

Ethics, Science and Society

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**Edited by
Maurice N. Cauchi**

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Ethics Science and Society

Foreword

**Maurice N. Cauchi, Chairman Bioethics
Consultative Committee**

As far as I know, this is the first conference held in Malta to deal specifically with the ethical issues raised by science, and to try to bring together the scientists on the one hand and the general public on the other.

Most professionals have a certain amount of resistance to be drawn into discussion of their work with those who by definition cannot understand the details of their work. Many scientists believe that they should be left to do their work in peace without too much interference. Many even see the imposition of an Ethics Research Committee with its requirements for adequate documentation, patient consent forms and what have you, as so much extra work to be done. I remember when I started on my scientific career back in the 1960s there was no such thing as an Ethics Research Committee, and no specific regulations that relate to what is allowed and what is not allowed in experimental medicine, which included both animal experimentation, as well as research which specifically involved human beings. I believe I was one of the first chairmen of an animal research ethics committee in the institution where I worked in Australia in the 1970s.

But I believe that this attitude is beginning to change. It is a fact now that most peer-reviewed journals will not accept a paper for publication unless it had been vetted by a Research Ethics Committee. Legislation is in place in most countries in Europe about the need for setting up such committees. In Malta we still lag behind, unfortunately, and only in the last few years has reference been made in our legislation to ethics committees at all. It is still a lamentable fact that there is no obligation on the part of our scientists and researchers to submit their work to an Ethics committee, and certainly there is currently no supervision by ethics committees of any research work carried out. While there is no doubt in my mind that research that is being done currently is of the highest standards possible, it is nevertheless worrying that it has taken so long to have a system to ensure that there is transparency in this area also.

The public has an interest in all of this. In the first instance, they are likely to benefit from any advance in science and medicine. Moreover, there is mutual benefit in bridging the gulf between the scientist and the non-scientist. These two cultures, as C.P. Snow once pointed out, have tended to drift apart to the detriment of both. And yet, our public in Malta is still unfortunately one of the least informed of all candidate countries of Europe.

A few words for those of you who are not aware of the Bioethics Consultative Committee. This is a committee set up by the Minister of Health as an advisory body to the Minister and the Department of Health. It is made up of members selected by the Minister for a period of one year, after which time membership may be renewed. It is the job of the Committee also to do its best to disseminate information about bioethics among the health professionals as well as the general public. This is done not only through organising annual conferences of the kind we have today, but also through publications, newsletters, a website relating to bioethics, radio programmes and articles in the papers. I believe we are just beginning to make a tangible dent in this task. I hope that more people now are aware of the issues relating to bioethics than was the case a few years ago. I am very aware, however, that the task is only just begun, and there needs still a lot of work to be done in this area of communication with a public, which gets excited only when there is some major ethical tragedy, like the Siamese twins case, or some major paradigm shift in experimental results, such as those relating to cloning, to really get interested in this subject at all. It is the job of the Committee to try to overcome this inertia by providing information and stimulating discussion.

I would like finally to welcome all of you to this conference. I would like in particular to thank the Minister of Education, the Hon Dr Louis Galea for kindly accepting to open this Conference for us, and to the Hon Dr Louis Deguara to close it. I would also like to thank Professor Judit Sandor for finding time in her busy schedule to come to talk to us, and to all our speakers on the panel who will be taking part in the discussion this morning. Our thanks also go The Malta Council for Science and Technology, and to Dr Wilfred Kennely and his staff for helping organise this Conference.

You will notice that the format of the Conference is rather different from

the usual. Instead of the usual short papers, we have decided on giving maximum time for panel discussion. For this purpose we have a number of experts on the panel who will discuss any issue brought up by anyone here today. It is meant to be an interactive discussion, and therefore, it depends for its success very much on audience participation. I am mentioning this now to ensure that you have plenty of time to think about science and the ethical issues that it raises, so that you come well prepared to fire your questions and comments.

Introduction

The Hon Dr Louis Galea, Minister for Education

Our contemporary society is dominated by science. It invades all matters of policy, lifestyle, health, home and work. It has been held in high esteem, even unquestioned awe. Although social and economic progress inevitably depends on science, and science and scientists have largely enjoyed the public trust, not all are happy. Now, the public may be unsure. Fear and mistrust result in expressions of scepticism and wariness on certain issues such as new medical procedures, global warming, food safety, security, environmental degradation and other risks. There is a call for more open public debate on the issues, in particular, the ethical issues.

Article 28 of the Convention on Human Rights and Biomedicine of the Council of Europe states that the parties shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

Earlier this year Alan Leshner, who is Chief Executive of the American Association for the Advancement of Science, wrote in a broader context about the “Public Engagement with Science” which was the theme of the annual meeting of the Association. He concludes by stating that the centrality of science to modern life bestows an obligation on the scientific community to develop different and closer links with the general population. That convergence will help evolve the contract between science and society so that it will better reflect society’s current needs and values. We need to move beyond the perception of a paternalistic stance, to engage the public in an open and honest dialogue about science and technology and their products, including not only their benefits, but also their limits, perils and pitfalls, to respect the public’s perceptions and concerns even when we do not fully share them, and we need to develop a partnership that can respond to them.

The public trust is weakened in many ways. In a recent interview, the French journalist Jeane-Claude Guillebaud writes about the blurring

distinction between man and matter which is threatened by three concurrent revolutions. The first is the economic globalisation due to advanced communications which he says separate political decisions from the market place. The second is the genetic revolution. This year, the fiftieth anniversary of the description of DNA, has seen the completion of the Human Genome Sequence. It is a powerful tool with which to improve the human condition, but we navigate uncharted waters. The third lies in information science and computing; a new dimension "Cyberspace" that we still have to learn to domesticate. The three forces influence each other and drastically change the relationship of mankind with life and the planet. As a society we need to understand them, not to reject them but to govern them and not be forced to abandon oneself to their own devices.

Clearly, science and technology has social implications beyond the strictly economic progress. Scientists are clearly called to high standards of good conduct and social responsibility without in any way obstructing progress in research. Scientific research has an intrinsic value of its own. In its search of truth, substantiated by the sheer weight of objective evidence, it has intrinsic goodness which when applied well benefits all. Like other human activities it is not perfect. It is unfortunate, however, that the wrongdoing of rogue scientists such as the "Schone affair", or unjustified claims of human, cloning dominate the front pages of the world media to the detriment of hundreds of thousands of honest researchers and diminish the public trust.

We need time to reflect on the risks and hazards that confront the scientific community in particular and society at large. The matter of "guardianship" has received much attention in the structural organisation of the scientific enterprise, especially with respect to the new genetics and presumed rights of future generations. Can they be applied to the good conduct of Science? Some hold that it should be the onus of our elected representatives, but this runs the risk of subjecting Science to an over-riding political agenda. Others maintain that existing peer review methods have largely functioned well in ascertaining that limited resources are distributed efficiently and that concerns regarding the rights of human subjects in research or undesirable outcomes are protected. Perhaps, it does not need much more than reform to increase the participation of the lay public. Or is there, we might ask, the need for a stronger "Guardian"? In Medicine, we have had institutional review boards and a

national bio-ethics commission for quite some time now. Although the Council of Europe's Convention on Biomedicine has not yet been signed by the Maltese government, it is to a large extent adhered to by most research investigators in Malta. Should the remit of these bodies be extended to cover all aspects of science and technology? Is this another role of the Malta Council for Science and Technology?

The European Research Area seeks to assemble in a community framework the efforts of the member states to improve the European public's ability to assess the scientific and technological issues of the day and to motivate it to become more involved in Science. The plan proposes three main actions of high community added value designed to promote scientific and education culture in Europe, bring Science policy closer to the citizens and also to put responsible Science at the heart of policy making. Much emphasis is made on the third mission.

Most policies have a scientific and technical dimension and decisions must be supported by transparent, responsible opinions based on ethical research. The rapid pace of scientific progress passes through periods of uncertainty that give rise to serious concerns, some of which bear on future generations.

It is therefore necessary to strengthen the ethical basis of science and technology, to detect and assess the risks inherent in progress and to manage them responsibly on the basis of past experience together with foresight into the future.

The plan calls for the systematic dissemination of information on ethics in Science and the engagement of public dialogue between stakeholders. Actions to raise awareness of good scientific practices including the ethical dimension, research integrity and the key elements of legislation, conventions and rules of conduct are encouraged and even taught formally in courses and in training. However, ethics is best learnt by the example of one's mentors. Nevertheless there is huge scope to increase the teaching of ethics in our schools and in higher education. Recent reforms in the National Minimum Curriculum provide for science literacy for all students in the future. An educated public is better equipped to make judicious choice on lifestyle, health, and career, and is better placed to participate in a real debate on ethics, science and society.

In politics, the legislator is occasionally pressured to enact law on matters that usually arouse public emotions such as reproductive medicine. One has to wonder whether that is the best way forward. Science moves fast while the law is painfully slow. As I said earlier, it may be better to reflect on the possibility of an authoritative “Guardian” to ensure good conduct in science and technology.

Society and Genetic Information: Contemporary Challenges in Biomedical Law

Judit Sándor

Introduction

“Due to the spectacular advances of molecular genetics more and more of what we are ‘by nature’ is coming within the reach of biotechnological interventions.” These words of Jürgen Habermas from the book *The Future of Human Nature* refer to a new èpoque in which the functions and the scope of biomedicine will change dramatically. By extending the scope of biomedical interventions the question has to be raised: where does the boundary between healing and enhancement lie? In the not very far future, facing this boundary may cause ethical dilemmas in the everyday practice of healthcare. But the conceptual problem of distinguishing between prevention and eugenics will become also a matter of law and health policy.

As many of the new technologies and choices are offered within health care, further complications may occur in allocating health care services, since the label of “health service” often indicates some claim for covering (partially or entirely) the costs of that service (by insurance). The fear that some services will be accessible merely on a commercial basis may deepen the gap between richer and poorer patients.

Potential tests and interventions may effect not only the patients concerned, but more and more the offspring and the future generations.¹ Every parent would like to have a healthy baby. Due to the emergence of pre-implantation and pre-natal diagnoses, now it seems that this wish can be technically fulfilled. These technical possibilities, however, have also created many painful dilemmas and choices relating to whether parents should make choices based on limited genetic knowledge, and how far should the law promote those choices.

In this paper I would like examine how science, ethics, law, and the media communicate the relevance of genetic data towards society.

¹ According to Habermas “The parents’ eugenic freedom, however, is subject to the reservation that it must not enter into collision with the ethical freedom of their children”, in: Jürgen Habermas “*The Future of Human Nature*”, (Cambridge: Polity Press; 2003); p. 49.

Perhaps by mapping these links of communication, one can get closer to understanding why genetic research provokes ethical-legal worries, even though it is a source of superb pride to the scientific community.

Science and Ethics: Lessons from history

If one looks back at the history of regulating science, it becomes evident that it was only after the Second World War that the idea of putting scientific research under normative control became institutionalised. These institutionalised normative responses, however, are *retrospective* and often *react* exclusively to the potential threats and abuses of the various scientific practices.

Among natural sciences, the history of biomedical research is especially burdened by risky interventions and hazardous research. But it is important to note immediately that problematic paradigms, such as the different eugenic episodes in biomedical thought and practice, were often supported by sympathetic branches of social sciences, as both were influenced by the same general discourse. There was a time when aggressive patients received transfusion of lamb blood with the hope that it will calm them down, the mentally ill were sterilised and pregnant women received Thalidomide for relieving their morning sickness. Still, despite the regrets that followed these tragedies, despite the acknowledgement of misconceptions and mistakes, nothing could hinder the continuation of scientific discoveries, and nothing could tame human curiosity.

If one examines the chronicle of these scientific errors, it can be observed that a specific form of reductionism, namely 'biologism' played a crucial role in the process. Biologism, or the naturalisation of social and cultural differences, became a central part of social ideologies as well, thus encouraging further the taking for granted of these scientific practices. Of course, by looking at the roots of these researches, one can easily see that *unethical* scientific research was simply bad scientific research at the same time. The other conclusion, which can be illustrated by numerous episodes of the eugenic movement, is that bad science was reinforced by bad social science and consequently legitimised legal norms that were later regarded as unconstitutional. The abuses that were investigated by lawyers in the Nuremberg trials were later interpreted by scientists as being also examples of bad science and were considered to be severe violations of human rights as well.

Even the more recent history of medical research reveals a disturbing pattern of discrimination against races, ethnic minorities and women. And this indicates that it is not self-evident what are the frontiers of the competence between science and law. Formulation of the research and control groups is regarded as part of the scientific method, nevertheless these categories may be culturally, morally or legally problematic and require communication between various disciplines.

In one infamous example, a discriminatory research was also scientifically unsound. This is the *Tuskegee Study* which ran from 1950s until the early 1970s where researchers studied the effects of untreated syphilis in a group of African-American men. The researchers studied the long-term effects of infection with syphilis by withholding treatment from the research subjects. The researchers never disclosed to the research subjects that they continued to suffer from a treatable but serious illness.

For a long time, the routine exclusion of women from research trials led to the fact that many of the conditions specific to women remained unknown, or discoveries that were applicable to men were simply taken for granted for women patients.

Examples can be found also for biological prejudices when otherwise relevant scientific information leads to severe mistakes in social policy simply because of adopting a scientific paradigm in a broader area without testing the verity of the extension.

If one looks at the examples of the scandals and abuses in science, one can notice that not only the ethical, but also the scientific merit has been questioned in those cases. If basic ethical values are compromised we can not talk about good science.

