

Dr. Brigitte Jansen
Director, European Academy of Environment and Economy/Lueneburg
University

Abstract:

The legal debate about stem cell research in Europe

Introduction A discussion of the legal debate about stem cell research in Europe is interesting in one sense due to the differing positions of the constituent members in the European Union; at the same time this discussion can be understood as a contribution to the reflection as to whether a common legal framework might be expedient. The legal solutions related to embryonic research are not completely new. At the moment, scientific interest is focussed upon the use of in vitro embryos where, to a certain extent, the legal problems are quite fundamental. The primary legal question to be solved is the status of the in vitro human embryo for our society. What should be his/her ethical and juristic status and what values are embodied by the embryo? For example, is dignity a quality which can be ascribed to the embryo? This question cannot be answered but briefly here. However, through the comparison of different laws, indirect conclusions can be drawn as to how the social perception of in vitro embryos differs in certain relevant member nations of the European Union. At the same time, it is precisely in the sense of a clear legal analysis to show that up to the present, science has been engaged solely with promising research which has not yet lead to any therapeutic applications to human beings. This means that the effective treatment of a serious illness is currently not yet possible with embryonic stem cells. Thus, the current question of interest is consequently directed towards a legal judgement as to whether human embryos may be used as material for research and tests. Nonetheless, the current research situation should not be a barrier to setting the goal of developing legal perspectives for effective future treatment of humans. From this perspective, we should place as the middle of our reflections the analysis of the creation and use of human embryos as a source of therapeutic biological materials. Furthermore, it would make sense to discuss the connections which exist between the use of in vitro embryos for research and the legal right to abortion. In the European legal debate, a frequent topic has been the different biological situation of the embryo as compared to that of an implanted fetus and the differentiated interests which might be touched upon as a consequence.

Human Cloning and Embryonic Stem Cell Research

A View from Theravada Buddhist Morality*

Somparn Promta

Philosophy Department and Center for Buddhist Studies
Chulalongkorn University
Bangkok, Thailand

I

When the issue of human cloning and stem cell research has been raised to public discussion, people have responded to the issue in various ways. We can group the views of the people into two parts. The first is what I would like to call the *empirical* view and the second the *non-empirical* one. The empirical view is the view that based on the empirical survey or observation of the opinions of people in community. This view represents the variety of the opinions of the people and ultimately the majority's view is preferred. The non-empirical view refers to the view that is not gained from the survey of public opinions, but from authorities in society such as religious texts, religious thinkers, or philosophers. It could be possible that the non-empirical view does not accord with the empirical view of the public. However, public opinions concerning moral issues are normally related to community's shared morality and culture. In some community where the authority in religion has strong influence over the belief of people, a conflict between empirical public view and non-empirical view of authority seems to be hardly found. What we have said, however, has an exception as sometimes we would find that philosophers say another things that differ from what is said by lay people in the community. In Buddhist communities like Thailand philosophers who play a notable role in moral debates are mostly Buddhist, so it is not much found that there is a conflict between the view of Thai (Buddhist) philosophers and the view of the lay people.

In Theravada Buddhist culture, the authority of the texts is placed on the highest position among things comprising the body of Buddhist ethics. This follows the last words of the Buddha shortly before his passing away that: "The doctrine (*dhamma*) that I have taught and the discipline (*vinaya*) that I have stipulated shall be your master after my passing away."¹ Following the Buddha's sayings, the Buddhist texts namely the Pali Tipitaka (the collection of Buddha's teachings written in the Pali language) are respected as the main source of Buddhist morality. However, the Buddhist community has some remarkable characteristics that even though the religious authority namely the Saṅgha (the Buddhist church) is understood to play the leading role in moral decision, the moral power of the church is not absolute in the sense that the belief of the church never dominates the activities run by the state. What the Buddhist church has done during the long history of Buddhism is to give moral *advice*, not moral domination. There are some domains of the state's activities and policies which are known that the Buddhist morality should skip over.

For example, intoxicants are prohibited by the last clause of the *Five Precepts* of Buddhism, but the sale of intoxicants in Buddhist communities such as Thailand is permitted by law. In my previous research concerning Theravada Buddhist view on

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¹ *Dhigānikāya*, 10/141. The Pali Tipitaka used in this paper is the *Syamrattha* Version containing 45 volumes. The first number refers to the volume, the last number refers to the passage.

the relation between morality and law,² I have found that In Theravada Buddhist culture we distinguish between *personal morality* and *social morality*. Personal morality is the system of self cultivation to liberate ourselves from all defilement. *Nibbana* is the final goal of life. Any attempts leading to *Nibbana* are counted as part of this personal morality. The ethics of Buddhism in its early times belonged to this personal moral fulfillment. The Buddhist church led by the Buddha himself considers ethical problems in human life in terms of personal matters. The Buddha says: "Buddhas are merely the way-teller, to walk along the way is solely your responsibility."³ Following this understanding of the nature of Buddhist ethics, the Buddhist church could accept some immoral phenomena if they are supported by reasonable necessities such as social benefits or the well-being of the greatest number of people in community. At this point, we will find that Buddhist ethics in its starting form at the time of the Buddha was not intended to play the role as social ethics.⁴ However, when Buddhism was adopted by different countries other than ancient India Buddhism continued to transform itself to be social institution playing the role as the source of culture and tradition of the country. Buddhism in the institution form began to play a role in another dimension. That is, it started to present the social ethics in which the advice how to formulate the ideal community according to Buddhism is found.

The social ethics of Buddhism is notable in that it never stipulates the fix rules to dominate society. I have analyzed somewhere that the social ethics of Buddhism contains two basic principles. The first is called by me the *Harm Principle* and the second the *Critical Principle*.⁵ The Buddhist harm principle, seemingly very close to Mill's harm principle, states that the sufficient ground to prohibit personal freedom is that it harms other people in society. This rule considers every harmful action to be immoral action. No any action can be harmful but moral. However, it is evident that there are some personal actions considered to be immoral according to Buddhist morality, but these actions do not harm any persons in society. It is only he or she who commits that action to be affected. How does Buddhist social ethics deal with such actions. As said above, the Buddhist culture does not prefers the domination of personal freedom in the name of the church, taking intoxicants is wrong viewed from Buddhist Precepts but Buddhist communities never prohibit the sale of intoxicants on the ground that it is personal freedom to do such a thing as far as it does not affect other persons in society. This does not mean that Buddhist social ethics tolerates all kinds of personal immorality. The Buddhist Critical Principle states that there are two kinds of personal actions the state has the right to prohibit even though those actions could be considered not harmful to other people. The first is the action that leads to serious physical damage. Under this rule, the sale of personal organs cannot be permitted even though the owner has the full consent *if* we interpret that this causes a serious physical damage to the person who commits it. The second is the action that leads to critical spiritual damage. Under this rule, voluntary prostitution cannot be permitted *if* we have strong evidences to judge that the person who enters prostitution will lose some important human values such as a value not to be treated as animal. It could be also said that under this second rule slavery cannot be permitted *if* we have strong reasons to believe that even voluntary slavery is seriously immoral as it dehumanizes the slave, notwithstanding the slave is well fed by the master.

