CONFERENCE REPORT

Bimal K. Bachhawat symposium on genome research: Emerging ethical, legal, social and economic issues.

22 – 25 May 1997, Goa.

Introduction

Dr. Bachhawat's death has left a void that is deeply felt by workers in the field of science in general and those in biochemistry, the neurosciences and novel drug delivery systems in particular. One manifestation of the depth of feeling was the decision by the National Academy of Sciences, India, to hold its inaugural symposium in the series on *Interface of Science with Society* in his honour.

In his letter inviting participants to this meeting, **Dr. M. G. K. Menon** wrote of how recent developments in molecular biology and genetics have provided an unprecedented insight into the basis of many traits and diseases and enabled us to probe, diagnose and treat hitherto unapproachable conditions. But these advances have also raised ethical, legal and socio-cultural issues with significant long-term implications for humanity. Whilst they provide powerful tools, they are also open to abuse which could threaten society. As we consider ways and means for developing genetic research in India, it is imperative that we work in parallel to evolve techniques for addressing the ethical, legal and socio-economic implications of such research.

Thirteen delegates from the United States, United Kingdom, Canada, Brazil, Egypt and Japan joined thirty-two delegates from India in the four day deliberations held by the seaside. Having everyone staying together throughout the duration of the symposium ensured close interaction between all participants.

Whilst inaugurating the symposium, Dr. M. G. K. Menon set the tone by quoting from a letter sent to him by Dr. James D. Watson on 15 May. Whilst apologising for his inability to attend, Dr. Watson made these observations:

"I believe that genetic knowledge has the power to transform for the better all aspects of human life and that individuals have the right to make choices based on genetic information. But this must be done responsibly and with due regard to the differing needs of different peoples.. ."

Dr. Menon organised this meeting in India to focus on implications for developing countries as the deliberations of such organisations as UNESCO tend to consider aspects concerning the western world.

A brief analysis of some of the discussions at this meeting is provided below.

The human genome project

Dr. Jan Witkowski, Cold Spring Harbour traced the origins of this study to the need to spend the twenty million dollars left over after construction of the telescope in Hawaii. The Department of Energy, USA was then keen on studying genetic mutations in workers in nuclear facilities in the country. The project took off after Dr. James Watson organised the meeting on *Molecular biology of homo sapiens* at Cold Spring Harbour in May 1986. Walter Gilbert and Paul Berg led the discussion on the sequencing of the human genome. The budget for such research has risen from eighteen million dollars in 1986 to one hundred and ninety million dollars in 1997.

When Watson was asked to head the project, in a far-sighted move, he allocated upto 5% of the total budget allocated for it by the US Congress to studies on the ethical aspects of such studies. It is also significant that a debate on whether or not it was right to patent DNA sequences was conducted almost at the start. Alongside the research, discussion on such topics as whether there was a genetic predisposition towards sub-optimal performance and criminal tendencies prompted such headlines as *Man's genes made him kill, his lawyers claim* in the *Wall Street Journal.* The feature on Dolly in *The New Yorker* was accompanied by a cartoon on the cover showing cloned Einsteins. In a light vein, Dr. Witkowski pointed out that there is no guarantee that clones of Einstein would not develop into master drug dealers. He also saw, in the future, a scenario where a prospective employer may conclude an interview with the statement: "Your résumé is satisfactory. Please leave your DNA sample with my secretary." so as to use genetic data to weed out undesirables.

He touched briefly on some ethical issues. Who owns the human genome and the DNA samples acquired during the studies? How can researchers ensure that benefits are transferred to those from whom genetic material was obtained? Is there a need to debate and, if necessary, counter statements implying [illegible] deficiencies and anti-social behaviour and activities can be attributed to our genes? Can genetic findings be used to explain abnormal behaviour at all, given that upbringing and the environment play such important roles?

