Committee 2 Genetic Knowledge, Human Values and Human Responsibility DRAFT-##55
For Conference Distribution Only



REDUCTIONISM IN MEDICINE? GENETIFICATION OF CONCEPTS OF HEALTH AND DISEASE

by

Hans-Martin Sass Professor of Philosophy Kennedy Institute of Ethics Georgetown University Washington, D.C., USA

The Twentieth International Conference on the Unity of the Sciences Seoul, Korea August 21-26, 1995

© 1995, International Conference on the Unity of the Sciences

REDUCTIONISM IN MEDICINE? GENETIFICATION OF CONCEPTS OF HEALTH AND DISEASE? Hans-Martin Sass

MORAL AND MEDICAL CHALLENGES FOR GENETIC KNOWLEDGE

A revolution of Copernican dimensions is occuring in medicine and health care. As Kegley has pointed out, there is a DNA mystique and the term 'gene' has become a powerful icon, an icon of hope, sometimes unjustified, for some, an icon of angst, sometimes unjustified, for others. Moleculargenetic information and prediction will change traditional concepts of and attitudes towards disease and health, away from crisis style acute intervention towards non-acute predictive and preventive forms of health care. Implications for individual carriers and society include challenges in health risk literacy and health responsibility as well a new understanding of the individual genetic gifts and burdens of all of us as each of us is a unique carrier of genetic heritage. Genetic knowledge will increase the capabilities of modern medicine and calls for the development of new forms of communication-in-trust and cooperation-in-trust between the lay and the professional. Traditional concepts of health and disease as well as traditional forms of discrimination towards fellow humans with genetic disorders, as we have to recognize that we all are carriers of our very personal genetic heritage and that we have to make the best out of it in predictive and preventive medicine and in finding our own individually defined qualities and visions of life.

We human are created differently and we have different callings, some of them depending on internal genetic factors, some on external social and familial callings. Says the Lord to Jeremiah: '"Before I formed you in the womb I knew your, and before you were born I consecrated you; I appointed you a prophet

to the nations". Then I said, "A Lord God! Behold, I do not know how to speak... Then the Lord put forth his hand and touched my mouth; and the Lord said to me: "Behold, I hae put my words in your mouth. See, I have set you this day over natins and over kingdoms, to pluck up and to break down, to destroy and to overthrow, to build and to plant."' (Jer.1:5-10). God's plan with Jeremiah included the two steps: the genetic setup and the existential calling. Only both together form the prophet's personality and cause his deeds and responsibilities. The prophet learned about his calling together with knowledge about his being chosen and prepared before he was formed in his mother's womb. We now may know some of our genetic setups by moleculargentic testing, but such genetic knowledge is void without its integration into one's calling, environmental or social challenges and opportunities. Advantages or disadvantages of individual genetic heritage can only be defined in personal terms and within the individual familial, cultural and biological envorinment, not merely in technical terms of DNA prediction and disorder. Even the term 'disorder' becomes ambiguous when there is no general order, only individual heritages and challenges.

While moral risk associated with genetic manipulation dominate public debates on moral risk in biotechnology, the more actual and concrete challenges, benefits and risks of genetic knowledge have not found urgently needed attention. Knowledge provides for power; power increases opportunities for freedom and self-determination, also for exploitation and domination. Changes in the balance of power also result in shifts of rights and responsibilities among players as moral subjects. The availability of reliable instruments for contraception is a classic example for how biotechnological progress in personal human fertility has changed millennium old scenarios of family planning and sexual culture. The availability of oral contraceptives has done more for the liberation and emancipation of women than thousands of pages of writings and legislations as it allows for differentiating between procreational and

recreational forms of sex. The contraceptive ethos makes women and men more equal, but changes the equations in making moral choices, e. g. not using available technology is a choice deliberately made and may not be excused by deliberate regression into pre-technological innocence: use or no use of available technology is always a moral choice, related to responsibility not to technology.

