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HUMAN RIGHTS AND SCIENTIFIC AND TECHNOLOGICAL DEVELOPMENTS

Protection of the human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry

Report of the Secretary-General

Addendum

DIVISION LINGUISTIQUE
SECTION DES RÉFÉRENCES
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CONTENTS

	Paragraphs	Pages
INTRODUCTION	1 - 2	1
PART ONE. DEVELOPMENTS IN BIOLOGY	3 - 51	2
I. THE QUESTION OF THE "GENETIC BURDEN" PLACED UPON MANKIND BY THE FACT THAT INCREASING NUMBERS OF PERSONS SUFFERING FROM GENETICALLY TRANSMISSIBLE DISEASES CAN BE KEPT ALIVE UNTIL THEY ARE ABLE TO PROCREATE	3 - 51	2
1. Introduction	3 - 7	2
2. The nature of the burden	8 - 15	4
3. Meaning of genetic health	16 - 23	7
4. The feasibility of the practice of eugenics	24 - 30	10
5. Sterilization and marriage bars	31 - 51	13
PART TWO. DEVELOPMENTS IN MEDICINE	52 - 182	21
I. THE HUMAN RIGHTS IMPLICATIONS OF PRE-NATAL GENETIC DIAGNOSIS AND GENETIC COUNSELLING	52 - 145	21
1. Introduction	52 - 56	21
2. The use of genetic data as it affects the right to privacy	57 - 68	23
3. The procedures of prenatal diagnosis	69 - 73	26
4. Dangers of amniocentesis	74 - 82	28

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	Paragraphs	Pages
5. Ethical, psychological and social aspects of genetic screening and counselling	83 - 96	30
6. Attitudes towards defectives in view of advances in genetics	97 - 103	36
7. Rights of parents and the rights of society .	104 - 125	39
8. The child's right to life and the parents' right to procreate as opposed to the burden borne by the child subject to genetic defect	126 - 139	45
9. Proposals made for assessment of parental genetic diagnosis and counselling	140 - 145	50
II. MEASURES NECESSARY TO SAFEGUARD THE HEALTH, SAFETY AND LIFE OF PATIENTS WHO ARE EXPOSED TO ELECTRICAL, ELECTRONIC, MECHANICAL AND OTHER TECHNICAL DEVICES DURING DIAGNOSTIC OR THERAPEUTIC PROCEDURES	146 - 182	54
1. Inherent defects of certain devices and dangers arising from improper use of devices	146 - 158	54
2. Measures adopted or proposed to proctect human rights	159 - 182	57
PART THREE. EXPERIMENTS ON HUMAN SUBJECTS	183 - 312	64
I. PROTECTION OF THE INDIVIDUAL AGAINST UNJUSTIFIED EXPERIMENTS, INCLUDING THE QUESTION OF FREE AND INFORMED CONSENT TO EXPERIMENTS PERFORMED ON THE INDIVIDUAL	183 - 233	64
1. Statement of problems involved	183 - 189	64
2. Professional codes of ethics	190 - 201	67
3. Review committees	202 - 209	72
4. Legislation	210 - 215	74
5. Special categories of subjects of experimentation	216 - 222	78
6. Views of Governments	223 - 233	81
II. THE MORAL AND LEGAL POSITION OF THE PHYSICIAN WHO IS INVOLVED IN EXPERIMENTAL PROCEDURES	234 - 267	85
1. Statement of problems involved	234 - 236	85
2. Moral position of the physician involved in experimental procedures	237 - 248	85
3. Legal position of the physician involved in experimental procedures	249 - 260	89
4. Views of Governments	261 - 267	94

		Paragraphs	Pages
III.	THE PROTECTION OF THE PUBLIC AGAINST HARM FROM CHEMICALS INTRODUCED INTO FOOD PRODUCTION, PROCESSING, PACKAGING AND STORAGE	268 - 308	96
	1. Uses of food additives	268 - 269	96
	(a) Flavourings	270	96
	(b) Colours	271	96
	(c) Preservatives	272 - 274	97
	(d) Texture agents	275	98
	(e) Miscellaneous additives	276 - 278	99
	2. Threats to human rights posed by the use of food additives	279 - 285	100
	3. Existing and proposed safeguards	286 - 308	102

INTRODUCTION

1. The parent report on protection of the human personality and its physical and intellectual integrity, in the light of advances in biology, medicine and biochemistry was circulated as documents E/CN.4/1172 and Add.1-2. The complete table of contents of the report appeared at the beginning of document E/CN.4/1172. At various points in the report it was stated that six subjects would be treated further in the present document (E/CN.4/1172/Add.3).1/

2. The sources of the present document are the same as those of the parent report,2/ with the addition of replies from the Governments of Hungary, Yugoslavia and Zaire furnished on 19 August, 7 May and 24 July 1975 respectively.

1/ See E/CN.4/1172, paras.12 and 16(ii), E/CN.4/1172/Add.1, paras.435-439 and E/CN.4/1172/Add.2, paras.535-542.

2/ See E/CN.4/1172, paras.8-11.

PART ONE. DEVELOPMENTS IN BIOLOGY

I. THE QUESTION OF THE "GENETIC BURDEN" PLACED UPON MANKIND BY THE FACT THAT INCREASING NUMBERS OF PERSONS SUFFERING FROM GENETICALLY TRANSMISSIBLE DISEASES CAN BE KEPT ALIVE UNTIL THEY ARE ABLE TO PROCREATE

1. Introduction

3. The biological evolution of the human being has taken millions of years, and through the function of national selection has produced twentieth century man. Individuals with hereditary or other defects and limited power of survival have perished and the strongest have survived. Although natural selection has been fortuitous and ineffective in many respects, it seems probable that since man has acquired his present form his quality has gradually improved. Group formation, cultural development and tradition have also contributed to a positive selection.1/

4. This tendency toward self-improvement has been partially lost, however, as a result of the development of medical-care services and public health measures, as well as socio-economic programmes. These advances are altering the genetic endowment of the population to which they are applied, and ultimately, the genetic endowment of mankind as a whole. In the long run, depending on environmental conditions, various of these alterations may prove undesirable or harmful.2/

5. Certain genetic disorders are so harmful to the organism that the afflicted foetus never survives to birth; some estimates of natural abortion are as high as 50 per cent of all conceptions.3/ The less severe genetic defects permit the foetus to come to term only to survive in an incapacitated state. Since the sacredness of human life is a basic ethical tenet, and the duty of the medical practitioner has traditionally been seen to maintain life, and where possible, to restore health, the great advances in medical technology have resulted in increased survival of genetically defective human beings. "Some of those whose lives are saved and whose health is restored are, however, carriers of genetically conditioned defects and constitutional weaknesses of various kinds. These individuals are often enabled to produce offspring, and thus to pass on their genes to the following generations."4/ The Government of Hungary reports the following:

> "Previous to the discovery of insulin juvenile diabetes was lethal in most cases. Today, due to complex treatment, the adaptation of diabetics to society is almost invariable, and their number of children is identical with that of non-diabetics. Among their children a 5-8 per cent occurrence of diabetes may be expected, which is significantly higher than the average for the whole population." 5/

1/ Ole Jacob Brock, Det Kunstige Menneske (The Artificial Man), (Oslo, 1969), p.150.

2/ "Human genetics and public health", Second Report of the WHO Expert Committee on Human Genetics, WHO Technical Report Series No.282 (Geneva, 1964) p.26.

3/ "Science and the quality of life", Three Reports from Church and Society, World Council of Churches, Geneva, Switzerland, 1971, Study Encounter, vol.7, No.3, p.5.

4/ "Human genetics and public health", op. cit., pp.22-23; similarly, information furnished by the Government of Sweden on 12 March 1974.

5/ Information furnished by the Government of Hungary on 19 August 1975.

Dr. L. Charles Birch has written as follows:

> "From the genetical point of view, euphenics is the biochemical engineering of development to counteract the deleterious effects of genetical disease. A classic example is the treatment of the genetical disease Phenylketonuria. This disease is caused by a double dose of recessive gene. A child with a double dose becomes mentally retarded. However, early diagnosis followed by a diet free of phenylalanine results in fairly normal development. The treated persons still possess the deleterious genes but the effects of the genes are overcome. There is no doubt that treatment will result in an increase in the incidence of the disease, since treatment is not a cure and individuals will propagate the deleterious genes ...". 6/

If through medical intervention the person who would otherwise die, or who would survive but be infertile, now survives and reproduces at the normal rate, this would on the average double the incidence of the deleterious gene in each successive generation. The doubling occurs because the defective gene would be expected to appear in each generation as a result of spontaneous mutation; due to reproduction by the mutants of the prior generation the result is cumulative. 7/

6. Other factors of modern life exacerbate the situation: "factors that may increase the mutation rate, such as exposure of the population to larger average doses of ionizing radiation delivered to the gonads, increased exposure to chemical mutagens of many kinds, including most carcinogens, and exposure of the reproductive cells to high temperatures." 8/

7. A demographic analysis in Wales, United Kingdom, illustrates statistically the nature of the problem:

> "A consequence of the successful control of diseases due to exogenous factors is the increasing relative importance of genetically determined diseases and congenital abnormalities among the remaining causes of death and disease. In 1900 the infant mortality rate was 154 per 1,000 in England and Wales; in 1970 it was 18 per 1,000. In this period the deaths from congenital malformations have shown only a small reduction so that their relative importance is much greater today; whereas in 1900 congenital malformations accounted for 1 in 30 of infant deaths, they account for 1 in 5 today. Further, a high proportion of infants with genetically determined diseases and congenital disorders reach adult life." 9/

6/ L. Charles Birch, "Human implications of the discoveries in the biological sciences", paper presented to World Council of Churches, Exploratory Conference on Technology and the Future of Man and Society, Geneva, June 28-July 14, 1970, p.4. Similarly, information furnished by the Government of Hungary on 19 August 1975.

7/ James F. Crow, Population Perspective, p.74; see also Bruce Hilton, Daniel Callahan, Maureen Harris, Peter Condliffe and Burton Berkley (Eds.) Ethical Issues in Human Genetics, (A symposium sponsored by the John E. Fogarty International Center for Advanced Study in the Health Sciences and the Institute of Society, Ethics and the Life Sciences, October 10-14, 1971), p.73.

8/ Bentley Glass, "Ethical Problems Raised by Eugenics", World Council of Churches, Consultation on Genetics and the Quality of Life, Zurich, 25-29 June, 1973, No.8, p.2.

9/ Human Genetics, The Standing Medical Advisory Committee for the Central Health Services Council, the Secretary of State for Social Services and the Secretary of State for Wales; Department of Health and Social Security, Wales, July 1972, p.1.

2. The Nature of the Burden

8. It has been estimated that "an anomalous baby is born somewhere in the world every thirty seconds".[10] More than 1,600 human disorders have been determined to result from defects in the content or the expression of the genetic information in the DNA molecule.[11] Some, such as cystic fibrosis[12] and sickle-cell anaemia[13] are relatively common while most others are quite rare.[14] Approximately one-half of all congenital blindness and deafness is due to genetic causes.[15] It is estimated that approximately 4 per cent of populations studied are born with genetic defects.[16] Some 20 per cent of these are caused not by inherited defects but by environmental factors - drugs, disease, radiation - occurring during pregnancy, while some 60 per cent of these births are believed to be the result of interaction between heredity and the environment.[17] The 4 per cent of the population born with genetic defects constitute 200,000 persons per year in the United States of America;[18] the 500 arrivals per week in Great Britain maintain a total genetically-handicapped population of about 2 million.[19] It is further estimated that fifteen out of one hundred babies born alive later manifest some form of inherited disorder, ranging from a readily recognizable defect to a high susceptibility to such ailments as cancer and heart disease.[20] The care of such

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10/ John Fletcher, "Attitudes Toward Defective Newborns", The Hastings Center Studies, Vol. 2, No.1, January 1974, p.29.

11/ Theodore Friedmann, "Prenatal Diagnosis of Genetic Disease", Scientific American, November 1971, p.34.

12/ The most common serious recessive defect (occurring 1 in 600 births in New York, 1 in 700 in Sweden); lungs, trachea and intestines fill with fluid; a major child-killer; treatment is possible but arduous, expensive and incomplete. Gerald Leach, The Biocrats; Ethics and the New Medicine, Pelican 1972, p.142.

13/ A "construction error" in the blood protein haemoglobin; no treatment is currently known.

14/ Theodore Friedmann, op. cit., p.34.

15/ Charles Birch, "Genetics and Moral Responsibility", World Council of Churches, Consultation on Genetics and the Quality of Life, Zurich, 25-29 June 1973, No. 4, p.4.

16/ Charles Birch, ibid., p.4; Gerald Leach, op. cit., p.126.

17/ Robert W. Stock, "Will the Baby be Normal?", The New York Times Magazine, 23 March, 1969, p.82.

18/ Ibid.

19/ Gerald Leach, op. cit., p.126.

20/ Walter Sullivan, "If we master the gene", New York Times, 14 June 1970, p.9.

persons constitutes a major use of medical facilities. Statistics showed that in Northern Ireland 26 per cent of the hospital beds were occupied by persons with genetically caused defects and approximately 6 per cent of consultations with general practitioners and 8 per cent of those with specialists concerned such persons.[21] Dr. J. Bernard, Chaire de clinique des maladies du sang, Faculté de Médecine, Hôpital Sant-Louis, Paris, has stated:

> "To take another example from my discipline, for the last ten years we have succeeded in not losing a single haemophilic. This means that these people, who formerly lived only to the age of ten, are now able to marry and have daughters who transmit the condition and seriously increase the number of haemophilics in countries such as Scandinavia, the Netherlands, France and the U.S.A. where this disease is most common." [22]

The fear has been expressed that due to a gradual degeneration of the genetic stock, "[a]t a certain stage in its evolution, half the human race would turn into a pitiful flock of incurable invalids who would have to be looked after by the other half".[23]

9. A not uncommon misconception is that genetic disease is untreatable. This is true of a number of disorders, but is far from being true generally. In some, early detection and treatment can prevent the disorder from manifesting itself, in others partial amelioration is possible.[24] It should be recognized, however, that certain advances in medical science have themselves made manifest otherwise benign genetic defects; for example, genetic sensitivity to some of the newer therapeutic drugs.[25] Defects which were severely disabling or even fatal, not in themselves but in man's early struggle for survival (such as myopia or defective teeth, now corrected by spectacles and dentures), have become minor defects through the advances in technology. A similar instance is diabetes when controllable by insulin.[26] Dr. L. Charles Birch has written as follows:

> "The practice of euphenics increases the 'genetical burden' of mankind, though the felt burden is relieved to a large extent by treatment. Dobzhansky points out that a slowly increasing incidence of genes for myopia can probably be tolerated; opinions may differ about diabetes and defects of similar gravity; what of diseases of greater gravity such as phenylketonuria?"[27]

The Government of Sri Lanka reports that "[E]pileptics and haemophiliacs are observed in larger numbers, and that the burden placed on the State is great".[28]

21/ Charles Birch, "Genetics and moral responsibility", op. cit., p.4.

22/ UNESCO, Science Policy Studies and Documents, No. 16, Proceedings of the Symposium on Science Policy and Biomedical Research, p.46.

23/ David Klein, "Genetic manipulations", Impact of Science on Society, vol. XXIII, No. 1, January-March 1973, p.21.

24/ "Human genetics and public health", op. cit., p.33.

25/ Ibid., pp.24-34.

26/ Dr. Theodosius Dobzhansky, "Human evolution and ethical issues", Address, World Council of Churches, Exploratory Conference, The Future of Man and Society, Geneva, 28 June-4 July 1970, p.6.

27/ L. Charles Birch, "Human implications of the discoveries in the biological sciences", op. cit., p.4.

28/ Information furnished by the Government of Sri Lanka on 5 March 1974.

10. It has been said:

> "Mankind is living in environments that are strongly influenced by his over-all culture, and these environments include medical care. This situation is here to stay. The genetic endowment of mankind will have to be continuously fitted to such new cultural environments, not to the environments of the past, even though these are sometimes referred to as 'natural' ones." 29/

11. Different disorders manifest themselves among different ethnic groups with varying frequency. What may be considered a tolerable level of defects in one geographic area may not be so in another. It has been reported that "...[a]s far as Ghana is concerned, Sickle Cell Disease is considered as the only genetically transmissible disease of public health and social importance".

> "It is recognized however that genetically transmissible diseases with far more social, economic and health implications than Sickle Cell Disease are found in other countries especially in Europe and America". 30/

12. The Government of Hungary reports:

> "Congenital dislocation of the hip is the more frequent congenital aberration in Hungary (with a frequency of 2.7 - 2.8 per cent at birth). Formerly a grave dislocation of the hip represented a serious obstacle to marriage, to pregnancy and to childbirth; it represented a selective factor. The early orthopaedic screening tests and the suitable treatment of suspected cases can essentially eliminate the manifestation of the tendency to congenital dislocation of the hip. However, since the selective factor is pushed into the background the proportion of affected persons ... may increase." 31/

13. As to the actual increase in the incidence of defective genetic material, it has been written that:

> "Calculations have been made by various people [which] show that the time to double the frequency of mutant genes can be very long (hundreds of years) or very short, depending on the inheritance pattern of the allele, the family size, and the mating patterns in practice. However, estimates of this type will be greatly modified should the art and science of carrier detection be applied widely enough to influence selection of spouse and the pattern of childbearing in families carrying mutant genes." 32/

14. A great deal of emphasis has been put on genetic inheritance but the mutation rate remains important. One writer analyses the situation as follows:

29/ "Human genetics and public health", op. cit., p.26; see also David Jenkins, "Problems of biology and the quality of life", Anticipation, February 1972, No. 10, p.25.

30/ Information furnished by the Government of Ghana on 21 March 1974.

31/ Information furnished by the Government of Hungary on 19 August 1975.

32/ Carol L. Clow, Clark F. Fraser, Claude LaBerge and Charles R. Scrivner, On the Application of Knowledge to the Patient with Genetic Disease: Progress in Medical Genetics, Arthur Steinberg and Alexander G. Bearn, eds; Grune and Stratton, New York, 1973, p.207.

"However, the mutational part of the genetic load must be considerable, and this is related to the rate of mutation (informational deterioration) in the genetic material. A certain level of mutation is an inevitable byproduct of molecular accidents in cell metabolism. However, if we argue from the relative incidence of environmental compared with intrinsic carcinogenesis, which may be a parallel phenomenon, we may judge that four-fifths of our ambient mutation rate is of environmental origin, and could be eliminated by environmental hygiene (relating to drugs, food additives, and possibly some natural foods, water and air pollutants, certain virus infections). About ten percent of that quota can be attributed to the natural radiation background, which is essentially not avoidable, and an equal proportion to artificial radiation (mostly incidental to diagnostic X-ray), much of which is avoidable." 33/

15. At a UNESCO symposium the following comment was made:

"Man is the first species to be in a position to modify its genetics; we have fettered the natural selection and we should not take this lightly. In the last few decades, natural selection has ceased to apply, survival of the fittest is no longer the rule, and the sickly and weak are kept alive and procreate. This is not necessarily bad - it depends on whether we look at this development from the viewpoint of the individual or of future society." 34/

3. Meaning of Genetic Health

16. There is particular difficulty in arriving at a precise definition of genetic health. The occurrence of gout in Philippine males may be used as an illustration:

"A Philippino male living under the restricted diet and the harsh environment of the Philippines will generally not develop gout. Yet, because it is a genetically determined trait, we know that the predisposing factors may be present. When some of these same individuals move to the United States and live on a relatively rich diet, under less rigorous conditions, they are more likely to develop overt, clinical gout. Are these genes then healthy in the Philippines and unhealthy in the U.S. according to where disease occurs, or are they only unhealthy genes if they produce disease under any circumstances? According to the latter view, all genes are unhealthy since there is, at least hypothetically, the chance that there is an environment under which every gene is to some degree maladaptive." 35/

33/ Joshua Lederberg, "Biomedical frontiers: genetics: The Challenge of Life", Biomedical Progress and Human Values, Roche Anniversary Symposium, Basel, Switzerland, 31 August-3 September 1971, p.234.

34/ UNESCO, Proceedings of the Symposium on Science Policy and Biomedical Research, No. 16, Science Policy Studies and Documents, p.50.

35/ Murray, Robert F. Jr., "Genetic Disease and Human Health ... A Clinical Perspective", The Hastings Center Report, Vol.4, No. 4, September 1974, p.5.