II

² Somparn Promta, "Law and Morality : The Buddhist Perspective," *The Chulalongkorn Journal of Buddhist Studies* 5 (May-December, 1998), pp. 3-57.

³ *Khuddakanikaya*, 25/30.

⁴ "Social ethics" here means the ethics that tries to solve moral problem in terms of the stipulation of social rules. These rules possibly lead to a legal determination at the end.

⁵ Somparn Promta, "Law and Morality : The Buddhist Perspective," *Ibid.*, pp. 47-50.

Human cloning and embryonic stem cell research are involved with the interpretation of human life and its value. Normally, theistic religion seems to have more explicit religious grounds to point out that how the human possesses the values worth respecting for any persons who are involved in the research on human being. God is the source of human dignity in theistic religion. Buddhism, as atheistic religion, is based on another grounds in moral reasoning. The Buddha says that what he teaches are natural phenomena. The *dhamma*, which refers to the teaching of the Buddha, is understood by Buddhists as natural things and natural laws. For non-Buddhists, the best way to understand the Buddhist teaching is to understand it like understand the natural sciences such as physics, chemistry, or biology. Buddhism teaches that the universe is naturally given, and the Buddha himself clearly declares that he is not interested to explore its origin and the end. The great enlightenment brings him the insight that the universe is regulated by the five kinds of natural laws (*niyama*) namely the physical law (*utuniyama*), the biological law (*bijaniyama*), the law of action (*kammaniyama*), the law of mind (*cittaniyama*), and the law of dhamma (*dhammaniyama*). The Buddhist morality is based on the belief in these natural laws. Goodness and badness in human actions are not based on God's judgment, but on the laws of nature.

It is interesting that Buddhist ethics does not use the concept of being natural to determine moral phenomena. For example, one of the major arguments against human cloning is that it is unnatural. One who argues like this states that what appears in the world is natural, meaning further that it is prepared by God. Sexual reproduction is natural in this sense and thus it is prepared by God. Human cloning is an attempt to produce a human being through unnatural way, thus it is against the work of God. In this line of argument, we will find that a concept of being moral is equated to a concept of being natural. On the contrary, a concept of being immoral is equated to a concept of being unnatural. Some scientist tries to respond to this argument by showing that human cloning is natural as it has been permitted by nature already in the case of identical twins. Buddhism considers ethical phenomena independently from the concept of being natural because according to Buddhist teaching there seems to be impossible to say that such and such phenomenon is unnatural.

In Buddhist texts, for example, reproductive methods other than the sexual one as we are acquainted with are mentioned. For us who never see those things, they could be counted unnatural. But they are natural in the sense that they are permitted to appear in the universe through any law of the five natural laws mentioned above. So Buddhist ethics does not considered the issue of human cloning through the concept of being natural. In general, Buddhism admits that whatever happening in the world is natural. It does not matter that it appears by human technology or not. Natural things in Buddhist perspective include both what is given by nature and what is created by human being.

The fact that Buddhist ethics does not utilize the concept of being natural makes it is more hard for Buddhism to deal with modern bioethical problems. But this could be also considered as a strong point in Buddhist ethics as it provides more space for the debate. That is, sometime we could find that to point out that such a thing is immoral because it is created by human being is seemingly irrational. The world today has greatly benefited from "unnatural" products of science and technology. It seems that the very difference between Buddhist ethics and theistic religious ethics is that Buddhism holds the humanistic attitude while theistic religious ethics does not. For theistic religion, human beings are just like a new born baby of the universe, while God is the father who knows everything. The attempts to reveal the secret facts hidden behind natural things by the scientist is considered not different from an action of the innocent baby to put the fingers into the unknown holes at the walls of the room. Inside some holes there could be some dangerous things, we cannot know. For the sake of safety, what we should do is not to go beyond what already prepared by God as found in nature. Human cloning is questionable forever in terms of safety regardless of the data gained from scientific

research because there could be unsafety inside it because it is not prepared by God. Buddhism partly agrees with such a warning. However, the best way to decide whether such a thing contains danger or not is to undertake experiments. Buddhism supports the attempts to find new knowledge as far as they are run on wisdom. Wisdom in Buddhist teaching is a process of learning through doing, not imagination or speculation. The enlightenment of the Buddha is not a state of mind gained independently from a process of long-term learning. In short, wisdom in Buddhist teaching is a *practical* term.

III

Before going further, let me remind you of the two systems of morality which are a personal morality and a social morality. In discussing moral issues, sometimes we do not distinguish between them and it makes us confused.

Consider this example. It is very clear that abortion is wrong according to Buddhist ethics. But to say that abortion is a sin in Buddhist perspective could be misleading as sometimes people understand that this means that abortion must be illegal in Buddhist society. Saying that abortion is a sin is saying within a personal mode of morality. That is, abortion is equated to killing a human being, so committing an abortion violates the first clause of the Five Precepts. The Buddha says that to attain *Nibbana*, one should avoid unwholesome actions. Abortion is an unwholesome action, meaning that committing it will lead to the opposite way to *Nibbana*. Following the advice of the Buddha, a Buddhist who is confronted with a dilemma concerning abortion should consider by herself how to handle the problem. The Buddha never claims that a woman confronting such a dilemma must not commit abortion. He just says that a woman should consider by herself what is the best thing within such a condition. Suppose finally she finds that the best way is committing an abortion, Buddhist ethics has nothing to say. It is her choice and her responsibility. However, Buddhist ethics still continues to claim that as abortion is the killing of a human being, the woman who decides to choose abortion must be responsible for the choice in terms of the *kamma*. It is a bad *kamma*, and its result is already determined by the law of *kamma*.

What said above is a consideration of abortion in terms of personal morality. As there is a child playing a role as a victim of killing, so abortion cannot be solely considered within personal morality. The Buddhist Harm Principle as stated previously should be brought to deal with the issue. It is so evident that abortion is very harmful to a child, even in his/her very early stages of development. So the state as the authoritative power between people whose one basic function is to provide justice for the people involved in a conflict of interest has the right to prohibit abortion *if* it is interpreted that between a mother and a child the right to life of the child is more weighty to protect.

It is so clear that the Buddhist personal ethics is based on the law of *kamma* taught by the Buddha. To judge a given moral situation is wrong or not according to the personal ethics is not difficult. Human cloning according to the personal ethics is not immoral action as far as it is done for the reproductive purpose. Buddhism has a moral criterion saying that what conduces to the harm and suffering of oneself and other is unwholesome. On the contrary, what conduces to benefit and happiness of oneself and other is wholesome. Destroying life or prohibiting birth can be considered as harmful, while prolonging life or giving birth is beneficial. Reproductive cloning is judged not immoral in this sense. On the contrary, stem cell research could be interpreted as harmful as the embryo is destroyed. What I have said above does not imply that according to the Buddhist personal ethics reproductive human cloning is right and stem cell research is wrong. What I have said just means that we can interpret the issues in which directions.