After the World War II, as result of the Nuremberg trials, German doctors and scientists were held liable for their abuse of human subjects in biomedical experiments. The Nuremberg Code² emphasised the importance of *voluntary consent* and the necessity of disclosing the general nature of the experiment. The principles of conducting research

² "Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10", Vol. 2, Nuremberg, October 1946 - April 1949. (Washington, DC: US Government Printing Office, 1949), pp 181-182.

on human subjects were further developed in the Helsinki Declaration in 1964.

In 1965 researchers found a high prevalence of the *karyotype XYY* among prison inmates in Britain. As a result, many people quickly took this finding to justify the link between an extra Y chromosome and a tendency to hyper-aggression and violence. Even if later this assumption was rejected by genetic researchers, it still resulted in an enduring popular belief. Some other authors believe that the increased risk of arrest or conviction may stem from increased likelihood of getting caught.³ This story is an eloquent example of the interrelation between bad science and bad social (criminal) policy.

The fear of potential abuses by science and the systematic normative control over science developed only after the Second World War. The need for this one-sided, prohibitive control was totally justified at that time. Nevertheless the retrospective and prohibitive pattern that still governs the relationship between science and social norms has become too static and insufficient for the complex genetic or biotechnological researches of the present.

Necessity of common interpretation

Though it is essential to learn from the history of science, it is equally important to avoid the demonization as well as the uncritical appraisal of scientific activities and achievements. The illustrations given above have demonstrated that science and its broader cultural, ethical, legal and social interpretation are interdependent. It is a pluri-disciplinary enterprise, a system of sophisticated mutual controls: social and scientific checks and balances. If any one of them claims superiority, fatal mistakes can be made. Interpretation of scientific discoveries has many traps. Ethical analyses are not necessarily based on an accurate assessment of scientific developments, and these interpretations sometimes misread the effects of applying new biotechnologies. Moreover, normative interpretations may also be distorted due to factors that are entirely independent from scientific research. The complex issues in the contemporary life sciences and biotechnology have to be addressed

³ David Wasserman-Robert Wachbroit, "*Genetics and Criminal Behavior*" (Cambridge University Press, 2001), pp.9.

within a broader cultural and social context. The trust in science can be enhanced by making the science more transparent and accessible to the public.

Different societies in Europe have very different attitudes towards science.⁴ Various political and cultural factors determine how much the public is involved in monitoring new scientific applications and what is the position of ethics. While in the Scandinavian countries social control over science is relatively strict, post-communist and Mediterranean countries seem to be more sceptical towards taming scientific endeavours.⁵ In certain Central and Eastern European countries - due to the past repression of the social sciences, including sociology, anthropology, and more specifically, bioethics - the natural sciences have an authority and claim competence almost in every area of research and maintain their right to provide ultimate answers to many scientific and even social questions. Therefore, in those countries there is little room for social sciences in interpreting scientific discoveries. Drawing a sharp demarcation line between the life sciences and social sciences seem to be very disadvantageous in the domain of human genetics where a common interpretation would provide more sophisticated results. Of course, such co-operation would presuppose solid knowledge of biology among the social scientists, and an understanding of social scientific and ethical perspectives among the life scientists.

From recent discoveries in genetics we have learnt more about ourselves than ever before, at least at the level of the genes. Nevertheless, we should avoid overestimating this knowledge, and should not rush to make ungrounded predictions from them.

Science and the Media

Molecular biology has a privileged position in these discoveries and in the media reports about them: “the gene of the week”, the production of another artificial chromosome, or the birth of new cloned and transgenic animals all make headlines in the media. As sensations, these news

⁴ As it was revealed by the World Value Studies.

⁵ According to the interpretation of Isobars by Christian Welzel, Western Europe scores higher in emancipative values than Eastern Europe, and Northern Europe higher than Southern Europe, with the post-Soviet societies being consistently at the lower end, and the Scandinavian countries at the higher end of these scales.

easily become tabloid topics; more complex analyses of the related ethical and philosophical, social and legal consequences are usually left out even from the weekend supplements of major newspapers. Biological curiosities, therefore, often remain without reflection and live a kind of independent life in fantasies. It explains why expectations are often much higher than the actual possibilities of science.

Scientific news is naturally future-oriented and provides just a glance into the possibilities of the future biomedical science. Our fantasies, however, cannot always make the difference between the real options which develop from scientific predictions and the dreams or fears associated with new discoveries. Expectation often precede scientific discoveries, and this explains why often it is the wider public with its expectations that accelerates the development of science. Human cloning, for example, was discussed in science fiction literature several decades before the birth of Dolly.

The media also looks with disfavour on the figure of the self-critical, hesitant scientist. It is also frequently the case that a scientist expressing doubts and hesitation is pictured as an envious rival of the optimistic and efficacious scientist. In societies where human rights are relatively recently incorporated in legal thought and practice, ethical-legal control often meets with hostility and is seen as an unnecessary block in the advancement of science.

From an ethical point of view, there is another recent disturbing development. Specific groups of patients or health consumers are often used by business-oriented scientists and the pharmaceutical industry to claim acceptance of new research technologies on their behalf. This puts ethicists and lawyers who consider their mission to protect research subjects and individuals against unscientific or unethical research in a very controversial position. If the only hope for a patient or a family is the further development of stem-cell research, unlicensed gene therapy, or access to a not yet registered drug, the concerned patients and family members regard ethical-legal or administrative procedures as obstacles to enjoying their rights. Moreover, some people regard science as an *a la carte* menu of possibilities, and would like to choose the sex of their children without any compelling reason⁶, or even select gametes and

⁶ I.e. not related to elimination of disease that is inheritable by only one of the sexes.

embryos with specific characteristics. Decisions relating to selection and therapeutic choices are therefore fundamentally different even though they may be offered by the same health professionals.

Ethics and Law

These new tendencies could be regarded as necessary consequences of the patients' rights movement. Ethicists and lawyers who until very recently saw their positive mission as raising consciousness in protecting patients' rights, codifying them, and developing *fora* for rights, such as ethics committees, ethics review boards, patients' rights advocates, organisations etc. now often find that patients consider themselves (often with good reason) experts in rights. As a result of this, the role of mediators is not regarded as so important any longer. Obviously, no one can claim exclusive authority in the domain of ethics. Patients' groups may formulate their own needs, research ethics bodies may adopt their principles and guidelines, and more recently, pharmaceutical and biotechnological companies follow their own principles based on business ethics. In this new situation law has an important role as it lays down general solutions, solutions that are not just attached to one specific research protocol but rather norms for a longer term.

Recently, pharmaceutical and biotechnological companies have also become interested in getting direct access to the gene donors, pregnant women (for instance for umbilical cord blood), to prospective research subjects and to pharmaceutical product users. Whether we like it or not, health care has to operate under new circumstances where commercial actors contribute and seek the benefits of biomedical science, and patients, as consumers, seek health care and other biomedical services.

It is not surprising that law and ethics cannot keep up with the rapid changes in scientific paradigms. In my opinion, it should not even be a desirable goal for ethics and law to provide automatic solutions and ready-made normative frameworks that always adjust to the actual state of science. Laws need to be formulated on the basis of consensus and followed by social recognition. Consensus-reaching and recognition, however, both require a long time. Consequently, by the time a universal normative answer could be given to one particular scientific question, a new discovery may reshape even the original problem. This paradox should stimulate a continuous dialogue between science and law. The

reaction time by which ethical and legal thinking follows new scientific developments in the field of biomedicine has recently shortened. In the past, it took decades before legal regulations institutionalised the practice of administering vaccines. Regulation followed slowly after the first live donor transplantation and the various methods of assisted procreation as well. In the field of genetics, however, one cannot observe this long time lag. Legal thinking has developed in parallel with scientific progress. Soon after the Human Genome Project was launched, another joint committee was formed to investigate the ethical, legal, and social implications (ELSI) of the project.

However, when the reaction of the law follows too closely the scientific advancement, it may endanger the credibility of the new legal norms, because a new, even minor scientific discovery might shatter the legal and ethical consensus that had been developed. Moral dilemmas on the other hand, may actually appear even before the scientific breakthrough takes place.

The challenges posed by genetics are felt in legislation in nearly every aspect of law, and at the very least force us to re-evaluate terms. Law in part reacts to the current social potential of science, but in addition takes an overview of the basic ethical norms affecting future risks, basic rights and social values, health policy, and scientific research, and then attempts to develop legal norms based upon these.

Legal changes have been much more restricted than is warranted by the pressure for innovation arising from science. If a new technical or scientific development arises, legal thought is likely to tend towards legal incorporation and analysis, rather than the development of new legal institutions.

Genetic data

Genetic data is precious at the individual level because, in addition to providing an exact diagnosis of an existing illness, it may also give us a glimpse at the future by showing our predisposition to certain other conditions. However, genetic data also poses unique problems in data protection, and in the use of genetic information⁷. Even the term 'genetic

⁷ Mulholland, W.F., Jaeger, A.S. "Genetic privacy and discrimination: A survey of state legislation." *Jurimetrics*, 291 (1999).

data' is difficult to define. Certain family medical records can also qualify as such, but so can pre-dispositions to disease, or monogenic disorders (that is, disorders caused by the lack of, or error in a single gene). The precision of data, and our ability to handle it is, therefore, variable. Genetic data is also unique in that while other medical data is only related to the health parameters of the individual in question, genetic data is significantly different. Knowledge of inherited disease has a serious effect on the lives and decisions of even those family members who may not have wanted to submit themselves to testing.

Genetic data can affect a person's lifestyle, future plans, partner choice, plans for children, career choice, and even educational ambitions. If a person thinks s/he would like to become acquainted with his or her genetic parameters, s/he has the right to do so within the medical system. The question from a legal standpoint is rather how genetic data should be protected and used.⁸

I believe a special legal status must be afforded to genetic data, because such data does not only refer to health issues, but can also be used to identify the individual. Another significant difference from traditional medical data is that, besides providing insight into the health of the individual, certain medical conditions of affected family members, and even unborn babies can be identified with genetic data. Thus we could say that affected individuals may not even know of the existence of health data related to them.

Although there is as yet no internationally accepted comprehensive legal solution to the unique data protection problems raised by genetic information handling, the sprouts of one can be recognised.⁹

One of the major dilemmas relates to the way anonymisation of genetic data can be interpreted. According to traditional health practice, it is sufficient to remove attached personal identifiers, such as name or social security numbers, so that the data will remain anonymous. Some experts,

⁸ Henn, W. "Genetic screening with the DNA chip: A new Pandora's box?" *Journal of Medical Ethics*, 200, (1999).

⁹ The suggestion made by a Canadian commissioner concerned with the right to privacy in 1995 was particularly significant. He suggested that the goal of genetic data collection should be transmitted to the person affected even if the Privacy Act does not so prescribe.

however, express their doubts as to whether genetic data can be regarded as anonymous even if such identifiers are unlinked with the data. This is related to the fact that genetic data in itself may be used for personal identification (e.g. in forensic medicine). This identification is based usually on matching samples. If the genetic data is not digitised and stored in a computer without identifier, it is very unlikely that the data subject will be identified. However, if the data is already computerised, it is a matter of having a computer program enabling matching to be achieved by accessing the “cyber” version of the DNA.

Genetic data banks—genetic research

Within the field of research there is a growing demand for the establishment of national or other institutional genetic databanks. Genetic databanks, whether used solely to store genetic data, to process such data, or to operate as a tissue bank, require special regulation. If genetic databanks are established in relation to psychological illness, or to explore the genetic background of human behaviour, even greater legal issues arise.

Many countries face the dilemma today as to whether they should establish large-scale biobanks. Apart from the technical issues of financing and data protection, the major concern of society is how to provide guarantees that genetic data are not used for any discriminatory purpose, either at the time of collection or later in the phase of data processing. In other words, to ensure that these data are not to be used to discriminate against a minority or to create new genetic minorities. The memories of eugenics and biological determinism play an important role in the current protest against any discriminatory use of genetic data. However, the idea that differences in social, political and economic status between various racial and ethnic groups are the result of biological differences keeps recurring in many contexts all over the world. Moreover, following the completion of the Human Genome Project, the concept of genetic determinism has only strengthened.

Magnus Kaijser differentiates between four different kinds of biobanks: (1) banks where biological material are collected for diagnosis, (2) banks where material is collected for future clinical and diagnostic use, (3) banks for mapping of patients with different characteristics (e.g. for the purposes of bone marrow donation) and (4) materials collected for research

exclusively. One specific type of biobank is the genetic data bank, where genetic samples are collected for the purposes of genetic research.¹⁰

It seems that Nordic countries can be regarded as especially interested in collecting samples. The first large scale DNA collections can be found in these countries.

Of course, relatively homogeneous communities are specially interesting resources for genetic research. This has been recognised in 1996 by Dr. Kari Stefansson who established the company, deCode Genetics Inc. in order to finance genetic research in Iceland. The company asked for an exclusive license to the country's genetic information. According to opinion surveys, the population of Iceland supported the idea to provide a 12-year exclusive license to deCode. In 1998 in the Parliamentary Act on Health Sector Database, explicit consent was not required and presumed consent [opting-out model] was adopted. That was the basis for major legal criticism against this law. Support by the public for large-scale data collection was taken for granted and an individual who did not want to participate had to express the refusal.

Tissue collections and related health and genetic databases are of great interest to scientists, public health experts, insurance, the pharmaceutical industry and society in general. Biotechnological companies are also concerned with generating, processing and even selling health and genetic information since they are interested in the relationship between specific genetic sequences and particular diseases. In this "information-market", the source of data usually comes from the medical-therapeutic sector through an additional consent to research.