Genetic research in India

Dr. H. G. Sarat Chandra, the Indian Institute of Science referred to the special challenges offered to geneticists in India by the diversity of populations, the consequence of the social dictates of the caste system and our tribal populations. He was sorry that there are few laboratories in the country that can offer diagnosis based on DNA studies and that several of them are divorced from medical colleges and hospitals. Results offered in the absence of such proximity are likely to lead to misinterpretation or worse as there is no direct responsibility to patients. He also showed that the fact that no new human gene has been mapped or cloned in India is an indicator of the poor quality of research in the country. Dr. Obaid Siddiqui's laboratory is the only one to have to its credit the identification of the gene for olfaction in melanogaster. Referring to the protests against shipping blood and DNA samples abroad for the diagnosis of genetic disorders or research, he asked how such shipments can be stopped without setting up a chain of DNA laboratories. The present regulations call for clearance from the Indian Council of Medical Research before every export of tissue -- permission that may take six or more months! In any event, do we have the mechanism for monitoring the shipping of blood samples or DNA by any individual in the country? Instead, would it not be better to ensure that a model agreement safeguarding the interests of the individual, the laboratory sending the tissue and the country is signed each time tissue is exported?

He pleaded for the development of a well-planned, equipped and staffed chain of DNA laboratories connected with medical colleges and hospitals, grouped into consortia. Once this is achieved, large numbers of tests can be performed with the consequent development of confidence in their reliability.

He identified some peculiarly Indian [illegible] that deserve genetic

study: hot water epilepsy and choline-esterase mutations that cause prolonged apnoea and disallow rapid emergence from general anaesthesia in some communities (e.g. vaishyas in south India). He also discussed the need to study the human diversity seen on this subcontinent and use genetic studies as a tool to understand the evolution of languages and migrations.

At the same time he cautioned against the misuse of genetic data. He pointed to the manner in which sonography was used by parents not to detect malformations in the foetus but to abort the girl foetus.

Legal aspects of genetic research

Dr. Harold Edgar, Professor of Law at Columbia University restricted his observations to American law where rulings can vary from state to state. In general, law on genetic research deals with the issue of information obtained from tests and research. To whom does it belong? Who can use it? American law was designed to encourage research. To this end, universities were permitted to patent and commercially exploit information even when it was gained from federally funded research. Under this proviso in the law, American universities carefully monitor the transfer of tissue or DNA from their laboratories to other universities or centres, safeguarding their own interests. Negotiated agreements precede such transfers. Patenting has led to several complications. A single process may involve so many steps that are patented that the payment of royalties can be quite a complex issue.

In a case that came before a court, it was ruled that an individual does not have property rights over his own tissue once this has been removed as part of therapy and handed over to the clinic for analysis. This decision is under debate. When material is collected for research, it is mandatory that informed consent be obtained after explaining possible commercial benefits from the patenting of sequences or other information obtained from such studies.

American law prohibits discrimination on the basis of genetic information especially in such areas as insurance and employment.

Dr. David Robert (U.K.) argued on behalf of pharmaceutical companies, for whom the patenting of life forms and genes is important. Me referred to the massive expenditure involved in genetic research and felt that if rewards in the form of the proceeds from patents were prohibited, there will be little research in this field and few cures emerging from it.

Dr. N. R. Madhava Menon, National Law School, Bangaiore referred to the Indian apprehension that tissues and other genetic material have been and are being taken out of India for the financial benefit of foreign agencies. He felt that human rights cannot be encapsulated under informed consent and must be individually referred to in documents of such consent. Indian courts will strike down any patent interfering with the right to live.

He suggested consideration of an international, multilateral treaty on genomic research ensuring fair play and guaranteeing the right to live with dignity in all countries.

India needs to take cognisance of the impact of genetic research on family law (surrogate parenthood or the demand by one partner, seeking marriage, for genetic information on the other), employment law (demands for genetic information from prospective employees), criminal law (genetic fingerprinting) and so on. Special care is needed as our courts of law are dilatory, enforcement is lax and poverty rampant.