On the contrary, in the Buddhist social ethics stem cell research could be considered differently from what we have seen in the Buddhist personal ethics. In reliable reproductive cloning no one is harmed, so it is not against both personal and social moralities of Buddhism. It is only therapeutic cloning, the cloning for medical use in which the clone (including the clone generated solely from a woman's egg) is

destroyed, that could be *problematic*. However, therapeutic cloning and embryonic stem cell research are problematic not in terms of what explicitly immoral, but in terms of what needs more strong justifications to show that it should be permitted by society's law. Previously we have referred to the concept of benefit (*hita* in Pali) and happiness (*sukha* in Pali) as one of the criteria comprising the body of Buddhist ethics, both personal and social. It could be asked that when we talking about benefit and happiness we mean *whose*.

Modern ethical dilemmas are usually concerned with the conflict of interest between two persons or two groups of persons. In the issue of abortion, who are involved are a mother and a child. The mother's interest is protected if an abortion is permitted, while the child's interest is protected if an abortion is prohibited. Likewise, in therapeutic human cloning and embryonic stem cell research, there are two persons or two groups of persons involved. Talking in terms of right, the right to health of the patient is protected if therapeutic cloning and stem cell research are allowed. But in doing so, the right to life of the clone or the embryo is violated. The hard task to be undertaken by any ethical school or ethical theory including Buddhist ethics is to give reasonable arguments that between the two sides in the conflict of right or interest, whose right or interest should be protected and on what grounds. At this point, we will find that the ethics that is at the heart of the issue is the social ethics, and social ethical dilemmas are more difficult to solve comparing with personal ethical dilemmas because in personal ethics a person only is involved. The conflict inside one's life is more easy to find a solution. When a man is deciding whether or not he should clone himself to have a clone for medical healing, the principles of wholesome and unwholesome deeds given by Buddhism seem enough to give him a solution. Religious ethics normally endorses the altruistic way in moral decision. So, the devout Buddhists are those who prefer not to clone themselves for the reason that death is not dreadful comparing with committing a sin in cloning the embryo for medical use. But when the society looking at that issue and trying to judge that suppose some members of the society claim that they have the right over their body implying that they have the right to clone themselves for medical use, finding the solution is not easy. Whose rights should be protected between the patient and the clone. Between the benefit of the greater number of people and the violation of the embryo's rights, which should be chosen. How does the Buddhist social ethics deal with such a dilemma, it seems not easy to answer even for those who are well-versed in Buddhist doctrines.

IV

The spirit of Buddhism is not-harming (*avihimsa*). The problem is that: is there some kind of the harm allowable in Buddhist community, or any kind of the harm is strictly prohibited. In utilitarianism, it seems that there is some kind of the harm permitted. That is, for the benefit of the greater number of people the violation of the right of the minority could be possible. But the violation of rights mentioned in such a case is understood in terms of the right to property, not the right to life. The state's policy in any country in the world is more or less utilitarian. The express ways in Bangkok are obtained from the harm to the people whose lands are chosen by the state to be the ways. But for the benefit of the majority, this kind of harm can be accepted. It should be noted that this kind of harm can be compensated by the state because it is an *economic* harm. On the contrary, the harm to life seems to be immoral in every aspect because it is the harm that we cannot compensate. Therapeutic human cloning and the use of embryonic stem cell could be considered in terms of the harm to life of the embryo. The serious question then arises: can we accept the harm to life of the embryo for the benefit of us or not.

According to Buddhist teaching, we distinguish between *life* and *property*. The right to former is considered as the primary right while the right to the latter is the secondary one. The great difference between the primary right and the secondary right is that the primary right can never be transferred, while the second right can be. In the Buddhist texts, it is recorded that voluntary euthanasia causes the violation of

one of the four rules of defeat for the monk who commits it. That is, in Buddhist monastic rules, a monk violates the four rules of defeat if he commits sexual intercourse, robbery, human killing, and claim for not existing higher goodness. Killing a human being at his or her request with compassionate mind is wrong on the grounds that the right to life cannot be transferred. Suicide is found in the Buddhist texts and in some case it could be interpreted that there is no guilty for a monk who commits suicide.⁶ The difference between suicide and euthanasia according to Buddhist teaching is that in committing suicide a person is not violating the right to life because he is the owner of that right, while a person who commits euthanasia at the request of somebody is violating that right. The request cannot justify euthanasia because the right to life can never be transferred. The owner of the right only can use it.

Applying what we have considered above to the embryo, it could be the case that the embryo, as a person—Buddhism believes that at the moment of conception “that thing” is human, must be accepted as the owner of the right to life. There are many sources in the Buddhist texts pointing out that killing the embryo is not different from killing the adult. So, the use of embryonic stem cell even for curing disease of the patient, according to Buddhism, is not different from the use of the life of one adult to cure the life of one another adult. If what we have said about the use of adult life for the benefit of another adult cannot be accepted, the question is : on what grounds the use of the embryo can be justified.

As the Buddhist view on any subject is not absolute in the sense that what the Buddha teaches is not the dogma to be accepted unconditionally, the view of Buddhism about the right to life as said above could be discussed further. Actually, the use of one’s life for the benefit of another can be found in the world including a Buddhist country like Thailand. We have the soldier acting as the guard of the country. The death of a soldier for his country means what. It means we accept that in some case the use of one’s life for the benefit of the country or the majority of people in the country is necessary. In Buddhist literature, a life donation is sometimes found. A *Bodhisatta* (a person in the process of accumulation of merits to be a Buddha in the future) sometimes donates his life for the benefit of another and such doing is counted goodness.⁷ This seems to imply that the right to life in some case can be transferred.

By distinguishing between life donation and euthanasia, it could be possible to find the way Buddhism thinks of the issue. What is the difference between these two issues. In a donation of life, the donor is fully aware and understands that what merit will occur by doing that. In euthanasia, a man who requests for the death is understood by Buddhism as acting so from unwholesome impulse, and a man who commits euthanasia is understood as doing so unauthorized. That is, no one can take other’s life without violating the right to life regardless of conditions. But the case will change if the owner of life donates it. The issue of therapeutic human cloning and embryonic stem cell research, if could be justified, seems to be justified within the category of life donation.