Within the field of research there is a growing demand for the establishment of national or other institutional genetic databanks. Genetic databanks, whether used solely to store genetic data, to process such data, or to operate as a tissue bank, require special regulation. If genetic databanks are established in relation to psychological illness, or to explore the genetic background of human behaviour, even greater legal issues arise.

The first law that we know of in this specific field is the Act (No. 139 of

¹⁰ Magnus Kaijser "Examples from Swedish Biobank research" In: Mats G. Hansson, Marianne Levin (eds) "*Biobanks as resources for health*", (Uppsala University Press, 2003).

1998) on the Health Sector Database of Iceland (passed by Parliament during the 123rd Session, in 1998–1999). In 1998 in the Parliamentary Act on Health Sector Database, however, the presumed consent [opting-out model] was introduced instead of explicit consent. And that is the basis of major legal criticism against this law.

Under the Estonian Genome Research Act every gene donor has the right to remain anonymous after coding, to permit disclosure of his or her identity, to disclose the fact of being or not being a gene donor and the circumstances thereof, unless otherwise prescribed by law, not to know their genetic data, to access their data for free except genealogies stored in the Gene Bank, and to receive genetic counselling upon accessing their data.

In the Latvian Human Genome Research Act¹¹, gene donors' rights are based on the informed consent procedure.¹² This is an agreement to provide a tissue sample for the Genome Database, to obtain health information and genealogy, and to use the tissue, health information and genealogy for genetic research, public health research and statistical purposes. In this model all personal data is replaced by a code, which enables the reverse identification of the gene donor, including the name, personal code and residence. The code is to be indicated on the written informed consent of the gene donor. Under the Latvian law, gene donors have the right to access their data stored in the Genome database and the right to genetic counselling.

The UK Biobank includes collecting samples and analysing multi-factorial diseases of adult life in 500,000 volunteers aged 45–69 selected at random from the UK population. From this study important personal information such as lifestyle information may be derived. The UK data collection includes also follow-up by tracking through healthcare records over an extended period including the use of existing disease registers.

In the UK Biobank, both the database and the biological samples will be made accessible to the academic and commercial research communities under a carefully planned ethical and legal framework on an anonymised basis. Volunteers will be recruited entirely on an opt-in basis (i.e. consent has to be explicit), and there has been and will continue to be considerable open debate and consultation on all issues surrounding the project.

¹¹ Adopted by the Saeima (Parliament of the Republic of Latvia) on June 12, 2003.

¹² The Human Genome Research Act will come into force on January 1, 2004.

What is genetic discrimination?

One of the issues that provoked most worries in different societies all over the world is whether genetic information will create new grounds for potential discriminatory treatments. Perhaps that is why the European Union was surprisingly quick to include genetic discrimination among the traditional forms of discrimination prohibited under the Charter of Fundamental Rights.¹³ However, if we examine the notion and the existing jurisprudence of discrimination we may not find the concept of genetic-based discrimination so evident. Maybe the only consensus that exists is that racial, ethnic and national minorities should not suffer further discrimination as a result of genetic testing.

Difficulties emerge concerning the *time dimension* of genetic information. In comparison with a traditional disease which may prevent someone from fulfilling a job in the present, a predictive genetic test may reveal a probability for disease to develop later with the potential loss of capacity to work.

One further specificity of genetic discrimination is that it may make distinctions between people based on predictions of future handicap. As such it can be regarded as a new form of discrimination since the classical grounds for discrimination refer to present or past disadvantages.

Discrimination on the basis of genetic attributes differs from previously known types of discrimination also in that although these attributes are insurmountable, they are for the most part *invisible*. If these conditions of an individual become public, uncertain and unpredictable, prejudice may arise against the affected individual, and this unpredictability allows for abuses.¹⁴

Another possible effect of the growing genetic knowledge can be that if

¹³ Charter of Fundamental Rights of the European Union 2000/C 364/01, Article 21 on Non-discrimination states that "Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited."

¹⁴ If, for instance, an employer discovers that some employees are more likely than others to be prone to certain illnesses, then it is easy to imagine that those workers could still be adversely affected merely because they are at a greater health risk (even though the condition is not a monogenic defect, but just a predisposition).

some genetic traits are significantly more common in a certain ethnic group, then the exclusion of this trait from insurance contracts, for instance, may result in a new form of indirect discrimination.¹⁵

Since some genetic conditions occur more often in particular segments of the population, the possibility of misinformation and discriminatory use may appear in the analysis of genetic studies.

Genetic data, as a form of prognostic information, have a substantial financial value. Although commercialisation is not necessarily prone to discrimination, the processes by which economic interests may generate discrimination should be carefully scrutinised. Thus, we need to consider what are the diseases that are regarded as priorities in medical and pharmaceutical research, and who should be offered what genetic test.

There is another form of discrimination that may occur in the use of genetic data. Most people know what to make of the results of, say, a blood sugar test. However, data coming from a genetic test are much more complex, their reading and interpretation require special expertise. Therefore it can be foreseen that those individuals are less likely to be able to get access to genetic counselling, and even if they have access to such counselling, they may lack the necessary education to understand the information. As a consequence, they will suffer an additional form of discrimination, that is, the discrimination in the accessibility to sensitive and complex medical data.

I would like to emphasise that genetic-based discrimination is a very complex notion. Therefore, in future, courts, ombudsmen, and insurance companies may find the interpretation of genetic data and information difficult in concrete cases. It will also be difficult to avoid discrimination, as genetic discrimination may often occur in a form of multiple discrimination, in conjunction with ethnic, or gender-based discrimination.

The ongoing collection of a vast range and number of biological samples for biobanks will create an unprecedented level of transparency not only on the individual sphere but also in finding out genetic differences between groups of people. While enhancement of privacy with respect to genetic

¹⁵ In 2000 the European Parliament accepted a resolution to propose a directive that would include the prohibition on the use of personal medical data such as genetic data which would enable insurers to act in a discriminatory way.

data may protect the individual against unauthorised disclosure of his/her genetic data, groups of individuals are not protected by privacy and they have to rely on the vague concept of prohibition of discrimination.

Even when some data is recognised as anonymised, it may be presented as a special genetic characteristic of an ethnic or other minority group, and thus it may contribute to new forms biological difference-based prejudice and stigma (for instance, in the case of Askhenazi Jews).

Genetic research will force us to reconsider our references to contested terms such as 'race' and 'ethnicity'. By carefully designed protocols, discrimination based on wrongful study can be minimised. Discrimination that may occur as a result of properly conducted genetic research can be eliminated by providing better criteria in the interpretation and the impact of the discovered causality or susceptibility.

Insurance

In much of Europe health services rely on general insurance based on citizenship rights. This is why the measurement of genetic risk is of little significance at present, for it will not lead to higher insurance rates or exclusion from insurance. In the case of life, accident, and disability insurance the situation is markedly different. Here the broad legal principle of *uberrimae fides* rules. This principle assumes the greatest degree of trust between the contracting parties. This is why the individual to be insured may not keep secret any information that may be of significance in the determination of risk.¹⁶ Therefore, if an individual is in possession of a genetic 'finding' that affects the risk incurred by the provider of life insurance, then in theory the individual may not keep the information secret from the insurer.¹⁷

Cases may also arise in which the genetic test would indicate more favourable insurance payments than those traditionally calculated. If, for instance, the insurer's questions regarding illnesses that have occurred in the family provide a negative picture, but through genetic

¹⁶ McGleenan, T., Wiesing, U., Ewald, F., *Genetics & Insurance*. (Oxford: Bios., 1999).

¹⁷ Doherty, N.A., Posey, L.L., "On the value of a checkup: Adverse selection, moral hazard and the value of information." *Journal of Risk and Insurance* pp. 189-211, (1998).

testing it can be shown that the person to be insured does not carry the gene responsible for the development of the illness, then he or she might avoid paying high premiums set because of the high risk that would otherwise have been determined.

According to Article 12 of the Oviedo Convention, a diagnostic genetic test is to be carried out based on proper genetic consultation, and only for medical or scientific research purposes. Accordingly, the insurer may not compel the insured to undergo genetic testing. It is true that this has not entirely solved the problem because those few who are already in possession of unfortunate results from genetic tests are in a disadvantageous position in establishing the insurance contract. If we add the norms of data protection to this Article, then we find that from restriction of data provision to the goal of research, existing data can only be used for other purposes with the express permission of the affected individual.

Another problem arises from the fact that insurers ask their clients a fairly broad spectrum of health-related questions. Although the majority of health data requested is traditional medical information, more and more such information will, in the future, also be genetic in nature. That is, as we learn more about the genetic underpinnings of certain diseases, the genetic component of such data will also increase.

We may note here that insurers have long been interested in diseases in the family. They ask about how long parents and siblings lived, and about the causes of death. This is, in point of fact, a form of genetic data, for in addition to collecting information on their client, they examine the family's health conditions as well.

Certain insurance companies will only consider such data as an environmental effect, while others will use it as indirect proof of higher health risk. If, for instance, there have been a number of cases of cancer or diabetes in the family, this information can affect insurance premiums.

Employers and genetic information

Usually the employer does not have the right to see an employee's genetic data, with a few exceptions, for instance if it is required for health reasons. In practice, however, it is not easy to separate genetic data collected for various reasons. This is not even a simple task in the case of traditional

medical information. If, for instance, the employer provides life insurance for a number of employees, the employer can fairly easily come to a conclusion about the health of an individual employee through the behaviour of the insurer without gaining access to the employee's health documentation. If, for instance, an insurer does not wish to insure three out of forty employees, or is only willing to do so at a higher premium rate, although not warranted by the employees' age, it would be rather easy to come to the conclusion that these employees have a considerable health risk. This fact alone can indirectly affect the employer's decision-making regarding an employee's future career.

In the case of mental illness, because of the increased threat of stigmatisation, individual research projects should examine whether an exposure of genetic factors might lead to further discrimination. During genetic research on mental illness, constant attention is to be paid as to whether the illnesses might not be described through a variety of approaches, only one of which being genetic. The danger of genetic reductionism is especially high in the genetic examination of mental illness.

One unique characteristic of research on mental illness is that it is difficult to apply the correlation of physical, biochemical, or genetic factors to the more complex socially and culturally specific aspects of the determination of psychological illness.

Without an exploration of the connection between genetic factors and environmental effects, genetic information can appear to provide the final word on a condition. This could lead to the conclusion that research results should not be disclosed to relatives. The issue, however, is not so simple. There are cases when a relative may have a legally supportable claim to information that also says something about him or herself. According to Hungarian law, for instance, relatives cannot be banned from receiving health information also effecting them.

Closing thoughts

In the future, genetic information will become increasingly important to society, for it can improve our understanding of the appearance and development of disease and can increase the effectiveness of treatment. Of course, serious economic interests also underlie curiosity on genetics.

Employers and insurers have real interest in using their employees', clients', and future partners' genetic data to reduce risk, or optimise the use of labour. We should be aware that as our knowledge of genetics accumulates, we ourselves also become more "transparent".

Our knowledge of human genetics will doubtless provide us with many advantages, but if we deprive our individuality of every non-genetic attribute and separate it from its human and cultural connections, science could fall into the trap of genetic reductionism. Like every new scientific paradigm, the raising of the genetic 'code' above the social context can thus carry hidden dangers.

However, one should not forget the numerous benefits that may ensue in the genomic era. In order to enjoy these benefits, it is necessary to spread education across the disciplines, and to allow for mutual interpretation and reinterpretation between them.

I think genetics can provide us with a new opportunity to establish a better co-operation between various sciences. Besides the biological, mathematical and environmental knowledge that is crucial to understand the 'genetic codes', we also need to examine the cultural and social context in which humans with specific genetic characteristics live. Many of the present worries about studying human genes will perhaps be forgotten in the long run, as we shall be able to tell how and in what sense genes contribute to various environmental factors that play role in our life.

Genetics, nevertheless, remains an exciting and attractive topic for the media and the general public. This attention becomes more intense as the use of genetic information in insurance policies and in establishing genetic databanks gains acceptability among the public at large. Moreover, it was genetics that provoked a growing interest even in the use of various non-integral parts of the human body, such as removed tissues and cells. These biological materials will also become the subjects of privacy protection, as they are carriers of genetic information. This is why we may say that genetics is the one of the most important driving forces in the development of biomedical law and ethics in the present times.

Ethical issues and transgenic crops

Marion Zammit-Mangion

Abstract

To date, a large variety of transgenic crops have been developed. These crops have been modified to express traits such as tolerance to herbicides, resistance to insect pests and viruses and production of enhanced nutrients. Proponents of GM technology argue that these modifications can only be beneficial to humans, as they reduce harmful effects to the environment as well as enhance crop yields. Opponents, however, cite different studies and rebut these arguments. This paper addresses the ethical arguments most commonly cited for and against transgenic crops and analyses these issues.

Introduction

Genetically modified organisms (GMOs) or transgenics are organisms which have had their genetic message altered in a way that would not occur in nature. The technology for the creation of these GMOs was developed in the early 1970s (1) with the first modified organisms appearing soon after. Despite the large number of GMOs that have been created, it is the subject of genetically modified or transgenic plants that generates the most antagonism, particularly in Europe. The subject has become an extremely emotive one, polarising society into extreme factions, proponents and opponents with very few middle-of-the-road opinions. Consequently, many of the arguments are also strongly emotive, with journalists complicating the discussion with talk of 'Frankenstein foods' 'demon seeds' and 'rogue genes'(2). Other arguments have addressed the issue of playing God, the sanctity of nature and ownership issues.