The truly revolutionary explosion of knowledge and its challenges to moral risk competence can best be demonstrated by developing moral and medical scenarios of predictive medicine based on genetic prediction and medical prevention [25; 26; 22]. The medical and moral challenge in predictive medicine is to translate the certainties of hereditary and diagnostic facts into the uncertainties of quality of life parameters, health literacy and self-determination of the citizen/patient, and the design of prevention and therapy. The classical nosological difference between health and disease does not hold any more in carrierstatus prediction and prevention. Risk factor medicine has started to revolutionize existing forms medical treatment away from acute crisis style intervention with the physician being the prime moral agent and the patient's ethics reduced to compliance towards non-acute long term prediction and prevention with the pre-symptomatic citizen as the prospective patient being the prime moral agent in making and implementing preventive decisions and the physician being the expert partner for prediction, information, and education [[20; 21]. Solidarity based health care financing systems will have to include the principles of responsibility and subsidarity into the foundations of workable, affordable and fair systems of health care financing. Individual lifestyle decisions in leisure activities and carrier planning will have to be based in information on individual health risk [22]. Traditional principles in medical ethics such as truthtelling and confidentiality will have to be re-formulated for the scenarios of prediction. As there is a right to selfdetermination and to protecting one's own health there has to be

a societal and medical duty to inform and to educate the individual on his or her health risk parameters in order to allow for the implementation of rights to health and self-determination. Whenever more and more sensitive information is available the protection of data becomes a prime technical and moral issue: research in epidemiology and individual risk management need collection, storage, and differentiated and controlled access of data, while principles of privacy and respect for persons call for strict data protection. A third principle, the right to know, carries a new weight and for the first time in modern medicine becomes a leading principle in bioethics, in particular where knowledge relates to severe individual health risk or severest forms of genetic disorder in possible offsprings.

As far as I see it, there is not only a right, but a duty to know about one's own health risks such as diabetes, hypertension, hypercholemia, and the risks of excessive lifestyles including smoking and heavy drinking. I also see positive rights to know, but not a duty to know, where prediction and risk knowledge cannot yet be translated into preventive scenarios, such as information on carrier status of Alzheimer. But I see a definite duty to know about one's carrier status before making reproductive choices, ranging in obligatory weight from some of the severest forms of genetic disorders such as the Lesch-Nyhan Disease to severe disorders such as Autosominal Dominant Polycystic Kidney Disease the onset of which may be later in life or can be postponed by prudent risk management and which can be dealt with by renal dialysis or organ transplantation, and to genetic predisposition for hypercholemia or Alzheimer [10]. The moral challenge and risk is in differentiating scenarios of genetic prediction precisely enough according to technical and moral parameters and to allow for individualized and patientoriented - better carrier-based - decision making. Knowing that one in 25 British are carriers of Cystic Fibrosis, challenges the moral and medical assessment of new epidemiological and

individual aspects of moral scenarios of screening for the medical profession, for the health care system, and not a least for the carrier [2; 6; 10]. Again, as I already mentioned, the new scenarios of duty to know versus right not to know call for careful assessment in differential ethics not for moral generalizations, which carry the hazard of indoctrination and the risk of medically and ethically harming carriers, their qualities of life and reproductive choices [1; 17]. I summarize these reflections on the ethics and risks of new genetic information in a first thesis: There is a duty to know about individual health risk factors for the promotion of selfdetermination in lifestyle and reproduction. The truly Copernican turn in modern medicine and new knowledge in molecular genetics calls for a shift of emphasis on physician's ethics to emphasis on lay ethics in future medical ethics; this can be highlighted by the following interactive set of maxims in lay ethics and expert ethics for health care which are structured after Dr. Gong Tingxian's famous two set of ten rules each for the physician and the patient:

EIGHT HEALTH CARE RULES FOR THE LAY PERSON

- 1. Find truly educated and trustworthy health experts.
- Develop competence and responsibility in health risk management.
- 3. Make extended use of predictive and preventive medicine.
- 4. Expect healing or relief from acute medicine, but be aware of the limits and risks of any medical intervention.
- 5. Expect information and advice from medical experts and be a fair partner with them.
- 6. Define and implement your sense of qualities of life, from childhood to old age, in sickness and in health.
- 7. Prepare advance directives and name proxy decision makers for circumstances of incompetence.
- 8. Act responsibly in the use of communal health care funds.

 EIGHT HEALTH CARE RULES FOR THE HEALTH EXPERT
- 1. Treat your patient as a person, not just his or her symptoms.