17. Another example may be drawn from sickle-cell anaemia. Persons carrying one gene for making abnormal haemoglobin, are said to have the "sickle-cell trait"; when they receive the gene in duplicate they suffer from sickle-cell anaemia. Carrying the trait may be deemed undesirable, for, although the person does not suffer from its effects, it does put him or her at risk of producing a child who may receive two like genes and consequently the disease. The same single gene is, however, advantageous in a malarial environment since it offers protection against malaria. Consequently, can it be said that a carrier of the trait has good genetic health in one part of the world and is genetically defective in another?36/

18. Furthermore, the demarcation between disease and non-disease has changed with advances in medical knowledge. This is particularly evident in psychiatric disorders which may have a genetic element in their origin. Citing depression as an example, one writer describes the situation as follows:

> "Some depressions may represent the lower end of the normal distribution curve of feeling tone and may affect anyone because of an overwhelming grief-producing event in the environment. In other cases there may be a genetically-determined biochemical abnormality which leads to depression even in the absence of strong environmental determinants. At present, the differentiation of the qualitatively abnormal organic types of depression from so-called 'reactive' depression often is difficult. However such distinctions will remove from the real 'disease' category a considerable number of people who only differ quantitatively but not qualitatively from the rest of the population. Until recently, many psychiatrists have rejected ideas that some patients might owe their symptoms to qualitative differences in their brain chemistry."37/

19. The difficulty in reaching a definition of genetic health lies in the lack of an ideal genotype. Choice of one blood type over another - no one of which is considered a genetic endowment or disability - may affect health. Type A blood may offer some protection against duodenal ulcer, but may predispose the person for infection with smallpox.38/ An apparently healthy man may carry the gene for a defective enzyme which, if exposed to any of a variety of drugs - including aspirin - may develop a serious, if not fatal, anaemia.39/

20. Although the authorities vary in their estimates, there is general agreement that every human being carries a number of recessive genetic defects. The defective genes to not affect the individual, but will possibly pass to a certain proportion of his or her offspring. And at some stage of descent, one such gene may be paired to a similarly defective gene and result in a person with a demonstrable genetic disorder.40/

21. One authority dismisses the possibility of agreement on a definition of genetic health:

36/ Ibid., pp.5-6.

37/ Arno Motulsky, The Significance of Genetic Disease, Bruce Hilton, op.cit., p.62.

38/ Marc Lappé, "Genetic Knowledge and the Concept of Health", The Hastings Center Report, Vol. 3, No.4, September 1973, p.2.

39/ Marc Lappé, op. cit., p.2.

40/ Ibid., pp.1-2.

"One thing, however, is clear. It might be possible to establish very broad agreement about a certain section of the meaning of the phrase 'genetically handicapped'. This would refer to acute physical and mental defect passed on in the genes and which were liable to promote rapid death or very clear malfunctioning (e.g. phenylketonuria, Down's syndrome, retinoblastoma). Once this area of acute malfunctioning was left behind, however, any further question of 'genetic defect' and still more any positive definition whatever of what should be promoted as 'genetic advantages' would be highly questionable and unlikely to receive any broad agreement of the kind that cannot be argued against very strongly."41/

22. Furthermore, "... a recessive gene that today seems undesirable may be able to defend the body against some as yet unseen disease".42/ On this issue, the Government of Sweden has pointed out:

"It is obvious that predispositions which in a certain combination give rise to a disease may be described as 'bad'. It must be pointed out however that predispositions can only be judged in this way when they are present in certain combinations and in a particular environment. After a certain number of generations of re-combination with other predispositions, or if the predispositions are present in another environment, then perhaps a predisposition that has been termed 'bad' may be a benefit to the person concerned. To sum up, today no one has the knowledge and the wisdom making it possible to determine what can be described as 'good' or 'bad' genes."43/

23. A not dissimilar approach is embodied in the following statement:

"[F]rom a population perspective, many geneticists seem to view genetic disease and the presence of deleterious traits as a positive sign of genetic diversity much to be desired, rather than a negative sign of genetic pollution." 44/

41/ David Jenkins, op. cit., p.27.

42/ Walter Sullivan, op. cit., p.9.

43/ Information furnished by the Government of Sweden on 12 March 1974. Similarly, information furnished by the Government of Hungary on 19 August 1975.

44/ Sumner B. Twiss, Jr., "Examining the Pros and Cons of ... Parental Responsibility for Genetic Health", The Hastings Center Report, Vol. 4, No. 1, February 1974, p.11.

4. The Feasibility of the Practice of Eugenics 45/

24. It has been urged that it would be desirable, in general, if persons suffering from serious hereditary diseases with risk of transmitting the disorder to their offspring were to refrain from having children.46/ As long as any reproduction occurs, however, deliterious recessive genes will be perpetuated since all persons carry several of them. Eugenic measures can never cause the complete disappearance of hereditary disease or disabilities since spontaneous mutations and breeding between heterozygous carriers of recessive traits will always result in persons suffering from genetic disabilities.47/ The recent advances in genetics, by the utilization of genetic screening, counselling and prenatal treating of the foetus (see paragraphs 52-145 for a fuller discussion of these techniques) aim to avoid unfavourable combinations of undesirable recessive genes, but do not aim at, or achieve, the lessening of the incidence of these genes in the population.

25. One writer has expressed this opinion:

> "[S]ooner or later mankind will be forced to manage its evolution by negative as well as by positive eugenics. Some of my colleague biologists have constructed brave new world programs of eugenic betterment, which they urge to be put in execution immediately. What amazes me most is that the authors of these programs are fully confident that they know what sort of man would be the ideal not only at present but for all time to come. Has it ever occurred to them that their views of the future may be limited by their preconceptions? Their utopias may not be so glamorous to our remote descendants, who will live under conditions that we can scarcely imagine. Negative eugenics faces somewhat fewer uncertitudes than the positive one. It will be easier to reach near-unanimity on which genotypes mankind will b etter off without, than an agreement on what the ideal man should be."48/

26. The question arises, however, as to the effect that negative eugenics, through, for example, prenatal diagnosis can actually have in the elimination of recessive genes with deleterious effects. Authorities have shown that programmes of prenatal detection and selective abortion may actually bring about an increase in the frequency of recessive genes for certain diseases.49/

45/ "The science of improving off-spring" (The American College Dictionary. Random House, New York, 1947).

46/ Human Genetics and Public Health, op.cit., p.31.

47/ Ibid.

48/ Dr. Theodosius Dobzhansky, op.cit., p.10; see also Bentley Glass, op.cit., p.3.

49/ Information furnished by the Government of Hungary on 19 August 1975.

The birth of a defective child, the time and concern devoted to it and the economic implications of its upbringing have been found to be factors limiting the number of children that a couple will have. Had such a child not been carried to term because its defective genetic makeup was discovered by prenatal diagnosis, and the foetus was aborted, the couple would tend to have a replacement child, and possibility even a larger number of other children. These overtly normal children may carry to defective gene, and thereby increase its incidence in the population. This phenomenon is expected to occur as shown by the following:

> "Under past conditions, an affected child would usually remain in the home for a variable period of time, absorbing parental love and attention. Not only would it make its contribution towards the completion of the sibship but, given any kind of family planning, it seems a reasonable hypothesis that such a child would as often tend to inhibit the birth of further children."50/

27. With the advent of prenatal detection, the situation may instead evolve as follows:

> "[L]et us assume that in the future each family will have two normal children and will compensate for foetuses lost through abortion. Under these conditions the prevention of natural gene loss through death or nonreproducibility of the affected homozygotes could lead to an increase over many generations of 50 per cent in the [deleterious] gene frequency."51/

Certain genetic disorders are linked to the sex-determining chromosomes.52/ With respect to certain of these disorders, the results of eugenic practices have been dramatic:

> "[A] ... startling effect could occur in X-linked diseases such as hemophilia, where no distinction can yet be made between affected and normal males in utero. If abortion of all male foetuses in carrier mothers were to become widespread, the result could be a 50 per cent increase in the [deleterious] gene frequency with each generation."53/

50/ James V. Neel, "Ethical issues resulting from prenatal diagnosis", Early Diagnosis of Human Genetic Defects - Scientific and Ethical Considerations: Fogarty International Center Proceedings No. 6, Maureen Harris, Ed. HEW Publication No. (NIH) 72-25, 1970, p. 222; see also Amitai Etzioni, op.cit., pp. 85-86.

51/ Theodore Friedmann, op. cit., p. 40.

52/ Females carry two X chromosomes, males an X and a Y. A sperm carries either an X or a Y chromosome. If a sperm carrying an X chromosome fertilizes an ovum, the child will be female; if the sperm carries a Y, the child will be male. The ovum will contain one or the other of the mother's chromosomes. If she carries a recessive genetic defect linked to one of her X chromosomes, her male offspring have a 50 per cent chance of being afflicted.

53/ Theodore Friedmann, hoc.cit., p. 49. Similarly, information furnished by the Government of Hungary on 19 August 1975.

28. The Government of Sweden has summarized the situation in the following:

> "The prenatal diagnosis of hereditary diseases does not only mean that diseased foetuses are removed by abortion but also that healthy foetuses are not removed. But these healthy foetuses will in all probability become carriers of the predisposition to disease which made the examination necessary. In this way, these predispositions will gradually increase in the population as a result of prenatal diagnosis."54/

29. Although there is a general acceptance of the fact of increase in the incidence of defective genes as a result of prenatal intervention, the question remains: how substantial will that increase be? A number of authorities agree that the increase will be slight and slow.55/ At a symposium dealing with ethical issues in human genetics the following example was given:

> "We have considered the genetic impact of screening and prevention of one recessive disorder, Tay-Sachs disease. If one were to screen every married Ashkenazi Jew of child-bearing age in the United States, abort each pregnancy in which a homozygous recessive fetus is identified, and enable each couple in the population (including doubly heterozygous couples) to have two unaffected children, it would take 8,750 years to double the carrier rate in the American Ashkenazi Jewish population as the result of the slight increase in heterozygous children which would result."56/

30. It might, therefore, be suggested that any attempt to create a genetic public policy is hopeless. However, it has been deemed clearly not so. One writer contends that:

> "[W]hile we may not be able to reduce the defective rate, we can at least catch nature's errors and eliminate them before they turn into miserable children, agonizing parents, and public charges. We may well have to repeat the process for each generation, but this does not make it without value. While it would be preferable to eliminate these illnesses once and for all, the next best thing is to eliminate their consequences - their human and economic costs."57/

54/ Information furnished by the Government of Sweden on 12 March 1974.

55/ Amitai Etzioni, "Doctors Know More Than They're Telling You About Genetic Defects", Psychology Today, November 1973, p.31; Amitai Etzioni, "Social Implications of the Use or Non-Use of New Genetic and Medical Techniques", C.I.O.M.S. Round Table Conference on Human Rights, 14, 15 and 16 November 1973, RT8/A3.1, p.8.

56/ James F. Crow, op.cit., p.81.

57/ Amitai Etzioni, "Genetic Fix," op.cit., p.110; see also Amitai Etzioni, "Social Implications .... and Medical Techniques", op.cit., p.14.

5. Sterilization and Marriage Bars

31. Prevention of disease has always been considered by society as a desirable aim, and the promulgation of regulations to that end, the proper function of government. Thus, innoculation, quarantine, control of food and drugs have been instituted. Extrapolating from this, one authority has written:

> "Genetic disease is certainly a 'communicable' disease even though it is transmitted vertically rather than horizontally. But genetic isolation by compulsory sterilization of individuals with lethal genes is not as acceptable to our society as physical isolation of the patient with tuberculosis or leprosy. One could argue that more individual freedoms are encroached upon by quarantine than by sterilization -- freedom of movement has always been a cherished constitutional right."58/

Another authority describes the state's concern as follows:

> "The state, accordingly, has an interest in, and may be expected to pursue, methods of preventing the transmission of genetic defects; one method will be the discouraging, preventing or punishing of such sexual congress as might be expected, for genetic reasons, to give rise to defective progeny."59/

32. The Government of Hungary has expressed the opinion that:

> "Within the limits of humanity and practicability it is right to promote the voluntary birth control of genetically seriously affected persons. Possibilities for this end exist in genetic consultation, in intrauterine embryo diagnosis and in the effective application of methods of birth control. These voluntary and well-founded eugenic activities serve the concerted interests of the individual, the family and society. However, such activity as selective abortion, based on intrauterine diagnosis, cannot be directed towards a limitation of the birth of asymptomatic disease carriers (recessive heterozygotes, hemizygotes) although this means an increase of the pathological genes in the population."60/

58/ Clark F. Fraser, "Survey of Counselling Practices." Bruce Hilton, op.cit., p.15.

59/ Lord Kilbrandon, "The comparative law of genetic counselling", Bruce Hilton, op.cit., p.252.

60/ Information furnished by the Government of Hungary on 19 August 1975.

33. Although the risk, from the genetic viewpoint, of breeding between closely related persons and the resulting increased probability of offspring manifesting undesirable traits has been scientifically confirmed only in recent times, religious and secular bars to incest of varying degrees have long existed. It has been observed that "'[s]ome minimal rules of this sort are practically universal in human societies.'"61/ Lord Kilbrandon summarized the situation in this manner:

> "The universal enforcement of incest laws demonstrates that in every country at all times the state has claimed the right to interfere, by prohibition or punishment or both, with the liberty of its subjects to join together sexually, whether in marriage or not, and to do so with the object of protecting the health of unborn generations. This is done for genetic reasons which can only have been guessed at as a result of empirical reasoning; ..."62/

34. Whereas genetic counselling is directed primarily to the individual family, marriage bars, and even to a greater degree laws relating to sterilization of persons, are eugenic measures concerned primarily with the population as a whole.63/ At the Abidjan World Conference on World Peace through Law, the sterilization laws of various states were discussed:

> "No compulsory population controls exist in the world except with respect to compulsory eugenic sterilization.
>
> "Compulsory eugenic sterilization laws in Japan allow the operation when it is deemed in the public interest, as determined by the Eugenic Protection committee. Mentally infirm persons confined to state institutions are subject to compulsory sterilization in twenty-six states of the United States ... [O]ther countries have similar provisions ...
>
> "Significant legal barriers to such measures have been noted including those having human rights dimensions. In the United States, eugenic sterilization has received constitutional approval but the right to procreate and the right to marital privacy present formidable obstacles to more extensive measures. The right to freedom of religion, where divisible into religious belief and religious conduct, has been found to be subject to limitations in the United States where a 'compelling state interest' could be shown."64/

61/ Lord Kilbrandon, op.cit., pp.252-253; see also Who Shall Live - Man's Control over Birth and Death, a Report prepared for the American Friends Service Committee, Hill and Wang, New York, 1970, p.67.

62/ Lord Kilbrandon, op.cit., p.253.

63/ "Human genetics and public health", op.cit., p.31.

64/ James P. Downey, "Population Control and the Law", Abidjan World Conference on World Peace Through Law, 26-31 August, 1973, p.4.

35. The line between voluntary and compulsory sterilization practised for eugenic reasons is not always clear. Minors or incompetents are often the subject of such a procedure, and generally incapable of giving legal consent. In the United States of America where it is reported that 100,000 persons are sterilized each year in clinics supported by federal funds - though only some of these sterilizations are for eugenic reasons, most being for birth control - a specific protective procedure must be followed where the subject is legally incapable of giving consent: the decision is taken by a special committee which is then reviewed by a court.65/

36. In the case of Buck v Bell 66/ the United States Supreme Court in 1927 upheld a state statute imposing involuntary sterilization on mental defectives. The procedure would permit the subject, who was both daughter and mother of a defective, to leave the hospital and return to the community. A writer has stated: "Mr. Justice Holmes with his famous 'Three generations of imbiciles are enough' 67/ made short shrift of the substantive due process argument involved in sterilization: that is, whether the evil to be ameliorated by the legislation called for this drastic solution."68/ The question is open, however, whether today in the absence of a strong scientific showing of transmissibility of mental deficiency, involuntary sterilization is legally possible in the United States of America, although currently many of the states maintain compulsory sterilization laws for a variety of bases.69/

37. In Denmark, sterilization is required of women whose I.Q. (intelligence quotient) is less than 75.70/ The Government of Finland has provided the text of The Sterilization Act, No.283 of 24 April 1970:

65/ "Regulations set on Sterilization", New York Times, 21 September 1973.

66/ 274 U.S. 200 (1927).

67/ Ibid., p.206

68/ Leila Obier Schroeder, Some Legal Aspects of Population Control, a paper presented at the Third World Congress on Medical Law, Ghent, Belgium 19-23 August 1973.

69/ Theodore Friedmann, "Conflicting Rights and Human Life", C.I.O.M.S. Round Table Conference on Human Rights, 14, 15 and 16 November 1973, TR8/B/2.3, p.11; see also Jeannie I. Rosoff, "Sterilization: The Montgomery Case and its Aftermath", The Hastings Center Report, Vol.3, No.4, September 1973, p.6.

70/ Amitai Etzioni, op.cit., p.11.

"Section 1

Sterilization may be performed at the request of the person concerned in observance with the provisions of this law:

(1) when there is reason to assume that his/her offspring would be mentally retarded or that they would have or develop a serious disease or physical deformity;

...

Section 2

If because of mental disease, mental retardation ... the person is incapable of understanding the significance of sterilization it may, if there are weighty reasons for the measure, be performed under items 1 and 2 of paragraph 1 ... in Section 1 with the consent of a guardian or a specially appointed trustee."

38. The government adds:

"When abortion is induced under the provisions of paragraph 5 of Section 1 with reason to assume that the child will be mentally retarded because of the woman's mental retardation, sterilization must also be performed in connexion with interruption of pregnancy unless there are weighty reasons to the contrary."71/

39. The Government of Ghana has expressed a different viewpoint:

"Ghana is unable however to find any ethical or other justification for legislation or any measures aimed at preventing marriage between persons who are potentially capable of transmitting diseases of this nature to their offspring. It is felt that national health authorities should organize information and education programmes on diseases of this nature and their implications and also within their resources to provide services for genetic counselling."72/

40. The Government of Yugoslavia has reported:

"[T]here exist neither legal practice nor legal provisions regarding persons suffering from genetically transmissible diseases. This question remains completely open for the time being. Nevertheless, considering the incomplete elaboration of the matter in legal literature, as well

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71/ Information furnished by the Government of Finland on 25 February 1974 on the Sterilization Act, No.283, 24 April 1970 and Statute On Induced Abortion, No.359, 29 May 1970, Section 3.

72/ Information furnished by the Government of Ghana on 21 March 1974.

as the ideas of humanism prevailing in Yugoslav legal theory, it is difficult to presume that the position of the Yugoslav law concerning this matter would favour the taking of any measures towards "genetically burdened" persons (castration and the like)."73/

41. On the issue of compulsory sterilization, the League of Arab States has taken this position:

"We may also raise in this connexion the question of sterilization operations performed either by force or deception because they deprive man of his right to have children. It is therefore deemed necessary to have provisions banning the performance of such operations without the approval and free will of the person concerned."74/

42. Despite the existence of legislation and some case law on the subject, the legality of compulsory sterilization remains a question of dispute. It has been urged that "... compulsory eugenic controls of a 'positive' nature would violate the due process clause of the fifth and fourteenth amendments, as well as the ninth amendment of the [United States] Federal constitution as most recently interpreted."75/ The writer also refers to Article 12 of the European Convention on Human Rights which provides: "Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right." He suggests that this Article would make sterilization, for a number of reasons, unlawful. The writer goes on, however, to state the following opinion:

"It might well be, however, that the European Court would not condemn 'national laws governing the exercise of' the right to found a family if those laws were designed to prohibit the wilful transmitting of genetic defects. Such laws would stand on exactly the same footing as those which, for genetic reasons, forbid marriage and punish sexual intercourse between persons of particular degrees of consanguinity."76/

43. At a C.I.O.M.S. Round Table a discussion of conflicting rights and human life prompted the following statement:

"And most importantly, the resolution of conflicting rights must not be decided only on the basis of what is legal, but also on what is just. There are some who argue that compulsory sterilization on any grounds is unjust, and recent experience should convince us that the interests of the state lead so easily to abuse of human rights so as never to justify the abridgment of what courts in this country have called the basic civil right of procreation."77/

73/ Information furnished by the Government of Yugoslavia on 7 May 1975.

74/ Information furnished by the League of Arab States on 11 April 1970.

75/ Lord Kilbrandon, op.cit., p.254.

76/ Ibid.

77/ Theodore Friedmann, op.cit., p.12.

44. In a report prepared for the American Friends Service Committee the following position was taken and explained:

"We are opposed to compulsory abortion and to compulsory sterilization and believe that such laws should be repealed.

"In cases of severe mental retardation where voluntary sterilization is refused, it may be necessary to institutionalize the afflicted persons in order to protect them and society.

"The abuse of eugenics in the Nazi experiments points up some of the dangers of human manipulation to serve eugenic purposes. We believe that legal barriers to private and voluntary eugenics, such as artificial insemination, as well as to birth control and abortion, should be removed, and that some degree of preventive genetic counselling may be justified and helpful."78/

45. Another writer attacks the negative eugenics movement in this manner:

"This phase of the movement is best opposed by reliance upon a traditional principle of natural law philosophy. Stated simply, it is that man has a right to procreate.

...

"To obviate this right is to infringe upon one's substantive due process liberty. The nature of man, his body capabilities, deserve the highest possible protection that a culture can provide. If we cannot accept this intuited truth, we are less than men.