The nature of genetic modification

Proponents of genetic modifications argue that humans have been altering the genetic make-up of plants and animals for centuries. By repeatedly mating plants and animals with desirable traits, humans have been increasing the yields, quality and content of various organisms (3). For example, Jersey and Guernsey cows have been bred for milk yield

while Hereford and Aberdeen Angus cows have been bred specifically for meat production. More recently, in plants, this process has been accelerated by induction of mutations¹, the purpose of which is to produce changes in the genetic make-up of seeds which can then be selected and bred (4). In such plant breeding programmes, the most promising lines are selected while the rest are discarded. This is obviously a lengthy process which can take years, for the number of different lines (combinations) generated are virtually infinite.

It is however possible to reduce the generation times through the use of modern biotechnology techniques. With these methods, a single gene coding for a desired trait from any organism can be identified and integrated into the recipient plant's genome. The donor organism can be a plant, animal or microorganism and the transfer is not limited to organisms of the same species. At this point a genetically modified, recombinant or transgenic plant is created.

Producing transgenic plants

Various methods exist to produce transgenic plants, but that most commonly used involve the soil bacterium *Agrobacterium tumefaciens*. This bacterium contains a tumour-inducing plasmid, called a Ti plasmid, that can be used to transfer a desired gene into a plant. Once injected by the bacterium into plant cells, the plasmid contains a short piece of DNA called the T-DNA which leaves the bacterial genetic material and integrates with the plant's own DNA causing infection. Plant biotechnologists modify the Ti plasmid so that it can inject a segment of its DNA into a plant but does not cause uncontrolled growth. A selectable or marker gene is also engineered into the plasmid. This is usually a fragment of DNA that codes for resistance to an antibiotic such as kanamycin, and this will allow breeders to select positive transformants or plants that express the desired trait. Additionally, the foreign gene that the breeder wants to be expressed by the plant is also inserted.

Uses of genetic modification

Plants have been modified for a range of characteristics but the most

¹ These include ionizing radiation γ - and X-rays, α -particles, non-ionizing radiation (UV-B light) and chemical mutagens such as ethyl methansulphonate, diethyl sulphate, nitroso compounds and sodium azide.

common traits are summarised in Table 1. These include the insertion of genes to make plants tolerant to herbicides and naturally resistant to pests or pathogens, to delay ripening of fruit and to improve nutritive qualities (5).

TYPE OF GENETIC MODIFICATION	DESCRIPTION
Herbicide tolerance (potato, tomato, rape-seed, tobacco)	Produced by inserting a gene from <i>Salmonella typhimurium</i> into plant cells. This gene makes the plant produce an enzyme with a single amino acid substitution (proline to serine) resulting in a decreased affinity for the herbicide glyphosate (5).
Insect resistant crops (corn, maize)	Produced by pasting a gene from the bacterium <i>Bacillus thuringiensis</i> into plant cells. The gene results in the production of a toxin called the Bt toxin (5).
Virus resistant crops	DNA coding for resistance to the leaf roll virus is inserted into potatoes protecting them from the corresponding virus (5).
Enhanced nutritive qualities (golden rice)	A series of genes coding for enzymes critical in the production of a particular molecule are inserted into the plant.
Slowing down of ripening	Ripening is slowed down by switching off the gene controlling the production of the enzyme polygalacturonase that causes cell wall degradation (5).

Table 1: Table summarising the main types of genetic modifications in plants.

Regulations in Europe, the Precautionary Principle and Risk Assessments

In the European Union (EU), the situation that is of greatest local relevance, the deliberate release of GM crops into the environment and their placing onto the market are closely monitored and regulated by various directives and regulations (6-15). An extremely cautious stance has been adopted, and only those crops that have satisfied the numerous obligations laid out within the relevant directives of the Acquis Communautaire are approved for release within the member states. A list of these can be viewed on websites such as the Belgian Biosafety Server (16).

When placing a new GM crop onto the EU market, regulations require that a notification be submitted to the State where release is to take place. The notification must include a risk assessment to detect any possible risks to the environment or human health (14)². In making an assessment, the Precautionary Principle must be applied at all times. This principle, whilst avoiding dictating any direct actions required, is based on the rationale that in the event of an uncertainty, one must err on the side of caution to avoid harm. It is sufficient, therefore, for there to be a threat of a risk or harm for policy makers to reject a proposal.

The risk assessments used to determine whether a modified plant is likely to constitute a health or environmental hazard are described in the same Directive. Environmental impact assessments, for example, are intended to answer the following main questions:

- Can genetic alterations be transferred to other organisms and if so, what might the consequences be?
- Will the genetic alteration modify ecologically relevant properties of the organism?
- If a new genotype is added to the environment what will the consequences to the ecological community be?

Health assessments are intended to assess mainly the following questions:

- Is there a risk that a disease be transmitted to humans, animals or plants?
- Can the genetic alteration be transmitted to pathogens, facilitating the dissemination of infectious diseases?

Ethical arguments

Despite the regulatory systems operational within the EU, there still is great resistance to the introduction of GM crops and major debates whether GM crops should be used. The ethical arguments that are most often presented can be summarised into four main areas, namely:

² Modifications and contained use of microorganisms are also strictly regulated by the European Union, and the obligations of any operator are laid out in Directive 98/81EC (15). All directives referred to in this paper have now been transposed fully into Maltese law.

- Possible effects of transgenics on the environment,
- Possible effects on human health,
- Possible effects to reduce world hunger,
- Various general arguments.

Transgenics and the environment

Many scientists regard the ability of engineered plants to resist environmental stresses as less damaging to ecosystems and therefore as an ethical advance. Others regard this ability to target specific stresses as unnatural as the use of agro-chemicals. In deciding which argument carries more weight, one approach would be to look at which is more harmful in aggregate terms. For example, amongst the many crops that have been engineered to withstand herbicide, GM cotton requires just three sprayings per season compared to the 45 sprayings with broad spectrum chemicals used with traditional cotton crops (17). Surely, this should be considered as an ethical advance, especially in the light of the many environmental problems generated by the use of broad spectrum pesticides. Systematic opposition to genetic modification can also lead to inconsistency of argument. For example there are varieties of oilseed rape (*Brassica rapa*) that have been generated by conventional means to carry genes for resistance to two varieties of herbicides (18) and these are not opposed. However, if the same end is achieved through traditional means, one questions on what basis this should be regarded as ethically correct, particularly since the genetic modification has been the result of human intervention in both cases.

Opponents to the development and use of transgenic crops argue that transgenic traits such as herbicide resistance can be passed on to related species creating herbicide-resistant invasive weeds (19). There is evidence that transgenic crops and their genes can, in fact, spread through pollen dispersal (20) and this is one of the main concerns raised against the introduction of transgenic rape-seed. The risk of this happening would be expected to differ in different ecosystems. In Mediterranean ecosystems, for example, rape-seed is related to a number of important agricultural weeds and many wild relatives of the *Brassica* family, and so the risk would be expected to increase. Other factors that could contribute to increasing the risk of cross-hybridisation include the presence of an overlap of the flowering period of the cultivated plant and

its wild hybrid, and whether successful crossings between the cultivated plant and its wild relatives appear regularly.

Another related issue is the concern that genetically modified organisms may contaminate conventional or organic crops. Farmers should be free to cultivate crops of their own choice, but accidental contamination by genetically modified organisms (GMOs) could result in loss of revenue, since farmers would then have to sell their product at a lower price due to the presence of GMOs (21). This issue is still being resolved by the EU Commission, but possible farm management strategies that could be adopted and recommended include the introduction of isolation distances between fields, pollen barriers, crop rotation and planting arrangements that cover different flowering periods.

In answer to fears that GM plants may transmit new traits to other plants, companies have adopted a strategy called the 'terminator technology' (22). This technology involves the engineering of seeds so that they cannot be collected at the end of one crop cycle for subsequent planting. Consequently, seeds containing the technology would not aggregate in the environment after a growth cycle. Opponents of the strategy have argued that this method disadvantaged the farmer by putting him under the control of large companies and precluding the use of home produced seed. Opposition to the technology was so strong that it was subsequently withdrawn by biotechnology companies. However, the need for a system to control gene flow is still deemed to be necessary. In fact, in Canada there have been cases where plants resistant to weed killers have spread to other crops on farms. A new technology dubbed the 'Geneguard' is being developed in the shape of a tobacco plant that can self-pollinate but cannot reproduce with any other plants (23). The premise behind 'geneguard' is simple. A modified plant is given two extra genes. Gene 1 blocks germination and is linked to the disease resistance gene, while Gene 2 stops Gene 1 working. If a plant accidentally crosses with other crops or relatives, the added genes separate³ and each plant inherits only one of the two extra genes. Half the seeds die through failure to germinate while the other half live but do not carry the disease resistance genes. The system, which is still being perfected, is not without its detractors, who claim that poor farmers will not be able to breed their own varieties.

³ Self-pollination obviously does not occur.

The transformation of plants with pest resistance is another area of transgenic technology that has been heavily criticised, as there are fears of unintended deleterious effects on non-target organisms. Unlike conventional agrochemicals, no studies that demonstrate these effects on humans or organisms higher up in the food chain exist. However, some studies such as that by Cornell University reported adverse effects when Monarch butterflies (*Danaus plexipus*) ingest Bt corn⁴ pollen (24). Yet, according to Wolfenbarger and Phifer (25), none of the studies have addressed the rate at which larvae encounter the toxin in their natural habitat or how the risk of ingestion of these chemicals compares to the risk with traditional chemicals. Certainly, agrochemical control of crop pests is extremely inefficient, environmentally more harmful and damaging to bio-diversity, and hence ethically unsound and at least in this respect transgenic crops may offer a partial solution to the environmental problems seen with extended use of agrochemicals.

Transgenic crops and human hunger

A major argument presented in favour of transgenic crops by biotechnology companies is that transgenics are critical to reducing poverty and hunger in many third world countries (26, 27, 28,), as these result in better crop yields through the control of insect pests. However, this argument depends on the assumption that food shortage is the only cause of hunger and ignores other more complex issues that also affect food supply such as unequal distribution of land and water, environmental constraints such as drought, political issues and economic instability, patterns of social hierarchy and poor health. Realistically, companies would want to see a return on their investments, and it would be highly unlikely that seeds would be distributed for free, or that companies would develop GM strains specifically for crops grown in third world if no foreseeable returns are expected. Moreover, it is unlikely that third world countries would have the human, financial and scientific resources and infrastructure needed to identify any potential impact of introducing GM crops on their flora and fauna. Poorer countries could consequently find themselves being used as a testing ground for the introduction of GM crops.

⁴The caterpillar of the *Danaus plexipus* actually feeds on milkweed, which, in some parts of the United States grows next to corn, and so there is the potential for some modified pollen to drift onto the milkweed.

Transgenics and human health

Another argument cited by opponents of transgenic crops is that transgenic foods may bear toxic or allergenic components. Franck-Oberaspach and Keller (29) reviewed many classes of toxins and allergens and showed that these are part of a plant's natural defence systems and are not specific to transgenics. Furthermore, the methods employed to produce transgenics use specific, well characterized vectors, and unless the foreign insert gene was taken from one of the classes of genes known to code for allergy generating proteins, there is actually less chance of transgenic foods being allergenic. In fairness, GM-derived foods are also subject to more stringent tests than conventional foods. Furthermore, in response to commercial demands, there is a concerted effort by food companies to genetically modify common allergenic generating foods such as soya to reduce the allergenic component (30, 31). As this would benefit a component of human society, should this then be regarded as an ethical advance?

Some opponents of transgenic varieties fear that antibiotic resistance genes such as those coding for kanamycin resistance may be passed onto bacteria present in the gut rendering future use of the antibiotic useless in the event of a bacterial infection. An organism's intestinal tract, however, is capable of digesting DNA into pieces that are too small to code for a functional protein. A related fear is that the inserted gene may be transferred to cells of the gut or the respiratory system. Again the same argument holds. However, the opposition to GM-derived foods is so great that in some countries it has led to the withdrawal of GM foods from supermarket chains and restaurants. As the same establishments also sell alcohol, fatty foods and cigarettes, their action, which has mainly been taken on the basis of sales and public perception, can hardly be regarded as consistent from an ethical point of view.

Another human health concern arises from the fear that the antibiotic resistance gene may be transferred from the transgenic plant to wild plant populations and hence to any bacteria that may infect that plant. These bacteria may then be advantaged in their natural environment. Although the World Health Organisation (WHO) has judged antibiotic resistance genes to be safe (32), there is evidence that gene escape can occur as a result of transformation using *Agrobacterium* as the gene vector (33). This has led the European Union to recommend that use of

antibiotic marker resistance genes used in GMOs intended for market release, be phased out by 2004 and those used in other GMOs by 2008 (15).

Finally, human health already suffers from current agricultural techniques involving the use of agrochemicals. Women working in banana packing plants in Costa Rica, for example, suffer twice the rate of leukaemia and birth defects, while a fifth of the country's male workers are sterile due to exposure to dibromochloropropane (now banned). Commercial banana production also requires the application of up to 40 sprayings of fungicides per year to control the continual outbreaks of fungal disease such as black sigatoka (34). It can therefore surely be argued that it is ethical to produce a transgenic banana that would allow a reduction in the use of pesticides, for example by producing fungal resistant bananas.

Other arguments

One of the most common arguments raised by the general public is that the process by which GMOs are created is not natural and hence 'not good'. However, many beneficial processes ranging from water sourced from reverse osmosis plants to GM-derived medicinals such as insulin and artificially fattened livestock have been altered or developed by man. As to the point that natural is always best, we would not treat disease or combat plagues, sterilize water and so on. This would quickly lead to the extension of many health problems faced in third world countries to the rest of the world, rather than the advancement of the former countries to higher health standards.