- 2. Assist you patient in developing health risk competence.
- 3. Integrate the 'clinical status' and the 'value status' of your patient into differential ethics, diagnosis and prognosis.
- 4. Be aware of the benefits, limits and risks of acute intervention and discuss those with your patient.
- 5. Be an expert partner with your patient and respect her or his wishes and values.
- 6. Continuously educate yourself and provide the best possible clinical and personal service.
- 7. Assist your patient in preparing advance directives and in working with proxies for the benefit of your patient.
- 8. Act responsibly in the use of communal health care funds.

ETHICS AND RISKS IN DNA-MANIPULATION

Manipulation literally means to change things 'hands on'. Manipulating and cultivating raw and cruel nature into the house and home of humans and human culture has been with humankind since the earliest times. Indirect manipulation of DNA by means of breeding and cultivating is as old as 'culture' and came with technical as well as moral and cultural challenges all the time.

Here is the story of Jacob. At about 2500 years ago, during the century of Lao Tzu, Kung Fu Tze and Buddha, Jacob the father of the house of Israel served as a herdsman to Laban, his father in law, for many years without pay. Laban was an avaricious and mean person and did not pay Jacob during his years of service. One day Jacob made what Laban thought was a modest request: to get title to all crossbreeds of Laban's herds. After the new contract was in place, Jacob started to increase the number of cross breeds by canny and prudent means of encouraging crossbreeding among previously strictly separated flocks.

Incentives included watering and even feeding previously separated herds together to provide for extra breeding time across previously established and protected breeding lines. When the time came to count the flocks, Laban got very angry and Jacob got very rich as his flocks increased exceedingly, or in the

word's of the German version of Dr. Martin Luther 'daher ward der Mann über alle Massen reich' [Genesis 31:13].

We have two sets of problems in this story, both of which are related to risks in biotechnology. One set represents four purely technical risk parameters in indirect biotechnological manipulation by breeding methods and in direct biotechnological manipulation by moleculargenetic methods: stability of genetic expression and survival, multiplication, and migration in environment [17]. These four risk parameters have been widely described in contemporary DNA hazard management and are mandatorily used in corporate and government risk assessment schemes in agriculture, drug research and gene therapy [4; 24; 23; 27]. Jacob's story plays well before the background of a history of well established means and goals in genetic selection, purification and improvement of wild animals and wild plants into domesticated animals and cultivated plants. Genetic improvement of wild forms of life into domesticated and cultivated forms of life is an essential part of humankind's culture since her prehistoric days. The goal of genetic cultivation was the improvement of human living conditions, better survival risk management and lower risk rates for good, civilized and cultivated forms of life. The technical challenge in conditioning and manipulating hardware instruments and machines as well as living entities such as herbs and plant, dogs, horses, cats and chicken was and is to identify goals and to shape the instruments appropriately so that can do the job with a minimum of unwarranted side-effects. The Jacob story does not confront us with the beginnings of human cultivation of raw nature, rather it presupposes an already long history of genetic knowledge and genetic cultivation; it describes some technical parameters of furthering the ongoing process of cultivation of already manipulated genetic material, this time by re-merging previously separated genetic lines for a well designed purpose.

The strategically designed goal of Jacob's biotechnological manipulation was not technical improvement of already cultivated

stock, rather a business purpose with related moral aspects. And here we face the second set of risks in his story: moral risk. Mating and breeding in Jacob's story is not considered to be a moral risk, but his business attitude is. He played the cards of his herdsmanship in an unexpected and unusual, canny and prudent way for his own benefit and at Laban's loss. It is the old moral problem of contracting with parties who are unaware of loopholes of contracts and those who exploit the loopholes; we face business ethics issue such as this one in many areas of wheeling and dealing, not just among breeders, horsetraders or researchers and businessmen in modern biotechnology. Jewish and Christian ethics, of course, was and is concerned with business ethics; writes the Stuttgart annotated German bible edition: 'Jacob used the trick, calculating on the mistakes of the breeding animals. God did not tell Jacob to do so. He let it happen in order to punish Laban for being mean', i. e. the animals were to blame for making mating 'mistakes', and God was not to blamed for anything as he did not support actively what seems to be a moral, not a legal breech of contract this, rather he passively watched and let it happen. Without going into a detailed analysis of the commentators moral reasoning in Jacob's biotechnological deeds, let me just finish the story by telling you that the bible reports on increasing tensions between Laban's house and the the house of Jacob and that 'the Lord said unto Jacob, return unto the land of thy fathers and thy kindred and I will be with you' [Genesis 31:13].

