980s was hot, but it settled down in the first half of the 1990s. The debate is rather late, as more than half the soybean and corn in the USA is GM.

Consumption of products like cheese made using enzymes that are made using genetic modification is more controversial, however, given that an enzyme produced in a bacteria has no risk of transmission of animal viruses or prions to human beings, it is also safer than extracting the enzyme from animal tissue. This is providing that a standard safety evaluation for medicines is used.

The extension of the production system for medical compounds and industrial compounds and enzymes from bacteria or yeast fermentation tanks, to plants could still be contained in glasshouses if there were environmental risks. However, safety studies of the release of GMOs to date suggest that there is negligible environmental risk as long as the plants pass the field release experiments.

I think there are two major concerns that we face over the current use of genetic engineering, one is environmental risk and the other is consumption of the GM food by animals including humans. As public opinion surveys reveal, a third major concern is whether GM is natural or not. This type of concern has been growing in the past few years, both in the media and in results of opinion surveys. In Japan, my studies show that the concerns expressed by scientists are very similar to those expressed by the public (Macer, 1992; 1994; Macer et al. 1997; Chen Ng et al. 2000; Macer & Chen Ng, 2000). The results are similar in all countries, showing a significant change and polarization over GM technology in public opinion between 1997 and the year 2000. People vary in the extent of balancing of the positive and negative sides of GM.



A fourth concern, that triggered the large public reaction to GM is a justifiable concern about the government regulation of food safety, which was triggered by the UK episodes of BSE (Mad cow disease). There was already high suspicion of industry and multinational corporations, especially when it comes to international trade from the USA into other regions of the world. The intransigent US position that they would not label soybeans to Europe was a critical turning point in the European resistance to GM products, which through the media instantly spread to Japan and later to New Zealand and other countries. Public opinion studies in 1997 in New Zealand and Japan suggest that cloning of Dolly was not a significant event in terms of making people negative towards GM technology (Macer et al. 1997).

In food safety the concept of substantial equivalence is used as the guiding principle for risk assessment. This is the accepted standard by Codex Alimentarius Commission, FAO and WHO, and was supported also in recent reviews by Panels of Experts at a joint WHO/FAO Consultation in June, 2000. To be frank, small countries will have to largely rely on data obtained by companies and presented to the US FDA and the European Food Standards Authority. Their decision will influence global policy. International trading is regulated by Codex Alimentarius, and international standards should be sought. There cannot be different standards for food eaten in New Zealand and food exported, although the tolerance level for GM-free labeling, 1% in Europe is different to the 5% figure in Australasia, Japan, and under discussion in other Asian countries.

Regarding the release of GMOs, in my judgment there are adequate controls on GM research and trials, and the new varieties are not so novel to warrant all the attention they have been given. In fact some of the controls are too elaborate and I would like those resources put into long term environmental monitoring of GM crops under commercial conditions, which is where we should be looking for ecological change. I worry more about environmental estrogens and long term impact of chemical (including organic) pesticides than I do about biological control means like GMOs. I want to be able to eat any food I chose, and I would prefer to eat GM soybean or corn to those crops made in the older production system.

In Asia and Oceania we have persons who lack sufficient nutritious food and GM can help develop better varieties. It is predicted at the First Meeting of the Asian Pediatrics Congress in Thailand in the year 2000, that by the year 2020, there may be 1 billion children in Asia permanently harmed by malnutrition. This means that their mental and physical capability is permanently harmed, no matter what we do to them afterwards. Therefore, there is no option but to enable better food security.



Human genetic modification and human genetics

Let us also consider human genetic modification. Since 1995 I have served on the Ethics Committee of the Human Genome Organization (called HUGO). The current report I am working on is to develop a HUGO position statement on human gene therapy. If you have any questions on this aspect I am also happy to discuss them. Although gene therapy is unusual in that the technology was preceded by ethical debate, only some countries and regions have regulations on how to conduct clinical trials in this field. As the technology improves, and new options become available, broader guidelines may be needed, for example, for gene therapy using stem cells. Therefore, the HUGO Ethics Committee believes that a statement on human gene therapy is timely and will fulfill five main purposes:

- a. Providing a framework for the regulation of gene therapy research and eventual access to gene therapy technology;
- b. Responding to public fears about the ethical conduct and safety of gene therapy;
- c. Extending ethical reflection so as to distinguish somatic cell therapy from germ-line gene therapy and enhancement genetic engineering.
- d. Debating whether society can limit individual access to gene therapy.
- e. Stimulating the early adoption of guidelines at the international level so that national bioethics committees, other national bodies and lawmakers will have a foundation upon which to proceed.