I am not in the position to judge that actually the issue of therapeutic human cloning and the use of embryonic stem cell can be looked at as a donation of life. I just present that we seem to have the most reasonable way to look at the issue in this category. Taking one’s life for the benefit of another is not necessarily evil in Buddhist perspective. At least, there is some aspect of the taking of life permissible in Buddhist doctrine. However, donation is a concept in personal ethics. Donation must come from consent and wisdom. We do not know the embryo is willing or not. This is the most difficult problem to overcome. Maybe the “*enforced donation*” could be the way out from this difficulty. Enforced donation is self contradictory in the Buddhist personal ethics, but it could be possible in the social ethics of Buddhism. In Buddhist Thailand, a girl being raped and getting pregnant has the right to abort the child. The

⁶ *Majjhimanikaya*, 14/741.

⁷ *Khuddakanikaya*, 27/565.

child in this case can be understood in terms of the “enforced donor” of his life. For what. For the benefit of the mother. Why we think the mother deserves such protection. The answer is : because not giving the right to her to do so is *socially* immoral. If we can prove that in some case not giving the right to a person to be benefited from therapeutic human cloning or the use of embryonic stem cell is socially immoral, it means that we have found the way to justify the issue.

Human Genetics Research in Vietnam and Ethical Aspects

Prof.Dr. Le Dinh Luong
Vietnam National University

This presentation is aiming at providing a very general picture on current human genetics research in Vietnam and ethical issues coming from that. To do this, author of the paper will briefly consider the key topics, such as: human genetics research in national program, the institutions involved in it, 2003 year publications as examples of the research activity, practical applications of human molecular techniques, BioArchive system in Vietnam, relevant bioethical issues and some specific bioethical topics to Vietnam.

Human Genetics Research in National Research Programs

In Vietnam, there are several levels of research programs: national, ministerial and institutional. National research programs are of the highest level and most financed. In average, each project in this program gets a budget of two dozens of thousands USD per year. In total, the whole program includes 10-20 projects, depending on the priority of the field. Below are the human genetics research projects in the national research program on biotechnology for 2001-2005.

1. *Sequencing of mitochondrial DNA of different Vietnamese ethnic groups and directed applications.*
2. *Application of molecular techniques for diagnosis of human genetic diseases in Vietnam.*
3. *Application of molecular techniques for human pedigree determination and for forensics in Vietnam.*
4. *Animal stem cell research for genetic engineering.*

Besides the projects in national research program, there are hundreds human genetics research topics on ministerial and institutional levels.

The Main Institutions Involved in Human Genetics Research

In the period 2001-2005 there are 11 major institutions involved in human genetics research in national research program, which are listed below.

1. *Institute of Biotechnology, NCST, Hanoi*
2. *Nat. Institute of Malariology, Parasitology and Entomology*
3. *Institute of Oncology, Hanoi*
4. *University of Natural Sciences, VNU, HCM*
5. *Hanoi Medical University*
6. *National Institute of Pediatrics, Hanoi*
7. *Center of Biotechnology, VNU, Hanoi*
8. *Pasteur Institute, HCM City*
9. *University of Natural Sciences, VNU, Hanoi*
10. *Biochemical Technology Dept, Ministry of Public Security*
11. *Forensic Science Institute, Ministry of Public Security*

A part from those institutions, mentioned above, there are dozens minor units, such as local hospitals, provincial medical colleges, which are doing smaller research on human genetics.

2003 Year Publications on Human Genetics Research

The 2003 year publications, which are listed below, were taken from the annual scientific conference in July 2003. In this list, there are 12 publications on the research of human genetics. All publications can be divided into two types. The first type is molecular detection of mutations causing diseases in different ethnic groups in Vietnam. And the second type is application of molecular techniques for individual identification and also for determination of allelic frequencies of polymorphic loci in Vietnamese populations, which could be used later for practical applications.

1. *The Polymorphism of HLA-DRB1, -DBB1 And G6PD Deficiency of Muong Ethnic In Hoa Binh – Vietnam. Vu Trieu An at al. Hanoi University of Medicine*
2. *Screening 3 Case Mutated Dystrophin Gene In Total 11 Vietnamese Duchene And Becker Muscular Dystrophy. Nguyen Duc Bach at al. Inst. of Biotechnology, NCST, Masafumi Matsuo Kobe University Graduate School of Medicine, Japan*
3. *Molecular Study on Breast Cancer of Vietnamese Patients Using Mitochondrial D-loop as Markers. Nguyen Thanh Dam at al. Institute of Oncology*
4. *Establishment of Ames Test And Application In Detection of Carcinogen, Mutagen. Huynh Ngoc Vi Ca at al. University of Natural Sciences, VNU, HCM*
5. *Detecting G6PD Deficiency And Analyzing Variants of DNA Mutation of Some Individuals with G6PD Deficiency from Kinh, Muong, Racle, Tay, Katu Ethnic Groups Living in Hanoi, Hoa Binh, Hue and Khanh Hoa Provinces. Nguyen Thi Ngoc Dao at al. Institute of Biotechnology, Kaoru Nishiyama Kobe University School of Medicine, Japan*
6. *Determination of D13S317 Allele Frequencies In A Group of Vietnamese. Nghiem Xuan Dung. Biochemistry Technology Department*
7. *Identification of Remains by mtDNA Analysis. Le Quang Huan at al. Institute of Biotechnology, NCST*
8. *Designing Expression Vector for a Gene Coding Antigen CD25 Specific for Blood Cancer. La Thi Huyen at al. Institute of Biotechnology*
9. *DNA Fingerprinting in Vietnamese Populations by Sex Chromosome Located Loci. Le Dinh Luong, at al. Center of Biotechnology, VNU, Hanoi*

10. *Primary Determination of Allele Frequencies of CSF1PO Locus in Vietnamese Populations.* Ngo Tien Quy at al. Institute of Forensics
11. *Using PCR Multiplex for Forensic Analysis and Paternity Determination by Some Single Locus STR Primers.* Trinh Tuan Toan. Forensic Science Institute
12. *Detection of the 30bp Deleted Mutation in C-Terminus of LMP1 Gene from Vietnamese Nasopharyngeal Carcinoma.* Nguyen Van Do at al. Hanoi Medical University.

Applications of Human Molecular Genetics

Some results of the above-mentioned research as well as routine molecular techniques worldwide now are applied to the service areas as listed below:

1. Genetic Testing
2. Diagnosis of Genetic Diseases
3. Genetic Counseling
4. Forensics
5. Courts

The genetic testing has been carried out in Vietnam since 1990 and now became routine in four institutions for meeting the demand of forensics and courts.