It is a long way from Jacob's parameters of technical and moral risk to those in modern biotechnology, from breeding sheep and cultivating grain to transgenic forms of life, cross-species hybridization, genetic manipulation in somatic and germ-line cells, organ transplantation and artificial organs, microorganisms producing human insulin or eating away pollutants. Technical challenges and moral risks are similar, but the stakes in miscalculation and misappropriation of technology assessment and moral assessment and societal assessment have risen, a fact

already recognized by Lao Tzu: 'the sharper the weapons the people possess, the greater confusion reigns in the realm; the more clever and crafty the men, the oftener strange things happen; the more articulate the laws and ordinances, the more robbers and thieves arise' [11:117]. The review of the Jacob story leads to my second thesis: Genetic knowledge is not new, nor are the technical and moral risks associated with it. But, as the dimensions of knowledge and manipulation have widened, so have associated ethical dimensions which need careful assessment in the light of traditional moral and cultural principles. Such re-confirmation of moral and cultural traditions and values and risks associated with their implementation has to include a reevaluation of (1) the interaction between genetic knowledge and human self-understanding, (2) goals, risks, and limits of genetic manipulation, (3) concepts of nature and culture, and (4) the ultimate challenge to an ethics of responsibility.

It was a long way from Jacob's biotechnological manipulation by means breeding and cultivating to the strategically targeted moleculargenetic design of drugs and multiple forms of life. Stakes have become higher and call for improvements in the ethos and ethics of manipulation. There is a special responsibility in human stewardship towards those form of life which have been modified by humans, no matter whether by indirect or by direct means, and to those forms of life which may become extinct as a result of human activity. Dachshunds have been designed as assistants in hunting rabbits, dachs and fox, with good technical and moral breeding results. But dachshunds carry a construction blunder as they develop painful spinal cord destruction in their later years; therefore an improved ethos of manipulation and they ethics of biotechnology call for terminating the breeding of dachshunds, at least not making them run staircases or just as pets for kids. The protection of endangered species of life rests on two different and strong moral arguments, one is the respect for the diversity of life as an end in itself, the other the preservation of as many diverse forms of life as material for

future cultivation and manipulation. It would be moral malpractice to call for the ban of certain forms of technology just because they may be misused by the bad guys. As history tells, black powder has been used in China for cultivating the fine art of fireworks while in Europe it was used in guns for killing fellow humans. In stone age times the axe could be used either for cultivating wilderness or for killing foes or friends, three different ethical scenarios with different balances of right and wrong. As in the story of Jacob, scenarios are different and they demand careful technical and ethical analysis and assessment, not moral generalizations and prohibitions [1; 17; 18; 21].

Of particular concern has been the manipulation of human cells and tissue. I do not see any particular moral risk in using biotechnologically altered human somatic cells and tissue for healing or relieving which would be different to the risk parameters of other forms of medical intervention. First experiences in the ethical review of somatic cell therapy [23] have confirmed that additional to special risks associated with the control of genetic stability all other problems are either related to technical risks in prediction, professionalism, and support and to ethical risks in patient selection and informed consent. Some time before somatic cell therapy was technically possible, a moral risk assessment board, an ethics committee, convened at the US National Institute of Health and developed checklists for ethical risks assessment which then were used when first somatic cell protocols were submitted; submission of somatic cell therapy protocols have already become routine; they lack all the sensations of moral curiosity and call for differentiated moral judgement rather than moral generalizations.

Worst-case scenarios in human <u>germ-line manipulation</u> have been used to morally ban biotechnology in general or at least in human medicine; thousands of identically cloned soldiers or slaves, genetically designed laborers immune to pollution or simply so called eugenic improvement of the human race or of some

of the human races are the utensils in Dr. Mabuse's cabinet. But this is not a realistic picture of the future of germ-line modification in humans. Traditional forms of manipulating fellow humans by means of indoctrination, exploitation, and the withholding of instruments and means for individual selfdetermination are still and will for the foreseeable future still be the best means to make fellow humans means instead of respecting them as persons and ends in themselves; it is a fiction that genetic manipulation can do the same jobs as well as disinformation and indoctrination do. Years ago, the European Community rightly has included the right to a not manipulated genetic identity into the list of citizen rights and that position should be universally supported by all nations and cultures. But if and when reliable methods become available to 'heal' by means of modification one or the other of the severest forms of human genetic disorders already in germ-line cells the benefits and risks, medical and moral, will have to be compared to the benefits and risks of indirect 'prevention' by preimplantation diagnosis or abortion, or of without further moral considerations knowingly giving birth to severely handicapped offsprings. Germ-line therapy then will be an issue for responsible parenthood to decide whether or not germ-line intervention is a moral good or bad.