Yet another argument raised against the introduction of transgenic crops is that farmers would be totally dependent on large companies for seed purchase and there is the fear that this would reduce agricultural biodiversity. Resistance to increased globalisation is particularly high at the moment. Undoubtedly, GM crops are produced by a few major players and this control of food production is likely to meet increased resistance.

Conclusion

In conclusion there are no straightforward answers to any debate on GM foods. Undoubtedly they are unlikely to increase in popularity, particularly in today's economic climate where the business ethic is seen to prevail over concerns for human welfare. GM crops are also unlikely

to reduce world hunger and be the panacea biotechnology companies claim.

The large numbers of GM crops that have been grown, harvested and used in food and feed material with no harmful effects would appear to discredit arguments that such crops are harmful to health and the environment. Moreover in future, food production will have to be increased, and present farming techniques, with their heavy dependency on application of agrochemicals, cannot be sustained without much more serious degradation of the environment, human health and loss of biodiversity. If GM crops can reduce some of these negative impacts, they represent an ethical advance.

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Comparing and contrasting ethical problems in bio-informatics with computer ethics.

Albert Leone Ganado

The information world has in its half century of existence thrown up a wide range of ethical problems involving privacy issues, personal data protection breaches, societal and work issues, and new ways of undermining social order and culture.

To these issues can be added the emerging concept of a global village with, however, more visible discrimination and inequalities between the 'haves' and 'have nots', and a new political order where the military might of America, based on its digital weaponry, has made it the sole dominant superpower.

Certainly, recent developments in the bio-informatics field especially in the field of genomics and in the field of knowledge acquisition within the medical field point to ethical and moral issues similar to those which are the concern of digital researchers and which have as a focus the continued survival of the human species.

These issues merit a serious study from an ethical and moral standpoint of concerns implicit in their future development and which carry an ever-increasing risk of tainting or handicapping our future existence as a human race.

Bio-informatics still lacks the diagnostic tools to ensure that it can forecast the effect of its actions, especially when it tinkers with gene sequences and structures. Back in 1966, in my first excursions into computer programming we lacked the debugging and testing tools so essential to modern programming development. The only tool available was a memory dump of the whole program consisting of the sequences of 0's and 1's. Compare and contrast this to the hit-and-miss tinkering currently applied to the more than three billion base pairs, which comprise a human genetic map.

In debugging, we had the problem of where does one start his search in looking and putting meaning on those strings of zeros and ones. Where did the data end, which parts were controlling modules, and which

performed specific execution tasks on the data? We knew that the answer was in the mass of strings and ones, but how could you make meaning and sense to emerge from a long string of zeros and ones typical of any binary system?

We used to cut bits and pieces and try to execute them separately to see whether we could understand behaviour of a specific sub-program and possibly re-use it in a different situation. Little by little one managed to put together the different sub-functions and give meaning to the whole system.

How often did it happen that by misplacing just one bit, the whole program failed or produced unexpected results? Of course, what some of the experimentation people are starting to perform in bio-informatics is of a higher order of risk and verging on trying to play God. Can we afford getting things wrong and are we prepared to start such experimentation? At present we obviously lack the necessary diagnostic, testing and reverse engineering tools as well as a comprehensive understanding of the underlying biochemical structures and the way they react and operate,

One thing which is sure is that nature is more ingenious and economical than any human programmer can be so that certainly within those billions of bio-data strings there are some perfectly logical, beautiful and super efficient operational structures which one day will be decoded and deciphered.

As an information scientist it is perhaps worth my reflecting on some major discoveries and advances in the field of computing which no doubt are being mirrored in similar bioethical road maps. No doubt future explorations in the bio-informatic world will make the manipulation of biological data more controllable and less risky.

The first point to note is that it was quite a watershed when Boehm and Jacopini proved that only three control structures, namely, sequences, iteration and selection, were required to control a computer program. What are the basic canonical structures in nature, which control the production of human life? Certainly the rules must be there, but the sets of dimension which govern life production are certainly more complex.

The basic structures involved for example in the human process involve

no less than ten thousand proteins which trigger on and off production pathways, three billion base pairs and two million molecules involved, having the radix of base four strings. To these have to be added the dimensions of reaction times, temperature, and location in space and density. Also the means of process operation will be closer to that of parallel machine architecture rather than a Von Neumann sequential process. This makes for a puzzle of awesome complexity which will probably require much more than the half century to unravel, which was the time required to resolve many computing issues.

The ethical and moral issues involved in tampering with such a structure in a reality of incomplete knowledge raises many troubling questions for the ethical scientist.

A second major development in computing was to recognise in systems the role of modularity and interfaces, and the consequent 'divide and conquer' approach first promoted by Knuth and Niklaus Wirth in their seminal works on the art of programming. Certainly we are seeing this happen in the bio-informatic field with the current attempts to recognise functional structures that perform specific real world recognisable tasks. These sub-units will most likely start being utilised as structures in repairing human defects and as human spare parts well before the whole set of functional components are fully recognised and interfaced.

Stemming from this second point one has to recognise the importance of a clear separation of the data required to perform a function, its relationships to other data, and the methods which act upon it. In bio-informatics we are still struggling to identify the various inputs required for the successful implementation of a specific function, and often it is still a hit and miss action whether all the required information has been identified for the successful execution of a process. However, we know that base pairs make amino acids which result in proteins assembled by an RNA template. So that the similarity of the methodologies required with those of traditional computing makes for more than probable prospects of new life creations with all their ensuing ethical issues

The third point is that computing made big advances when it moved towards object orientation which recognised that one has to focus on specific functionality, the data it requires and the interfaces it must provide to communicate with other objects in order to allow that object to execute.

Looking at the well-specified functions of our organs, limbs and senses, there is no doubt that nature must organise its structures and operations in some similar way. Once we recognise the key factors which such body parts require, we will be able to focus on relatively very few areas of the genetic map and consider the rest as black boxes. This will allow for information hiding as well as allow re-use of specific objects such as the programming of new organs and limbs.

The fourth point is that nature seems to operate in a form of parallel processing, as is so evidenced in the function of our brain and sight organs. As computing people we are much less adept at understanding parallel machines than we are with traditional sequential machines. So in trying to understand the creation of life we will soon find ourselves handling a flow of concurrent operations for which we have less experience in handling and understanding.

Recent times have shown the importance of multimedia and virtual reality in simulating real world events and providing visual and aural cues. As computers get more powerful we are blurring the divide between what happens in the real world reality and the virtual reality – the world which the information scientist creates on his machine.

One might have observed that in the recent Gulf war a lot of gadgetry was utilised. From the operational point of view, to a viewer or player, there is hardly any difference between the controls a kid uses when playing a war action game zapping Klingons on his SEGA computer, and a military pilot using virtually the same joystick and panel control in his fighter cockpit. The consequences are of course very different when some very real mass destruction of life and property is inflicted on the enemies' camp when the pilot uses his joystick.

This blurring will make it very difficult in future for bio-scientists to resist the temptation of playing life-manipulating games on their computers which could at any moment be translated into real-world creations and aberrations.

There are other uncanny similarities, which are worth noticing. Programmers often comment out code which they no longer need, leaving it as junk code within the finished product in the same way that there are junk sequences within a genetic map. Programmers also leave partially

uncompleted code for development of a better system in a future revision. They also leave hooks for future updating of the system. Often they leave their own signature code for others to recognise their creation. Is there in the same way within our genetic map, pointers to our past existence and evolution, or perhaps hooks to our future evolutionary path? Has some God who created us left his signature within our life program?

These considerations lead to a plethora of moral and ethical issues, which in future will increasingly require the need of a legislator, the need to enact laws to control what is permissible and what is not. Failing this, we may shorten or distort the natural evolution cycle of existing life forms to the point where we will be swamped by potentially dangerous, new, aberrant life forms. Most of these issue will need addressing on an urgent basis and will require the employment and engagement of ethical experts to provide guidelines.

Some issues, which need addressing, include:

- The issue of data privacy and the extent to which an individual has a right to control his genetic information as well as disclose or not disclose it.
- The issue of the extent to which we can allow automation of the processes of analysis and synthesis of bio-information to take place without overall human supervision. Increasingly we find that automata and robots are being assigned and carrying out the tasks of analysing and manipulating bio-information at a pace which leaves no time for human reflection of the consequences. This will lead, as happened in the case of the genome project, to an accelerated rate of information generation concurrent with less time for rational and ethical analysis. Bio-information scientists must control such advance and take hard decisions on what is morally and ethically acceptable.
- The issue of ever improving data analysis and data matching and discrimination tools is creating a new breed of ethical problems. Data-mining tools are constantly improving, and coupled with ever-increasing amounts of bio-information will enable us to discriminate better between beneficial and damaging traits in our genetic makeup. How are we going to preserve our individuality in such a situation and preserve what may initially appear to be unwanted traits?

If DNA Decode projects like the Icelandic one becomes more universally applied what will be the consequences? Will pattern analysis on such data condemn certain ethnic or other groups of people to second class designation to the extent that one may decide that certain genetic types are not worth procreating? What if military warfare scientists start creating designer chemical agents which will attack only those having particular genetic characteristics? Would this be the ultimate weapon of racial and ethnic cleansing and destruction?

Certainly the computing world has led to a rapid increase in our ability to handle and exploit huge amounts of data. In the case of bio-informatics, this points to the urgent need of creating more general awareness of ethical and moral concerns, of providing a higher order of professionalism for researchers in this area, and superior codes of conduct and practice in dealing with bio-information. There is the need of constant monitoring of an evolving scenario where quick action will have to be taken as new risks emerge. There must be new ways of handling rogue behaviour by a few irresponsible researchers and the establishment of a global authority similar to the Atomic Energy Commission to monitor all activities on a global dimension to ensure that proper sanctioning and logging is kept of all activities.

Certainly these new and exciting challenges ahead require us to take note and perfect our ethical frameworks in line with scientific advance

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OVERSIGHT OF SCIENCE AND TECHNOLOGY

Alex. E. Felice

The health and wealth of contemporary society depends on scientific research and technological innovation. Gone are the days when economic might depended on fuming engines. Instead we face the challenges of a “Knowledge Economy” and societies that are “brainy” rather than “brawny” In particular, as practising scientists, we are asked to communicate openly with the educated public and to take into more consideration those matters which impact on the integrity of the research, “future generations, human dignity and integrity, info-ethics and sustainability”. The guidelines for the new European Research Area give them substantial prominence.¹

One of the most important questions that require reflection is this: How does one ensure that limited resources are allocated most appropriately to ensure the best return to society in terms of advancing knowledge and promoting development? Consequently, how does one provide oversight of science and technology?

I use the term “oversight” specifically instead of “regulation” because the latter may imply undesirable legal or political intervention that could well damage science. There is considerable experience with oversight mechanisms depending on peer review. They are employed by most advanced research programs to approve and fund proposals, to protect the participation of human subjects, and the use of animals or hazardous substances in research. They give due weight to the social and economic implications of the proposed research.

Despite their imperfections, peer review mechanisms have functioned much as a “Guardian” of ethics in science, at least in so far as providing oversight of publicly funded science in advanced countries.²

The current US government is now proposing that all agencies submit

¹ See *Science and Society - Action Plan*. European Commission, 2002.

² Felice A; ‘Guardianship by Peer Review in Genetic Engineering and Biotechnology’ in: E. Agius and S. Busuttill (eds): *Germ Line Intervention and our Responsibilities to Future Generations*. Dordrecht and New York, Kluwer Academic Publishers 51 – 63, 1998.

to peer review all scientific evidence that shapes any regulatory or policy decision: "The proposal enshrines a basic scientific process".³

However, little attention is given to the field of privately funded science which has expanded mostly in the more sensitive areas connected with life science research in the last few decades. Clearly, boards of directors and outside advisory bodies must carry part of the onus. However, while protecting the essential privacy of corporate research, one has to find ways to empower oversight of this sector too.

One can see that strong oversight mechanisms depending on peer review are an integral as well as essential component of a well-organised and well-funded national program for scientific research, technological development and innovation.

³ Science, 301, p 1307, 2003.

Ethics in science: should it be part of the core curriculum?

Alfred J.Vella

It is likely that the reason why the absence of ethics from a science degree course is not missed lies in the belief that good science has got to be performed in a completely objective and disinterested manner so that having any kind of predisposition to a set of ethical or moral values might actually be prejudicial to the scientific process itself. According to this point of view, the mind has to be untrammelled by any considerations other than those involved in the investigation of the phenomena being examined. Indeed, some might even argue, that since ethics deals with essentially human interests, ethical considerations are irrelevant to science which argument would then lead to the absurd conclusion that good science can only be performed by androids or robots since scientists cannot possibly leave their human dimension outside the laboratory door.

Naturally, good science does require objectivity on the part of the scientist and this in turn requires all actions to be performed with total honesty, integrity and a commitment to truth above everything else, thus showing that certain basic ethical values are actually inherent to and form an integral part of the very essence of the scientific method. Moreover, since scientific findings generally need to be replicated if they are to become part of the corpus of established science, then the need to work honestly is incumbent on the experimenter if s/he is to survive the onslaught of peer review so that possibly even an amoral person who would not mind applying dishonest means to reach ends in other spheres of activity would still be forced to work honestly in his laboratory. Whether or not this Dr Jekyll and Mr Hyde type of personality can be sufficiently versatile to work in two opposed modes depending on circumstances is another matter; although historians of science do tell about charlatan-scientists who made fortunes peddling alchemical lore while hobnobbing with royalty and at the same time were capable of making important contributions to truly "honest" science.¹

¹ P. Strathern, writing in "Mendeleyev's Dream: the quest for the elements" (Penguin, 2000) describes Paracelsus (1493-1541) as a remarkable exemplar.