As far as medical diagnosis is concerned, nowadays 28 diseases, which are listed below, are diagnosed worldwide:

1. *Alpha-1-antitrypsin deficiency (AAT; emphysema and liver disease)*
2. *Amyotrophic lateral sclerosis (ALS; Lou Geri's disease; progressive motor function loss leading to paralysis and death)*
3. *Alzheimer's disease* (APOE; late-onset variety of senile dementia)*
4. *Ataxia telangiectasia (AT; progressive brain disorder resulting in loss of muscle control and cancers)*
5. *Gaucher disease (GD; enlarged liver and spleen, bone degeneration)*
6. *Inherited breast and ovarian cancer (BRCA 1 and 2; early-onset tumors of breasts and ovaries)*
7. *Hereditary nonpolyposis colon cancer (CA; early-onset tumors of colon and sometimes other organs)*
8. *Charcot-Marie-Tooth (CMT; loss of feeling in ends of limbs)*
9. *Congenital adrenal hyperplasia (CAH; hormone deficiency; ambiguous genitalia and male pseudohermaphroditism)*
10. *Cystic fibrosis (CF; disease of lung and pancreas resulting in thick mucous accumulations and chronic infections)*
11. *Duchene muscular dystrophy/Becker muscular dystrophy (DMD; severe to mild muscle wasting, deterioration, weakness)*
12. *Dystonia (DYT; muscle rigidity, repetitive twisting movements)*
13. *Fanconi anemia, group C (FA; anemia, leukemia, skeletal deformities)*
14. *Factor V-Leiden (FVL; blood-clotting disorder)*
15. *Fragile X syndrome (FRAX; leading cause of inherited mental retardation)*
16. *Hemophilia A and B (HEMA and HEMB; bleeding disorders)*
17. *Hereditary Hemochromatosis (HFE; excess iron storage disorder)*
18. *Huntington's disease (HD; usually midlife onset; progressive, lethal, degenerative neurological disease)*

19. *Myotonic dystrophy (MD; progressive muscle weakness; most common form of adult muscular dystrophy)*
20. *Neurofibromatosis type 1 (NF1; multiple benign nervous system tumors that can be disfiguring; cancers)*
21. *Phenylketonuria (PKU; progressive mental retardation due to missing enzyme; correctable by diet)*
22. *Adult Polycystic Kidney Disease (APKD; kidney failure and liver disease)*
23. *Prader Willi/Angelman syndromes (PW/A; decreased motor skills, cognitive impairment, early death)*
24. *Sickle cell disease (SS; blood cell disorder; chronic pain and infections)*
25. *Spinocerebellar ataxia, type 1 (SCA1; involuntary muscle movements, reflex disorders, explosive speech)*
26. *Spinal muscular atrophy (SMA; severe, usually lethal progressive muscle-wasting disorder in children)*
27. *Thalasseмии (THAL; anemias - reduced red blood cell levels)*
28. *Tay-Sachs Disease (TS; fatal neurological disease of early childhood; seizures, paralysis) [3/99]*

At present in Vietnam we are carrying out diagnosis for only three genetic diseases, namely hemophilia, Duchene muscular dystrophy and beta-thalassemia, and only in the framework of some research programs.

BioArchive System in Vietnam

In June 2000, the Thermogenesis Corporation sold a BioArchive System to the Blood Transfusion & Haematology Center in Ho Chi Minh City for about US\$ 200,000. The system can be used by major Cord Blood Banks. The BioArchive System is the international standard for collecting, processing, and archiving cryo-preserved hematopoietic stem cells sourced from placental/ cord blood. With this acquisition, Vietnam is adopting the same state-of-the-art stem cell technology as the major industrialized nations.

In August 2003 with this facility the abovementioned center has successfully done marrow transplantation for a patient.

Bioethical Issues

Bioethics awareness in Vietnam came from outside, mainly through media (radio-broadcasting, television programs, internet and newspapers), and through international conferences organized either abroad, like this workshop, or in Vietnam. There were also national workshops or training courses on bioethics, but not regularly, and mostly organized as joint effort with overseas experts. Bioethics understanding is limited. At the moment, there is no regular curriculum in schools and higher educational institutions.

In human genetics research and service, including genetic testing, diagnosis of genetic diseases, and genetic counseling, some questions arise:

Firstly, for genetic testing, 1) Is genetic testing regulated? 2) Does insurance cover genetic testing? 3) Prenatal testing is a modern eugenics or not? The answer for the first question is, at the moment, “no”. The second one is also “no”. For the third question, the answer is not simple, depending on concrete case. For example, if the case concerning the sex, the answer would be “no”. But if the case is concerning some genetic diseases, the answer from our point, may be “yes”. So prenatal testing in the case for genetic diseases, the answer may be “yes”.

For the second area, the diagnosis of genetic diseases, also some questions may arise: 1) Are patients being properly informed about the risks and limitations of genetic technology? The answer is “no”, at least at the moment because if the answer is “yes”, the patient cannot understand as he/she is not educated enough. From our point of view, there is a limitation of genetic technology, but not so much. 2) How does personal genetic information affect an individual, and society’s perceptions of that individual? 3) Who owns and controls genetic information? Certainly, one should keep genetic information personal and create a registration system, which would be effective enough to allow individuals to keep their genetic information personal. The next item is using human materials for genetic disease detection, sex diagnoses, and paternity determination. So for these items, there are not official regulations yet at the moment.

To regulate some bioethical aspects, Vietnam government issued a decree on 15th February 2003. This decree is very general, namely Governmental Decree on Population Policies. However, there are some concrete articles in the decree, which are rather specific, for example, an article bans completely human cloning for reproduction, but human cloning for therapeutic goal can be considered for each concrete case. The decree also bans surrogacy and all means of choosing the sex of embryos, but animal cloning is acceptable. At the moment research topics for cow cloning is included in the national research program. The decree allows the application of reproductive technology such as in vitro fertilization and foreigners can use assisted reproductive technology services in Vietnam, but they are banned from donating or receiving eggs, sperm and embryos.

As far as assisted reproduction is concerned, several cases of successful human reproduction *in vitro* were reported. Regarding the sex preference, nowadays in Vietnam there is a boy-biased

psychology. But free abortion has not had a negative impact on the sex ratio, because Vietnamese may have two children in the family, according to the regulations, which has been effective for many decades.

Specific Bioethical Topics to Vietnam

- 1- Vietnam should improve public understanding of bioethics in several ways: a) Introduction of regular bioethical courses into secondary and high schools; b) Organizing international and regional training courses; c) Establishment of a bioethics society; and d) Setting up regular programs in media.
- 2- Like some other countries, Vietnam should improve the public knowledge on modern biotechnology as many problems we are face now in bioethics are coming from the gap between traditional cultures and modern knowledge of sciences. So, one of the goals, we should aim at, is to narrow the gap.
- 3- One should facilitate individual right to keep personal her/his own genetic information. To do this, Vietnam should set up a legislation and appropriate health care system.

ASEAN-EU LEMLIFE Project

Chulalongkorn University

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Intellectual Property Rights

Prof. Carlos María Romeo-Casabona, LLD, MD⁸

1. Introduction

The classic **requirements for the patentability** are the following:

They must be new (an object, procedure or technique, before non-existent: originality), they must really be an invention, that is to say, an inventive advance with regard to the previous situation (not obvious or evident) and at last, they must have industrial application or practical application (practical use, against a mere esthetic or intellectual merit). According to the European Convention on Patents of 1973, in its article 52.1: "The European patents will be granted to any invention susceptible of industrial application, being new and implying an inventive step".