I consider it a malpractice in moral argumentation to resort to generalizations when particulars of moral assessment are requested; philosophical and theological generalizations are a moral and technical hazard and great risk for those in need of medical help in information and intervention. Thomas Aquinas already mentioned that generalization loose their authority the more one moves to the details of moral scenarios, 'quanto ad particularia descenditur' [ThAq SummaTh I-II 94 art 4], where the particularities count in what I call differential ethics. These arguments lead to my third thesis: Progress in methods of manipulation calls for progress in the development and support of an ethos and ethics of manipulation; a ban on manipulation would

be moral and cultural malpractice.

RAW NATURE AND THE CULTURES OF MANIPULATION

The word and the concept of culture comes from the Latin cultivare which means cultivating and plowing the raw ground into productive garden lands and field. It includes the weeding out of unwanted weeds, the protection, nursing, and improvement of herbs, vegetables, fruits for nutrition, medicine, and enjoyment. The hortus, the garden, is protected by a fence, a hedge, or a ditch from the surrounding wilderness, its beasts and weeds. Wild nature traditionally had been the enemy threatening and endangering human survival and cultivated and civilized life. Houses, hedges, walls, gardens and fields, domesticated animals protected against cruelty, uncertainty and unpredictability of nature. Cultural and civilisatory evolution can be understood as the prolongation of natural evolution through tools and technologies [9]. Only when the walls of culture have been build strong and high enough, we start to romanticize wilderness and find in nature a part of our own nature which we feel we have lost in the processes of rationalization, instrumentalization, and cultivation [8; 9; 15].

The way we humans see nature tells us as much about nature as about ourselves, we mirror ourselves in the way we cultivate, nurse or dominate nature. This can best shown in comparing different attitudes towards nature as displayed in different architectural concepts and designs of parks and ornamental gardens. Well known is the hortological difference between the French and the English park, which clearly displays anthropological differences in human self-understanding. In the French park we find domination, uniformization, rationalization of natural vegetation into geometrically shaped hedges, borders and beds by means of cutting, clipping, and trimming, everything under strictly controlled design oriented towards the house as the center of control, manipulation and domination in a timeless fashion, distrusting the genuine powers of nature and calling for

high maintenance and permanent control, punishment, and rectification of unwarranted natural powers. The English park is famous for fairly and gentlemanly protecting, nursing, and appreciating the personality of the individual and solitary tree or of groups of shrubs and trees by low but determined and strategically applied forms of control and maintenance; borders between lawns and ways are 'naturally' designed, not geometrically; the park is open towards the surrounding landscape, not walled in, the house not necessary in the middle; some artificial ruins include the time horizon of the 'memento mori', reminding of the limited span of lives, products, and efforts in controlling and nursing. The English park looks more 'natural', but is no less a carefully designed product of human hortological biotechnological manipulation. The same is true for Chinese hortological culture. The Chinese garden is not a park, rather a place of well controlled growths and interaction between the cultural and natural side of the owner who may also be the gardener and who, if climate allows, cares for interrelating house and garden as cultivated living spaces for cultivated and cultivating humans. Greatness and smallness, natural and even bizarre forms of growth, bridges, lakes, fish, houses, boats and humans together form a cultivated landscape which resembles 'naturalness' but is artificial, strategically designed, microcontrolled as the European parks. Goldfish are products of severe and intense biotechnological manipulation, so are certain bonsai trees. While the French park stands for representation of power and dominance and the English park for controlled fairness and a culture of low control, the Chinese garden is a symbol as well as an instrument for human interaction with nature by clipping branches, cultivating roses, and feeding fish for the purpose of revering and cultivating nature, for meditation and selfrecognition, and a culture of integrating labor and leisure. Where are the garden of our times?, they are inside the lobbies of luxury hotels and shopping malls; reminders only of nature inside the house, not surrounding the house, truly domesticated

biotechnologically controlled and designed nature inside the centers of commerce and civilization, as the spaces outside the buildings have become parking places and driving places towards other buildings.