"Acceptance of this proposition carries with it the following inferentially related results. Punitive, eugenic, and environmental compulsory sterilization laws should be repealed as they interdict constitutionally sanctioned behaviour. Criminal statutes should be enacted penalizing anyone who performs a non-consensual sterilization. The aim of such statutes would be to manacle the over-zealous judicial executors of eugenic policy."79/

46. Amitai Etzioni found the compulsory elimination of undesirable genes intolerable and repugnant. He states:

78/ Who Shall Live - Man's Control Over Birth and Death, op.cit., p.69.

79/ John Batt, "Law and the Bedroom", Saturday Review, 3 August, 1968, p.48.

"Unlike excessive use of autos, or even the abuse of one's teeth, the union between two persons which gives life to a third one should be kept free of all government intervention. I would be horrified if the government budgeted the number of children per family or put a contraceptive drug into the water supply or forced mothers to abort 'surplus children'. One need only think of what would happen if some official decided that in order to reduce criminality, chromosome tests on all pregnant women would be required and abortions demanded of all mothers who carry XYY 'criminal' foetuses. We would end up with policemen dragging women to abortion clinics and mothers going underground to protect their embryos. If the government uses its force with respect to these matters, it would constitute the ultimate violation of the contract which keeps people tolerant of the state. It would completely undermine the legitimacy and the moral basis of government.

Because genetic technology will improve, the appetite to interfere may well be excited. Therefore if any attempt is made to move in the direction of coercive intervention, I favour it being met with the utmost opposition by citizens and their representatives. To symbolize and ingrain the rejection of forced genetics, I would welcome the repeal of all genetics-by-legislation, that is, by force of law, which now exist." 80/

47. At a Kennedy Foundation Symposium in the United States of America the rights of the retarded were examined and the contention was heard that "[t]he rights of the retarded are often negated by people who claim that the protection of the retarded is their chief aim."81/ The routine sterilization of the retarded was decried and the popular belief that retardates were incapable of regulating their sexual impulses was denied. The control of procreation by institutionalization or sterilization as requested by parents was opposed - the parents being deemed unqualified to make an assessment of the situation. The following issue was raised:

"'whether parents should be permitted to deprive their children permanently of the opportunity of reproducing merely on the basis of their own concerns or fears.' If the parents are not qualified, then does society as a whole have the right to act on behalf of the retarded? For example, can society designate selected arbiters and authorize them to provide an informed consent? Could these guardians rationally decide what is right and just for a 16 year old girl on the basis of the symptoms that are readily available at the time, but which may disappear."82/

80/ Amitai Etzioni, "Genetic Fix" op.cit., pp.107-108.

81/ "Ethics in Biomedicine: A Call for Action", Science News, Vol.100, No.18-30Oct. 1971, p.294.

82/ "Ethics in Biomedicine: A Call for Action", op.cit., p.294.

48. It has further been contended in the United States of America that parents do not legally have the right to obtain sterilization of minors or incompetents. "Only a court can take away the God-given right to bear children," it has been maintained.83/

49. Opponents of legal restriction on the proliferation of deleterious genes further argue that it would be difficult to determine which genes are sufficiently undesirable to come under control. It has been suggested, however, that certain particularly severe afflications might be a starting point "... on which all (or nearly all) would agree."84/

50. Nevertheless, whatever arguments may be put forward on the ethics of coercive genetic control, one writer points out that, as a practical matter, "the scope for such action is limited. Even systematic sterilization of individuals with certain inheritable diseases would take centuries to produce an appreciable result."85/

51. See paragraphs 83 to 96 below for a discussion of other approaches to the limitation of procreation in view of genetic implications.

83/ Drummond B. Ayres, Jr., "Ethics and the Rights at Issue in Sterilization Case", The New York Times, 2 July 1972, p.10.

84/ Clark F. Fraser, op.cit., p.16.

85/ Professor Ole Jacob Brock, op.cit., p.152.

PART TWO. DEVELOPMENTS IN MEDICINE

I. THE HUMAN RIGHTS IMPLICATIONS OF PRE-NATAL GENETIC DIAGNOSIS AND COUNSELLING

1. Introduction

52. In recent decades a population explosion has focused attention on controlling the quantity of reproduction but only more recently has attention turned to the quality of offspring. The family itself has traditionally been bred for quantity, in view of high infant mortality and limited medical arts and facilities. Only recently, due to advances in the science of genetics, have reliable data become available whereby parents may determine the biological quality of their children. The process began as follows:

> "The discovery of Mendelian ratios underlying the genetic transmission of specific characteristics marked the first discovery of scientific knowledge of inheritance. Much later, when specific diseases were linked with specific modes of inheritance, there resulted increased accuracy in predicting the occurrence of some diseases and biological conditions." 1/

53. The recent development of screening of potential parents for genetic traits and interuterine diagnosis of fetal biological states has provided information and offered options not heretofore available. Potential parents may make educated decisions about the feasibility of procreation in the light of their genetic make-up, and, where a pregnancy is commenced, may have the health of the foetus assessed. 2/

54. Adult trait carriers of recessive genetic diseases - who themselves do not manifest any defect but may pass the disease on to their offspring - may be identified by a simple blood test. 3/ Prenatal diagnosis of a foetus may be done by examining a small amount of amniotic fluid withdrawn from the womb of a pregnant woman and analysing it to determine the genetic make-up of the foetus. The procedure, done during the fourth month of pregnancy - the earliest it can safely be performed - is called amniocentesis (from the Greek "amnion" meaning membrane, and "kentesis" meaning pricking). 4/ It is performed by inserting a long needle in the abdomen of the pregnant woman and drawing out a small amount of the amniotic fluid, the liquid in which the foetus floats. This fluid has special analytical value since it contains

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1/ James R. Sorenson, "Sociological and psychological factors in applied human genetics" in Bruce Hilton, Daniel Callahan, Maureen Harris, Peter Condliffe and Burton Berkley (eds.), Ethical Issues in Human Genetics (A symposium sponsored by the John E. Fogarty International Center for Advanced Study in the Health Sciences and the Institute of Society, Ethics and the Life Sciences, 10-14 October, 1971), Plenum Press, New York, London, 1973, pp. 284-285.

2/ James R. Sorenson, op. cit., p.285; similarly, Information furnished by the Government of Hungary on 19 August 1975.

3/ Bruce Hilton, "Will the Baby be Normal? ... And What is the Cost of Knowing?", The Hastings Center Report, Vol.2, No.3, June, 1972, p.8.

4/ "Man into Superman: The Promise and Peril of the New Genetics", Time, 19 April, 1971, p.38; Jane E. Brody, "Prenatal Diagnosis is Reducing Risk of Birth Defects", New York Times, 3 June, 1971, p.53.

cells washed from the foetus and its sac, and are genetically part of the foetus. Approximately one cell per thousand is still alive in the fluid and can be cultured in the laboratory. 5/ The technique first performed in Denmark in 1960 has spread rapidly to major medical centres, 6/ and the chromosome analysis of the amniotic fluid has lent itself to computerization. 7/ But whether the chromosome analysis is done manually in several hours or in thirty seconds by the computer, or applied to adult white blood cells or amniotic fetal cells, the procedure is the same and has been described as follows:

> "Once a cultured cell is ready to divide, a drug is applied to fix it at that point, because chromosome spreads can be seen only during division. The fixed spread is then photographed under a microscope, and the images of the cell chromosomes are cut out like puzzle pieces and pasted up according to the normal human chromosome arrangement, called an "idiogram." If the pieces do not fit the normal arrangement - if certain ones are, say, missing, misplaced or added - certain kinds of anticipated birth defects can be diagnosed." 8/

Analyses of 10 to 30 cells are usually done to ensure a correct chromosome diagnosis; the procedure costs approximately $100-$150 in the United States at present 9/ but is expected to drop to approximately $6 to $12 shortly with the expansion of automation. 10/

55. While there are more than 1,600 identified genetic disorders, 11/ only a small number - the authorities have reported figures ranging from 12 to 70 12/ - can be detected by amniocentesis at present. The number continues to grow as research progresses.

56. The techniques for detecting unaffected carriers of genetic disorders are also in the course of improvement. The list of detectable defects will grow, tests will become more discriminating, and with advances in technique, faster and less expensive.

5/ Walter Sullivan, "Wider Detection of Prenatal Flaws Expected to Spur Abortion", New York Times, 13 June, 1970.

6/ Jane E. Brody, op. cit., p.41.

7/ Joan Lynn Arehart, "Prenatal Diagnosis: How Fast, How Far?", Science News, Vol.100, No.3, 17 July, 1971, p.45.

8/ Ibid. As regards the procedures of prenatal diagnosis, see also paragraphs 69 to 73 below.

9/ Theodore R. Van Dellen, "Role of Fetal Cell Testing", New York Daily News, 16 January, 1974, p.64.

10/ Joan Lynn Arehart, op. cit., p.45.

11/ Theodore Friedmann, op. cit., p.34.

12/ "Man into Superman", op. cit., p.38. Amitai Etzioni, Genetic Fix, Macmillan, New York, 1973, p.23; Jane E. Brody, op. cit., p.53; Joan Lynn Arehart, op. cit., p.45.

2. The Use of Genetic Data as it Affects the Right to Privacy

57. Recent advances in genetics have consisted mainly in an increased capacity to diagnose conditions. Little can at present be done to cure a diagnosed condition; it is the other uses to which the diagnostic information can be put that is the present value of the advances. Genetic information may be used in a variety of ways, and, in view of this, it has been submitted "... that over the next 10 to 20 years we must re-examine and possibly modify attitudes towards privacy." 13/ The question stated succinctly is: "How can optimal use of genetic data best be coupled with the maintenance of privacy." 14/

58. The right to privacy involved is shielded by two basic rights: the individual's general right to privacy and the privileged doctor-patient relationship. 15/ It does not appear that a person found to harbour a deleterious gene is anywhere under any legal obligation to reveal this fact to his or her spouse, or potential spouse. The doctor-geneticist is not free to communicate this information to relatives or to public health authorities. However, the capacity to transmit a genetic defect is as great, if not greater than the capacity to transmit a venereal disease, which capacity in many jurisdictions is required to be reported to the health authorities and is frequently under statutory regulation for obtaining a licence to marry. 16/

59. Two levels of privacy are implicit, however, in even the most simple situation: "(1) The individual's own privacy and (2) that of other family members, including future offspring." 17/ Furthermore, there are two general routes by which privacy may be invaded: the first is through the individual who directly seeks medical attention. Upon discovery that the condition is genetic, the doctor may (properly from a medical point of view) seek genetic information from relatives, and even provide genetic counselling to them. The privacy of these relatives is thereby invaded. The second route is the identification of persons with genetic disorders through genetic screening processes or surveys. Some are legally required, such as the PKU screening of infants 18/ or for research purposes. These investigations are expected to increase. The peculiar ingredient of this invasion of privacy is that it is not initiated by the individual as a patient seeking medical assistance, but it is society which probes the individual and reveals to him - and possibly to others - the existence of a genetic defect. 19/

13/ Herbert A. Lubs, "Privacy and Genetic Information"; Bruce Hilton, op. cit., p.267.

14/ Ibid.

15/ Clark F. Fraser, "Survey of Counselling Practices", p.15; Bruce Hilton, op. cit., p.7.

16/ Clark F. Fraser, op. cit., p.15.

17/ Herbert A. Lubs, op. cit., p.267

18/ Phenylketonuria (PKV) the lack of an enzyme causing severe mental retardation unless a strict diet is instituted at birth. Mandatory screening of infants is required in many jurisdictions (Gerald Leach; op. cit., p.142)

19/ Herbert A. Lubs, op. cit., p.268.

60. In many situations the hazards involved in the collection of confidential information from segments of the population are acceptable because of the presumed benefits to society as a whole. One authority describes the advantages to be gained in connexion with the present subject:

> "In genetics, for example, the identification of trait carriers would be of great value in estimating the gene frequency among different populations. From this information we could calculate the number of individuals who are likely to be affected within a particular population. This would improve our capability to plan for and control genetic disease." 20/

61. Genetic information may be used in various ways. An advantageous use may be disclosure of information to an individual so that he or she may make an intelligent decision on whether to procreate, or, where permissible, to terminate a pregnancy where the foetus is determined to be defective. Misuse of such information may be the dissemination of it so as to injure the individual in his or her social or professional life. "Nonuse" of such information, while rendering complete privacy may deprive the individual of the opportunity to make knowledgeable decisions and represent a lost opportunity to use genetic information for the benefit of other family members. 21/

62. It is contended that:

> "The human rights of personal inviolability, self-determination in marrying and founding a family, and voluntary procreation imply freedom of parental choices in reproductive behaviour and the right to determine what is in the best interests of prospective offspring." 22/

63. Even in the present age of expertise in so many areas, it has been urged that "... parents are in the best and perhaps unique position to ascertain the total impact that a genetically defective child may have on themselves and their families." 23/

64. It has been proposed that "... parents have a duty to permit relevant genetic information to be transmitted to relatives in the extended family if this is medically/genetically indicated." 24/ The rationale for this proposition is that:

> "The affirmative considerations for recognizing this duty far outweigh the negative factors. Countervailing considerations raise problems which seem more practical and technical in character rather than representing matters of principle. The duty to communicate genetic information impinging on the welfare of other family members is, by its very nature, not merely a matter of purely personal and private concern, but would seem to have a solid moral basis."

20/ Mark S. Frankel, "The Application of Genetic Technology: Ethics and Pitfalls", UNESCO, Impact of Science on Society, Vol. XXV, No.1, January-March, 1975, p.86.

21/ James R. Sorenson, op. cit., p.283.

22/ Sumner B. Twiss, Jr., "Examining the Pros and Cons of ... Parental Responsibility for Genetic Health", The Hastings Center Report, Vol.4, No.1, February, 1974, p.11.

23/ Sumner G. Twiss, Jr., op. cit., p.11.

24/ Ibid., p.11.

"These proposals are made in the spirit of attempting to formulate an acceptable view of what can be called a "minimal ethic of genetic responsibility" in an area where so many different moral views and values prevail." 25/

65. Furthermore, the question has been asked: "Who owns the information about our genetic shortcomings?" 26/ Since all of us carry a number of deleterious genes, all persons are affected by this issue. Upon discovery of a condition does the doctor have a duty to inform relatives of his findings since they may also be affected? It has been strongly urged that the confidentiality of the data be protected. 27/

66. The computerization of genetic information and its storage in data banks has increased the possibility of the misuse of such data. Although at present there appear to be no nationwide genetic data banks, a number of local genetic registries are being developed in the United States. 28/ A registry records, by computer, all families with genetic disorders. The aim is to contact the families periodically, providing information about available treatment. The registries are run on a voluntary basis and one of the aims of the project "... will be to determine the families'" reactions to this intrusion into their privacy." 29/

67. Efforts are being made to assure the confidentiality of the information and the issue has been raised as to who should have access thereto. It is reported that in Sweden a data bank for certain diseases has been operating. 30/ It has been suggested that a board of medical geneticists, laymen and social scientists might be constituted to monitor any such arrangement. Although recognizing the hazards involved, Dr. Herbert Lubs of the University of Colorado, United States of America, rather than opposing the creation of such banks, analysed the role of the scientist in extracting the benefits from such data banks as follows:

"It is the history of science that, if something can be done, it will be done. Our role, I believe, is to see that something is done well, not to prevent its being done at all." 31/

68. Dr. Lubs also summarized the potential hazards and benefits of the loss of privacy attendant upon the uncovering of genetic data as follows:

"Potential Hazards of Loss of Privacy

Loss of feeling of 'privacy', per se.
Prejudicial use of genetic information by other persons.
Disastrous effects on the patient of 'loaded' information such as chromosomal sex. 32/
Creation of unnecessary concerns in other family members.
Control of reproduction in a biased or unsound fashion by society."

25/ Ibid.

26/ Bruce Hilton, "Will the Baby be Normal?...", op. cit., p.9.

27/ Ibid.

28/ Herbert A. Lubs, op. cit., p.273.

29/ Ibid.

30/ Ibid., p.274.

31/ Herbert A. Lubs, op. cit., p.274.

32/ See paragraphs 111 to 118.

"Potential Benefits of Loss of Privacy

Opportunity of realistically dealing with a high reproductive risk.
Opportunity to alleviate unnecessary fears in relatives at complications of genetic disease in relatives.
Opportunity to offer selective reproduction via therapeutic abortion to relatives at risk.
Opportunity to offer benefits of research to affected families, without the usual 5-10 year delay." 33/

3. The Procedures of Prenatal Diagnosis

69. The detection of birth defects at a time when the foetus can still be aborted has changed drastically the nature and potential of genetic counselling. 34/ Previously, persons known to carry genetic defects could only be counselled that they had a statistical probability of bearing a child with the disease. The same statistical probability exists for each successive pregnancy regardless of the results of prior pregnancies. Genetic counsellors who use amniocentesis and other fetal diagnostic procedures report that the availability of these tests are attracting as patients many persons who might be classified as having a "high risk" of producing genetically defective offspring. They further report that:

"As a result, the birth of many severely abnormal children has been prevented and hundreds of normal babies have been born to parents who might not otherwise have dared to have children." 35/

70. With the use of amniocentesis when the foetus is afflicted with a genetically caused illness ascertainable by the procedure, the foetus can be aborted. "Frequently the parents then follow-up with another pregnancy, which is again tested, until a child free of inherited disease is conceived." 36/ It is reported that half of all mongoloid children are born to women over the age of 35. By screening all such mothers during pregnancy it should be possible to halve the birth rate of such infants. 37/ Such age criteria, do not, however, apply in most other genetic disorders. 38/

71. Amniocentesis as a prenatal diagnostic technique has proved extremely accurate. A United States pediatrician who performed the test on 155 pregnancies where there was high risk of mongolism diagnosed 10 as defective. The aborted foetuses were thereafter examined and the prenatal diagnoses were borne out in all cases. 39/ The

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33/ Lubs, op. cit., pp.274-275.

34/ Jane E. Brody, op. cit., p.41.

35/ Ibid.

36/ Dr. Amitai Etzioni, "Genetic Fix", New Scientist, 17 January 1974.

37/ Walter Sullivan, "Wider Detection ..... to Spur Abortion", op. cit.

38/ Theodore Friedmann, "Prenatal Diagnosis of Genetic Disease", Scientific American, November 1971, p.38.

39/ Man into Superman, op. cit., p.38.

economic impact of the development of the technique is substantial. It has been reported that: "by 1975 the cost to the nation of caring for mongoloids alone would probably reach $1,750,000,000 a year. Yet by prenatal screening (if it were socially and economically feasible) all mongoloid foetuses could be identified and aborted before birth." 40/

72. While most other recent advances in medical technology involve costly equipment or procedures and high cost to the patient or the state and thereby may be available to few, amniocentesis is a relatively inexpensive procedure which by also avoiding costly institutional care for the defective permits funds allocated for medical care to be used more fruitfully. From a social viewpoint, doctors have found that the majority of women prefer to undergo the procedure, despite some dangers which it entails, and, in appropriate cases, have the foetus aborted, rather than bear a deformed child. 41/ It is reported that "diagnosis of this kind is nowadays a routine in Sweden among families with a medical history indicating that there is a risk of a child being born with a hereditary disease. Investigation of this kind has not as yet been carried out on all pregnant women in Sweden." 42/ The Government of Sweden further points out that

> "pre-natal diagnosis of hereditary diseases outlined above must be seen in the light of the abortion legislation of a country. In Sweden legal abortion has been accepted to a very large extent. Consequently, problems associated with pre-natal diagnosis are less complicated here than in countries where legal abortions are prohibited or only permitted in extenuating circumstances." 43/

73. At present, only certain types of disorders can be detected prenatally. Although there are reliable tests for determining whether a pregnant woman has any of the virus diseases that represent a risk to the foetus, it is at present not possible to determine whether the foetus is affected. Therefore, the decision to abort is based purely on mathematical risk. A similar situation persists with respect to biochemical abnormalities. It is felt, however, that tests will become possible which will obviate the present situation as described by one writer:

> "Nowadays, wherever ... abortions are legal (and often where they are not) most doctors will abort if the defect is severe and the risk is higher than the 20 to 30 per cent usually cited for a mother known to have had rubella in the first three months. They would rather take the higher chance of killing a normal foetus than the low one of letting an abnormal foetus go to term against the mother's wish. Some, however, would not. Early detection will help to cut through this fog of uncertainty. It will make it almost impossible to refuse abortion when the defect is diagnosed for certain; at the same time, it will reduce the number of foetuses that are aborted but turn out to have been normal." 44/

40/ Walter Sullivan, op. cit., p.9.

41/ Amitai Etzioni, op. cit.

42/ Information furnished by the Government of Sweden on 12 March 1974.

43/ Ibid.

44/ Gerald Leach, The Biocrats: Ethics and the New Medicine, Pelican 1972, p.170.