Since the results and the products of science are not confined to laboratories but extend outwards towards society and its manifold needs, then clearly, this interface between science and society has to have an ethical dimension as is true of all societal interactions. In the past, popular enthusiasm for science has been generally good; however, more recently, science suffers from a serious image problem and people no longer take for granted the view that it is a benign activity from which everybody stands to gain. This erosion of optimism in the scientific enterprise is not occasioned by people's lack of confidence in the ability of scientists to do their laboratory work well but rather it is a result of a decline in the trust of scientists who are seen as espousing ethically dubious and irresponsible attitudes. The old trust is being replaced by suspicion and fear of abuses of various kinds. The creation of chemicals of mass destruction, the deliberate release into the environment of poisonous substances designed to increase material gain, the spectre of genetically engineered Frankenstein monsters and similar stories feed the public mind with dread and mistrust of modern science. The Code of Ethics for Scientists originating from the Pugwash Conference of 1984 was established precisely in response to a concern by the general public about the applications and consequences of scientific research.

Even if a reality ever existed wherein science was practiced as a socially secluded quest for 'objective knowledge', this is certainly not the picture today where project-oriented scientific teamwork is promoted through such initiatives as the European Framework Programmes. In such a scenario, any financially-supported scientific actions need to justify themselves in terms of potential human benefits. On the one hand, such a development is bound to inculcate in science an explicit ethical and social dimension since, in exchange for public funds, science will reasonably be expected to produce visible returns to society. On the other hand, there is a risk that only that science which has a good public image or which is identified by the political class as deserving of priority treatment can survive because it receives appropriate funding levels: laboratories toiling on problems that are less visible, if equally or possibly more important, might be driven out of work for lack of support.

Be that as it may, it is unlikely that the situation will change away from this model in the near future and arguably such an approach to scientific support is not unreasonable on a number of counts. But the point is that

given this situation there is added reason why scientists in training should, in addition to studying the nature of things, be exposed to principles that dictate the nature of man. They need to be trained to think conscientiously, to own up to their responsibilities towards society and to the profession itself. They also need to know how to deal with the important interface between science and political power. It was unfortunate that the founding members of the Royal Society felt that this first scientific think tank launched in Oxford in 1663 should work to improve “knowledge of natural things, and all useful Arts, Manufactures, Mechanick practices, Engynes, and Inventions by Experiments” but should not meddle “with Divinity, Metaphysics, Moralls, Politicks, Grammar, Rhetorick, or Logick”. Maybe this resolve by the Society to insulate science from power (and religion) might have been expedient at the time in view of the rather turbulent political climate in England (Charles I had lost his head a few years before and most members of the nascent Society were royalists!) but it is certainly not realistic today to expect scientists not to interact with politics and power especially when social progress can be so dependent on scientific progress. It is thus important that scientists are trained to have an effective and prudent interface with the political class and moreover, because scientists are empowered by their special training and knowledge, they should also realize that their ethical behaviour probably carries even greater responsibility.

In any university, the introduction of ethics into the core science programme will no doubt have to contend with the problem of finding appropriate academic space in the teaching curriculum; there will be resistance from those who view the subject as an “enrichment course” rather than as part of science education proper and these would want to relegate it to the corner of the optional studies. At the University of Malta, ethics in science is taught in a rather patchy manner and it is not a requirement for all science students. The computer science and informatics departments run special classes dealing with certain aspects of unethical behaviour mainly as it relates to plagiarism by students, a problem which has recently been exacerbated by the Internet. In my view, however, we still lack a robust programme that is a common requirement for all science students which would encompass the various aspects of ethics and ethical behaviour peculiar to science. Such a programme might for example include discussion of mechanisms for ethical decision-taking, conflicts on interest and data ownership, authorship, publication and disclosure rights and obligations, peer-review,

mentor-student and employer-employee relationships and means for rectifying unethical practices.

It has to be mentioned that the formal teaching of scientific professional ethics at university is not accepted by all and among those that favour such instruction, some would prefer that it takes one form while others would argue for different forms of learning. Indeed, there are even some strongly held views against the institution of special codes of ethics for scientists or for any other professionals.²

Opinion on this matter is not yet tested locally and the level of sympathy to the introduction of such studies at the Faculty of Science in particular has yet to be established. One would hope that the debate starts in earnest so that a reasoned decision can be reached which would inform future faculty policy on this matter.

² For example, see J. Ladd "The quest for a Code of Professional Ethics: An intellectual and moral confusion". In *Ethical Issues in Engineering*. Ed. Deborah G. Johnson. Englewood Cliffs, NJ: Prentice-Hall, 1991, pp. 130-136.

CREATING AN ACADEMIC HAVEN

Pierre Mallia

This has been a stimulating conference in the sense that its structure has allowed more participation by the public and fewer academic papers. The interventions by Prof. Judith Sandor and indeed that of the Minister for Education, the Hon. Dr. Louis Galea have shown one important thing which is missing both in our public and in our academic milieu – we need a haven for discussing ethical issues in science and technology. So far, this haven has been available only within the Bioethics Consultative Committee, and were it not for the one seminar we organise every year, there indeed would be no such thing as a public or academic discussion of ethics.

For instance, the Data Protection Act has been mentioned. Now data protection is nothing more than the protection of privacy. But, on the other hand, defining privacy, and indeed what we mean when we anonymise data is not so simple. At a workshop of the European fifth framework programme held recently, a considerable amount of information was made available which was not previously discussed in Malta. It is interesting for example, that the EU has produced a Directive (EU Directive 95/46/EC) which allows for the free flow of information between EU states. Now this is a good thing and unites research work in Europe to say the least. But this Directive assumes, of course, that all countries have data protection Acts, and that they are not only compliant with the EU Directive, but that the country is also implementing it well. We are all aware how much concern there is for the protection of data in our own country. Similarly there is great concern that when one moves from west to east across Europe, some countries may not be implementing their data protection laws well enough for other countries to feel comfortable to share their data. Yet because they all form part of the EU family they cannot do anything about it.

Article (28) of the Maltese Data Protection Act prepares us for a move into such a union. Indeed Article 28(3) states that “the Commissioner may authorise a transfer or a set of transfers of personal data to a third country that does not ensure an adequate level of protection within the meaning of Article 27(2)”¹. At face value one may not feel so concerned

¹ This Article continues: “Provided that the controller provides adequate safeguards, which may result particularly by means of appropriate contractual provisions, with respect to the protection of the privacy and fundamental rights and freedoms of individuals and with respect to their exercise.”

about the use of data, especially after it has been anonymised. But the truth of the matter is that, even after data has been anonymised, meaning that nobody can trace a data subject personally, one should still have a right to know what one's DNA is being used for. If DNA is being used, as pointed out by Prof. Deryck Beyleveld, for studies on contraception or abortion, a Roman Catholic woman may feel that she has a right that her tissues and/or DNA are not used for such experiments and research².

The point is that we only learnt about these details by participating in these FP5 projects. Yet we do this out of our own free will and time. What is worse, is that we go practically unprepared and *learn* when we are there. The Minister, in his intervention, rightly mentioned the importance of teaching ethics at all levels of education and especially within the university courses. Were it not for this yearly seminar which a few of the energetic of us in the committee organise, nothing is really being done about ethics. This brings me to the second reflection which came out of the panel discussion on education.

The teaching of ethics

The trend in medical education at least, supported of course by educational psychologists, is to move away from didactic teaching to a more reflective process of *learning*. The teacher is the facilitator. Translated into the ethics realm, the educator is not there to teach any ethics but to promote discussion and indeed challenge the beliefs we hold dear and put them to the test. This may create moments of crises which are indeed turned into windows of opportunity to reflect and then perhaps consolidate what we actually believe in. My personal experience with medical, dental, law and medical technology students so far has been this. Provoking questions shows that both sides to an argument may have flaws in their reasoning. Why do we do what we do? Why do we believe what we believe? Is it simply a matter of faith? For if it is, then there is no place for rationality. We need to facilitate the *inner apprenticeship*³ of the person, moving away from indoctrination, and respecting the human

² Beyleveld, D., and Townend, D., "When is personal data rendered anonymous? Interpreting Recital 26 of Directive 95/46/EC", Paper presented at the World Congress on Medical Law, August 2002.

³ Neighbour, R. *The Inner Apprentice. An Awareness-centred Approach to Vocational Training for General Practice*, Petroc Press, 2000

being as having the potential, given the right environment and time, to come to sound ethical conclusions, and also to reflect on certain weaknesses his or her beliefs may have. Many students have come back saying that it is better that they have learnt this whilst still at university than to be faced in a court of law, for example, trying to defend an issue which one has never really reflected upon. And in general, students respond well to innovative methods of teaching which move away from didactic lecturing and being asked direct questions in public.

Now, during the Conference, this has been challenged as a *relativist* approach. It is not the place here to go into a discussion about relativism. But it is indeed unfortunate that people feel afraid that our faith will be challenged if we allow students to reflect and discuss issues like euthanasia, stem cell research and the case of the Siamese Twins, and that the only way to teach ethics is by prescription. Is this reflective of a lack of faith in students or in their upbringing within our society?

Indeed as a Catholic country we should also include the teaching of the church and reflect on the rationality and how these teachings can be arrived at naturalistically. If one really believes that one can arrive at the truth by rational thought, which is after all the position of our Mother Church, we should have the courage to help students to come to these conclusions on their own. Doing otherwise means you simply either do not have the time or that you do not know the 'how' and 'why' of modern adult educational principles, or worse still, that you do not have the faith that people can indeed come to the conclusion, through their own values of upbringing that euthanasia and abortion indeed do not respect human values.

Far from being relativist, the facilitative teacher allows, and has faith in the inner potential of the student – what the much acclaimed Roger Neighbour refers to as the 'inner apprentice'⁴. Both teacher and student encounter each other in dialogue and respect for their human nature. This is not pragmatism. Indeed there is a place for didactic teaching, when bringing together a subject and summarising points of view, including the reflection of Catholic teaching. But this is done after the student has had time to think. Even assignments are practical in this way, asking students to look up a case history, reflect upon it and present

⁴ Neighbour, R. *op.cit.*

it to the group. The rest of the group then gives feedback on the presentation and on what they believe. Ethics teaching is not about clear-cut cases of euthanasia or abortion; it is more about why a “life” prisoner has a right to be put on a transplant list whilst a woman with three children and no insurance is not. The presenter of the case then has opportunity to put down what was reflected in the group and thus produce an assignment which is a *lived* experience rather than a boring look-it-up-and-what-you-see-is-what-you-get assignment. The feedback from the group is as important as the research done.

Science is not the enemy

We have been speaking of ethics in science and technology and our conversation has focussed on teaching scientists ethical values. I find myself disagreeing with such an outlook. Who is teaching whom, here? Who are we and who are *they*, the so-called scientists. We often conceive scientists as being white-coated people in laboratories concocting experiments, as the Maltese say, *ta' barra minn hawn*. Scientists are themselves people. They come out of the same society that purposes to teach them. Speaking about our local scientists, these are a product of our own society. Saying that they now need teaching is in fact acknowledging a failure of society as a whole which has not thought enough ethical/social/religious values to people, some of whom now became scientists and evidently are conceived as needing more teaching.

I think nobody can teach ethics to anybody. But what we need is a mutual understanding and reflection on the things we are dealing with. Science is not the enemy. We ourselves can be the enemy if we do not reflect enough on our values and thus suppose that we can get along by ignoring them. Indeed people who profess abortion, euthanasia, and that the embryo is not a human being, often are not themselves scientists.

This of course does not mean that we do not need people who have an in-depth knowledge of ethics as applied to science and who expound and facilitate ethical principles and values by which we deliberate and think about ethics. And as pointed out above, it does not mean that we should not be making students aware of what the Catholic Church tells us about some issues and what indeed other religions and groups feel and think on these same issues. But if we continue thinking that teaching ethics is simply teaching ‘religion’ to scientists, as has been stated, then

this is something which should have been done earlier, or at any rate should be proposed to everybody, not only the scientist. Whilst it is good acknowledging that so far ethics has not been thought in our science classes, we need to start on the right footing.

Thus courses need to be tailored to individual fields. For example biology students would be more interested in knowing and reflecting upon environmental ethics, animal rights, genetics, stem cell research etc, whilst the medical student may need more focusing on end-of-life issues, current research, or Do-Not-Resuscitate orders. The modern student is not only interested in Cardiopulmonary resuscitation (CPR), but also in issues relating to when to make the choice of not to resuscitate, and who makes that choice. Patient rights need to be discussed as part of the curriculum.

Good scientific ethics can only come from people versant in science. Having an ethics teacher coming from the humanities may be fine, but if he or she gets goose skin at the mention of the word 'genetics' or 'DNA', then the same teacher may need to reflect on what he or she is teaching. When we speak of the danger of databases, it is the scientist himself or herself who can give us the answer. Therefore science cannot be conceived as the enemy here either. To do so and to warn against databases is tantamount to impeding progress. Science is knowledge. There is a God-given impetus in human nature to ask questions and to seek solutions. This is epistemology at work. Naturally, as pointed out by Prof. Leone Ganado, the same screen on a fighter aircraft is the same as we have on our PCs. But this begs the argument of the ethics of just and unjust wars and the ethics of a computer society. We cannot 'teach ethics' here by prescription but by facilitative reflection. By telling me that something is wrong you may have gained my attention; by allowing me to *see* it as wrong through internal reflection and group work, allowing the 'inner apprentice' to work, you have given me a life experience.