It was Francis Bacon who in his 'Novum Organon' (1670) underlined that the history of nature is never a history of free and uncontrolled nature, but even more a history of bound and dominated nature, pushed, pressed, and formed by human ingenuity and activity. The cultural and moral risks of uncritically using concepts of 'nature' and 'culture' spells over in poor assessment of goals, limits, and risks in technological development and application, and in limited self-understanding and selfdetermination. If we understand ourselves and our interaction with nature - raw and cruel nature and cultivated or manipulated nature - as homo faber, then the product will be able to tell a lot about the producer, it mirros her needs, visions, goals, and struggle. Our review of the epistemological, biotechnological and anthropological aspects of ornamental gardens and parks can be summarized in a fourth thesis: Human manipulation of nature mirrors human self-understandings, values, and morals; the clue to avoid risk in technology is to strengthen individual and cultural competence in moral risk assessment and personal responsibility.

GENETIC KNOWLEDGE AND THE CULTURES OF RESPONSIBILITY

New knowledge and new forms of manipulation challenge human race and human culture with wider dimensions of responsibility and risk competence, not just in predictive medicine. They call for the development of an ethos and ethics of responsibility, i. e. for improved forms of moral risk management in using tools, defining ends, and respecting limits. I take issue with those ethicists who in using worst-case scenarios request a ban or severe forms of governmental tutelage of the development and use of new technology, which additional to biotechnology singles out nuclear and information technology such as Hans Jonas does [7].

Their thesis is that technological progress has outdistanced human moral capacities and therefore call for a retardation in developing and applying modern technologies. I hold the contrary view based on the study of the history of moral and cultural risk management and on own experience that regulating technology does not result in morally and culturally less risky environment, on the contrary heteronomous regulation carries moral hazards and risks of its own as it reduces the individual's options to choose and to follow his or her consciousness. The ethically beneficial response to increased technical capabilities is the increase in education of and support for individual risk competence and the training in moral responsibility training.

Moral and cultural traditions play an important role in shaping individual and societal competence to deal with new challenges. But tradition may not be used in an uncritical way, as traditions do not just contain truly moral values but also antiquated customs which have to be cut off like the old queues once fashionable [16]. There are at least three different forms to introduce moral traditions into modern discourse on moral assessment and to instruct individual: (1) the authoritative and regulative way which is favored by the patrons of hierarchical value assessment such as recently expressed by the Vatican Encyclical Veritatis Splendor [14], (2) the educative and exhortative way in which the individual conscience seeks guidance from the wisdom of the past, often in seeking guidance from God in interpreting classical texts [5], and (3) the discursive and adjuvantive way of making the best use of traditional forms of moral risk management. The risks of the authoritative model include the suppression of the individual conscience and the promotion of double standards and the risk that the authorities might change the course of fatherly instruction. The discursive model fits best into the scenarios of moral assessment by educated and risk competent individuals; it is the model of the future but it needs to more carefully make good use of the treasures hidden in the moral history of many cultures [18; 19].

Cultural traditions are different, so will be the morals solutions which they will support or not support. Western definitions of brain-oriented models for death which are based on concepts of a difference between the immortal soul and the mortal body or on concepts of understanding and self-understanding face many obstacles in Asian cultures treasuring the nondivisible nature of the human person [20; 21]. The more the moral issues are related to the basics of life, death, pain, liberty and justice, the more will we find cross-cultural consensus for prima facie human rights and obligations, the more the issues are culturally rather than biologically defined there more widespread will <u>cultural diversity</u> be [16]. The protection of the basics of human and civil rights is an issue of solidarity within pluralistic societies and among the plurality of cultures, the recognition of those basic rights, which can be called precultural rights and obligations as they have to be respected in all cultures of human dignity.

The Human Genome is a heritage of humankind, as the International Bioethics Committee in 1994 at UNESCO headquarters in Paris declared. It has to be protected and treasured. But it is more than just a heritage of humankind such as biosheres or heritages of culture and the arts. The human genome first of all is a very personal heritage from my parents to me, predetermining my individuality, capability, challenge and vision, and only thereafter and as such a common heritage of humankind.

Traditional moral principles such as autonomy, privacy, justice, equity, literacy, and responsibilty have to be re-defined in the light of benefits, risks, and uncertainties of applying genetic knowledge.