4. Dangers of Amniocentesis

74. Although there is general agreement that the reliability of amniocentesis is high, provided that appropriate laboratory facilities are available, some diseases are more difficult to diagnose than others and it has been cautioned that much experience will be required before amniotic fluid can be used as a routine method of antenatal detection, for example, of metabolic disorders. 45/ There also exist dangers as a result of insertion of the needle into the amniotic sac; damage to or infection of the foetus are possible, or spontaneous abortion may occur as a result of the trauma of the procedure. 46/ Errors in diagnosis can occur causing emotional shock to parents who have been incorrectly reassured about the outcome of the pregnancy, and some "false positive" tests result in the abortion of normal foetuses. 47/

75. Further dangers are presented since, in 10 per cent of cases, tests must be repeated in order to obtain a diagnosis. Apart from possible harm to the foestus, the mother also runs certain health risks. It has been pointed out that "blood cells from the foetus pass into the maternal blood in 10 per cent of the cases [where amniocentesis is performed]. This passage could pose a problem by sensitizing Rh-negative mothers with Rh-positive babies." 48/

76. One doctor analyses the situation as follows:

> "[I]t is conceivable that the risk of amniocentesis in terms of incorrect diagnosis, in terms of catastrophic effect on the foetus or the mother, may well be greater than one per cent when all the risks are considered. It seems to me that, rather than applying amniocentesis to all pregnancies, it would be more preferable at this time to accurately define those high risk groups where pregnancies are at risk greater, certainly, than one per cent. I suggest that every effort be made to establish which chromosomal anomalies are truly associated with serious abnormality. This would then constitute a high risk disease and would allow for reasonable intrauterine interpretation.
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> I do not think that amniocentesis should ever be advocated for all pregnancies, even if the risks of chromosomal anomalies are one in 100. I think there are serious social implications to this at the

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45/ Barbara H. Sanford "Ethical Problems in Foetal Diagnosis and Abortion", World Council of Churches, Consultation on Genetics and the Quality of Life, Zurich, 24-28 June 1973, No.2, p.2.

46/ Ibid., p.2; similarly, information furnished by the Government of Hungary on 19 August 1975.

47/ Ibid.

48/ Joan Lynn Arehart, op.cit., p.44.

present time. In addition, if all pregnancies are monitored, the rare normal pregnancy that would be lost because of the complications of the procedure would be an undefendable catastrophe and something that we should make every effort to avoid." 49/

77. Another writer points out that "a small risk of grave injury is a great risk" and that it should not be forgotten "that the lives in question are not interchangeable." 50/

78. It can be argued that amniocentesis ought never to be performed because of the possibility of inducing damage. There are no present findings excluding the risk of "induced" congentical malformation or subtle damage such as some loss of intelligence which is almost impossible to evaluate. It has been said that "[i]f such grave damage from the procedure has not been excluded, intrauterine screening can hardly be justified by comparing only the probabilities." 51/

79. Other authorities weigh the probabilities and suggest that the procedure be used only when a couple shows a moderate or high risk of giving birth to a child with genetic defect. Recognizing that "increasing age at pregnancy is correlated with an increasing incidence of chromosomal abnormalities 'one suggests that' [i]t may be warranted, therefore, to implement a programme of prenatal diagnosis for prospective mothers who are above a certain age." 52/ Another sums up the issue in this manner:

> "Since any diagnostic procedure with a small but irreducible rate of complications is justifiably used only if the conditions being searched for lead to disease or damage more frequently than the diagnostic procedure itself, it is important that these questions of safety be answered." 53/

80. At a meeting of the American Academy of Pediatrics held in Washington D.C., U.S.A., in October 1975 the procedure "was pronounced safe ... and recommended to pregnant women 35 and older ... A four-year study, financed by the National Institute of Health [of the USA] of 2,032 women - 1,040 of whom had the test - showed the procedure had 'no significant adverse effects' on the women or the babies". 54/

49/ Herbert A. Lubs, Cytogenetic Problems in Antenatal Diagnosis, p.85; Maureen Harris, "Early Diagnosis of Human Genetic Defects - Scientific and Ethical Considerations", Fogarty International Center Proceedings No.6, HEW Publication No. (NIH) 72-25, 1970, p.67.

50/ Paul Ramsey, "Screening, An Ethicist's View", Bruce Hilton, op.cit., p.155.

51/ Ibid.

52/ Mark S. Frankel, op.cit., p.86.

53/ Theodore Friedmann, op.cit., p.37.

54/ Victor Colin, "A test on fetus for defects of genes is pronounced safe", International Herald Tribune, 22 October 1975, p.3.

81. The Government of Hungary has expressed the following opinion:

"[A]n intrauterine examination of the foetus is indicated if the risk of foetal [abnormality] is higher - perhaps substantially higher - than the risk of the intervention." 55/

82. The Government of the United Kingdom has expressed the following opinion on the use of amniocentesis:

"The general view of the United Kingdom is that such techniques should be applied by a clinician only where there are specific indications for them and only with the full and free agreement of the woman concerned given after explanation of the procedure and its possible sequel." 56/

5. Ethical, psychological and social aspects of genetic screening and counselling

83. The Government of Sweden has posed an ethical issue with respect to the use of the procedure of amniocentesis:

"The problems connected with pre-natal diagnosis we are concerned with here are thus not associated with the investigation procedure itself or the abortion operation, but rather where the line is to be drawn between a grave or less grave foetal condition. It is practically impossible to make such a distinction, as people's experience of life and their values vary. Therefore, efforts should instead be made to guarantee that parents are given the opportunity of making up their minds, on the basis of their own experience, knowledge and values as to whether they want a pre-natal diagnosis of the foetus. It would seem that the ethical problems are mainly associated with the giving of information to parents about the nature and prognosis of the disease and the risks involved in a foetal diagnosis." 57/

84. The Government of Romania has expressed an opinion on the circumstances where pre-natal diagnosis is indicated:

"The indications of pre-natal genetic diagnosis are well established: it is recommended in every situation in which the fetus has an increased risk of presenting chromosomal abnormality, a metabolic disease or a recessive disorder with X linked transmission.

Pre-natal diagnosis is not justified and represents an infringement of the rights of the child to be born and to live if it is used for the following purposes:

55/ Information furnished by the Government of Hungary on 19 August 1975.

56/ Information furnished by the Government of the United Kingdom on 8 August 1974.

57/ Information furnished by the Government of Sweden on 12 March 1974.

(a) The detection and abortion (for eugenic reasons) of the heterozygotes: [carriers who do not manifest the disorder].

(b) The predetermination of the sex without medical motivation and in order that the parents may be able to decide to continue the pregnancy only if the new born will have the sex desired by the parents.

Another problem [concerns] ... detecting a XXX or XYY abnormality pre-natally. In particular, it is known that XYY subjects have a bad reputation from the ... behavioural point of view (which is questionable from the scientific point of view). Having in view that an XYY individual might develop normally from the psychological and social points of view, we hold the opinion that it is not right to interrupt the pregnancy for the reason of having discovered some abnormality of the XYY type in the fetus and even less in cases of karyotype XXX ..." 58/

85. In 1968 one writer saw the influence on society of the recent advances in genetics as follows:

"For a long time to come, the structure of most human communities is likely to remain based on the institution of marriage. Yet both the present practice of selecting marriage partners according to romantic predilections, which is common in the West, or according to practical socio-economic considerations, which is more general in Eastern societies, may well be affected by the advances in genetics and the spread of genetic counselling.

The influence will probably be in a negative sense rather than a positive one. The genetic counsellor will not be called on to make recommendations on whom to wed, choosing being done much as at present, but simply to advise whether a choice is a genetically wise one, in terms of the probabilities of procreating defective off-spring. I feel that the seeking of the advice of the geneticist before marriage will be done with increasing frequency." 59/

Irrespective of the strides made in interuterine diagnosis of genetic defects, doctors have stated that "the ultimate goal is prevention of birth defects before conception". They foresee all prospective parents having chromosome karyotypes before conceiving a child, just as they now have blood-tests before marriage. 60/ Mass screening would be aimed not at determining whether persons have recessive genes (everyone has them) but at ascertaining whether couples have the same recessive traits. It has been written that where couples have been found to share a deleterious recessive gene,

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58/ Information furnished by the Government of Romania on 29 April 1974.

59/ Marco Fraccaro, op.cit., p.269.

60/ Joan Lynn Arehart, op.cit., p.45.

"when the severity of the disease or the rigours of treatment was explained to them, it seems likely from present genetic counselling experience that most would voluntarily refrain from parenthood. Instead they could adopt or opt for artificial insemination by a donor who was cleared for that recessive." 61/

The same writer sees the problem as the choice between volition or compulsion and asks what pressures society should put on couples whom screening has identified as carriers. Extrapolating from the popular demand for cervical cancer screening he feels that compulsion would not be necessary and that the complaint might instead be that facilities for screening were developing too slowly. 62/ There is a further suggestion that screening might better be done before marriage, or even before people are old enough for mate-selection. Thereby, it was explained, people could avoid the agony of genetic incompatibility after mate-selection. There remains, however, the problem of communication of this information. 63/

86. Genetic counsellors report that a small proportion of their patients come for counselling prior to marriage, and those are usually couples seeking information because of known consanguinity. It is predicted that the information received rarely deters marriage, but that it may alter reproductive decisions. 64/ At present the vast majority of persons seeking counsel are couples who have already borne one defective child. One study reports that where couples were advised that the risk of bearing another defective child was "... one in ten or greater, 67 per cent opted against having further children of their own. Obviously the magnitude of the risk has a significant impact on parental decisions." 65/ At present, when a woman finds that she is a carrier for hemophilia 66/ she is faced with parental responsibility that did not exist prior to the knowledge available as a result of the recent advances in genetics. If she learns that she is a carrier while she is not pregnant three options exist:

61/ Gerald Leach, op.cit., p.147.

62/ Gerald Leach, op.cit., p.147.

63/ "Professor Linus Pauling has suggested small taboos on the forehead, which might seem bizarre, but we must remember that we carry avoidance signals already, including skin colour, language, wealth or poverty, accent, religion and education. Genetic signals in addition might be hardly noticeable, especially since they would say 'stop' only very rarely", (Gerald Leach, op.cit., p.148).

64/ James R. Sorenson, op.cit., p.288.

65/ Ibid.

66/ A condition causing persistent bleeding from wounds, producing deformed or wasted limbs. The condition manifests itself only in males. Partial treatment is available making long-term survival possible under highly controlled circumstances (Gerald Leach, op.cit., p.143).

1. To forego pregnancy and either remain childless or adopt children.

2. To become pregnant with the intention of using amniocentesis to determine the sex of the foetus, aborting all male foetuses. This option presents a problem since there is a 50 per cent chance that the aborted foetuses are free from the disorder. Furthermore, she knows that her female children may face the same problems as she, as they may be carriers.

3. To bear children without regard to the consequences to herself, her family and the possibly affected child.

87. If the woman learns of her carrier status after she is already pregnant, the choices are more limited. She may take the 25 per cent risk of bearing a child with hemophilia, or proceed with amniocentesis and, if the foetus is male, abortion. Ethical or religious views may preclude abortion and the parents may choose to take the risk of bringing into the world an afflicted child. Having recognized that these options exist a writer has urged:

> "Whatever choice parents make, it is crucial that they not be subjected to coercion in this matter, either to abort or to carry the baby to birth." 67/

88. A major difficulty arising out of widespread genetic screening is the lack of comprehension by the lay public of the nature of genetic disorders. An example of widespread confusion is that surrounding sickle-cell anemia. 68/ At least one state (Georgia) in the United States of America has a law requiring screening of new-born children for this disorder. However, the disease may not be detectible until some months after birth; furthermore, it has been pointed out that since current medical assistance can only give relief from pain at time of periodic crises, testing of the new-born is unproductive. Moreover, there appears to be a demonstrable disadvantage: there is widespread confusion in the minds of many, between the homozygotes, who receive the gene from both parents and therefore actually suffer from sickle cell anemia, and heterozygotes, who receive only one gene and are therefore said to have the "trait", as a carrier, but as far as is known suffer no effects. As a result of the confusion many carriers believe that they have the disease; it is said that employers and insurance companies think so too - all to the detriment of the individual. Social scientists go further and decry the consequences of "labelling" of persons. It has been said that "[a]s the result of mass-screening tests people will be labelled as carriers of such genes, which may harm their social standing and their view of themselves." 69/ It has, therefore, been pointed out that such mass screening programmes must necessarily be accompanied "... with carefully designed and executed public information programmes." 70/

67/ Sissela Bok, "The Threat of Hemophilia", The Hastings Center Report, Vol.4, No.2, April 1974, p.9.

68/ A "construction error" in the blood protein haemoglobin; no treatment is currently known. (Gerald Leach, op.cit., p.142).

69/ Amitai Etzioni, Genetic Fix, Macmillan, New York, 1973, p.194.

70/ Ibid., p.196.

89. Opinions vary as to whether programmes of carrier detection "would be socially, economically and genetically viable or acceptable... Some geneticists call carrier screening a low-priority luxury. Nearly all recessive defects are too rare for the enormous effort of mass screening to be worth while. Others urge that screening should be started now. For example, the direction of the U.S. National Institutes of Health, Dr. James Shannon, has said that genetic counselling and carrier screening is 'becoming not merely a moral obligation of the medical profession but a serious social responsibility as well'." 71/

90. The needs of the community must be considered in developing new programmes of genetic screening, but it has been said that

> "the ethical considerations and needs of the individual patient or couple must still come first. It is probably unjustified on ethical grounds to mount large-scale screening programs for disease or carrier detection in conditions where the patients and carriers cannot be offered specific effective medical therapeutic alternatives, including intrauterine diagnosis and abortion.
>
> "It is on the one hand unfair that everyone cannot yet know his or her 'mutant gene carrier status', since all of us are heterozygous for at least several mutant genes, and also unfair that those whose mutant carrier status can be determined may be stigmatized by their peers. It is probably also unjustified at this time to make screening programs compulsory. Even large-scale educational programs can result in a kind of indirect coercion from peer group pressure that might be exerted. The current state of genetic knowledge is such that we cannot and, I feel, should not use any kind of coercive methods either direct or indirect to insist that carrier couples should not have children in those cases where intrauterine diagnosis is not yet available." 72/

91. The opinion has been expressed that screening programmes should not be undertaken unless the condition sought to be detected could be ameliorated as a result of advance diagnosis. The anxieties created would outweigh any possible advantages. At a CIOMS Round Table Conference on Human Rights the opinion was expressed that:

> "[I]t is often the case that those most at risk do not respond to the invitation to be tested leaving those who do respond to suffer the psychological disadvantages. This is an example of a measure which may be advantageous to one individual (and thus legitimately come to be regarded as a right for him or her) and at the same time be an infringement to another of the right to peace of mind." 73/

71/ Gerald Leach, op.cit., p.146; see also Robert F. Murray, Jr., "Problems Behind the Promise, Ethical Issues in Mass Genetic Screening", The Hastings Center Report, Vol.2, No.2, April 1972, pp.11-12.

72/ Robert F. Murray, Jr., op.cit., p.13; see also Daniel Callahan, "Ethics, Law and Genetic Counselling", Science, Vol.176, 14 April 1972, p.198.

73/ A.S. Duncan, "Scientific and Technological Development in Biology and Medicine which may lead to the Infringement of Human Rights", CIOMS Round Table Conference on Human Rights, 14, 15 and 16 November 1973, RT8/A/2.1, p.3.

92. Genetic counsellors have always assumed as part of their role the psychological support of persons to whom they have revealed that they were carrying "bad genes". However, due to the growth of wide-scale screening programmes and new techniques and procedures, a whole new group of heretofore undiscovered carriers of genetic disorders are being discovered and have "made them vulnerable to a host of ... psychiatric problems. The guilt and humiliation of having one's inadequacies exposed, even if they are only pieces of DNA, ... may be an increasing problem." 74/

93. Where the screening is done by amniocentesis and the foetus is found to carry the deleterious trait another problem may arise: abortion, even where legal, is not acceptable to all persons. One writer poses some issues:

> "What are we going to do in situations where the husband and wife don't agree on this issue, and one wants their abnormal fetus to be aborted while the other does not? The attitudes of the physician, the laws of the state, and decisions of the courts on this point may all be important in safeguarding, or perhaps in determining, the rights of the husband and wife in situations of this kind." 75/

94. Other problems relating to amniocentesis are just beginning to be recognized. Very little is known about the social and psychological effects of these procedures on the family. Such questions as the following have been asked:

> "How does the family tolerate the stress of second trimester abortion? Might a mother who really did not want to undergo pregnancy under these conditions feel guilty about her decision? What might be the effects upon an abnormal child already present in the family and upon his siblings? (Might he perhaps wonder about his own right to live or about his parents' attitude towards him as reflected by their unwillingness to risk another affected child?)" 76/

95. Moreover, amniocentesis reveals not only physical genetic disorders but also potential psychological attributes. For example, as regards the so-called "criminal genes", it has been reported that

> "[t]here is accumulating evidence that people born with XYY genes, one out of every 1,000 male births, may have a predisposition towards criminal insanity. Many social scientists do not believe that genes could affect behaviour in that way ... but this is beside the point. As long

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74/ Judith Hall, "The Concerns of Doctors and Patients", Hilton, Bruce; op.cit., p.26.

75/ Orlando J. Miller, "An Overview of Problems arising from Amniocentesis", p.29, see also, Maureen Harris, op.cit., p.23.

76/ Barbara H. Sanford, op.cit., p.4.

as some scientists hold that genes have a predisposing effect, i.e. that one child is somewhat more likely to be criminally insane than others, and have some data to support their position, should the parents be spared the information? And who shall decide whether they should be spared or not? Does each doctor decide? The state health authorities?" 77/

96. Furthermore, since certain genetic disorders have been found to occur with greatest frequency in certain ethnic groups - sickle cell anemia in persons of African origin; Tay-Sachs disease in the Jewish population of Eastern European origin; Cooley's anemia among Italians - concern has been expressed that the mounting of programmes directed toward screening these ethnic groups, and the dissemination of information of the incidence of these disorders in these groups may tend to attach a stigma to them. 78/

6. Attitude Toward Defectives in View of Advances in Genetics

97. It has been reported that "an anomalous baby is born somewhere in the world every thirty seconds". 79/ The availability of pre-pregnancy genetic screening and amniocentesis and selective abortion requires an evaluation of its effects on "(1) attitudes towards the defective newborn and (2) attitudes towards the present generation of growing defective children and adults in the society". 80/

98. Once having borne a defective child and having become familiar with the facilities available for counselling and amniocentesis parents may be prone to abandon the defective and turn to the geneticist for help with producing a normal child next time. It has been said that

> "[m]ost parents in our society if given the choice would prefer abortion of an affected fetus to a sick child who requires any but the most trivial treatment. This preference is likely to become more definite with rapidly changing attitudes to abortion at a time when the low risks of amniocentesis will become fully established and when simple abortion technics become available." 81/

77/ Amitai Etzioni, "Doctors Know More Than They're Telling you About Genetic Defects", Psychology Today, November 1973, p.35.

78/ Paul Ramsey, op.cit., p.163; see also, Tabitha M. Powledge, "Laws in Question: Confusion over Sickle Cell Testing", The Hastings Center Report, Vol.2, No.6, December 1972, p.4.

79/ John Fletcher, "Attitudes Toward Defective Newborns", The Hastings Center Studies, Vol.2, No.1, January 1974, p.29.

80/ Ibid., p.29.

81/ John Fletcher, op.cit., p.31.

It might therefore also be expected that there will be a change in parental attitude toward the newborn defective who requires any but the most trivial treatment. One authority has stated that "[o]ne might predict a rise in the number of parents who attempt to instruct physicians not to elect to keep a seriously defective child alive". 82/ The same writer askes: "Would it seem so difficult for modern persons to withdraw care from the defective newborn, when they know that [through amniocentesis and abortion] they might have done it only a few months earlier?" 83/

99. A recent case where the parents of a mongoloid infant refused to permit surgery to correct an intestinal blockage - resulting in death - gave rise to considerable public indignation. 84/

100. Concern has also been expressed about balancing the decision to abort defectives against the later acquisition of knowledge for their cure. 85/ Furthermore, how is a "defect" defined so as to render the foetus sufficiently abnormal to warrant abortion?

101. Another area of concern lies in the possibility of threats to care and safety of existing defective persons in view of the knowledge that their existence might have been prevented had the relevant techniques been previously available. The view has also been taken that the struggle for medical funds between those to be used for genetic diagnosis, and those spent on care of existing handicapped individuals may be resolved to the detriment of the latter group. 86/ On this point the following has been written:

> "Yet the morality which has controlled the relations between medicine and society in the modern era would not condone a depletion of the fund of justice which has been won for the handicapped in order to extend new control over in-born handicaps through early diagnosis." 87/

82/ Ibid., p.31.

83/ Ibid., p.31.

84/ "Ethics in Biomedicine; A Call for Action", Science News, Vol.100, No.18, 30 October 1971, p.294.

85/ Marc Lappé, "Genetic Counselling and Genetic Engineering", The Hastings Center Report, No.3, December 1971, p.13.

86/ John Fletcher, op.cit., p.31.

87/ Ibid., p.31.