⁸ Director, Inter-University Chair BBVA Foundation – Provincial Government of Biscay in Law and the Human Genome, University of Deusto and University of The Basque Country, Bilbao (Spain). E-mail: cromeo@genomelaw.deusto.es

The patentability also brings out that the subject of the invention can be reproduced or repeated by a third-an average expert - using the documentation presented by who claims the patent.

The important European Directive on the “legal protection of the biotechnological inventions” (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 (OJ EC of 30 July 1998)) will have to be considered by the Member States bringing into force laws, regulations and administrative provisions necessary to comply with this Directive, what has already happened in many States. On the other hand, the European Convention on the Patent of 1973 has also been revised in 1999 to adapt it to the new legal framework settled down by the Directive.

The new European regulation has given a general answer to the numerous conjectures that this matter rises: that the biotechnologies will be legally protected, in a main or exclusive way, through the patent. Any other artificial solution different than the patent has been rejected, settling down the relevant aspects that differentiate a discovery from an invention. As it has been checked, this was one of the most controversial points on the favourable or contrary arguments to the patent.

On the other hand, in the Preamble it is proclaimed that it is not sought to substitute the existent national general framework on patents, but rather “the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions”. (“Whereas” clause n. 8). However, there has been a lot of interest in remarking that it should be demonstrated, anytime that the presumed novelty or biotechnological innovation fulfils each and every one of the traditional requirements of the patent. And, concretely, the Preamble and the articles of the Directive insist that the applicant must demonstrate convincingly the industrial application of the biotechnological product. That is to say, their utility should be fully defined and clearly exposed, although it is certain that the Directive makes more flexible the understanding of the other two requirements of the patent (new inventions and not obvious) when it deals with Biotechnology.

Another concern of the authors of the Directive (the Parliament and the Council) is to make as clear as possible what can be patentable or not on biotechnological matter, mainly in connection with human biological elements or when the human body is somehow involved; but also when animals or vegetables are affected.

This reiterated concern in the conceptual clarity explains that, the Preamble has 56 “whereas clauses”, while the articles are only 18. That is to say, it has worried more to clarify what it is sought to regulate and with what sense than the regulation itself.

In summary, which is the new European normative framework that the Directive on the protection of biotechnological inventions establishes? Explicitly it appeals to the national law on patents, notwithstanding the necessary adaptations to take account of the provisions of this Directive (art. 1°). Consequently, according to this prescription, the adequate legal framework for the protection of the biotechnological inventions is the law of patents.

The Directive declares, as a general principle, that the product consisting of or containing biological material are patentable or also, the process by means of which biological materials is produced, processed or used; as long as they comply with the traditional requirements of the patent: new inventions which involve an inventive step and which are susceptible of industrial application. (article 3.1)

Consequently, biological material which is isolated from its natural environment is patentable, or also if it is produced by means of a technical procedure, even if it previously occurs in nature (art.3. 2).

The nuclear approach of this Directive, regarding the patentability of human genes or parts of them, is based on this precept, just mentioned; because such a possibility is admitted under the above- mentioned conditions. This does not prevent the Directive from clarify it even more specifically, as we will confirm next.

2. The specific framework on elements of the human body

Regarding the human biological material, it points out expressly that they will be able to be considered as patentable invention. “An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.” (art. 5.2). In any case, it insists that “the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”(art. 5.3).

On the contrary, “the human body, at its various stages of formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions”(art. 5.1).

As for the exposed patentability conditions, there is still a debate on whether the sequence of a gene or part of it, isolated in a laboratory or obtained by other technical process, really constitutes an inventive activity. Indeed, it is pointed out that a gene or a functional fraction of DNA can be identified with a chemical molecule. But an essential difference remains: what really interests of that molecule is the genetic information of which is carrier, and not its basis itself. If the structure of this information “is identical to the one of a natural element, we have a discovery, not an invention”. Consequently, against the approach of the Directive, according to the contrary opinion, the reproduction by means of a technique procedure or the isolation of that information would not constitute an inventive activity, what is an essential requirement for recognising the patent. Without prejudice that the technique procedure for the reproduction or isolation of the element of the human body may constitute an inventive step.

3. Provisions on other biological materials

The object of the directive is not limited to the biological components of human origin. So, inventions concerning plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety (article 4.2), according to the juridical tradition in this matter.

In accordance with the Directive, microbiological or other technical processes, or a product obtained by means of such a process, are also patentable. (article 4.3) This is not a novelty either because it was allowed before. Nevertheless, this recognition is just an exception to the exclusion of the patent of the essentially biological procedures for obtaining plants or animals. (article 4.1b) The explanation of this normative lies in that, once the micro-organism has been produced, it is capable of natural, fast and abundant self-reproduction or self-multiplication.

Another issue gave place to concern, in this case of the breeders. It was the risk of becoming dependent of the big companies of seeds and livestock improved by genetic procedures. So that, for each new sowing or reproductive period they would have to acquire the corresponding products onerously (e.g., seeds or breeding animals) or to pay a canon or any other kind of payment to these companies, with the corresponding price increase of their agricultural exploitations. This fear has been wanted to solve with the so-called "breeder's privilege". According to this privilege, the farmer will be able to use the product of his harvest for propagation or multiplication by him on his own farm, and as well the use of the livestock or reproductive material for the purposes of pursuing his agricultural activity. (art. 11).

4. The order public limit

Regardless of the concurrence or not of the requirements of the patent, the new system excludes of the normative framework the inventions whose commercial exploitation is contrary to the order public, or morality (the good customs) (art. 6.1). It is an excluding clause that already appeared in the European conventional normative (the Convention of the European Patent of

1973). Although, in fact it has never been applied, neither by the Office of European Patents, or by any other national Court. Such an application lack responds to pragmatic reasons and to the difficulty of its application itself. On the one hand, there was an evolution regarding a more flexible concession of the patents. And on the other hand, it is always difficult to apply indeterminate juridical concepts.

Anyway, as projection or concretion of this general clause of exclusion, the Directive mentions expressly in connection with the human biological material (i) processes for cloning human beings, (ii) processes of modification of the germ line genetic identity of human beings, (iii) as well as uses of human embryos for industrial or commercial purposes; and in connection with animals: (iv) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes (art. 6.2).

As I have already pointed out in several occasions, the admission of the patent should not be mistaken for its admission or prohibition in another sector of the normative system. That is to say, appealing to an example, that the processes of cloning human beings is not patentable, but there could be, however, a law that allowed it-or, on the contrary that prohibited it -. So that, one thing is to allow the activity, and another very different thing is to recognise or not the patent of the product or process where the activity lies.