It would, be best to take legal steps to establish accountability so that no consideration other than science prevails. To do so, we must focus on two issues:

Professional responsibility. In the absence of an educated, responsible society, professionals carry the onerous duty of organising their activities along ethical principles and in the public interest. The code of ethics may need revision. The profession must take disciplinary action against malfeasants. The professions have been granted considerable autonomy and they must exercise it responsibly.

Interaction between medical and legal professions is essential. Only thus will legal minds be made aware of the intricacies of biomedical advances and of the legal steps that must follow in the interests of society. Scientists and medical doctors also need to understand legal niceties to realise the implications of their studies and findings.

Discussion on above papers

Dr. Prakash N. Tandon, President, The National Academy of Sciences, India highlighted the many questions thrown up by genetic research:

Can we evolve a system where, through mutual collaboration between developing and developed nations, equitable distribution of services, facilities and wealth is established?

Is it germane for developing countries to worry about genetic research when there are so many more relevant problems screaming for attention

When we are short of manpower and facilities to provide genetic counscling, should we permit multinationals to bring genetic therapy into India?

When individual informed consent is difficult (for a variety of reasons), should we accept consent of the leader of the community or tribal group?

Should an individual be screened for a disease -- such as Alzheimer's disease -- that may develop decades later?

Once genetic screening has been carried out and markers - for Afzheimer's disease for example -- detected in an individual, to whom can this information be released? To the family? To employers? To insurers? What about the genetic test showing that the husband is not the biological father of a child?

Addressing the latter problem, **Dr. Lalji Singh of the Centre for Cellular and Molecular Biology, Hyderabad** told us of the Indian couple living in England with three children. When the father returned from India with a fourth child, who, he claimed, was his, the immigration authorities requested DNA fingerprinting to establish paternity. It turned out that this fourth child was, indeed, his child but the first of the three children in England was not his biological offspring. The British expert confined his remarks in court to the fourth child, keeping the results of the first child confidential in order to preserve the integrity of the family.

Ethical aspects of genetic research

Dr. Bryony Soper, The Wellcome Trust, London spoke of the social and ethical implications of genetic research. Genetic researchers must forge links with others to ensure optimal use of their findings for the benefit of society:

- Other basic sciences
- Clinical sciences
- Social scientists
- Cultural scientists
- Psychologists
- Political scientists
- Economists
- Commercial interests.

Analysis of the outcome of genetic research must include consideration of whether it is of multi-disciplinary interest, has practical applications, is of mainstream interest and is of long-term importance. Research findings that can be converted, simply and easily, into practice and public policy are to be especially welcomed. "Facts must be put through the loom of adequate dissemination, overview and review by doctors and policy makers and

analysts concentrating on impact on society with the sole purpose of being woven into a fabric useful to society."

She also discussed the role of counselling before any genetic test. Counselling must elicit answers to such questions as: 'If the test is positive, would you like to be told? Would you like your family to be told? Which members would you like informed? Would you like to restrict information? Can you tell us of individuals and agencies you do not wish us to inform? If the studies carried on the material supplied by you lead to material benefit from patents or other spin-offs, would you like us to exploit them? How can we share those benefits with you?'

Dr. Troy **Duster, Institute for the Study of Social Change, Berkeley, California** discussed genetic screening. He asked the question, 'Who's screening whom for what?' and cautioned against individuals and groups working on the basis of conflict and mistrust. He spoke of politics in screening risk populations. Scientific screening necessitates the trust and co-operation of local medical practitioners.

The least controversial is prenatal screening of the foetus for the detection of life-threatening illness and postnatal screening intended to aid and direct therapy. The screening of carriers of serious illnesses is essential to ensure that couples get married not on the basis of horoscopes but on those of genetic screening so that their offspring are spared genetically transmitted disease. He told us of the rabbi in New York who has ensured that the results of genetic screening of his flock are sent only to him. When a couple declares intent to marry, he consults his genetic data bank and advises whether or not they are 'made for each other. This arrangement spares the individual knowledge that could be psychologically traumatic and, at the same time, eliminates the genetic transmission of disease.