102. It has been said that: "The allure of a genetic test for a normal, or in the future an optimal baby, threatens to reinforce an inexorable trend in Western society towards typecasting the less-than-optimal into categories for assortment and ultimate disposal". 88/ Jerome Lejeune of the University of Paris who first reported the chromosomal basis for Down's Syndrome (a type of mongolism) "has argued for the acceptance of the genetically 'unfit' as part of the human community". 89/ Marc Lappé has described society's responsibilities as follows:

> "First, we must be extremely conscious of the broad effects such knowledge may have in shaping our thinking and feeling about the genetically defective already alive. Second, we must resist the tendency to stigmatize those parents who, given full knowledge of the risks of child-bearing, still proceed to have a child with a defect like Down's Syndrome. Third, we must incorporate the new technologies surrounding the unborn into our lives as sensitively and ethically as possibly. This means that the expedient of selective abortion for the genetically defective must not become the 'final solution' in our attempts to ameliorate the sequelae of genetic defects." 90/

103. It has also been pointed out that, regardless of how widespread the use of genetic counselling becomes, that there will always be "some who escape detection or whose disease is undetectable in utero, others as a result of new mutations, birth injuries, accidents, maltreatment, or disease - who will require our care and protection. The existence of 'defectives' cannot be fully prevented, not even by totalitarian breeding and weeding programs. Is it not likely that our principle with respect to these people will change from 'we try harder' to 'why accept second best?'." 91/

88/ Marc lappé, "How Much Do We Want to Know About the Unborn?"; The Hastings Center Report, Vol.3, No.1, February 1973, p.8.

89/ Ibid., p.9.

90/ Ibid., p.9.

91/ Leon R. Kass, "Implications of Prenatal Diagnosis for the Human Right to Life", Bruce Hilton, op.cit., p.190.

7. Rights of Parents and the Rights of Society

104. In examining parental responsibility for genetic health a provisional conclusion reached by one authority was that "[i]n certain circumstances parents may have the duty to avoid bearing children with serious genetic defects, if this is possible." 92/

The rationale for this conclusion was stated:

> "In cases where the birth and subsequent care of a child with a serious genetic defect would radically endanger the welfare of other family members, especially extant children for whom there is a prior responsibility, then perhaps parental wishes and rights must give way to these more exigent and prior claims. Such situations may be viewed as constituting a legitimate circumspection of the proposed parental right." 93/

105. In certain legal systems there exist criminal penalties for infecting other persons with venereal disease; and knowledge of the condition is not an element of the crime. A writer asks: "Is not the act of transmitting an undesirable gene to be regarded just as criminal, and the actor just as culpable?" 94/ Another attitude is that parents might (properly) be considered healthy genetically despite the fact that they carry defective genes. They may also be able to give reasonable assurances of producing healthy offspring by exercising reproductive choices made available through genetic advances. Another writer has pointed out however:

> "Difficulties arise ... when we extend the responsibility of parents from that of acquiring the minimal information to assure the absence of gross abnormality to guaranteeing physical and mental normality in their offspring. Not only is the latter task confounded by our ignorance of what we mean by "normal", but, it also threatens to move us towards a goal of universal "normality" for all of our children - an often sought but dangerous Utopian view." 95/

106. A difficult question has been raised: Should a pregnant woman be allowed amniotic diagnosis if she is not willing to consider an abortion? Although there is a difference of opinion among geneticists, one view is that the willingness to accept abortion should never be a precondition for amniocentesis:

92/ Sumner B. Twiss, Jr., op. cit., p.11.

93/ Ibid, p. 11.

94/ Clark F. Fraser, op.cit., p.16.

95/ Marc Lappé, "Genetic Knowledge and the Concept of Health", The Hastings Center Report, Vol.3, No.4, September 1973, p.3.

"The geneticist may [not] abrogate a couple's decision by assuming that if the fetus is normal, she will carry it, or if abnormal, she will abort. The genetic component is one of many and clients must be helped to put them in perspective." 96/

107. The Government of Norway has described the situation as it exists in that country:

"[G]enetic counselling is being offered on a completely voluntary basis as part of the public health-care for mother and children. In high-risk pregnancies, pre-natal diagnoses will be as far as possible provided whenever requested, with the aim of preventing some of the suffering which is caused to both the patients and the family by genetic disorders. In cases where serious genetic disorders are diagnosed in the fetus, the decision to interrupt the pregnancy is left entirely to the parents." 97/

108. Another writer sees the choice resting with the woman and views it as reflective of current trends:

"[W]e think the women's movement has probably contributed, in some ways that are clear and simple and others that are amorphous, to other social factors facilitating the widespread introduction of prenatal diagnosis. For feminists, prenatal diagnosis is one more way a woman can control her body and her fertility ..." 98/

109. The Government of Hungary reported as follows:

"[W]e should like to stress that the geneticist's opinion is only advice and cannot be the basis for any compulsory measures; the right to keep or interrupt the gravidity rests with the mother." 99/

110. Amitai Etzioni at a CIOMS Roundtable expressed the following view:

"Surely no church or government should force parents to give birth to severely deformed children, and to force into the world children doomed to a distorted, miserable life. Genetic counselling, mass screening, and amniocentesis should be available to all.

...

96/ Joan Lynn Arehart, op.cit., p.45.

97/ Information furnished by the Government of Norway on 15 April 1974.

98/ Tabitha M. Powledge and Sharmo Sollitto, "Prenatal Diagnosis - The Past and the Future", The Hastings Center Report, Vol.4, No.5, November 1974, p.13.

99/ Information furnished by the Government of Hungary on 19 August 1975.

"The basic rights of an individual in a free society should include that of having as many of whatever kind of children a person is willing to have; society can try to persuade people to have fewer children or to abort severely deformed ones, but it cannot force these choices. However, the individual's rights do not include the liberty to charge the upbringing of their children to the public. One can easily picture a society going so far as to inform all prospective mothers, especially those in high risk categories, that a genetic test is highly advisable, and further, to inform those whose tests show them to be carrying a deformed fetus, that they will have to provide for it." 100/

111. Part of the issue of giving parents complete control over the genetic make-up of their offspring is the thorny question of whether anmiocentesis may properly be used to determine the sex of the foetus and where the parents so request, whether the foetus of the undesired sex may be aborted. One opinion has been expressed as follows:

"[O]ne may say that because of the marginal risk to the mother (and her future children) that is involved, [abortion] is tolerable for therapeutic, but not for breeding, purposes." 101/

112. Many doctors, including those who generally subscribe to the use of amniocentesis "adamantly oppose people taking the risk for such a 'whimsical, arbitrary' reason". 102/ There seems to be no reported cases where a doctor agreed to abort a foetus because it was not of the desired sex. However, "one doctor reported that he was tricked into doing so by parents who asked for amniocentesis to check against mongolism: told they had a female fetus, the parents proceeded to arrange for an abortion, for they wanted a boy." 103/

113. One writer sees the option of sex-choice as having an impact not only on the individual, but on society:

"At the very least, sex selection would have a destructive effect on the present trend towards equalization of the opportunities and roles afforded the two sexes. Replacing natural selection, which has maintained

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100/ Amitai Etzioni, "Social Implications of the Use or Non-Use of New Genetic and Medical Techniques"; C.I.O.M.S. Round Table Conference on Human Rights, 14, 15 and 16 November 1973, RT8/A3.1, pp.5, 14-15.

101/ Ibid., p.30.

102/ Amitai Etzioni, "Doctors Know More Than They're Telling you About Genetic Defects", Psychology Today, November 1973, p.35.

103/ Amitai Etzioni, Genetic Fix, Macmillan, N.Y. 1973, p.119. Cf. document E/CN.4/1173, p.8.

a delicate balance between the number of the two sexes, with human selection raises deep questions about the wisdom of encouraging the further development of sex selection technologies which would lend themselves to mass application. A society which would choose male offspring in preference to females (or vice versa) is probably not one which is ready for the responsibility of assuming regulation of the balance between men and women. Certainly, one which would preferentially deny rights and opportunities to women would appear to disqualify itself as having the necessary fairness and wisdom to proffer to its citizenry the option of sex selection." 104/

114. It has been estimated that in the United States, if sex-choice were practised, about 7 per cent more male than female children would be chosen each year. It was concluded that such an imbalance would strain every social institution and that one of the first to be hurt would be the family. 105/

115. The Government of Sweden has expressed the following opinion:

"It is unrealistic to believe that scientists could be prevented from trying to develop cheap, reliable and totally safe methods of determining a child's sex before birth. In the abortion debate it has been maintained that it is the mother who can best decide whether or not the child is wanted, and the [Commission on Medical Ethics of the Swedish Society of Medical Sciences] has supported ... the view that the woman's wishes should be the major consideration in early decision on abortion. If in due course the woman is able to obtain information on the expected child's sex, time will tell whether, with the application of liberal abortion legislation, she can show the sense of social responsibility that must be a prerequisite of society's confidence in her." 106/

116. The Government of Romania has taken the position that "prenatal diagnosis is not justified and represents an infringement of the rights of the child to be born and to live if it is used for the following purposes: ... (b) the predetermination of sex without medical motivation and in order that the parents may be able to decide to continue the pregnancy only if the new-born has the sex desired by the parents". 107/

104/ Marc Lappé and Peter Steinfels, "Choosing the Sex of Our Children, A Dream Come True or ...?", The Hastings Center Report, Vol.4, No.1, February 1974, p.3.

105/ Amitai Etzioni, Genetic Fix, Macmillan, N.Y., 1973, p.30; see also "Science and the Quality of Life"; Three Reports from Church and Society, World Council of Churches, Geneva, Switzerland, 1971, Study Encounter, Vol.7, No.3, 1971, p.681.

106/ Information furnished by the Government of Sweden on 15 March 1974; see also Gustav Giertz, "The Role of Scientists in Responsibility for the Protection of Human Rights", CIOMS Round Table Conference on Human Rights, 14, 15 and 16 November 1973, RT8/C/2.1, p.2.

107/ Information furnished by the Government of Romania on 29 April 1974.

117. Although the argument has been put forward that abortion to obtain a child of the desired sex is unacceptable because it is not for therapeutic purposes, it has been pointed out that abortions to limit family size are also not therapeutic, but are gaining in acceptance. In view of this, one writer asks:

> "Now, should doctors or the state decide that parents are not allowed to plan their children - their sex and, soon, other attributes - only their number? And what if a family of four boys feels one girl is essential to make it happy? It seems to me the decision should be up to the parents." 108/

118. The question of parental choice in selecting the sex of offspring is a discrete aspect of the larger question of whether genetic decisions should ultimately be made by the individual or society. At a symposium concerned with man's part in his own biological future the following proposition was put forth:

> "[I]t is now necessary to declare that the gene pool of mankind is public property. The gene pool is a working concept qualitatively and quantitatively definable by geneticists, and it may eventually have to be the subject of general monitoring or purview, inasmuch as it is increasingly threatened by forces now in motion." 109/

119. Various writers have concerned themselves with the distinction to be drawn between dominant and recessive disorders. Dominant traits - defects from which the individual himself suffers - present less of a concern to society since the individual may be expected to control his own transmission of the defect. He or she is actually suffering from the disorder and may be expected to take this into serious consideration in reproduction decisions since it would be his or her own children who will be similarly affected. However, the carrier of a recessive trait, unless the mate also carries the recessive "will probably have little personal interest because it is likely not to be his immediate descendants that are affected by the gene." 110/

120. One authority has viewed the advances in genetic screening and pre-natal diagnosis in this way:

> "the benefits, though obvious enough for the particular families involved, are accompanied by dangers for society at large, since the ultimate result may be to spread a recessive defective gene more widely through the community." 111/

108/ Amitai Etzioni, Genetic Fix, Macmillan, N.Y., 1973, p.120.

109/ Rollin D. Hotchkiss, "Man's Part in His Own Biological Future; Environment-Man-Survival", Wullstein, McNulty, Klikoff, (eds.), Grand Canyon Symposium, 1970, Department of Biology, University of Utah, Salt Lake City, 1971, pp.43-44.

110/ James F. Crow, Population Perspectives, Bruce Hilton, op.cit., p.75.

111/ Robert S. Morison, in the Chairman's Introduction to The Hastings Center Report, Vol.4, No.1, February, 1974, p.8; see also Maureen Harris, op.cit., p.7; see also paragraphs 24 to 30 above.

121. It has been pointed out that medical and non-medical practitioners in the field of genetics may hold radically different views on the balance between the individual's and society's rights:

> "this dichotomy will be manifest in advocacy of different goals: the physician qua genetic counselor, for example, may tend to favor policies which maximize individual freedom, while the population biologist qua counselor may tend to favor policies which generally subordinate individual needs to those of society." 112/

122. Bentley Glass, a science historian and geneticist, is quoted as asking whether an interventionist policy should not be enforced:

> "Has society, which must support at great cost the burden of genetic misfortune resulting from mutation, chromosomal accident, and prenatal harm inflicted by trauma or virus, no rights at all to protect itself from the increasing misfortune? Should not the abortion of a seriously defective fetus be obligatory?" 113/

123. Another biological scientist has declared that:

> "human heredity actually is a phase of public health. The heredity of the population should be of at least as much concern to each commonwealth as are infectious diseases." 114/

124. However, the predominant view of most geneticists has been reported as being that the genetic counsellor "owes his first allegiance to the individual, [and that he is the] advocate of his client and not the wishes of society." 115/ It has also been reported that "most international agencies have insisted that 'counsellors ... not pursue any genetic program designed to benefit future generations if it conflicts with the immediate interests of their patients.'" 116/

125. The Government of Norway has reported that in that country "no programme for safeguarding or improving the genetic health of future generations exists." The Government has also written:

> "[I]n No way, medical practice, including genetic counselling, is centred around the needs and well-being of the individual patient and his family, and it is left open to the individual himself to ask for information concerning any possible risk to offspring, and to draw the relevant conclusions." 117/

112/ Marc Lappé, "Allegiances of Human Geneticists: A Preliminary Topology", The Hastings Center Studies, Vol. No.2, 1973, pp.63-64.

113/ Ibid., p.71.

114/ Ibid., p.70.

115/ Ibid., p.70.

116/ Ibid., p.70.

117/ Information furnished by the Government of Norway on 15 April 1974.

8. The Child's Right to Life and the Parents' Right to Procreate as Opposed to the Burden Borne by a Child Subject to Genetic Defect 118/

126. At the CIOMS Roundtable it was stated that "the consideration of the origin of maternal, fetal, and societal rights, from both the moral and the legal points of view is clearly confused by inconsistencies and changes in our definitions of 'human' and of 'life', the uncertainty as to when it begins, and by constantly changing common and statutory law responding to constantly changing social standards and public policy." 119/

127. The Hypocratic Oath, according to some of its versions, follows the Pythagorean proposition that human life commences at conception and prohibits performance of abortion. As recently as 1948 the Geneva Declaration of the General Assembly of the World Medical Association required "utmost respect for the preservation of human life, from conception". 120/ It has been urged however that the implications of some of these admonitions no longer accord with certain public policies and laws and that "they should be reformulated and brought up to date [since] [t]hey do not take into account the conflicting rights of the unborn, the parents and the society". 121/ The statement has also been made that "it can be argued that by law a conceptus even if shown by amniocentesis to be genetically grossly abnormal has a right, equal with others, to life under article 3 of the Universal Declaration". 122/

128. An apparent inconsistency in approach has been pointed out with respect to the treatment of the foetus under the law:

> "Through recent upheavals in our social, legal and religious institutions we are now faced with the dilemma of assigning to the fetus certain rights. In several instances damages have been awarded on behalf of fetuses in criminal and tort suits. At the same time abortion laws have been liberalized to the point of suggesting that early fetuses do not have the right to life if the mother wants to abort a pregnancy." 123/

118/ Nothing in this section should be interpreted as signifying an indication on the part of the United Nations Secretariat of the point, if any, in the development of the foetus when it becomes entitled to the rights laid down in the Universal Declaration of Human Rights.

119/ Theodore Friedman, "Conflicting rights and human life", CIOMS Round Table Conference on Human Rights, 14, 15 and 16 November, 1973, TR8/B/2.3, p.12.

120/ Ethics in Medical Progress, Ed. G.E.W. Wolstenholme, Ciba Foundation Symposium, Little, Brown and Company, Boston 1966, p. 222.

121/ Theodore Friedman, op. cit., p. 12.

122/ A.S. Duncan, op. cit., p. 1.

123/ Theodore Friedmann, "Prenatal Diagnosis of Genetic Disease", Scientific American, November 1971, p.42.

129. In discussing the issue of parental choice on determining the genetic quality of their offspring, major considerations have been offered in opposition to the acceptance of the parental right.

> "First, it may be argued that the exercise of such parental rights conflicts with a fetal right to life. This conflicting fetal right to life embodies the notion that the fetus, as a person in prospect, cannot argue its own case for being allowed to come to term. A related point is the view that children, including those in prospect, are not the "property" of parents and therefore are not to be treated as such: this point amounts to a poignant statement of the critique against parental paternalism.
>
> A second countervailing consideration involves the assessment of the seriousness of a particular genetic disease which, in turn, invokes such notions as genetic normalcy. Here it should be noted that there is an absence, even within the medical profession, of clear-cut definitions and consensuses on what constitutes health, disease, normality and abnormality - much less genetic disease, or genetic normality or abnormality, in particular. Consequently, definitions and cutoff points in this area can be quite arbitrary, fluctuating and subject to much debate. Moreover, even the severity of most genetic diseases ranges along a continuum or spectrum of seriousness. In the absence of clear-cut definitions in the area of medical genetics, the exercise of the proposed parental right must inevitably be somewhat arbitrary." 124/

130. One practitioner of amniotic diagnosis sees the issue of the right to life in the light of the practical effect of the procedure:

> "Those of us who are involved in such diagnoses do not deserve to be classified as hand-maidens to the abortionists because, in fact, just the reverse is true. The cases which come to us with a high genetic risk involved and in which pregnancy has already been initiated, would all end in therapeutic abortion if prenatal evaluations were not available. These interruptions of pregnancy would be accomplished because of the known risk and the anxiety which it generates. Furthermore, they would be accomplished even with the knowledge that the fetus might be normal. Therefore, each prenatal diagnosis which predicts normal development for the fetus is literally saving the life of the child." 125/

131. The Government of Norway amplifies on this analysis of the issue in describing the practice in Norway as follows:

124/ Sumner B. Twiss, Jr., op.cit., pp.9-10.

125/ Daniel Callahan, "The Meaning and Significance of Genetic Disease, Philosophical Perspectives", Bruce Hilton, op.cit., p.96.

"It is lawful in this country to interrupt a pregnancy if there is a high risk of a serious genetic disorder. The advances in medical genetics which have made possible prenatal diagnosis of several genetic disorders represent major progress in this area. For many diseases, it is now possible to conduct diagnostic procedures in high-risk pregnancies in order to interrupt pregnancy if the fetus is affected. Thus no pregnancy with a healthy fetus would need to be interrupted. Thus, the procedure is life-conserving compared to the situation before these techniques became available. Furthermore, couples wanting children, who previously did not dare to initiate a pregnancy because of a known risk of genetic disease in their offspring, now have the opportunity to reproduce and to have healthy children. It is considered to be the right of the individual both to be born healthy and to choose to have healthy children, insofar as these aims can be attained by currently available methods." 126/

132. Another view has been expressed by the Government of Zaire:

"The primary concern is the preservation of human life. Nature should therefore be left to take its course, African ethics being generally hostile to other forms of intervention." 127/

133. In this area, several lawsuits have been brought in the courts of the United States of America during recent years. All were instituted on behalf of infants who were suffering wrongs in life and alleged that they should not have been permitted to be born. The suits were predicated on the principle of "wrongful life" and each alleged a court-recognized prenatal wrong committed against the infant plaintiffs. It was reported that: "while recognizing injury, the courts have all withheld awards of damages on the general principle that it is impossible to weigh the desirability of life with defect against no life at all, on procedural grounds of there not being sufficient precedent for these cases, and the courts' desire not to open the Pandora's box of suits by infants against parents for illnesses or other defects." 128/

134. The World Council of Churches in one of its recommendations in regard to foetal diagnosis and abortion stated:

"We propose that the paramount right in reproduction is the right of the child to a sound genetic endowment rather than the right to procreate." 129/

135. Bentley Glass has analysed the situation as follows:

126/ Information furnished by the Government of Norway on 15 April 1974.

127/ Information furnished by the Government of Zaire on 24 July 1975.

128/ Theodore Friedman, "Conflicting Rights and Human Life", C.I.O.M.S. Round Table Conference on Human Rights, 14, 15 and 16 November, 1973, TR8/B/2.3, p.9.

129/ Science and the Quality of Life, op.cit., p.6.