The principle of <u>subsidiarity</u>, first developed in Christian moral theology for social ethics [13] but very well designed to handle bioethical issues as well, on the other hand favors the support of moral risk management by those who are directly involved against the heteronomous rules and requirements of those who introduce general norms from the outside unto those who are

the prime and personally challenged moral agents. The principle of subsidarity reliefs governmental and societal institutions from consensus formation and implementation where consensus cannot be achieved because individual consciences calculate the moral options differently based on their individual set of moral priorities. It also strengthens the individual conscience by requiring final moral responsibility rather than the formal obedience to regulations and laws given by others [21]. As long as rights of other members of the moral community are not inflicted, the principle of subsidarity should allow for individuals to make moral choices whenever theologians, ethicists, lawyers and politicians disagree in such crucial questions as to when unborn life should be protected or when a human life is over, whether to give or receive organs, whether or not to differentiate between procreative and recreative forms of sex, whether to have or not to have children and how many. But the principle of subsidiarity must also be employed within the processes of crosscultural dialogues and intercultural conflict solution within the global village. It will have to support cultural attitudes and the cultural heritage which cannot be shared by others but which has its own distinct set of rules, goals, and obligations, as long as those traditions do not violate individual human and civil rights. The cultures of responsibility are not threatened by giving individual conscience and risk management too much room for responsibility rather by giving them too less. As Spinoza observed 1670 in his Tractatus Theologico-Politicus the freedom of individual responsibility from indoctrination does neither threaten truth nor society, but that the destruction of the individual conscience will finally result in the destruction of those powers of destructive dominance. The principle of subsidiarity originally was developed in social philosophy in order to provide for a multitude of attitudes of cae for the poor and sick and those in need in multicultural societies. It should also be used in a global dimension in order to honor and challenge the multitude of

visions, cultures and heritages of humankind to compete in making this world a more human, a more natural, a more civilized and cultivated place.

Of course, there have to be some <u>rules and regulations</u> on how to handle machines, technologies, biotechnologies, and the technicalities of regulation and enforcement. Human and civil rights have to be protected by law, police, courts, and governments. The moral hazard of over-regulating, however is a special risk in those areas of technology assessment and moral assessment where technologies are new. Anticipating high technical risks is not unprofessional for good technical risk management, it is even mandated when chartering into new and unknown territory such as expected risks to import dangerous microbes from the moon or to strive for highest possible safety standards in early DNA recombination. But it also a part of prudent technical risk management to reduce safety measures as soon as experience tells that they are far too high. There are moral and technical limits to the regulation of technology with the intend to avoid abuse [1;17; 21]. Rules and regulations are often a moral hazard themselves such as the German Embryo Protection Law, which makes pre-implantation diagnosis for certain severe genetic disorders a crime while allowing early and even late abortion for those cases as medically indicated [3].

Fletcher has described how new ethical issues evolve in <u>four stages</u>: threshold, open conflict, extended debate, and adaptation; Wivel and Walters have demonstrated that in somatic cell therapy these four steps have been followed and expect that new issues such as germ-line therapy will unfold in similar sequences [27]. Many countries have already implemented national or multinational review boards and developed moral assessment strategies for one or the other challenges of biotechnology in agriculture and medicine [4; 12; 23; 24]. Reading the protocols and following the deliberations of these moral risk review bodies, the absence of generalized statements and arguments is remarkable so is the capacity of ethicists to micro-allocate well

established and supported traditional principles and maxims into new scenarios of knowledge and manipulation.

There is a multitude of risk involved in biotechnology as in all technologies, technical risk and moral risk and risk in the calculation of risk. But there are methods to improve and sharpen technical devices and models of delibaration, consensus formation and accepting ambiguities and diversities in moral choice. There are many prudent ways for government to ease moral conflict and to reduce technical risk; there are many ways to research and to teach moral and technical risk competence and individual responsiblity. What finally counts are not these various devices but the wisdom in knowledge and the ethos in manipulation as, in the words of Lao Tzu 'we make doors and windows for a room, but it is these empty spaces that make the room livable' [11, 23]. Let me summarize my observation of the working of differential ethics in the assessment of technical and moral risk in well defined new scenarios of biotechnology in a fifth thesis: To master the benefits and risks of genetic knowledge and power we must further strengthen the ethos and ethics of responsibility in the support of individual self-determination, cultural diversity and political stability.