An Academic Haven

What we need, therefore, is a place where scientists, sociologists, mathematicians, clergy, philosophers, legal people etc come together and discuss issues. I have been careful to avoid the word 'lay', for if I am a sociologist I may be lay to science, and vice-versa. We are all lay with

respect to other fields. I think that this inclusion of a 'lay person' is stupid and an insult to modern thinking. Do we mean including the man in the street? Well the man in the street may just as well be a sociologist. The concept of a lay person on a Research Ethics Committee, for example, is to have a person not versant in ethics, in order to see if a patients would understand a questionnaire or an informed consent procedure.

This right environment for discussion must be within the university, for the university is (or should be) the seat of thought. It would be unfortunate indeed to have a university concerned only with teaching what the country needs. The university is a centre of knowledge, of epistemological reflection, if you may, which prepares us for those FP5 and FP6 projects, allowing us to take something with us. Only then can we dialogue and bring our experience to other countries and cultures.

A shudder goes down one's spine when someone expresses more interested in the jobs a genetic company would create rather than the ethics involved of genetic testing. Obviously this person was never given the opportunity to reflect on the issues. This is the society we are in danger of creating unless we take ethics seriously. It is the University's responsibility, in my opinion, to create the right milieu for reflection and research at both undergraduate and post-graduate level, and also an environment where scholars can meet to learn from each other's experience.

Biology, Bioethics and Society

M.N.Cauchi

It is common knowledge that science and technology have advanced at a bewildering, some would say alarming rate over the past decades. The non-scientific lay-person is often left wondering where we are all going, and whether scientists are often engaged in a game which provides great fun for themselves while endangering the stability of the world as we know it.

In the biological field, there have been advances particularly relating to unravelling the mysteries to be found in the genetic code, and secondly to utilising the capacity of cells derived mainly from an embryo to grow in vitro and reproduce vital organs and even whole embryos. These two areas have produced brilliant results and have at the same time raised several issues of ethical importance.

One may summarise some of the reasons why this research has raised such fundamental problems within society, a process not previously encountered in the history of science.

Firstly, society today is much more involved and attuned to the results obtained by science than it has ever been. This is the result of the concurrent revolution in the ease of accessibility and transfer of information, mainly through such means as the internet, a phenomenon which has barely celebrated its tenth anniversary. However, it is also related to the higher education level achieved by the general public today, compared to a generation ago, thus enabling more people to participate in the debate.

Secondly, there is the fact that biology involves every one of us, and therefore advances in this area are likely to affect us intimately. Compared to the earth-shattering advances in nuclear physics in the first half of the 20th century, which were intellectually brilliant and which have led to the construction of the most destructive weaponry, but where debate was largely limited to a relatively small number of involved persons, the biological revolution of the second half of the century has found a much more eager and numerous population which was ready, able and

interested in understanding the implications of the findings described.

A third reason for the widespread interest is the individual benefit that could be achieved through modern bio-technology. It is a fact that the initial techniques of in vitro fertilisation were of considerable benefit to the significant minority of infertile couples who could not achieve their ambition of parenthood in other ways. Likewise, pre-natal diagnosis ensured that couples were enabled to ensure that their children did not suffer from disorders to which they themselves were genetically prone.

The unravelling of the genetic code might very well prove to be the highest achievement by human beings throughout the history of scientific endeavour. Genetic information is on a totally different level from other data relating to the normal structure and function of the human body. It is predictive of future health, it is shared between different members of the extended family, it is relevant throughout the life of the individual and not merely over the disease-episode like other frequently performed tests. For these reasons it may lead to discrimination at the workforce, insurance, or to group and ethnic discrimination. Hence the importance of measures directed at ensuring that genetic information is obtained only after thorough counselling of the members involved, and that strict precautions are undertaken to ensure that data is kept secure and confidential. This is important both at the individual level, as well as that relating to large collections of tissues to be found in laboratories and data-banks.

More recently the public has been assailed with news relating to the creation of new life which bypasses the normal union of sperm and ovum. The production of Dolly was a landmark not so much due to the biological novelty of the technique, or the likelihood of widespread application in the medical (as opposed to the veterinary) world, but more to the power of the imagination in conjuring 'Boys in Brazil' type scenarios which many reasonable people find objectionable.

Lastly, and perhaps most important of all, we are now entering the stage where stem cell technology offers to provide the ultimate in spare-part tissues, organs, and other biological material to replace those lost through disease, age, wear and tear, etc. Stem cells taken from embryos, bone marrow, or other tissues which still have pluri-potential capacity to multiply and differentiate have been utilised and made to multiply in vitro to

produce, for instance, muscle cells, brain cells, etc which are functional when injected into a diseased host. Such technology obviously offers considerable hope to those suffering from diseases which include Parkinson's disease, heart disease, as well as conditions relating to kidney, liver and other organ failure.

It is therefore obvious that unlike previous scientific revolutions, the biological revolution of the latter half of the 20th century is unlikely to leave many of us unaffected. We would all eventually be looking forward with anticipation and great expectation to the time when all our illnesses will be cured, all our failing organs replaced, and all diseased tissue cured by replacement, implantation, injection or other manipulation of stem cells and their products.

What are the ethical issues involved in such procedures, and why is the public wary of such issues? I propose to summarise some of the more urgent or worrying ethical issues relating to advances in biology in recent years.

1. *Prenatal diagnosis and abortion.* There is no doubt that the biggest ethical issue in Malta relates to abortion. Malta is the only country in Europe which does not allow abortion even for the prevention of serious genetic disorders. As a result those requiring abortion for any reason find their way to centres overseas. Recent statistics from UK show that over one per cent of pregnancies end in the UK as abortions. Statistics for other abortions carried out in other countries in Europe are not available. The issue here is whether testing for genetic disorders (e.g. thalassaemia, fragile X chromosome etc) is justifiable when no measures may be taken to prevent the condition in the fetus. Pre-implantation genetic diagnosis (PGD) involves the genetic analysis of cells from the embryo prior to implantation with the idea of discarding defective embryos and implanting into the uterus only 'healthy' embryos.
2. *Cloning.* This topic has become the focus of media attention out of all proportion to its practical importance. The Council of Europe Bioethics Convention (Oviedo Convention) prohibits cloning of human beings. Visions of multiple cloned infants (as depicted in the film 'Boys from Brazil') have been encouraged and condemned. The technique has, unquestionably, value in veterinary practice,

but in the human situation it has been largely limited to the relatively rare situations where normal reproduction with other reproductive technologies has been impossible (e.g. infertility, lesbian relationships etc). Its use to provide 'designer babies' has also been rightly condemned.

3. Use of *embryo stem cells*. The flourishing technology relating to stem cell research often involves the destruction of the embryo. In most countries, 'left-over' embryos from in vitro fertilisation programmes are used for the purpose. Anachronistically, in the UK, embryos to be used for research have to be created *ad hoc*, a process which is forbidden by the Bioethics Convention. Countries like Germany which forbid embryo research have allowed the importation of stem cell lines which were in existence prior to January 2002 in an attempt not to stifle research in this important and growing area. The greatest moral dilemma in my opinion will arise when products derived from this research become available on the market. Will countries like Malta avail themselves of essential products to treat the various disorders mentioned above knowing that they have been derived from such technology involving destruction of embryos? This will raise considerable ethical issues comparable to the questions raised about utilisation of findings from unethical research performed during the Nazi era.

4. *Patenting the Genome*. One major issue relating to utilisation of research is the availability of the research findings to other workers and to society at large. The major involvement by private and commercial organisation in the potentially very lucrative genomics research has resulted in severe restriction in the use of research findings. One typical recent example is the patent issued relating to the use of the so-called 'junk DNA' – DNA which is not involved directly in coding, and which for a long time was thought to be inactive, but which now has been shown to be very much involved in controlling the coding of active DNA. Patents relating to the use of such DNA threaten to stop research in this important area, and result in unacceptable increase in prices of the products derived from this research. The whole issue of whether the human genome should be subject to patenting has been raised several times, and remains a thorny problem which needs to be resolved. The recent

report that the World Trade Organisation has succeeded in convincing several Western pharmaceutical companies to provide urgent drugs to the poorest countries in the third world at a fraction of the normal price leads one to hope that progress in this area is possible, and that altruistic considerations are not entirely dead.

5. *Data protection.* Two major factors have combined to make this a very urgent issue. The first factor results from the enormous quantity of data that is available and that may be considered personal and sensitive. This includes all health-related data, and in particular genomic data which may predicate present and future health conditions. The second factor depends on the ease of storage and access of computerised data which necessitates special procedures to ensure its protection. Data protection legislation has been promulgated as an EC Directive and has been adopted as Data Protection Acts in most countries. In Malta the Data Protection Act ensures privacy and transparency. It ensures that the data subject is aware of information kept about him or her. Other sources of stored data include data banks and also tissue banks held in most hospital and research laboratories. The informed consent of the individuals concerned is not always a priority with such banks.

Ethical issues and the public

Involvement of the public in unravelling ethical issues has been encouraged for a long time. Lay person participation in ethical committees, and in particular research ethics committees have been a requirement for some time. The public is also encouraged to participate in formulating views relating to current ethical issues, through public discussions, conferences, and the media.

The level of participation depends not only on the interest generated by the various topics but also on the level of preparedness by society as a whole. This in turn relates to the level of sophistication and education of the general public. It is no use emphasising the need for public participation and issues relating to public rights, (including patients' rights) if in general, people are not interested enough or motivated sufficiently to be assertive and demand that such rights are respected.

In Malta we have special issues that need to be tackled. In the first

instance the level of science education is relatively low compared to the rest of Europe. This has been the result of past neglect and lack of emphasis of the importance of science subjects at tertiary level – they were considered to be less useful in obtaining a job, and even now are considered to be less well-paid than other spheres of life, including particularly business, administration and computer studies, not to mention the older professions of law and medicine. Unless and until science studies are given their due importance, the level of education and sophistication in scientific matters is bound to remain at a low level. In particular, there is an urgent need for well-qualified science teachers capable of imparting an interest in science at an early (including primary school) stage, and of encouraging such interests at secondary schools.

From the ethics point of view, it is difficult to maintain an interest in this topic apart from the odd subject that occasionally hits the public through exposure in the media. On such occasions, chances are that the importance of such topics is blown out of proportion. One such occasion was the story relating to the Maltese Siamese twins which provided heated discussion relating to the morality of performing complex surgical interventions when the outcome involved the necessary death of one of the twins. The very extensive literature relating to this topic in the specialised journals is still divided on the issue. I say that the public interest as shown in the media was disproportionate not because the topic in itself is not important ethically, but because of the rarity of the situation that hardly touches on the lifestyle of anyone except the affected individuals and their family. On the other hand it is very difficult to involve the public in a debate involving the mundane, day to day issues of bioethical concern. Such issues include the role of informed consent, data protection, stem cell research, etc.

An important role of the Bioethics Consultative Committee is to bring such issues to the notice of the public and to encourage discussion and debate. For the past five years, this Committee has organised yearly conferences relating to various issues of ethical significance. The Proceedings of such conferences has been published and are available for the public. Moreover, the material presented at these conferences has been the subject of discussion in the media, and has thus been instrumental in disseminating such information. Other ways of preaching the message has been through the website (www.synapse.net.mt/bioethics), and through the use of a regular Newsletter.

This year the topic chosen has been one relating to Science, Ethics and Society, which puts particular emphasis on the role of the public in this area. Various views have been expressed relating to this role. In summary one may say that there is a very definite role of the public including:

1. *Watchdog role.* The voice of the public should be heard particularly in relation to what is considered acceptable scientific activity and what is not. Issues include genomic modification, (including the introduction of genetically modified organisms), the limits of research, etc
2. *Active participation in ethics committees* as mentioned above.
3. *Ensuring adequate legislation.* One of the biggest hurdles in Malta relates to the absence of adequate legislation relating to several issues. Legislators are influenced by what they perceive as issues of interest to their electorate and respond accordingly. Where there is little interest among the voters there could very well be inertia among the legislators.

The role of the scientist.

It is very easy for the scientist involved in unravelling the mysteries of science to become carried away by his or her own momentum and involvement, and to forget the broad scenario and responsibilities. Scientists are, in general, neither philosophers nor do they tend to be intimately involved in social issues. As a matter of fact, within the scientific community, self-selection usually favours those who shun political and social involvement to a life devoted to individual and often solitary research.

It has become, however, abundantly evident that scientists cannot lock themselves in ivory towers and remain uninfluenced by public opinion. Recent regulations in the US, for instance, outlaw funding for research involving cloning and this would automatically reduce the interest of organisations and individual scientists to embark on such work. These regulations arise as a response to the general concern expressed by the public. Another area where the public has had a very significant input into the sort of research work that scientists do is that relating to genetically modified organisms (as mentioned earlier in the paper by Dr

Marion Zammit Mangion). A public boycott of the products of biotechnology will result in significant curtailment of funds for research (and jobs) in the particular area.

The role of the scientist as a public educator cannot be ignored. It is often the case that there is a mutual interaction between what the public is interested in and what it is exposed to. One cannot expect the public to show even a minimal interest in science if its scientists are not prepared to come out and meet it half way. It is therefore the role of individual scientists, as well as science organisations, to stimulate interest in research and in science in general.

Scientists are a class of human beings engaged in a specific type of work. As in any such groups there are bound to be the mavericks, those who indulge in doubtful and shady practices, those who prefer to undermine the standards of scientific research in the hope of being first and being acknowledged as such. Every profession has to deal with a small minority of such persons, and it is the role of every profession to have a mechanism to ensure that such persons are censored and eliminated.