In summary I think that we should not ban anything in law including germ-line gene therapy or genetic enhancement, but rather entrust these decisions to international guidelines and case by case decisions of Ethics Committees. Although I do not think I would engineer my germ-line to enhance myself, when the technology is safe, there would be medical conditions I would consider using that technology for. Regarding somatic cell gene therapy, if it works, there is international consensus that it should be used. As I mentioned at the beginning of this presentation, we need to put everything into perspective.

In the 1996 Statement On The Principled Conduct Of Genetics Research the HUGO Ethics Committee considered some concerns of genetic research. The four principles used can be repeated here as being relevant to the ethical responsibilities that researchers have in conducting gene therapy research and practice, namely:

- Recognition that the human genome is part of the common heritage of humanity;
- Adherence to international norms of human rights;
- Respect for the values, traditions, culture, and integrity of participants; and
- Acceptance and upholding of human dignity and freedom.



In view of the significant potential benefits of somatic cell gene therapy in treating disease, and keeping in mind the HUGO Statement on “Principled Conduct of Genetic Research”, above we recommend the continuation of gene therapy research, including clinical trials. We recognise the need for special public oversight, in addition to existing safeguards. This oversight is necessary both because of the complexity of the research and the need to respond to public concerns. In addition, genetic therapy trials should undergo a specific ongoing review at regular intervals, perhaps every six months, with concrete data (as recommended by the ethical review board) provided to the gene therapy review committee.

Researchers and physicians must divulge any conflicts of interest to the patient and encourage the patient to seek a second opinion by a physician who is not economically involved with the company. Researchers, governments, and professional organisations should join together in educating the public about the benefits, risks and ethical conduct of research.

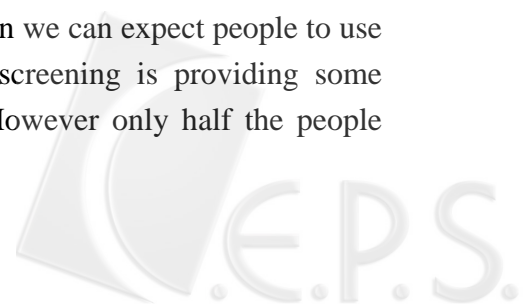
Our future multiplural society

The controversial issue is how do we balance the risks when parts of our society will continue to have different approaches to this question. The difficulty for policy is how to recommend policy in a democratic society upon divided issues like GM. I think we have to start with the process we have used in the past, and put the dilemmas into the context of what we know now. The UN has an important role as a forum for debate, especially when concepts like human dignity or international trade are involved.

These types of seminars where people can freely express their mind and ideas to work together at a cross cultural perspective on these issues are important. There needs to be wide social discussion on the future use of genetics for predictive testing, genetic enhancement and germ-line intervention, in the context of what is genetic disease, consistent with the UNESCO Declaration on the Human Genome and Human Rights, and the WHO Statement on Medical Genetics.

We must encourage the media in all countries to carry factual and informative (as distinct from sensational and entertaining) coverage of developments in genetics, and new technology in general, so that community decisions and laws can be based on sound data, not merely intuition, prejudice or misinformation. In this way what appears new may be reassessed in the light of the past. We can hope that we all do a better job of discussing the use of technology than some decisions in the past.

At the end the persons who will decide how we use science and technology are the users and the providers. If services are offered that make life better than we can expect people to use them. Not all technology is accepted, for example, genetic screening is providing some predictive tests which allow people to plan their life better. However only half the people



offered the tests have so far used the tests for Huntington Disease, suggesting that some people may not be ready for the knowledge this technology provides. It is a sign of bioethical maturity and informed choice that people refuse the tests, and we can hope that all will consider carefully what they really want or do not want. This is what we must try to build for the future, and it took the options of new technology to be available for us to realise this.

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