"in a not-distant future time, owing to the advances of human genetics, the right of individuals to procreate must give place to a new paramount right: the right of every child to enter life with a normal physical and mental endowment. This statement has been frequently misunderstood. I do not argue that some legal body must impose such a right upon reluctant or resistant parents who desire to procreate. I am speaking of a moral, not a legal, right. When the time comes that prospective parents can through genetic analysis of their own heterozygous genes becomes fully aware of whatever defects they may transmit as dominant genes, or whatever recessive genes both of them carry in common, and when amniocentesis makes more fully possible prenatal diagnosis of such conditions, we shall enter a new age of moral responsibility in respect to parenthood. Knowledge imposes responsibility and when such knowledge is potentially available, it is morally wrong not to avail one's self of it and to act upon it in the best light of the predictable consequences. The ultimate right to decide, in each individual case, may rest still with the prospective parents, but it will be the obligation of society to provide the fullest information about possible consequences and to give considerate, and at times stern, genetic counsel. In this way, the birth of defective children could be greatly reduced, whether by prenatal diagnosis followed by abortion, or by abstention and adoption of children (or of embryos) of other biological descent. I therefore reiterate that, in a not-distant future, advances in human genetics should make it possible to regard as the paramount right that of every child to be born with a normal, adequate hereditary endowment, one capable of utilizing fully and freely the advantages of equal opportunity in a better society." 130/

136. The pace of developments in the laboratory has generated novel dilemmas with not only social and ethical, but also legal ramifications. The duties of the medical/genetic practitioner to his immediate patient - the pregnant woman - and to the unborn infant are too new and complex to have been defined yet by law. Such factual situations as the following have been reported and discussed: 131/

- a doctor ascertains that a woman has contracted rubella early in pregnancy, but does not offer an abortion; the child born with congenital defects sues the doctor for "wrongful life".

- A woman undergoes amniocentesis to determine whether the foetus is suffering from Down's Syndrome; the test rules out Down's Syndrome but reveals that the foetus carried an extra Y chromosome - which some geneticist feel predisposes a person to anti-social behaviour. What is it the doctor's responsibility?

130/ Bentley Glass, "Ethical Problems Raised by Eugenics", World Council of Churches, Consultation on Genetics and the Quality of Life, Zurich, 25-29 June, 1973, No.8, p.7.

131/ Marc Lappé, "Genetic Counselling and Genetic Engineering, ...", op.cit., p.13; Orlando J. Miller, op.cit., p.29; Barbara H. Sanford, op.cit., p.4.

137. At a Symposium on Ethical Issues in Human Genetics held in 1971 a landmark case which arose in New Jersey, United States of America 132/ gave rise to a discussion of such issues. In that case, the doctor advised the pregnant woman that, although she had contracted rubella during pregnancy, it would have no effect on her child. The doctor was assumed to have known that the risk of a defective child was about 25 per cent but "withheld the information because he believed it unfair to abort three healthy foetuses to avoid one diseased one." 133/ The suit instituted by the parents and the defective child was found to be without legal basis. The child sued the doctor for his failure to give his parents accurate information on which a decision could be made by the parents acting on the child's behalf; the decision might have been that for him not to have been born was preferable to his being born deformed. The doctor was alleged to have violated a legal (and moral) duty when he failed to give appropriate medical advice. By contrast parents if they should choose not to abort are exercising their legal right to make such a choice. The parent's right is said to be derived from two sources:

> "One derived from the child's own right, in which case the parents are considered to be making their decision on behalf of their offspring, in what they judge to be his 'best interests', and ... one which focuses on the parents' own right to exercise control over an event which is of major importance to their lives." 134/

138. The Court found in favour of the doctor. In an obiter dictunn it added that a child who bears a genetic defect does not have a claim against the parents because they decided to give it birth despite the risks of the disease. It has been commented that:

> "the child is protected against intentional harm by the parents, as he would be after birth; and the parents are protected in the prudent use of the capabilities with which nature endowed them. This comports with our moral sense that it is unjust to blame someone for something (such as his genetic make-up) which he cannot (presently) control. It would be cruel to add to the injury of a defective gene (and the undeserved self-blame which is felt when the disease manifests itself in an offspring) the insult of a suit by the offspring. On the other hand, parents who knowingly and recklessly took a drug with a substantial teratogenic risk would be liable if their offspring were deformed. Similarly, major manipulations of the birth process, done in the face of adverse or incalculable risks, would expose their creators to liability for injuries suffered." 135/

132/ Gleitman v. Cosgrove.

133/ Alex M. Capron, "Legal Rights and Moral Rights." Bruce Hilton, op.cit., p.232.

134/ Ibid., p.237.

135/ Ibid., pp.237-238.

139. Another attitude as regards the social implications of certain legal decisions has been expressed:

> "In some of the American cases, the courts have recognized the justice of the child's claim (that he was injured due to parental negligence), although they have so far refused to award damages, due to policy considerations. In other countries, e.g., in Germany, judgments with compensation have gone for the plaintiffs. With the spread of amniocentesis and genetic abortion, we can only expect such cases to increase. And here it will be the soft-hearted rather than the hard-hearted judges who will establish the doctrine of second-class human beings, out of compassion for the mutants who escaped the traps set out for them." 136/

9. Proposals made for Assessment of Prenatal Genetic Diagnosis and Counselling

140. In the area which is the subject of this chapter, there being little awareness of the availability of the techniques discussed, much less of the social, legal and ethical issues involved, only tentative efforts have been made toward the establishment of local, national or assessment machinery. It is expected that some persons will attempt to have certain technologies banned by statute; the question has been asked whether this should be done, and whether such prohibition would be effective. 137/ In the United States of America the Senate endorsed unanimously the creation of an authoritative body - a congressional commission - to examine the area, although the House of Representatives never acted on the proposal. 138/

141. Also in the United States of America there was a plea for the creation of a "'National Genetics Task Force' to co-ordinate research in this area, spot developments amenable to immediate application and set priorities for Federal support." 139/ Similarly there was a call for "a National Health Ethics Commission established by Congress as well as state and city health ethics boards, to oversee hospitals, clinics, doctors, and researchers. The Commission would consider the ethical, social, political, and legal aspects of new breakthroughs." 140/

142. It has been proposed that in order to avoid the mistakes of the industrial revolution when new technologies were forced upon society which had to adapt to industry's needs, the new iological technology should be screened, examined and guided. It has been proposed that a "Council of Sages ... reflect on these matters and pronounce their recommendations." The author continues:

136/ Leon R. Kass, "Implications of Prenatal Diagnosis for the Human Right to Life," Bruce Hilton, op.cit., p.189.

137/ Walter F. Mondale, "Ethics and American Population Policy", The Hastings Center Report, No.1, June 1971, p.7.

138/ Amitai Etzioni, op.cit., p.37.

139/ Walter Sullivan, op.cit., p.9.

140/ Center for Policy Research, The First Five Years 1968-73, New York, p.30.

"The Council's advice should not replace or constrict individual choices but rather seek to inform the individual. Thus, the ultimate decision would continue to rest with each person. But she (and her husband, if any) will be made aware of the opportunities, risks, catches and considerations pointed up in the careful deliberations of a wise body.

"This modern equivalent of the tribal council will have to include not just scientists but also humanists, theologians and social scientists. Such a wide representation will help to assure that the whole person, not just specific individual needs, will be taken into account. Furthermore, such deliberations must be backed up by a research staff. Many of the issues involved require a command of empirical data." 141/

143. It has been reported that "[i]n Sweden today, the research councils require certain planned research projects to be examined by ethics committees. Such an examination should provide some guarantee that initiated research projects are ethically defensible. The projects to be investigated are, however, mainly experiments on human beings and not experimental investigations. There is no reason to put the brake on advances in this extremely important branch of biological research by, for example, forbidding a certain type of research because it may be potentially injurious. Reasoning of this kind would lead to a very great proportion of research being prohibited. On the other hand, there is every reason to exert some kind of supervision on how findings are applied." 142/

144. The Government of Norway reports that no programme for safeguarding or improving the genetic health of future generations presently exists in Norway, but suggests that:

"For the time being, the following measures would seem to be adequate: detailed records of genetic disorders; general information on the transmission of genetic diseases, genetic counselling, and surveillance of environmental and nutritional factors which may have the effect of increasing the mutation rate. Possible future initiatives will also be based on information which gives the individual adequate options where the question of the transmission of genetic disorders is concerned." 143/

145. At the eighth CIOMS Round Table Conference held in Geneva in 1973 a resolution dealing with advances in genetics was adopted:

"RESOLUTIONS

No. I: NATIONAL AND INTERNATIONAL ASSESSMENT OF NEW BIOMEDICAL PROCEDURES

The Conference,

NOTING that new biomedical procedures are being developed, as for example, amniocentesis (which makes it possible to obtain genetic information about the fetus during pregnancy); and

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141/ Amitai, Etzioni, "Doctor's Know More Than They're Telling you About Genetic Defects", Psychology Today, November 1973, p.36.

142/ Information furnished by the Government of Sweden on 12 March 1974.

143/ Information furnished by the Government of Norway on 15 April 1974.

CONSIDERING that this particular procedure (which is still in the experimental stages) may lead to active medical intervention for the elimination of certain genetic disorders such as Down's syndrome (Trisomy 21), etc., but may also lead to abuses;

HOLDING that amniocentesis sets a precedent which may apply to other medical developments, especially in the field of genetics, and to ways in which society may be called upon to deal with such developments;

RECALLING that in the case of drugs, vaccines and other therapeutic agents, extensive evaluation mechanisms have been and are being developed for the protection of society, but that no mechanisms exist as yet for the evaluation of new biomedical procedures;

URGES that health authorities and other parties concerned in all countries familiarize themselves with the procedure of amniocentesis and the problems it raises by:

1. Continuing to evaluate at national and international levels the safety and reliability of this procedure;

2. Determining the uses for which the procedure would be promoted, tolerated or allowed;

3. Considering such questions as:

(a) whether the procedure should or should not be limited to the detection of severe genetic disorders;

(b) whether it should or should not be used only for pregnancies at risk or for all pregnancies;

(c) whether it should or should not be used for such purposes as sex choice or the promotion of specific genetic attributes;

(d) who would make the necessary decisions and on what basis for the application of the procedure and for any intervention that may be indicated (the woman? the couple? the physician? health authorities? legislators? others?);

(e) whether society should or should not subsidize the procedure and the necessary laboratory facilities;

(f) whether society should or should not assure equal access to this procedure for all.

CONCLUDES that only if new medical procedures and interventions are subject to such critical assessments can mankind progress toward the determination of its fate rather than submitting blindly to technological developments; and, finally,

RECOMMENDS the wider application of preventive measures such as premarital detection and subsequent counselling of carriers of certain deleterious genes (for example, the ganglioside lipidoses) using available technology." 144/

144/ Simon Btesh, (ed), Protection of Human Rights in the Light of Scientific and Technological Progress in Biology and Medicine, Eighth CIOMS Round Table Conference, Geneva, 14, 15 and 16 November, 1973, WHO, 1974, pp.319-320.

II. MEASURES NECESSARY TO SAFEGUARD THE HEALTH, SAFETY AND LIFE OF PATIENTS WHO ARE EXPOSED TO ELECTRICAL, ELECTRONIC, MECHANICAL AND OTHER TECHNICAL DEVICES DURING DIAGNOSTIC OR THERAPEUTIC PROCEDURES

1. Inherent defects of certain devices and dangers arising from improper use of devices

146. In 1972 it was estimated that over 7,500 different electrical, electronic, mechanical and other technical medical devices were being marketed. 1/ From sophisticated operating rooms and patient monitoring equipment, to artificial organs and implanted apparatus, medical devices have intervened into most aspects of medical science.

147. The dangers of the new devices may arise from inherent defect or from inappropriate use. A Swedish expert, Jan Thorp, expressed the opinion that: "Safety is a relative concept which can never be absolutely realized. Safety and the efficiency of medical devices generally depend upon a combination of elements in the construction, installation and in application". 2/

148. In spite of the great advantages of many medical devices, some now on the market have been reported to be not only ineffectual, but even harmful. 3/

149. Dr. J.F. Davis, Director of the International Institute for Medical Electronics and Biological Engineering, Paris, has said:

> "I would like to remind the Assembly again of the fact that we are in an era of medicine in which there is a steadily increasing use of electromechanical devices, of complex engineering controls, of automatic monitoring systems and of computers and their corresponding software. We in medical engineering, who develop these devices, are aware that they carry, in addition to the obvious potential benefits to the individual patient (in the clinical setting and also in a clinical investigation), certain potential risks to him. The devices I am referring to use a number of powerful physical agents such as ultrasound, laser radiation, ionizing radiation, heat and cold as well as electrical energy in a number of forms. Many of the devices are connected directly to the patient during therapeutic intervention (e.g. pacemakers, defibrillators, artificial internal organs, etc.) and during diagnostic procedures (e.g. electrographic recorders, monitoring devices, etc.)...." 4/

1/ Henninger, Daniel, "Medical Devices Sometimes Maim Patients", The National Observer, 25 March 1972; see also, "Medical Devices: an Unhealthy Situation", Consumer Reports, 4/70, p.257.

2/ Information furnished by the Government of Sweden on 12 March 1974; similarly, information furnished by the Government of Ghana on 21 March 1974.

3/ Report of a Special Committee on Medical Devices, United States Department of Health, Education and Welfare, 19 September 1970, p.8.

4/ CIOMS Round Tables. 1. Biomedical Science and the Dilemma of Human Experimentation. Editions CIOMS 1968, p.93.

150. Attention has for instance been drawn to deaths or injuries known to have been caused by defective pacemakers, anaesthetic machines, catheters, heart valves, intra-cerebral electrodes, x-ray and fluoroscopic apparatus, and bone drills and other types of electro-surgical equipment. 5/

151. It has been pointed out that:

> "Medical and surgical instruments are the tools of a profession dedicated to the art of healing. Because such instruments are used with this laudable intent, it is all too easy to overlook the fact that they are still nothing more than specialized, mechanical, or electrical tools. They are subject to the same defects of design, durability, construction, and assembly as are the tools of the factory and machine shop." 6/

152. An authority reported in 1970 that the records of the Food and Drug Administration (F.D.A.), a United States governmental regulatory agency, have indicated that in the United States the pacemaker, an implanted device that causes the heart to beat regularly at a rate conforming to the body's physiological demands, had been responsible for 89 deaths and at least 186 injuries; 7/ inadequate anesthesia machines are known to have killed 47 patients 8/ while x-ray equipment had been implicated in more than 2,000 injuries. 9/ An insurance actuary's study on the United States indicated that during 1964 and 1965 about 2,400 patients were electrocuted in hospitals. 10/

153. Other examples of harm caused by defective or poorly designed devices are the following:

(i) "The regulator on a neurosurgeon's drill failed to turn off automatically once past the patient's hard, bony cranium, causing irreparable brain damage." 11/

5/ Edward M. Swartz, "Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments", 18 De Paul Law Review, 351; Arthur Allen Leef, "Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems", 1967 Washington University Law Quarterly, 284.

6/ Swartz, op.cit., p.349.

7/ "Regulating Medical Devices", Science News, 23 May 1970, vol. 97, No. 21, p.500.

8/ Ibid.

9/ Ibid.

10/ Consumer Reports, op.cit., p.258.

11/ Henninger, Daniel, op.cit.

(ii) "A premature infant's foot burned because it got stuck in the heating element of a poorly designed incubator." 12/

(iii) In a ventilator which anesthesiologists use for respiration of a patient during surgery, a patient's lungs were blown apart by high pressure gas by the fortuitous interchanging of two identical tubes. 13/

(iv) In procedures involving the subcutaneous insertion of a catheter, the catheter enters through a hollow hypodermic needle. The standard needle tip is ground in such a way as occasionally to cut off a small piece of the catheter, which then travels throughout the body. Lost catheters have resulted in: "thrombosis, embolism, bacterial endocarditis, myocardial damage, coronary vessel damage, pericarditis, lung abscess" and other complications. 14/

154. Even in circumstances where a device is properly designed, there exists the risk of human error, particularly in view of the sophisticated nature of much of the equipment.

155. The Government of Finland has expressed the standard of care required in the use of medical devices as an offshoot of the doctor's overall ethical responsibilities to his patient:

> "The quality and quantity of treatments in each individual case is decided by the attending doctor who is guided by his oath, the Geneva Declaration adopted by the World Medical Association, and the ethical regulations of the medical profession which, among other things, include that treatment with the help of electric, electronic or mechanical instruments must not cause the patient any mental or physical injury which is inconsistent with the purposes of the treatment." 15/

156. Hospital and medical personnel are sometimes inadequately trained to use the new equipment. An illustrative inspection of a hospital revealed that:

> "... Instruction manuals disappear so [that] operating instructions are passed on by word of mouth. Nurses trained to use a complicated piece of equipment designed by one company don't know how to use a similar device made by another manufacturer and used elsewhere in the hospital." 16/

12/ Henninger, Daniel, op.cit.

13/ Swartz, Edward M., op.cit., p.366.

14/ Ibid., pp.386-388.

15/ Information furnished by the Government of Finland on 25 February 1974.

16/ Henninger, Daniel, op.cit.

157. One instance of human error was reported as follows:

> "Because a nurse inadvertently reversed the electric connexions on a thermo-electric crysurgical stylet used to remove cataracts, the needle became hot rather than cold and destroyed the patient's eye." 17/

158. A further hazard is that the patient wearing an implanted device may not be properly briefed on the care to be exercised:

> "... all these devices are particularly sensitive to the external electromagnetic radiation emitted by an increasing number of medical devices (diathermy and electrocautery equipment) and household appliances (microwave ovens). For this reason, the United States Public Health Service has taken the initiative of distributing as widely as possible letters for the benefit of pacemaker wearers warning them of the serious dangers to which they may be exposed even in an electromagnetic field as weak as that created by a microwave oven." 18/

2. Measures adopted or proposed to protect human rights

159. One of the basic problems encountered in the field of defective medical devices is how the knowledge of either the actual or potential danger is made known. Unless accidents are particularly dramatic and attract the attention of the newspapers, the public usually does not hear of them. 19/ Controls over new drugs in the United States and other countries require that a dangerous reaction must be promptly reported to the government. 20/ With respect to medical devices no such rigorous control appears to exist. It has been said that:

> "A physician experiencing trouble with a device may simply stop using it; or he may publish his findings in a medical journal, which can take months, and may not be read by the right people anyway." 21/

On the other hand, it has been maintained that the physicians, who are the ones most likely to discover defects while using medical devices,

> "... are on the whole, a highly discriminating class of purchasers and provide manufacturers with intelligent and articulate feedback about defective products, often preventing serious injury before it could occur."22/

17/ Henninger, Daniel, op.cit.

18/ Centre d'Etude des Consequences Générales des Grandes Techniques Nouvelles, Bulletin No. 61, August-September 1971, Paris, p.13, (citing Scientific American, June 1971).

19/ Consumer Reports, op.cit., p.258.

20/ Henninger, Daniel, op.cit.

21/ Ibid.

22/ Swartz, Edward M., op.cit., p.350.

160. Defects often come to the attention of the public and manufacturers only when the victim of such a device sues for damages. 23/ In this connexion it has been pointed out that:

> "... as with all products liability litigation, there exists the problem of educating the injured person about his rights. In the majority of cases of personal injury no lawsuit is ever brought because the patient, or consumer, is never taught that a legal remedy is available to him. He considers his injuries a tragic act of God, accepts them resignedly, and fails to contact an attorney." 24/

161. Some hospitals, on their own initiative, have recently formed new departments whose function is to advise the hospital on what new equipment to purchase and to make certain that it is safe and well constructed, and generally to evaluate the devices. 25/

162. According to another approach, used by the National Heart and Lung Institute in the United States, no new heart parts will be tested in human beings until they have been evaluated by one of two test centres. Each of these test centres has:

> "... a multidisciplinary staff of engineers, chemists and medical personnel and is expected to operate on a budget of $1 million to $2 million a year. After ... scientists conclude their study of a device, their judgement will be reviewed by a panel of independent experts." 26/

163. It is with respect to devices like the X-Ray machine, and the medical use of radioactive substances, where the dangers are well documented, 27/ that most of the regulating legislation in this field is found. The diagnostic and therapeutic use of X-Ray is the major source of manmade radiation exposure:

> "More than 90 per cent of all human exposure to manmade radiation comes from the diagnostic use of X-Rays in contrast with about 1 per cent from radioactive discharges from nuclear power plants, about which there has been so much public concern." 28/

23/ Swartz, Edward M., op.cit., pp.348-407.

24/ Ibid., pp. 350-351.

25/ Science News, op.cit., p.500.

26/ Science News, op.cit., p.500.

27/ Cf. general comments appearing in Singapore Ministry of Health, Code of Practice, 1973, furnished by the Government of Singapore, Sections 1.1-1.7.

28/ Schmeck, Harold M., "F.D.A. Proposes New Rules on Diagnostic X-Rays in Effort to Reduce Radiation Exposure", New York Times, 11 October 1971, p.16.

164. In Luxembourg, 29/ Norway, 30/ Singapore, 31/ Sri Lanka, 32/ United Kingdom and United States, there are regulatory safeguards covering many aspects of the handling, operation and use of X-Ray and radioactive equipment.