With regard to this, it should not be forgot that the concession of the patent brings out the ability to prevent a third party from exploiting the invention with commercial purposes without the authorisation or consent of the holder of the patent.

Probably in connection with these matters and with the order public clause, the Directive contents a provision: “ The Commission shall send the European Parliament and the Council every five years a report on any problems encountered with regard to the relationship between this Directive and international agreements on the protection of human rights to which the Member States have acceded” (art. 16 a).

Lastly, and for the same order public reasons, the patent will not be granted to processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal and also animals resulting from such processes(art. 6.2, d).

5. The state legislations and the new community framework

Initially there was not a special diligence on the part of the Member States of the European Union to adapt the respective internal laws to the Directive.

Nevertheless, it can be affirmed that nowadays the States that have already adapted their systems to the Directive constitute a majority. However it seems that there has not been unanimity between the Member States as for their attitude in this respect. This attitude, we could classify it in three main positions.

The first of them would be integrated by the States that have already begun or concluded the adaptation process.

The second attitude would be represented by France whose National Consultative Committee of Ethics on Sciences of the Life and Health has intervened on this matter. In their conclusion on this question the Committee is openly contrary to the incorporation of the Directive to the French legislation (Law of 29 July 1994), since in these moments it would be ambiguous and it would not clarify the position of the investigators. The Committee considers necessary a debate, before removing the principles that inspire the French legislation: the knowledge of the sequence of a gene cannot be assimilated in any case to an invented product, and therefore it is not patentable. Their use, as of all knowledge, common good of the humanity, cannot be limited by the existence of patents that would seek, on behalf of the industrial right of industrial property, to protect the exclusivity of such knowledge. That is to say, the French Committee proposes the free access to the knowledge of the genes or parts of them. However, this juridical solution would not be peaceful either, since some private company of the consortium that made public the conclusion of the map of the human genome, renounce

the patent of the parts of the map obtained by them, but not to sell them as commercial information to those who could get an economic benefit from the investigations that they have carried out with them.

It is certain that the verdicts of the referred Committee are not binding, and that apparently the French government had already begun the adaptation process, but it is not less certain than their verdicts reflect a very influential and in general very respected opinion.

The following approach is reflected by the appeal interposed by two Member States of the EU on the European Court. It is an annulment appeal presented by the Netherlands in 1988 against the Directive 44/98/EC. A little bit later, in December 1998, the Italian government presented a similar annulment appeal. The Norwegian government also presented it, but they committed some procedural mistakes. The line of argument is based on several aspects, but we could highlight the argument that the Directive affects the fundamental rights, the human dignity since it allows the patent of human material. Moreover, it did not settle down any provision with regard to the receiver of material biotechnologically treated, what attempts against the principle of free determination of the patients.

The European Court of Justice has answered this appeal, having rejected it in each and every one of its terms (sentence of October 9, 2001). The most relevant arguments were the following ones: -It is not the creation of a new law, since it deals with national patents for which the procedure and the national law are applicable. -The Directive was the only way to guarantee the correct operation of the interior market, given the legislative divergences of the Member States in this matter, therefore, the subsidiarity principle is not harmed. -The Directive does not bring out a violation of the human dignity, because it limits the patent in a sufficient way so that the human body remains indeed not disposable and inalienable. For example, when excluding the patent of the human body and its parts at the various stages of its formation and development, and when considering some procedures specifically contrary to the order public and morality, and for that not patentable.

6. Some critics opposed to the Directive

Seemingly, the process of uniform regulation on the protection of the biotechnological inventions in the Europe Union was already closed since the Directive was approved by the corresponding community institutions.

Nevertheless, as we have been able to check above, it is not this the situation, and some important critics to the normative of patents that has been established, have raised. Here there are some of them:

- We have already seen before the form or content arguments presented against it, the reticences that it still brings out in relevant advisory institutions.
- It has also been censored that the Directive has excluded of its articulate the demand of the consent of the people from whom the biological samples come, when obtaining a patentable invention. Without wanting to judge whether it is or not an appropriate requirement -although at least I want to point out that it is a question that should be kept in mind -, the truth is that it does not seem a characteristic matter of the patent and that, in consequence, it should be solved by the industrial property law.
- Let's remind that it has been reasoned that the genes and their parts (the sequences of DNA), even though having been isolated in the laboratory, they contain information, and this is what really interests as object of a possible economic exploitation. This information already exists in the nature, for what, from this point of view, it would be a discovery and not an invention.
- There would not have been a sufficient reflection to order what can or cannot be patentable.

* Some patented inventions regarding health are already a reflection of the access inequalities to them, because they are giving place to exorbitant economic rights

(E.g., the case of the diagnostic products of predisposition to the breast cancer in the United Kingdom).

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Friend or Foe: The Position of Genetic Modified Organisms, and Agribusiness in The Realm of Agriculture

Jade Donavanik
Chief Counsellor, Manothai-Jade and Associates Law Office and Legal
Consultant to the Executive of BIOTEC

Since human beings have learned to sow and reap their own harvest, the era of hunting and wandering from one place to another has walked away little by little until we almost see no such society in today's world. The time when our ancestors started to settle down was the beginning of agriculture period: that age has remained with us until present.

Through searching, selecting and improving various kinds of plants and animals, we have obtained tolerant and productive varieties from time to time. Conventional breeding was the pioneer to develop living organisms at least in terms of their phenotypes. Many companies put much effort on improving new varieties of plants and animals through conventional breeding in order to advance agriculture. This in return expands opportunities for investment in new type of business: the so-called Agribusiness.

Notwithstanding, the time has come when alterations of phenotypes were not enough, the aim has shifted to manipulation of genotypes – the real players behind variations of particular traits of life forms. Conventional breeding, though provided significant answers to this demand, was not able to cope with the swift development needed. Scientists, especially those working in agribusiness circle, have realized this fact; therefore, develop new technology, which is known to the world as genetic engineering to achieve their goal.

The products that genetic engineering bestows to agricultural world are genetic modified organisms – whose genes have been modified to serve specific purposes of agriculturist globally. This is where the controversial begins, and leads us to our discussion.

Governance of global biotechnology: global ethics and perspectives from FAO

Dr.Minakshi Bhardwaj

In global debates, ethical issues in agriculture are oriented towards human needs versus protection of the environment. The norms for ethics in agriculture are changing as agriculture is turning more to focus on the targeted genetic mechanisms of improvements. This paper focuses on the ethical issues that were raised as of immediate concerns in the global governance of biotechnology by the experts of the *United Nations Food and Agriculture Organisation* during my time at the FAO. These issues of international governance have a strong ethical foundation and challenge us with balancing ideal principles of bioethics and governance of biotechnology.