Because of the very nature of scientific research, particularly commercial research where potential rewards may be very considerable and where, therefore, there is a considerable degree of secrecy, it is often difficult to know precisely what is going on until a very late stage of the work. Even research ethics committees themselves are often not in a position to monitor research work that has been approved. The need for peer-review, and if necessary 'whistle-blowing' has to be emphasised in this as in any other area of human endeavour.

Finally, in an age where research has become globalised, where participation with other groups has become almost mandatory,¹ it is important to ensure that ethical issues have been thrashed out and approval obtained by all the individual groups involved in the project. This is particularly important where research involves commercial organisations who prefer to do their basic research in countries where ethical standards are not as high as in their own country. Participation with such groups should be undertaken only if it can be clearly and transparently shown that no corners have been cut and not ethical principles have been sacrificed.

¹ Note, for instance, the current emphasis on the need to have multiple groups of scientists from different countries applying for EU grants.

Report of workshops

1. Science and Medicine

Chair Dr C. Scerri

Dr C. Scerri presented the problem of controlling the researcher working privately in his laboratory.

Professor A. Xuereb expressed the need for different ethics committees to service the different faculties at the University as well as on a national level.

Ms M. Sant Fournier presented the pharmacy model: research in this field is subject to on-site surveillance as well as peer review. It is difficult to maintain secrecy in research in the case of privately funded research if there is on-site surveillance.

Dr B. Gafa' said that there exists a law that lays down strict controls on laboratories, but enforcement is lacking. What is required is a culture of ethics that is based on objective criteria. This will not solve the problem but it can contribute towards regulation. The more widespread this culture the better the control.

Professor J. Sandor said that legislation cannot ever control all aspects of research and unscrupulous researchers will always find loopholes in the law. Mutual competitive control can be effective in this sphere.

There was consensus among members present that there should be some form of accountability, and that research should be regulated. It was suggested that scientists be issued with warrants. Moreover there should be regulations and some form of control that these regulations are observed.

2. Science and Pharmacy:

Chair: Ms M.A. Ciappara

Development of and innovations in pharmaceuticals and pharmacogenetics over the past twenty years have raised the following problems: Is it going to be ethical to stream patients according to

genotype? Is this type of information going to prove a burden to the patient? Should such tests be carried out?

The following comments were made from the floor:

- Tests should be carried out as long as they are beneficial to the patients. No ethical issues are involved since the information resulting from such tests is usually minimal.
- Cost effectiveness and economic feasibility of screening/testing for medicines should be taken into consideration when considering whether such tests are to be held under the national health scheme or privately.
- The public should know as much as possible about availability of tests. On the other hand limited knowledge can be dangerous.

Pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response to medicines. It is the application of genetic knowledge to predict the safety, toxicity and/or efficacy of medicines in individual patients.

Hereditary metabolic and molecular disorders and inherited variation in the drug metabolising enzymes, drug targets and drug transporters appear to affect a patient's response to a treatment. This may lead to increased toxicity to a treatment, risks of adverse effects and ineffectiveness of treatment. The source of these variations appears to be by genetic polymorphisms. The identification of single nucleotide polymorphism (SNPs) for drug metabolism and/or drug action can lead to personalised treatment and optimal medicine response.

Testing and screening people for the susceptibility of response to medicines: The ultimate purpose of these investigations is to elicit information that will enable the selection of medicines tailored to individual patients, thereby decreasing the incidence of adverse effects, and improving therapeutic outcome and quality of life of patients. Furthermore, there will be a reduction in unnecessary use of medicines, a more accurate method of determining the appropriate dose of the medicine and better health care. The group discussion focused on the impact of these tests on society, on health care costs, on the individual and on health care professionals.

Impact on society

How aware will patients be to the existence of these tests? Are these investigations justified? Given the availability of these tests, people should become aware of their existence. It was considered unethical not to inform people about the availability of these tests. Eventually, this may lead to widespread testing at an early age to identify genetic variants associated with drug response. The identification and prevention of a toxic response to a treatment justifies the use of these tests. There was no concern among the group that information elicited from the tests was going to be a burden on the patient. However, a dilemma arises when investigations reveal that the current treatment for a condition cannot be used, and that there is no alternative treatment. Treatment has a placebo effect on patient. If no treatment is available the patient may feel abandoned.

Impact on health care costs

Overall how accessible are these tests going to be to everyone? Who is going to fund these treatments? Ideally these tests should be an integral part of the healthcare system. These tests are expensive and can in the short term have a negative economic impact on health care. The group noted that there is going to be a shift from treatment to preventive medicine. While initially the cost is going to increase, in the long term, benefits may balance the cost for the increase in diagnostics and there may be a decrease in the cost of health care. The impact on cost of health care needs to be studied in depth. Economists and health care professionals need to be involved in these assessments.

Impact on the individual

It is envisaged having central databases containing information about patients' genotype which can be accessed at the time of treatment selection. This raises the issue of privacy and data protection. Individuals need to have the necessary safeguards placed in the system so that personal details are protected, and there is no misuse of genetic information. Such data can also have implications for insurance policies.

Impact on healthcare professionals

What sort of knowledge do healthcare professionals require? Doctors

and pharmacists need to receive training and education on pharmacogenomics. This includes the interpretation of test results and the selection of treatment on the basis of pharmacogenomics, thereby individualising treatment according to the distinct needs of the individual. The roles of doctors and pharmacists are going to evolve depending on how pharmacogenomics is going to be integrated into healthcare.

3. Science and the Layman **Chair, Ms C. Xuereb**

Ms Xuereb stated that in the mind of the general public, the real role of the scientist is vague, and people should be better informed about science and the scientist.

Ways of improving the teaching of science in schools to make it more relevant to everyday life and remove the taboo that it is only a subject for 'gifted' pupils were discussed. Hands-on experience is very important - hence the need for school labs and inter-active science centres for the public. The teaching of science in schools should be assigned to specialist and enthusiastic teachers from the earliest years.

There was the need for national campaigns to make pupils aware of, and able to understand more current scientific and ethical problems.

Ethics Science and Society: Concluding Remarks

The Hon Dr Louis Deguara, Minister for Health

There is no doubt that science and technology have been a great boom to society over the years, and will no doubt continue to provide us with solutions to problems, both current problems, as well as problems of which we do not even dream about at the moment. The recent SARS scare is a case in point, emphasising our near-total dependence on scientists to provide us with the wherewithal to defend ourselves against unknown viruses

There is also no doubt that with advances in science there seems to be a corresponding increase in ethical issues which affect society as a whole.

It is for this reason that Conferences of the kind that you are holding today are important. They highlight the particular scientific issues involved and grapple with the ethical and societal issues that they raise.

For many years the sort of dialogue that you have embarked on today has been difficult if not impossible to achieve. In the first instance, scientists have been reluctant to have any brakes or restraints of any kind put on them. Scientists are the sort of persons who have their heads buried in their scientific achievements, and they spend little time worrying about the impact that their work might have on society at large.

A second major problem has been the reluctance of the general public to endeavour to understand the scientific process and to try to keep abreast with scientific advances. Too often the general public finds these issues abstruse and complex, a situation compounded by the fact that scientists are often reluctant to come closer to the public, to explain the implication of their work.

To have a dialogue, it is not necessary for everybody to understand all the scientific details involved in a procedure. There must, however, be a commitment on the part of the scientist to discuss with non-scientists the overall plan and general implications of his or her work, and on the part of the non-scientist a desire to become informed about current issues.

In the last few years we have seen the public becoming much more

aware of issues arising from scientific research and much more anxious to become involved in having a say on these issues. Issues such as cloning, stem cell research, embryo research, genetic modification of organisms including foodstuffs - all these have become very publicised and there have been extreme reactions for and against such procedures, that stretched from the ordinary man and woman in the street, to the highest levels of investigation in the country, in the courts, and in legislature, both within a particular country and also at international levels.

There is no doubt that there is a great deal of anxiety out there that needs to be faced. Scientists can no longer work quietly behind closed doors isolated from the society which supports them. More and more they are coming under pressure to conform and comply with regulations that affect their work. Their programme has to be approved by the relevant research ethics committee, their work practice has to conform to laws and regulations which are increasingly becoming more and more restrictive in an effort to protect the general public. A recent example of this is the Data Protection Act which deals with the manipulation of data particularly that described as "sensitive" data.

On the eve of joining the European Union, we must make a special effort to ensure that our practices conform with those of the EU. We are sure to find that the work of scientists, both those working on relatively routine jobs, as well as, and in particular, those involved in research procedures are covered by detailed legislation, Conventions, and other legal instruments with which we need to become familiar.

It is to be hoped that this Conference which is the first of its kind in Malta, will not be the last, but will be followed by a concerted effort by all those concerned, to ensure that scientists are well aware of the ethical component of their profession.

It is also my hope that public awareness of scientific issues will become more and more tangible. Unfortunately science education and interest about scientific topics has not yet reached levels to be found in Europe, according to some recent surveys. It is surely in the interest of the country to ensure that science is given the importance it deserves. We cannot allow ourselves to fall behind in our appreciation of science and all that it involves.

It is part of the brief given to the Bioethics Consultative Committee to publicise issues of ethical interest among the general public, through Conferences of this kind, publications and other means. This I believe they are doing to the best of their capacity.

I am sure that the discussions that were held here today would serve to disseminate further issues relating to ethics and science as they affect society as a whole.

About the Contributors

Maurice N. Cauchi, AM., M.Q.R., M.D., M.Sc., Ph.D, F.R.C.P.A., F.R.C.Path Professor Cauchi graduated M.D. (Malta, 1961) and furthered his education at the Universities of London, Monash and Melbourne. He is professor of Pathology, University of Malta, and Chairman, Gozo Health Council. He represents Malta on the Bioethics Committee of the Council of Europe. He has written and edited several monographs and papers of a scientific nature. His most recent publication in bioethics is: *Bioetika fl-Ewropa tal-Lum (PEG, 2002)*. He has also written several articles relating to bioethics in the local press. For the past seven years he has been Chairman, Bioethics Consultative Committee.

Mary Anne Ciappara, B.Pharm., M.Phil. practices as a Managing Pharmacist in a private community pharmacy (1979 -), and since 1992 has taught Pharmacy Ethics to B.Pharm.(Hons.) students at the Department of Pharmacy, University of Malta. She is Vice-President of the Malta Chamber of Pharmacists (1991-92; 1996-). Internationally, she represents the Chamber on the Council of the Commonwealth Pharmaceutical Association (1995-). She is an elected member of the Pharmacy Board (1988-) and Vice President of the Malta Federation of Professional Associations (2002-). She serves as a member of the National Antibiotics Committee (2001-) and as a member of the Bioethics Consultative Committee (2002-).

Alex. E. Felice is a graduate of the Medical School of the University of Malta (M.D., 1971, M.Phil, 1975) and the School of Graduate Studies of the Medical College of Georgia (U.S.A.; Ph.D. 1981). He was appointed Assistant Professor (1981), and Associate Professor (1986) in both the School of Medicine and the School of Graduate Studies and on the Research Service of the Veterans' Administration Medical Center (Augusta, GA, U.S.A.) as Program Director in Hemoglobin Research (Molecular Hematology). During this time, his research was supported by grants of the US, National Institutes of Health and the US Veterans' Administration.

In 1992 he was appointed Professor (Biomedical Sciences) in the University of Malta. Here, he directed the establishment of the Thalassaemia and Molecular Genetics services and the development of a Molecular Biotechnology Program. He is the author of numerous

research manuscripts on the molecular genetics of haemoglobin disorders including thalassaemia and sickle cell disease and on the molecular (DNA) epidemiology of other conditions for gene discovery research.

He is an elected member of the American Association for the Advancement of Science, the American and European Societies of Human Genetics, The Human Genome Organisation (HUGO), the American Society of Hematology, and Foundation President of the Malta Chamber of Scientists as well as member of the board of the Malta Council for Science and Technology. For a number of years he has been Editorial Reviewer of The American Journal of Hematology, the British Journal of Haematology, The Balkan Journal of Medical Genetics and of HEMOGLOBIN.

Albert Leone Ganado is Professor and Head of the Department of Computer Information systems. He read Mathematics and Physics at the University of Malta. He was awarded the Rhodes Scholarship in 1965 and studied at Balliol College Oxford and the Oxford University Computing Laboratory. Here he had the opportunity to be tutored and attend lectures by some of the pioneers of computing such as Christopher Strachey and Leslie Fox. He carried out research in Numerical analysis and obtained his doctorate in 1970. He has been actively involved in sport and has always taken a keen interest in political, societal and ethical issues. He is also the pioneer in the introduction of the teaching of computing and IT in Malta. He has been the teacher and mentor of most of the current IT practitioners on the island.

Pierre Mallia graduated MD in 1992 from the University of Malta and in Biomedical Ethics. He read his PhD in Bioethics at the University of Nijmegen, Holland. Former secretary and currently member of the Bioethics Consultative Committee he is active both academically and professionally in biomedical ethics. He has published numerous papers in peer reviewed journals and has recently published book intended for students and the educated lay public: *Your Rights as a Patient* (2002) and *The Beginning and End of Life. Moral Controversy* (2002). His thesis on the *Nature of the Doctor Patient relationship* has been submitted to Oxford University Press.. He is currently assistant lecturer in the Department of Family Medicine and is a visiting lecturer in bioethics at the University of Malta. He is participating in a number of FP5 projects

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Having taught chemistry since 1968 and at all levels, Prof Vella is still involved in curricular development in school chemistry, participating actively on behalf of the university in syllabus design and development and also in examinations.

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