165. The Code of Practice for the Protection of Persons against Ionizing Radiations arising from Medical and Dental Use in the United Kingdom

> "... draws attention to the genetic and somatic dangers from radiation and advises on the need for clinicians to satisfy themselves that all examinations are fully justified clinically, and, in cases of doubt, to consult with their colleagues. The importance of records of previous examinations or therapeutic treatment is stressed and particular mention is made of the precautions necessary when examining women of reproductive capacity and those known to be pregnant." 33/

166. An example of efforts to keep legislation abreast of technological advances is the new Federal Drug Administration rule in the United States which requires all new X-Ray machines to incorporate features that increase the reliability of the equipment, thus avoiding multiple exposure to the patient; and to be equipped with protective cones which limit the size of the X-Ray beam to the size of the film and thereby avoid exposing the patient to more widespread radiation. 34/

167. A basic problem in this area however is that the dangers inherent in any medical device are often not discovered until it is marketed and in general use. In the United States, the President's Advisor on Consumer Affairs stated:

> "... the consumer does not have complete assurance that complex and potentially hazardous medical equipment has been thoroughly tested and proven safe and effective. Under existing law, corrections cannot be required until after a device has been shown to be hazardous, perhaps through actual patient injury." 35/

Although the use of X-Ray and radio-active devices is regulated to some extent in many countries, there are the thousands of other devices that do not share this type of control.

29/ Information furnished by the Government of Luxembourg on 14 May 1974.

30/ Information furnished by the Government of Norway on 15 April 1974.

31/ Singapore Ministry of Health, op.cit.

32/ Information furnished by the Government of Sri Lanka on 5 March 1974.

33/ Information furnished by the Government of the United Kingdom on 8 August 1974.

34/ New York Times, 15 August 1972, op.cit., see also Schmeck, Harold M., op.cit., p.16.

35/ Henninger, Daniel, op.cit.

168. In the United States, where the medical technology industry is most active, 36/ there is almost no general control over medical devices. The FDA is the only governmental agency that has authority to regulate all medical devices, but its power is limited to the seizing of an already marketed product and starting a court proceeding for an injunction. 37/ The burden is on the government

> "... to prove the device is unsafe and ineffective instead of making the manufacturer prove the device is safe and efficacious - just the reverse of the situation in marketing drugs." 38/

The manufacturer of the suspected device can continue to market his product until the case is disposed of - a period that can last years. 39/

169. One authority viewed the situation as follows:

> "The most alarming part of the medical device problem is that it is expanding into the area of legitimate medical devices. In years past the FDA was concerned almost exclusively with outright quack devices, ... At least the reasoning consumer could steer clear of those. But nowadays the issue extends to essential medical equipment ..." 40/

170. Since under United States law drugs are rigorously regulated, some attempt has been made to define certain medical devices as "drugs"; the courts did adopt this definition with regard to a suturing device and an antibiotic sensitivity disc device, and it was thought by some writers that this approach would be a remedy for the FDA's lack of control over devices. 41/ But this approach has drawbacks, and the United States Department of Health, Education and Welfare in a report outlined a course of action which, if followed, will lead to strict government control of medical devices per se. 42/ The report, prepared in consultation with the private sector, recommended that some sort of pre-testing and regulation of medical devices should be done by the government. Prevailing opinion ranges, however, from strict control and pretesting, as is done in the drug industry, to something much less. 43/

36/ Biomedical Science and the Dilemma of Human Experimentation, C.I.O.M.S. Round Table, Paris, 7 October 1967, p.12.

37/ Consumer Reports, op.cit., p. 256.

38/ Consumer Reports, op.cit., p. 257.

39/ Ibid., p. 256.

40/ Ibid., p. 257.

41/ Consumer Reports, op.cit., p. 258.

42/ United States Department of Health, Education and Welfare, op.cit., pp.1-18.

43/ Science News, op.cit., p. 500.

171. Dr. Davis added the following to the remark quoted in paragraph 149 above:

> "All such devices are, or should be, subject to the same searching questions and procedures of preclinical evaluation as are the new pharmacological agents. That is to say the devices themselves require to be evaluated like drugs." 44/

172. Some critics of this approach would argue that such an attitude would stifle progress in this field. 45/ It has been written:

> "Many manufacturers and physicians worry, justifiably, that unless Federal legislation is adroitly handled, restrictions in device preclearance could stifle innovation in design, thwart legitimate medical experimentation and drive out of business smaller companies that lack reserves for testing. Since progress in the medical-device industry is fast paced, some fluid method should be established to evaluate devices, so that they could be quickly approved - and removed if they become dangerously outdated by new knowledge or superseded by safer materials or techniques." 46/

173. It has been pointed out that, because of the diversity of medical devices, there is as yet in the United States no clear definition or classification, or legislation directing the regulation, of devices; it has been maintained that the system currently used for drugs would be inappropriate. 47/ In addition, since many of the injuries from medical devices arise from misuse of the device, such legislation would not solve all problems. 48/ Nor should standards be set that might tend to hinder unduly research and development. 49/

174. In the USSR the use of medical devices is regulated in the following manner:

> "Under USSR law, all medical goods, including electrical, electronic, mechanical and other appliances designed for use on patients for preventive, diagnostic and therapeutic purposes undergo clinical trials in accordance with established procedures with the approval of the Ministry of Health of the USSR; their use in medical practice is then authorized by the Minister of Health of the USSR. The trials must not only demonstrate the effectiveness of the medical product, but also show that it is harmless and safe for the patient.
>
> "When authorizing the use of such products, the Ministry of Health of the USSR also approves the relevant instructions for their use and safety procedures.

44/ C.I.O.M.S. Round Table, Paris, 7 October 1967, op.cit., p. 93.

45/ United States Department of Health, Education and Welfare, op.cit., p. 8.

46/ Consumer Reports, op.cit., p. 259.

47/ United States Department of Health, Education and Welfare, op.cit., p. 8.

48/ Ibid., p. 9.

49/ Ibid.

"At the same time, the requisite quality and safety standards are approved for those products, also by agreement with the Ministry of Health of the USSR.

"The law prohibits the use on patients of apparatus, instruments and other articles not authorized by the Ministry of Health of the USSR." 50/

175. It is reported that in France, in view of the fact that

"... the number of patients wearing pacemakers of all kinds will continue to increase, and in order to promote contacts between researchers, doctors and engineers, a biomechanical research association was recently established in France." 51/

176. In the United States it has been recommended that a distinction be made between types of devices, and that the scientific community be utilized to obtain a classification of devices into three main categories:

(a) Those that can be exempt from standards or pre-clearance;

(b) Those for which adequate existing standards or data permit certification of old or establishment of new safety and performance standards, together with compliance tests for design, manufacture, installation, and operation;

(c) Those devices that should be made subject to performance review prior to clinical application and marketing because the data do not yet permit development of standards." 52/

177. It is similarly the opinion of the Government of Argentina that:

"The health authorities are under an obligation to establish standards in this respect on the basis of expert opinion." 53/

178. The Government of Sweden has expressed the opinion that "[i]nternationally recognized requirements are necessary in order to safeguard the patient." 54/ The Governments of Ghana 55/ and Romania, 56/ are also of the opinion that, in addition to national standards, the matter is one of international concern.

50/ Information furnished by the Government of the USSR on 25 July 1974.

51/ Centre d'Etude des Consequences Générales des Grandes Techniques Nouvelle .....; op.cit., referring to Lettre de la Recherche, 18 juin 1971 (C.T.N. No. 18. 215).

52/ United States Department of Health, Education and Welfare, op.cit., p.11.

53/ Information furnished by the Government of Argentina on 30 May 1974.

54/ Information furnished by the Government of Sweden on 12 March 1974.

55/ Information furnished by the Government of Ghana on 21 March 1974.

56/ Information furnished by the Government of Romania on 29 April 1974.

179. It has been proposed by the Government of Sweden that increased efforts be made in the technical aspect of the field by international standardization bodies, and that "[w]here clinical aspects are predominant the necessary steps be taken by the United Nations". 57/

180. The Government of Ghana, viewing the problem as an international one, has made the following suggestions:

> "To ensure adequate protection of the health and life of both patients and the users of such devices, the United Nations should take the lead by urging all countries to develop minimum standards ... for the designing, manufacture, testing, use and maintenance of all electrical, electronic, mechanical and other technical devices for diagnostic and therapeutic procedures. ...
>
> "The United Nations Secretary-General should encourage, support and assist research activities to make such devices as safe as possible for both the patient and the person or persons handling them." 58/

181. The Government of Ghana, recognizing also the problem of human failure, has made two recommendations:

> "All persons using or handling such devices should be given adequate training in their use and application and should attain a proper level of competency before they are permitted to use or handle them.
>
> "In all establishments where such devices are used, efficient services for preventative maintenance and repairs should be established and a safety code of practice should be rigidly enforced." 59/

182. The Government of Hungary has reported as follows:

> "Order No. 15/1972.Eü.M., § 79, section (2) states definitely and unequivocally that the physician may not perform medical functions with an instrument if he does not possess the specified familiarity with its use, safe handling and in the professional evaluation of the results of examining or treating procedures performed with this instrument." 60/

57/ Information furnished by the Government of Sweden on 12 March 1974; similarly, information furnished by the Government of Romania on 29 April 1974.

58/ Information furnished by the Government of Ghana on 21 March 1974.

59/ Information furnished by the Government of Ghana on 21 March 1974; similarly, information furnished by the Government of Viet Nam on 27 March 1974.

60/ Information furnished by the Government of Hungary on 19 August 1975.

PART THREE. EXPERIMENTS ON HUMAN SUBJECTS

I. PROTECTION OF THE INDIVIDUAL AGAINST UNJUSTIFIED EXPERIMENTS, INCLUDING THE QUESTION OF FREE AND INFORMED CONSENT TO EXPERIMENTS PERFORMED ON THE INDIVIDUAL

1. Statement of problems involved

183. Human rights problems arising out of experimentation on human subjects have become increasingly important in recent years in the light of the increasingly experimental character of modern medicine and psychology. Professor Paul A. Freund has written:

> "Two centuries ago it was said by a court of law that a physician experiments at his peril; if he departs from the accepted method of treatment, he is responsible for any untoward consequence to the patient. Today we are more likely to say that all serious therapy is experimental. The deepened knowledge of complex biological processes, the proliferation of powerful and sensitive drugs and therapies, the range of options in treatment, and the idiosyncrasies of patients' reactions, all make it inevitable that sound medical practice be experimental in a sense that does not contradict the nineteenth-century admonition, but renders it much less meaningful and serviceable as a guide to professional conduct.
>
> "There is another sense in which medical practice has become increasingly experimental - namely, in the interrelation between therapy and scientific investigation of a systematic kind. The embodiment of this kind of medical practice is, of course, the modern teaching hospital." 1/

184. When human beings become the subject of experimentation the responsibility of the physician or surgeon to advance the frontiers of knowledge is in conflict with his commitment to individual worth and autonomy. At the heart of this dilemma lies the question: When may a society, actively or by acquiescence, expose some of its members to harm in order to seek benefits for them, for others, or for society as a whole? 2/ Professor Talcott Parsons of Harvard University points out:

> "The ethical problems involved in research that makes use of human subjects are by no means new, but they have become intensified in recent years through a number of circumstances ... Not only new but more daring and, presumptively at least until fully tested, riskier procedures are increasingly being employed. Organ transplants are, of course, the most commonly discussed example today.
>
> "Another reason for the increasing concern with these problems is the rapid growth of research in the behavioral and social sciences. Almost in the nature of the case, such research makes use of human subjects over a wide range. For example, the concern with child development and various aspects of education involves very sensitive areas. Survey research and various forms of

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1/ Paul A. Freund, "Introduction", Daedalus: Ethical Aspects of Experimentation with Human Subjects, Spring 1969, p. VIII.

2/ Jay Katz, Alexander M. Capron and Eleanor Swift Glass, "Some Basic Questions about Human Research", The Hastings Center Report, Vol. 2, No. 6 (December 1972), p. 1.

participant observation have been expanding rapidly, and these matters will undoubtedly call for careful scrutiny in the future." 3/

185. Recent experience with human experimentation in a variety of disciplines has prompted disquiet among the professions and the public. Professor Geoffrey Edsall has written:

"The striking upsurge of concern over the ethics of human experimentation during the past few years has arisen for a number of well-known reasons ... Suffice it to point out that in the tremendous expansion of experimental studies on man that has occurred since World War II, there have been numerous instances in which the ethical approach to the use of human beings for such purposes has appeared to be grossly deficient. There have been other situations in which this deficiency was considered as clear and unequivocal by the average informed layman, even though the scientists concerned may have been quite honestly and, indeed, vehemently felt that their actions had been wholly ethical. Be that as it may, documentation of a large number of actual or alleged instances of such violations has been published by H.K. Beecher, by M.H. Pappworth, and by others. 4/ Perhaps the most widely publicized example in recent years was the New York episode concerning the injection of cancer cells into elderly and chronically ill individuals who were not specifically informed that malignant cells were being injected into them. At all events, these and other episodes have focused attention upon the actual and potential risks, in our society, that human beings may be used carelessly or callously to accomplish the objectives of investigators whose ultimate goals may have been wholly admirable, but whose judgment as to the means for reaching these goals was unacceptable to the community." 5/

186. Dr. A.E. Confrey, Director of the Division of Research Grants, National Institute of Health, Bethseda, Maryland, said at the CIOMS Round Table Conference on Biomedical Science and the Dilemma of Human Experimentation, held in Paris in 1967:

"Principally as a consequence of Dr. Henry Beecher's recent articles, and a number of disconcerting episodes concerning questionable research on human subjects, a significant proportion of the American public is somewhat apprehensive about the propriety or safety of certain clinical or behavioral studies. Reduced to its simplest terms, the feeling is that scientist's preoccupation with the excitement of research may cause him to overlook, occasionally, patient welfare or human rights.

3/ Talcott Parsons, "Research with Human Subjects and the 'Professional Complex'", Daedalus, op.cit., p. 325.

4/ See, among others, H.K. Beecher, "Ethics and Clinical Research", New England Journal of Medicine, Vol. 274 (16 June 1966), pp. 1354-60; M.H. Pappworth, Human Guinea Pigs: Experimentation on Man, Boston, 1968.

5/ Geoffrey Edsall, "A Positive Approach to the Problem of Human Experimentation", Daedalus, op.cit., pp. 463-464.

"I doubt that anyone would seriously contend that there is no problem here, that no physician or scientist is neglecting proper consideration of human welfare. But what the actual dimensions of the problem are - how many are engaged in inappropriate research or clinical medicine - is a matter of conjecture." 6/

187. Professor J. Hersch said at the Symposium on science policy and biomedical research organized by CIOMS with the assistance of UNESCO and WHO in Paris in 1968:

"The growing powers of intervention that surgery and medicine are acquiring, the growing specialization and technicality of the most efficient forms of treatment, are tending more and more to turn the patient, in the doctor's eyes, into an object which he knows and can manipulate by technical means, whose personal inviolability is first overlooked in principle, then denied in theory, and at last ousted from perception by feeling or moral sense. At that stage it is the "moral fibre", in the words of certain great practitioners, which gradually becomes deadened in certain doctors, and is replaced by the passion for research or for technical triumphs. Little by little, with the deadening of the "fibre", ethical requirements are liable to become less exacting throughout the medical profession and to be impaired throughout the whole population. "The sense of humanity", implanted in our physical and moral affectivity, which has been slowly elaborated in the course of thousands of years, may perhaps not be indestructible." 7/

188. The present experimental character of heart transplant operations has been pointed out in a statement entitled "Cardiac transplantation in Man", issued on 28 February 1968 by the Board on Medicine of the National Academy of Sciences of the USA:

"... In the case of cardiac transplantation, ... the recipient's life cannot be salvaged if the transplanted heart does not function. Highly important is the fact that the length of time that the recipient can survive is as yet conjectural, even if the immediate result is favorable as indicated by prompt resumption of function by the transplanted heart. Thus the procedure cannot as yet be regarded as an accepted form of therapy, even an heroic one. It must be clearly viewed for what it is, a scientific exploration of the unknown, only the very first step of which is the actual surgical feat of transplanting the organ.

"... The ethical issues involved in the selection of donor and recipient are a part of the whole complex question of the ethics of human experimentation."

6/ CIOMS Round Tables. 1. Biomedical Science and the Dilemma of Human Experimentation. Editions CIOMS 1968, p. 57.

7/ J. Hersch, "Advances in medicine and the integrity of the human being", UNESCO, Science Policy Studies and Documents, No. 16, p. 74.

189. Doubt has also been thrown upon the justifiability of experiments in the psychological and pharmaceutical fields in which the success of the experiment depends upon the deliberate deception of the person on whom the test is being made. 8/

2. Professional codes of ethics

190. Attempts to control human experimentation and to protect the human personality from the dangers related to this experimentation have led to the elaboration of professional codes of ethics to guide medical research. The first of these was the Nuremberg Code of 19 August 1947 (a set of ten principles relating to medical experiments laid down by a United States Military Tribunal, acting under Control Council Law No. 10, in the trial of Karl Brandt and Others 9/). This code was followed by the Declaration of Geneva, the International Code of Medical Ethics and the Declaration of Helsinki, adopted by the World Medical Association in September 1945, October 1949 and June 1969, respectively. The Declaration of Helsinki comprised and further developed the basic elements of the previous codes and "has been very widely acclaimed as establishing the basic ethical principles that should govern research involving human subjects". 10/

191. At the 8th CIOMS Round Table Conference, Dr. J. de Moerloose mentioned the existence of national codes of ethics dealing with experimentation on human subjects in the USA, the United Kingdom, Australia, France, the Netherlands, South Africa, Switzerland and Czechoslovakia and of national ethical codes relating to the medical profession containing a reference to such experimentation in Costa Rica, Colombia and Canada. 11/

192. As Professor David D. Rutstein stresses, the ethical requirements that at present create the most difficulty are obtaining informed consent from the potential subject, the desirability that the subject derive a health benefit from the experiment and keeping the risk to the subject as small as possible. 12/

8/ See J. Seeman, "Deception in psychological research", American Psychologist, vol. 24, No. 11, November 1969, pp. 1025-1028; M.M. Katz, "Ethical issues in the use of human subjects in psychopharmacologic research", American Psychologist, vol. 22, No. 5, May 1967, pp. 360-363; Kenneth W. Mann, Deadline for Survival. A Survey of Moral Issues in Science and Medicine (New York, Seabury Press, 1970), pp. 50-52; Margaret Mead, "Research with Human Beings: A Model Derived from Anthropological Field Practice", Appendix I, Daedalus, op.cit., pp. 374-375.

9/ Law Reports of Trials of War Criminals, published for the United Nations War Crimes Commission by His Majesty's Stationery Office, London, Vol. VII, 1948, pp. 49-50.

10/ Document E/CN.4/1173, Annex, p. 15.

11/ Dr. J. de Moerloose, "A survey of international and national codes and legislation in selected areas", 8th CIOMS Round Table Conference, op.cit., p. 332.

12/ David D. Rutstein, "The Ethical Design of Human Experiments", Daedalus, op.cit., p. 523.

193. The main principle of professional codes is that requiring that the subject of an experiment should be fully informed and give his voluntary consent to the experiment. The Nuremberg Code states:

> "1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." 13/

194. The Declaration of Helsinki distinguishes between clinical research combined with professional care and non-therapeutic research. Some basic principles relate to both of them. Thus, in both cases, research should be based on laboratory and animal experiments, and conducted only by scientifically qualified persons and under the supervision of a qualified medical man. The objective should be in proportion to the inherent risk to the subject which should be carefully assessed. Special caution should be exercised when the personality of the subject is liable to be altered by drugs or experimental procedures.

195. In respect of clinical research combined with professional care the Declaration of Helsinki states:

> "1. In the treatment of the sick person, the doctor must be free to use a new therapeutic measure, if in his judgment it offers hope of saving life, reestablishing health, or alleviating suffering.
>
> If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation.
>
> ...
>
> 2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient."

196. Dr. Herrman L. Blumgart, emeritus professor of medicine at Harvard Medical School, pointed out that "the use of drugs by physicians is illustrative of experimental therapeutics within the doctor-patient relationship devoted wholly to

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13/ Law Reports of Trials of War Criminals, op.cit., vol. VII, pp. 49-50.

the welfare of the patient", which Dr. Blumgart characterizes as "a therapeutic alliance" in contrast to "scientific alliance" of experimenter-subject relationship. He goes on:

> "Every time a physician administers a drug to a patient, he is in a sense performing an experiment. It is done, however, with therapeutic intent and within the doctor-patient relationship since it involves a judgment that the expected benefit outweighs the risk. Even the most commonly used agents - such as quinidine, digitalis, the thiazides, and the hormonal agents (thyroid, insulin, steroids and progestins) - involve risk. We can standardize drugs, but we cannot standardize patients; medical care of the patient demands adjusting the drug to the individual's unique characteristics. Several studies have vividly portrayed the prevalence of untoward effects in everyday practice." 14/

He emphasizes that:

> "patients should be experimented upon, if at all, only with reference to their disease. Never should there be added to the gratuitousness of the experiment as such the gratuitousness of service to an unrelated cause. This follows simply from what we have found to be the only excuse for infracting the special exemption of the sick at all - namely, that the scientific war on disease cannot accomplish its goal without drawing the sufferers from disease into the investigative process. If under this excuse they become subjects of experiment, they do so because, and only because, of their disease." 15/

197. With regard to non-therapeutic clinical research, the Declaration of Helsinki specifies that consent should as a rule be obtained in writing after the subject has been fully informed of the nature, the purpose and the risk of the clinical research. It is stressed that the subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise his power of choice and at any time during the course of research should be free to withdraw permission for research to be continued.