He listed areas of concern in genetic screening:

- Unequal relationship between clinician in white coat and the person being tested.
- Need to add social context to data obtained from genetic tests before the report is passed on to the person being tested is not always followed.

Patients often find it difficult to understand that the mere presence of a gene does not indicate that the disease will develop or when it will develop.

They also find it difficult to understand such statements as 'The risk of developing this disease is one in four.' If the disease does develop, they inevitably ask, 'Why me?' Mothers expect that since they already have a child with the disease, the next three children will definitely be free of disease, neglecting the fact that for each subsequent child, there is a one-in-four risk of developing the disease.

Individuals requesting genetic screen tests expect a definitive answer whereas such tests often provide only probabilities.

In some instances tests lead to other tests that may involve risks. He gave the example of search for the gene for breast cancer. When such a gene is found in a woman, she is then advised serial mammograms which, by themselves, may increase the risk of breast cancer.

Dr. Marcos Palatnik, Brazil cautioned against the seduction of technoscience. Ethics is based on wisdom and experiences from the past whilst technoscience focuses on the future. We need a sagacious marriage of these two.

There is a need for the intelligent use of all available genetic tests but using only carefully selected tests to counter the fears of society – the permanent fear of death, cyclical fear of epidemic disease (such as AIDS), the fears of the majority (as of debilitating disease and poverty) and those of the elite (such as an invalid or indisciplined work force).

Dr. Partha Majumdar, Indian Statistical Institute, Calcutta discussed studies on the diversity of the human genome in India. Genetic distances between populations provide useful data for reconstructing and dating evolutionary history. Genetic differences between individuals in a population are responsible for conferring resistance to disease in some and susceptibility to the same disease in others. The goals of epidemiological genetic screening, then, are to quantify genomic variation and participate in the creation of a world-wide database of genetic polymorphism, trace genetic trails of human migation, reconstruct the evolutionary history of populations and identify susceptibility and resistance genes for diseases.

Any researcher in this field must possess three essentials: honesty, respect for the culture and values of the population being studied and a willingness to be subjected to peer review.

Ethical problems encountered during such studies include:

- Relevance to local needs
- Informed consent during the collection of blood and tissue samples.
- Laboratory analysis.
- Use and interpretation of data obtained from research.
- Sharing of samples.
- Sharing of data.

He suggested that great care be taken in *obtaining informed consent* and narrated his own experience and practice. Where no direct benefit is likely to ensue to the donor of blood or tissue, this must be clearly indicated. In many communities villagers are illiterate and hence cannot offer a written consent. Verbal consent is inadequate as witnesses may not be available or traceable after a few years. They are unwilling to place their thumb print on any paper as past experiences have shown that each time they have done so, they have suffered through exploitation or the loss of personal or communal property. Dr. Majumdar has therefore evolved the practice of recording on video-tape every discussion with the community at large and the individual donor to show that there was adequate explanation of the pros and cons and that the donation of tissue has been voluntary.

Traditional anthropology did not face these ethical problems. Those researchers lived as part of the populations they were studying. They thus established an intimate rapport with the local people and were often integrated into them. Verrier Elwin is an example. 'They collected data and let it speak for itself. The modern geneticist works in a diametrically opposite manner. First of all, he formulates a hypothesis. He then designs and carries out a study to confirm it. He has no time for the population being studied and has no understanding of their concerns and anxieties. There is, thus, a great need to ensure informed consent and transmission of material benefits from the study to the group studied.

It is also necessary to pass on vital information to the individuals studied. Data on blood groups and information on where treatment for diseases detected during or as a consequence of the study can be obtained fall in this category.