LITERATURE

- 1. Altimore M (1982) The Social Construction of a Scientific Controversy, Science, Technology and Human Values, 7: 24-31
- 2. Asch DA, et al (1993) Reporting the Results of Cystic Fibrosis Carrier Screening, <u>American Journal of Obstetrics and Gynecology</u>, 168 (1.1): 1-6
- 3. Bundesrepublik Deutschland (1990) Embryonenschutzgesetz [ESchG], <u>Bundesgesetzblatt</u>, 13. Dezember 1993
- 4. EC, Council of Europe (1990) Council Directives on the the Contained Use and on the Deliberate Release into Environment of Genetically Modified organisms, Official Journal of the European Communities, 17 (L):1-27
- 5. Fuchs J (1984) Das Gottesbild und die Moral innerweltlichen

- Handelns, Stimmen der Zeit, 6: 363-382
- 6. Handyside AH et al (1992) Birth of a Normal Girl after In-Vitro-Fertilization and Pre-Implantation Diagnostic Testing for Cystic Fibrosis, New England Journal of Medicine 327 (13): 905-909
- 7. Jonas H (1979) Das Prinzip Verantwortung, Frankfurt: Insel
- 8. Jünger FG (1960) <u>Gärten im Abend- und Morgenland</u>, München: Bechtle
- 9. Kapp E (1978) <u>Grundlinien einer Philosophie der Technik</u> (1877), hg HM Sass Düsseldorf: Stern
- 10. Kielstein R, HM Sass (1992) Right not to Know or Duty to Know? Prenatal Screening for Polycystic Renal Disease, Journal of Medicine and Philosophy 17: 395-405
- 11. Lao Tzu (1989) Tao Teh Ching, Boston: Shambala
- 12. Lenoir N (1991) <u>Aux Frotiers de la Vie: Une Ethique</u>
 <u>Biomedicale a la Française</u>, Paris: La Documentation Française
- 13. Pius XII (1931) Encyclica Ouadrogesimo Anno, Rom
- 14. Johannes Paul II (1993) <u>Encyclica Veritatis Splendor</u>, Vatican: Libreria Editrice Vaticana
- 15. Sass HM (1981) Mensch und Landschaft, <u>Landschaft und Mensch</u> hg G. Höhl, Mannheim: Verlag Humboldt Gesellschaft, 293-322
- 16. Sass HM (1986) The moral a priori and the Diversity of Cultures, <u>Analecta Husserliana</u>, 20: 407-422
- 17.. Sass HM (1987) Philosophical and Moral Aspects of Manipulation and Risk, <u>Swiss Biotech</u>, 5 (2a): 50-56
- 18. Sass HM (1987) Methoden ethischer Güterabwägung in der Biotechnologie, <u>Fragen der Gentechnologie und Reproduktionsmedizin</u>, München: Schweitzer, 89-110
- 19. Sass HM hg (1991) <u>Genomanalyse und Gentherapie</u>, Heidelberg: Springer
- 20. Sass HM (1992) Risiko aus der Sicht der Medizinethik, <u>Risiko</u>, hg K Giel, R Breuninger, Ulm: Humboldt-Studienzentrum, 125-174
- 21. Sass HM, (1992) Generalisierender Moralismus und Differentialethik, <u>Politik und Kultur nach der Aufklärung</u>. Festschrift für Hermann Lübbe, Basel: Schwabe, 186-205

- 22. Sass HM (1993) Ethik in der Epidemiologie, <u>Das</u> <u>Gesundheitswesen</u>, 55: 119-126
- 23. US, National Institute of Health (1985) Points to Consider in the Design and Submission of Human Somatic Cell Therapy Protocols Federal Register 50/160: 33463-33467
- 24. US, Office of Technology Assessment (1991) <u>Biotechnology in a Global Economy</u>, Washington DC: Government Printing Office [OTA-BA-494]
- 25. UNESCO, International Bioethics Committee (1995) <u>Actes.</u>
 <u>Proceedings</u>, Vol. I and II, Paris: UNESCO
- 26. Wertz DC, JC Fletcher, JM Mulvihill (1990) Medical Geneticists Confront Ethical Dilemmas: Cross-Cultural Comparisons among 18 Nations, <u>American Journal of Human Genetics</u> 46 (6): 1200-1213
- 27. Wivel NA, Walters L (1993) Germ-Line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives, Science [Oct. 22, 1993]