International governance of biotechnology has particular policy implications for developing countries and sometimes their global performance in various dimensions of biotechnology can be measured with the level and the speed of their integration into global economy. Influence of cultural, religious and social factors in the use of biotechnology can't be ignored; and the governance of biotechnology requires multilateral and multisectorial cooperation. The ideals of ethical norms may not be explicitly expressed but we can see that there is an attempt to define; articulate and integrate ethical principles in the global governance of biotechnology. This paper will discuss some of these principles.

Ethics and Semantics of Managing an Infectious Epidemic

The Star
April 15, 2003

Awhile ago, a friend asked me, what makes an epidemic take off? Mendacity, I replied, among other things.

In early 1999, shortly after the Nipah epidemic spread to Bukit Pelanduk and its nearby villages, Seremban Hospital clinicians who began treating Nipah patients (at the time, presumptively managed as atypical Japanese encephalitis cases) were instructed to refrain from discussing their cases with their Seremban Hospital colleagues who were not treating Nipah patients.

In June 1999, I received the preliminary program for the 33rd Congress of the Academies of Medicine of Malaysia and Singapore. Looking over the scheduled presentations, I was astonished to see that it did not feature a single speaker, let alone a panel to address the clinical, epidemiological, or virological aspects of the Nipah outbreak.

Here was the biggest event in tropical medicine in the world in 1998-1999, medical history in the making which had foreign researchers stampeding to this country, and which prompted the Massachusetts General Hospital to invite Dr Adeeba Kamarulzaman, University Hospital infectious disease specialist for a specially scheduled seminar on her clinical experience in treating Nipah encephalitic patients.

In Kuala Lumpur, barely an hour's drive from the southern epicenter of this momentous event, our local clinicians (and biomedical researchers) were being obliged to bury their heads in sand.

I wrote to the chairman of the conference scientific committee, enquiring about this glaring omission, and volunteered to convene such a panel on behalf of his committee. An infectious disease specialist himself, he weakly replied that the organizing chairman was a high official of the Health Ministry, and that this was still a sensitive topic (in late 1999!).

This was outrageous, I decided, curbs even within the confines of medical academe, completely at odds with the institution's goals of professional exchange and continuing medical education.

I hinted that I might lodge a complaint with the Malaysian Medical Association's professional ethics committee, for an unwarranted obstruction of information flow, collegial exchange and professional discourse which was vital to clinical and public health practice, and hence an unconscionable threat to the public interest. Eventually a panel was constituted, under spin control, to peddle the discredited theory of a "dual JE/Nipah" epidemic which continues to circulate to this day.

Evidently, the same mindset persists. In July 2000, the Minister of Science, Technology & Environment decreed that Air Pollution Index (API) readings would henceforth no longer be

released to the public, hoping that Malaysian residents (and CNN) would obligingly see “no smoke without API” during our seasonal smogs.

In 2002/2003, a markedly accentuated outbreak of dengue fever was denied along with outright refusals to divulge figures on dengue incident cases and fatalities to the press.

And now, in April 2003, we have a nationally televised hairsplitting over whether we have “probable” and/or “suspected” cases of Severe Acute Respiratory Syndrome (SARS) in Malaysia.

We can speculate as to whether this is the legal mind at work, or the Health Ministry’s sudden conversion to scientific rigor. By the criterion of isolated and definitively identified etiological agent (pathogen), there have been no confirmed cases of SARS anywhere in the world to date, since the World Health Organisation is still evaluating the evidence implicating a novel coronavirus, and the possible, independent or simultaneous involvement of a metapneumovirus, and possibly even other as yet unidentified pathogens. (<http://www.promedmail.org> April 3, 2003, SARS etiology)

By these semantic devices, the Health Minister may try to avoid Malaysia’s listing as a country where “probable” SARS cases have been “confirmed” (overriding consideration for the tourism and related industries), but public health responses to epidemic emergencies operate on the basis of the precautionary principle, i.e. you cannot wait for the *i*’s to be dotted and the *t*’s to be crossed, before you take action on a presumptive basis, i.e. on the basis of best available and rapidly evolving knowledge. No competent health professional seriously doubts at this point that we have probable SARS cases in Malaysia.

Sadly, the Malaysian Medical Association, instead of stepping into the breach with its professional expertise to display some medical statesmanship, seems more concerned with pursuing its turf battles with traditional healers (Star, April 4, 2003 “MMA: No Proof Folk Medicine Will Cure the Illness”), when not dueling with pharmacists.

This is in contrast to the courage and dedication of individual doctors (and nurses and other healthcare staff) whose steadfast service in the face of mortal risks deserve our highest accolades and sincere appreciation.

Among the eighteen designated hospitals nonetheless with special isolation wards for SARS patients, not a single private hospital is to be found. Indeed, when two foreigners insisted on being admitted into a private hospital for SARS observation, the Association of Private Hospitals of Malaysia (APHM) responded by persuading the Health Ministry to invoke emergency quarantine powers “if a patient refused to be admitted into a public hospital.... the district health officer concerned can issue a quarantine order making it compulsory for a patient to be admitted into a dedicated [i.e. government] hospital...The [private] hospital had to admit them [at the time] because there were no guidelines outlining what private hospitals could do if they had to handle such a case. Now they know what to do,” according to APHM president Dr Ridzwan Bakar (Star April 7, 2003).

Weighing on their minds, evidently, beyond the expense of maintaining a SARS isolation ward, was the further worry that a hospital’s fee-paying clientele would avoid a “SARS-tainted” hospital. One wonders what squabbles might break out between (for-profit) private hospitals if the hospital sector in Malaysia were ever to be completely privatized.

Three years ago, I ended a commentary on the Nipah epidemic with these paragraphs:

“Responsible Malaysians understand and accept that in an emergency situation of outbreak investigation and control, the government in principle should have the discretion for timely and responsible release of information. Having said that, CHI (Citizens’ Health Initiative) would add that the government must sustain the confidence of the public that it is doing a competent, just and credible job in the broader interests of the entire community.

In confronting national emergencies, we expect the government to exercise accountable, exemplary leadership in implementing well-considered and firm but necessary measures in a difficult situation, and in ensuring that these are equitably borne as a national, social compact. There is no other way to sustain confidence, broad-based support and unity in facing such challenges.

Gag orders on public and professional discourse, and media blackouts fail miserably in averting disquiet and panic -- this can only be achieved by accurate, timely information from a credible, competent and responsible source.

In its handling of information dissemination in two disastrous epidemic outbreaks (Sarawak 1997 and Ipoh/Negri Sembilan 1999), and in these recurrent seasonal smogs, the government has repeatedly transgressed the reasonable limits of responsible information management. Its mindset of obsessive, unwarranted secrecy and its unwillingness to divulge legitimate information to the Malaysian public, is reprehensible and totally unacceptable”.

Nothing has changed in the interim to make me revise this opinion.

*Chan Chee Khoo, Sc.D. (Epidemiology)
Co-ordinator
Citizens’ Health Initiative*

*April 5, 2003
Penang, Malaysia*