I-Ie made the important point that steps should be taken by all workers in genetic research, especially those involved in epidemiological research, that there is ***just one transfer of genetic material*** -from the point of collection to a single research laboratory. All further transfers must only be made under protection of a legal document safeguarding the interests of the persons and community where the specimens were obtained and the laboratory itself. Cell lines must only be stored in repositories within our national boundaries.

Confidentiality must be guaranteed in the

use. of data. When sharing data, the identity of the individual from whom the sample was obtained must be kept secret. No data should be provided for any purpose that will harm the community or the individual.

Patenting is a dilemma. Is it right for the researcher to patent tissue obtained from a voluntary donor? Should DNA sequences be patented? Can life be patented?

If patenting is required so that funds are made available for research, benefits to society must be ensured in all relevant legal documents. It is also necessary to make certain that entrepreneurs develop local laboratories and industries and not siphon off samples and proceeds to developed countries. It is also important to ensure that vital data is not suppressed by industry.

Dr. Mammen Chandy, Professor of Haematology, Christian Medical College and Hospital, Vellore emphasised that in a poor country such as India, modern genetic tools are all the more necessary to prevent genetically transmitted diseases that are such a drain on familial economies. We also need recombinant therapies for the treatment of patients with haemophilia, deficiency of human growth factor, erythropoetin and thrombopoetin.

Such tools can only be provided by heavy investments and the state must take the lead in making such investments possible. It is also important to ensure that all recipients of such therapy pay, the rich subsidising the poor. He cautioned against providing free services. Such services are often viewed with suspicion. 'What is the hidden or ulterior motive of this person who is offering this free of cost?' He found tablets to correct iron deficiency anaemia, offered free to the poor, being thrown away.

If collaboration is necessary between Indian and foreign agencies, there must be a genuine transfer of technology into India with tangible benefits to Indian science and society. We also need collaboration between all the centres within India with genuine sharing of expertise, facilities and data. Such interactions can also help in the development of inter-laboratory quality controls. Transparency is essential for such exchanges.

Discussion on above papers

Dr. R. R. Kishore, Assistant Director-General, Ministry of Health showed that genetic screening had social and economic implications. The findings of such screening can violate confidentiality and impose a stigma. He felt it should be restricted to the identification of populations with high-risk of genetically transmitted diseases such as thalassaemia and sickle cell disease.

Professor M. G. K. Menon felt that we should be concentrating on serious genetically transmitted illnesses with grave impact on public health and the economy. It is also important to start with diseases where we have something to offer either by way of prevention or therapy.

Dr. Mammen Chandy cautioned that where genetic screening and other studies have the sanction of the state, the borderline between voluntary and mandatory screening might get blurred. The imposition of quotas to state employees have been known to breed compulsion that the poor cannot resist. To ensure sensitivity to ethics down the line, he suggested training programmes that would educate the entire research team from the top down on ethical principles. He also requested built-in monitoring of practices all along the line to ensure that ethical considerations are not flouted. This should form an essential component of research on research.

In his experience with families having children suffering genetically transmitted diseases, the demand for counselling services far outstrips their availability. He pleaded for the development of a cadre that will provide such services. Recruitment to this cadre may be made from those trained in medical social work. It will be necessary to impart training in genetics to these counsellors. Ideally, counsellors must hail from the same ethnic and cultural backgrounds as the populations being studied so that they blend with them.

He also told us of an interesting experience in Rajkot, Gujarat. Here, genetic information, far from providing a stigma, has led to constructive social action. A social group working on behalf of families with thalassaemia found out that Amitabh Bachan is a thalassaemia carrier. A statement from him to this effect was given wide publicity. Thalassaemia carriers now voiced confidence. 'I am like Amitabh Bachan.' As a consequence, Rajkot newspapers now carry advertisements for marriage stating that the applicant is a thalassaemia carrier, requesting a partner who is free from such a trait to ensure that the offspring do not suffer from this disease.

Given the extent of illiteracy, radio and television may prove more effective in disseminating information on genetics than printed texts. We must learn from the efficacy of advertising campaigns and use professionals to transmit our messages to the populace.

The group generally felt that gene therapy is not yet at a stage where it can be considered as a serious option in India.

Property rights

Dr. Sandy Thomas, University of Sussex at Brighton pointed out that this issue arose when countries decided to protect their indigenous material against exploitation by others. Currently, it is necessary to ensure that there is mutual benefit – to the country providing material and to the more advanced country analysing it and providing the means for its exploitation worldwide.

Whatever the debates, DNA sequences have already been patented by individuals and institutions in Japan and the USA. Most of these patents are concerned with the use of these sequences in therapy, a few being related to diagnosis.

For a country such as India to be able to compete in this field it will be necessary to establish legislation providing rapid, simple and inexpensive procedures for patenting and for making it easy for national organisations to file and obtain national and international patents. There is little doubt that the availability and respect for patents results in investment and stimulates the economy. The down side, of course, is that for those patents that are held abroad, you have to pay royalties.

Debating this issue, **Dr. Vandana Shiva, Dehra Doon** argued against the patenting of life forms. She also referred to eco-piracy of such substances as neem and turmeric. The entire system of patenting was intended to encourage and reward the individual researcher who would turn over his invention to the state for public benefit. This has now been subverted such that it is the giant corporations that reap the benefit after buying out the individual researcher at a relatively low cost. She also referred to 'hedging patents' used to block further research in that field. The topsy-turvy situation is best illustrated by the fact that in times past, the sequence was Science → Technology → Commercialisation whilst now it is in the reverse direction, commerce dictating what technology is to be developed and science merely being allowed to use that technology, at a cost.

Bioethics – education, awareness and dissemination

Dr. Darryl Macer. Eubios Institute, University of Tsukuba, Japan described his very informative survey of awareness of bioethics in high schools. (These have been described in detail in the publication: Macer Darryl RJ, Asada Yukiko, Tsuzuki Miho, Akiyama Shiro, Macer Nobuko Y: *Bioethics in high schools in Australia, Japan and New Zealand.* Ibaraki, Japan: Eubios Ethics Institute 1996. p 194) The

response to the carefully planned, detailed questionnaire lent strong support to the view that it was necessary to teach students – and their teachers – the ethical and social issues associated with science and technology. The researchers also concluded that no teaching discipline has a monopoly over the teaching of these issues. it was possible to include these topics in every subject from biology and science to economics, geography and history. An interesting finding was that some teachers taught bioethics even though they were not required to do so. The survey elicited a large number of requests for teaching materials in the form of fact sheets, videocassettes and CD-ROMs. it was easiest for the team to send photocopies of what was available on the Internet but they have, since, prepared and sent a host oiothcr material. An important lesson learnt was that bioethics could be used as a means to foster respect for life. Students asked why it was necessary for them to kiil animals to learn biology when videocassettes could help them reach the same goal.

Dr. **Asis Dutta, Vice-chancellor, Jawahariaf Nehru University** (JNU) described his own survey that showed ignorance of bioethics in undergraduates at his university. Whilst postgraduates in biology were aware of genetic research, a minority (33%) were conversant with the principles of bioethics. Postgraduates in branches other than science fared just a little better than undergraduates.

He concluded that there was a need for innovative courses on bioethics in our colleges. Designing a cunicuium for such a course may not bc easy but an interactive course with questions and answers might bear fruit. Courses should also be designed and conducted during teacher training courses as are conducted by the academic staff colleges, at the JNU and other universities.

Dr. N. **K. Ganguly, Postgraduate** Institute **of Medical Education and Research, Chandigarh** advocated incorporation of bioethics in all biotechnology courses, He also advocated incorporation of bioethics into courses on research methodology in all Ph.D. and M.D. programmes with compulsory examinations in this subject. He favoured the creation of regional teams of bioethicists who would tour institutions in their zones to preach bioethics. Such an approach had worked when they were trying to popularise oral re-hydration therapy.

Dr. Manju Sharma, Secretary, Department of Biotechnology, immediately volunteered to set up a training programme in ethics for biomedical researchers.

Dr. **Marcus Palatnik felt that** what was needed was 'a small amount of information and a large amount of formation'. Analytical skills were also important. He pointed out that education and morality are not always companions. 'Look for the person within the individual and help him become a good citizen.' In teaching bioethics, he advocated the use of the history of medicine to demonstrate past problems and the ethical means by which the masters solved them.

A national consultative committee?

During the various discussions, the suggestion was made that a national consultative committee bc formed in India to regulate and oversee all work on genetic rcscarch. Such a body could then draw up the necessary guidelines. This committee must consist of distinguished and experienced research scientists, medical doctors. nurses, representatives of industry, health administrators, theologians, lawyers, members drawn from the educational profession and persons from the media voicing public opinion.

Some important questions will have to be resolved: Who will appoint such a committee and fund it? To whom will such a committee report? How shall we cnsurc that this committee is armed with teeth?

Dr. David Shapiro, Nuffield Council, suggested that the committee be kept free from government for the machinery of government is machinery as machinery -- unthinking and unfeeling.

The Nuffield Council was formed in the United Kingdom to deal with issues arising out of biomedical research. Such bodies become necessary because society is not willing to entrust politicians to make decisions on ethical and social issues, or because politicians are unwilling to take on such responsibilities and because legislation always finds it difficult to keep pace with changes in science. It is up to such national consultative committees to cnsurc full public discussion ahead of legislation and produce well-considered guidelines. The Nuffield Council is intended, primarily, to serve the public though it serves scientists and the government as well.

The grand daddy of such committees ts, of course, the US Presidential Commission. In 1983, the French formed a committee with a difference – it produces reports only at the request of government. In Denmark, in addition to producing considered reports, the committee also produces excellent educational programmes, which are brought before the public with the help of the media. It also serves as a producer of consensus and feeds public opinion directly to policy makers.

It is advisable to form a separate working party for the preparation of each report. The Nuffield Council has one or two Council members, two scientists who are in the field and a lawyer on each working party.

"Once a report is produced, you need to stop it gathering dust." The committee must ensure that the report is brought to the notice of the public, legislators and policy makers. To a query on how guidelines help, hc pointed out that in Britain, if it is shown that a doctor acted within the guidelines laid down by an agency such as the General Medical Council or agencies such as the Nuffield Council, It is unlikely that any court w-ill find the doctor guilty of ncgligencc. "It is the business of the Secretariat of the Council to make a nuisance of itself by keeping the pressure on government and researchers to ensure that guidelines are followed."

Dr. Bryony Soper suggested that the committee should help government develop foresight on what is to come. She also saw a role in research into research to ensure that it is relevant and cost-effective. It should also ensure that research findings are transferred to clinical practice.

At times there will be a host ofauthoritative bodies and experts voicing opinions on a given subject (such as cloning an animal). The committee can sift the grain from the chaff and cnsurc that the community is adequately educated on the subject especially on aspects of public concern, so that meaningful debates, discussions and decision making could follow. Such debates must involve a wide range of professionals and wise public figures so that there is adequate understanding of the ethical and social implications.

Such a committee should also be able to fight commercial interests no! 'beneficial to society and ensure that there is no bad legislation.

Dr. Georges B. Kutukdjian, Director, Bioethics Unit, UNESCO discussed the social and human consequences of scientific discoveries and emphasised the need for national and international standard setting bodies to safeguard human rights.

Dr. **Mammen Chandy** emphasised that if such a committee is seen as a regulatory agency as well, it will be imperative for it to ensure that it undertakes its tasks responsibly and acts within time frames essential to effective functioning of laboratories in terms of service provided to patients and research programmes.

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