198. In connexion with non-therapeutic research, Professor R. de Vernejoul, President of the National Council of Physicians of France, said at the CIOMS Conference on Biomedical Science and the Dilemma of human experimentation:

> "Experiments on healthy people are an entirely different matter. Their sole aim is to advance medical science and they raise a large number of questions. For a great many authorities such experiments should be strictly forbidden: in all such experiments man should be replaced by animals. The great danger must be pointed out, as Baruk has, of sacrificing human beings on the altar of science and glorifying subjects who volunteer to be guinea-pigs. Someone has written that voluntary death of that kind is not suicide but a sacrifice in the service of science. Such a view is the more

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14/ Herrman L. Blumgart, "The Medical Framework for Viewing the Problem of Human Experimentation", Daedalus, op.cit., pp. 252-253.

15/ Ibid., p. 241.

dangerous because it exhalts the spirit of sacrifice as an ideal. But the real ideal places the value of human life above all." 16/

199. It is stressed that the question of informed consent is of special importance in non-therapeutic research. The Board of Regents of the University of the State of New York, in a decision relating to unethical human experimentation, with non-therapeutic purposes, pointed out:

> "Any fact which might influence the giving or withholding of consent is material. A patient has the right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason, intelligent or otherwise, well-informed or prejudiced. A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision. It is the volunteer's decision to make and the physician may not take it away from him by the manner in which he asks the question or explains or fails to explain the circumstances. There is evidenced in the record ... an attitude on the part of some physicians that they can go ahead and do anything which they conclude is good for the patient, or which is of benefit experimentally or educationally and is not harmful to the patient and that the patient's consent is an empty formality. With this we cannot agree."

The Regents stressed that the physician, when he is acting as experimenter, has no claim to the doctor-patient relationship that, in a therapeutic situation, would give him the generally asknowledged right to withhold information if he judged it to be in the patient's best interest. In the absence of a doctor-patient relationship, the Regents said:

> "There is no basis for the exercise of their usual professional judgement applicable to patient care ... No person can be said to have volunteered for an experiment unless he had first understood what he was volunteering for. Any matter which might influence him in giving or withholding his consent is material. Deliberate nondisclosure of the material fact is no different from deliberate misinterpretation of such a fact." 17/

200. Estimating the role of codes of ethics relating to medical research in the protection of human subjects, Dr. Jay Katz, adjunct professor of law and psychiatry at Yale Law School has written:

16/ CIOMS Round Tables, op.cit., p. 88.

17/ Cf. Herrman L. Blumgart, op.cit., pp. 257-258.

"Taking as a point of departure the ten 'basic principles' set forth by the Nuremberg judges, numerous attempts have been made to propose 'improved' codes of ethics to guide medical research. The proliferation of such codes testifies to the difficulty of promulgating a set of rules that does not immediately raise more questions than it answers. At this stage of our confusion, it is unlikely that codes will resolve many of the problems, though they may serve a useful function later. Even the much endorsed Declaration of Helsinki - praised, perhaps, because it is the newest and therefore the least examined - will create problems for those who wish to implement it. What is meant, for example, by 'the subject of [non-therapeutic] clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice'? ... Codes, as long as they stand alone and are not surrounded by detailed commentary, are pious exercises in futility. Since they aspire to ideals and are divorced from the realities of human interaction, they invite judicious or injudicious neglect. If codes are to have meaning, they must be tied to procedures that permit constant interpretation of terms like 'mental state', 'legal state', and 'power of choice'." 18/

201. It may be added that M.H. Pappworth includes the following among the ethical principles which should govern therapeutic experimental procedures:

"No experiment should be contemplated, proposed or undertaken to which, if he were in circumstances identical to those of the intended subjects, the experimenter would even hesitate to submit himself, or members of his own family, or anybody for whom he had any respect or affection." 19/

18/ Jay Katz, "The Education of the Physician-Investigator", Daedalus, op.cit., pp. 482-483.

19/ Cf. Harvard University Program on technology and society, Research Review No. 1, Implications of Biomedical Technology, Cambridge, Massachusetts, 1968, p. 50.

3. Review Committees

202. Another approach to safeguarding the interests of human subjects is the establishment of committees to review the decisions of investigators. "It is increasingly accepted", the World Health Organization points out:

> "...that in addition to the informed consent of the subjects to the investigator responsible for medical research involving human beings there should be a detailed review and approval of the proposed experiment by a committee composed of members not directly involved in the project. Some consider that such committees should include one or more non-medical members, such as lawyers and ministers of religion.
>
> The case for review committees is all the stronger in that printed guides cannot adequately cover all contingencies. For example, the justification for the first community trials of a new vaccine in children calls for ad hoc review by a suitably qualified committee rather than reference to abstract principles." 20/

203. Speaking about guidelines for human experimentation, Professor A. Gellhorn of the Institute of Cancer Research, Columbia University, New York, said at the C.I.O.M.S. Conference on biomedical science and the dilemma of human experimentation:

> "The proposed research should be reviewed by peers of the investigator for approval. I stress that the review be carried out by other investigators knowledgeable in the field. This will provide the subjects with assurance that the proposed study is reasonable and has not already been performed, that the procedures will not lead to additional harm, and that the principal investigator is competent and has the necessary facilities to make valid observations." 21/

204. Stressing the necessity of the creation of an independent surveillance authority, John Batt, Professor of Law of the University of Kentucky, pointed out:

> "The authority should serve as reviewing agency to determine what experimental work is in the public interest. Scientific representation should be limited to one-fifth of the membership. The bulk of the membership should be men from nonscientific professions and academic disciplines. Journalists, novelists, philosophers, lawyers, economists and social workers should constitute four-fifths of the membership. The authority should be allowed to hire its own reviewing and liaison staff. Applications for approval of experimental projects would be required and applicants would be afforded a hearing and afforded the right of judicial review." 22/

20/ Document E/CN.4/1173,pp 17-18.

21/ C.I.O.M.S. Round Tables, 1, Biomedical Science, etc., op.cit., p. 41.

22/ John Batt, "Law and the Bedroom", University of California (Los Angeles) Law Review. 5 October 1968, p.47.

205. Bernard Barber, a sociologist, and his associates at Columbia University, authors of a comprehensive analysis of the methods used for consideration of human research and protection of subjects in the United States of America, make inter alia, the following suggestions:

> "It is clear that all research using human subjects should be reviewed in all institutions. Not only is such universal review required by biomedical research commitment to the highest ethical standards, but our findings seem to show that such universal review may be one of the conditions of greater efficacy for peer review. Morality and efficacy, for once, seem to coincide in the same process ...[A] mixture of internal and external controls is desirable in regulating the activities of a powerful profession like biomedical research. One of the appropriate sites for such a mixture of controls is the peer review committee, where not only the esoteric activities and special interests of researchers are at issue but also the special interests and moral welfare of patient-subjects". 23/

206. In the United States a number of the universities and hospitals already had review committees when the United States Public Health Service issued in 1966 a policy statement requiring their establishment for any grants under its jurisdiction. 24/ According to the requirements issued, which are periodically brought up to date, the review committees are to determine whether human subjects in experiments

> "... will be placed at risk, and, if risk is involved, whether:
>
> (1) The risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
>
> (2) the rights and welfare of any such subjects will be adequately protected;
>
> (3) legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part; and
>
> (4) the conduct of the activity will be reviewed at timely intervals." 25/

207. The current requirements of the Food and Drug Administration prescribe that if the study of a drug is conducted on institutionalized subjects or by an individual affiliated with an institution which agrees to assume responsibility for the study "assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed study". The membership must include sufficient "members of varying background, that is, lawyers, clergymen or laymen as well as scientists, to assure complete and adequate review of the research project". 26/

23/ Bernard Barber, John J. Lally, Julia Loughlin Makarushka, Daniel Sullivan, Research on Human Subjects, Problems of Social Control in Medical Experimentation, Russell Sage Foundation, New York, 1973, pp.193-194.

24/ Jay Katz, op.cit., p.483.

25/ United States, Code of Federal Regulations, Title 45, Part 46, Federal Register, Vol. 39, No.105, 30 May 1974, p.18917.

26/ Cf. Irving Ladimer, "Clinical Testing of Drugs: A partnership for Research", 8th C.I.O.M.S. Round Table Conference, op.cit., p.200.

208. A WHO scientific group on principles for the clinical evaluation of drugs expressed the opinion in 1967 that a review of the purpose and design of a proposed trial of a new therapeutic substance "by local research committees composed of physicians and experienced medical research workers ('peer Groups') may actually be more effective than laws in protecting both the patient and the investigator" and added that there had so far been "a failure to consider needs [in terms of financial compensation] of human subjects who are injured in the course of an ethically irreproachable human experiment". The group suggested that human subjects of experiments should be covered by a special insurance system that would provide appropriate compensation in the case of "injury or death during investigation". 27/

209. A study group at the consultation on experiments with man, held at the Ecumenical Institute, Céligny, Switzerland, in 1968, suggested that the following guideline should be included in the Helsinki Declaration:

> "Ethical aspects of experimentation should be subject to effective social scrutiny, and one practical way of achieving this goal is the establishment of local, regional and/or national committees to assess the ethical aspects of each project and its results. Each committee should be composed of ethically perceptive persons, representing medicine, other sciences, and humanities, who are not a part of the research team." 28/

4. Legislation

210. The third approach to controlling medical experimentation in order to protect human rights is the strengthening of regulatory authority of the government over research. For example in 1974 the United States Department of Health, Education and Welfare issued regulations on protection of human subjects to be complied with by organizations seeking grants or contracts from the Department for medical research involving human subjects. According to the regulations these organizations must provide written assurance acceptable to the Department of Health, Education and Welfare that they will comply with its policy on protection of human subjects. Any organization proposing to place any subject at risk is obliged to obtain and document legally effective informed consent, which is defined in the following way:

> "'Informed' means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:
>
> (1) A fair explanation of the procedures to be followed, and their purposes including identification of any procedures which are experimental;
>
> (2) a description of any attendant discomforts and risks reasonably to be expected;
>
> (3) a description of any benefits reasonably to be expected;

27/ Document E/CN.4/1173, nnex, pp.18-19.

28/ World Council of Churches, Experiments with Man, Studies N 6, 1969, p.25.

(4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) an offer to answer any inquiries concerning the procedures; and

(6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject." 29/

The agreement, written or oral, entered into by the subject, must include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence. The consent must be documented in one of the following ways:

"(a) Provision of a written consent document embodying all of the basic elements of informed consent. ...

(b) Provision of a 'short form' written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his legally authorized representative.

(c) Modification of either of the primary procedures outlined in paragraphs (a) or (b) of this section. Granting of permission to use modified procedures imposes additional responsibility upon the review committee and the organization to establish: (1) that the risk to any subject is minimal, (2) that use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and (3) that any reasonable alternative means for attaining these objectives would be less advantageous to the subjects ..."30/

211. In a number of countries regulations have been elaborated governing clinical trials of drugs. In France, an Order of the Ministry of Public Health of 1972 establishes the procedure applicable to clinical trials of medicaments. "Its primary purpose is to ensure that trials are conducted under conditions of maximum safety for the patient and to determine the conditions of use of medicaments so as to produce a beneficial therapeutic effect It therefore lays down general principles governing the preparation and conduct of clinical trials and their subsequent interpretation on the most objective basis possible. Within this framework, experts shall be free to determine the methods of approach that seem to them the most appropriate in each case, while bearing in mind the ethical principles governing trials involving human subjects".31/ The Decree, entitled "Control of the manufacture of and trade in pharmaceutical products: testing, presentation, and naming of, and marketing licences for, pharmaceutical specialities", of 1972

29/ United States, Code of Federal Regulations, op.cit., p. 18917.

30/ United States, Code of Federal Regulations, op.cit., pp. 18918-18919.

31/ International Digest of Health Legislation, 1972, Vol.23, p.740.

requires that pharmaceutical manufacturers should select experts to undertake clinical experiments from a list established by the Minister of Public Health on the advice of a committee of medical and pharmaceutical experts. These experts "may have no direct or indirect financial interest, even through a third party, in the commercial exploitation of the medicaments being tested by them.... The Minister responsible for Public Health may request the manufacturer to furnish him with the programme of a trial where he considers that the new project which is to be the subject of the trial is liable to entail an abnormally high risk or where there are serious and consistent presumptions of a prejudicial effect on public health. The Minister responsible for Public Health may object to the pursuit of the realization of the said programme...."32/

212. In Austria, the Circular of the Federal Ministry for Social Affairs of 1969 prescribes guidelines for the testing of new medicaments on man, the purpose of which is "to limit as far as possible, in accordance with scientific knowledge, the risks necessarily involved in the administration of new medicaments to man". The guidelines include the following provisions:

> "11.1 Only healthy persons, or at least persons not seriously ill, may be considered as subjects for a clinical pharmacological study.
>
> 11.2 The subjects must be informed of the conduct of the study, and of its possible consequences, and must have given their consent.
>
> 11.3 If the indication for a new medicament concerns conditions dangerous to life or progressive diseases of an intractable or incurable nature, a clinical pharmacological study may be made only on subjects on whom the new medicament may be expected to have a therapeutic or alleviating effect."33/

213. In the United States, the Food and Drug Administration has issued a number of Acts and regulations containing provisions on protection of the individual in experimental testing of drugs. These provisions are based on the Nuremberg Code and the Declaration of Helsinki and the definition of "consent" in the regulations is very close to that in the documents referred to. Before the consent is given the nature, expected duration, and purpose of the administration of an investigational drug, the methods and means by which it is to be administered, the hazards involved, the existence of alternative forms of therapy, if any, and the beneficial effects upon health that may possibly come from the administration of the investigational drug should be carefully considered and made known to the subject. The regulations distinguish between therapeutic and non-therapeutic investigations and allow no exception in respect of the provision of necessary information to the subject in order to obtain his consent in non-therapeutic studies. Consent should be obtained as a rule in a written form, but oral consent may be substituted where, taking into consideration the physical and mental state of the patient-subject, the investigator deems it necessary or preferable to obtain consent in an oral form. A record of the obtaining of oral consent must be placed in the medical history of the patient-subject receiving the drug.34/

32/ International Digest of Health Legislation, 1972, Vol.24, pp.307-309.

33/ International Digest of Health Legislation, 1971, Vol.22, p.22.

34/ Cf. William J. Curran, "Governmental Regulation of the use of Human Subjects in Medical Research: The approach of Two Federal Agencies", Daedalus, op.cit., pp.561-570.

214. On the basis of the analysis of regulations of different countries the World Health Organization points out that there are

> "different modalities of approach to the solution of the increasingly difficult problem of how to safeguard the rights of the patient and the healthy volunteer without placing vexatious and counter-productive obstacles in the path of therapeutic progress. At one extreme there are rigid, very detailed, and legally enforceable requirements covering not only the various phases by which a new medicament may be tested on humans and ultimately marketed but also specifying the type of information that should be included in labelling and advertising in respect of indications, contraindications and possible adverse reactions. At the other extreme, the highest medical authorities in the country nominate clinical investigators in whom they have confidence, and these are authorized by the government to conduct trials in accordance with their own conscience. An intermediate solution is that in which a panel of experts advises the responsible governmental authority what clinical trials should be authorized and what products should, after such trials, be licensed.
>
> All such solutions have the same objective: to deny to the incompetent or unscrupulous investigator the opportunity of exposing his patients or other human subjects to unjustifiable or unnecessary risks to health. Whatever regulatory system may be adopted, there will always be a few physicians who are not sufficiently sensitive to the innate rights of the fellow human beings to whom they are responsible. Under any system, the justification or otherwise of an experimental procedure performed on human beings must rest ultimately on the technical judgement of the general body of physicians, which provides the surest safeguard against abuses."35/

215. A general norm on protection of the individual in experimental procedures is included in the International Covenant on Civil and Political Rights adopted on 16 December 1966 by the General Assembly of the United Nations. Article 7 of the Covenant provides:

> "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation."

However the view has been expressed that this provision is too general to be of any use in practice. Professor René Cassin points out:

> "Whilst this clause, inspired as it is by revulsion against the atrocious experiments carried out by Nazi doctors during the Second World War on human beings who were powerless to defend themselves, is based on praiseworthy intentions, it is formulated in such a rigid, oversimplified way that it is impossible to apply it in practice. It goes too far in that it fails to make a distinction between experiments which are dangerous and those which are not. But it does not go far enough, in that the free consent of the persons concerned is not always sufficient."36/

35/ Document E/CN.4/1173, p.20.

36/ René Cassin, "Science and Human Rights", Impact of Science on Society, No. 4, 1972, p.338.

5. Special categories of subjects of experimentation

216. Special problems arise with classes that are under some disability or constraint - children, mental defectives, students, prisoners and the dying. Speaking about experiments on children, Professor A. Freund pointed out:

> "If the experiment may be of direct benefit to the child, the consent of the parent or guardian should be enough. If no direct benefit is indicated, may the parent consent (together with the child if he is at an age of understanding)? The subject is far from clear, but an absolute disqualific disqualification would eliminate much useful investigation. A more moderate rule is indicated, one that would permit children to serve as subjects where they are peculiarly suitable and there is no discernible hazard to them."37/

David W. Meyers of the University of Edinburgh has written:

> "The really difficult and unanswered question in this area, as might be expected, is to what degree of non-therapeutic experimental risk of harm may the legal guardians of a child expose him when the child either dissents or when he is incapable of understanding the nature of the risk and of consenting to his exposure to it? It is submitted that the exposure of a child, at least one under sixteen, to anything more than a very slight risk of harm or injury resulting from an experiment not for his benefit cannot be justified. Experimentation, in these circumstances, must give way. On the other hand, in situations where the children are approaching majority or are of such an age that they are considered to be capable of full understanding of the experimental procedure involved, some advocate that the child's consent alone is sufficient, at least in those cases where the experimental treatment is clearly therapeutic in nature."38/

As a policy Professor Henry K. Beecher proposes the following:

1. Informed consent of parents shall be required for all subjects under 21.

2. If the subject is too young to consent, the consent of parents is sufficient when no discernible risk is involved and the safety and value of the study are supported by the investigators' peers.

3. Limitation of research in children to studies directly beneficial to them is not necessary (such a restriction would hamper studies of inborn errors of metabolism).

4. Parents have the right to decide whether their children will participate even if not for their direct benefit, provided the studies have no discernible risk and have been approved by a review committee.

5. Research that entails discernible risk may not be performed on subjects too young to give mature, informed consent, unless it is for their benefit.39/

37/ Paul A. Freund, op.cit., p. XII.

38/ David W. Meyers, The Human Body and the Law, Edinburgh, 1970, p.91.

39/ Henry K. Beecher, "Scarce Resources and Medical Advancement", Daedalus, op.cit., pp.284-286.

217. Speaking about experimentation on the mentally ill at the C.I.O.M.S. Conference on protection of human rights in the light of scientific and technological progress in biology and medicine, Professor Paul D. Sivador said:

> "In psychiatry, experimentation is generally confused with therapeutic research, and it is by this means that it is justified.
>
> We shall not dwell upon the general problem of the testing of medicines, which has been studied elsewhere. Two important points should, however, be noted: firstly, a mental patient is not always in a condition to give valid consent to such testing and, secondly, the drug administered is liable to diminish further his freedom of choice, particularly as regards continuation of the testing"40/

218. The World Health Organization points out:

> "It is generally agreed that ... mental defectives and the mentally deranged cannot give valid consent, although their ... legal guardians may in certain circumstances give consent on their behalf. Normally such vicarious consent would be given in the expectation of some therapeutic benefit to the subject..."41/

219. Criticism has been made of the use for human experimentation of students because in their case there may be special incentives such as the desire of students to find favour with professors or to avoid the appearance of being unco-operative. Writing about the use of students as volunteers in experiments conducted by their superiors Professor Louis Lasagna pointed out:

> "If a student is of age to give consent, there would seem to be no special ethical problem about volunteering in general. But if a student in a classroom is asked to volunteer by his instructor, there is at least the implied threat of loss of affection (and decreased academic grade) if the student fails to volunteer... Furthermore, it has been the practice in some institutions actually to give extra credits for such participation, a procedure that raises the issue of infringement of the rights of those who do not volunteer or are not chosen after volunteering. Should the non-volunteers at least be allowed another means (non-experimental) of earning extra credits equal in amount to those earned by the volunteers, so as not to be academically disadvantaged? Perhaps, but the problems involved in being "fair" to all parties concerned suggest that it may be simpler, as well ~~as~~ more ethical, for professors to avoid soliciting volunteers from student groups whose academic standing or future employment may be in their hands. It is not enough to say that a professor will not be swayed in his marking or writing of reference letters by whether a student has volunteered; the belief that he will do so is enough to act as a troublesome influence on both the volunteer and the non-volunteer."42/

40/ Paul D. Sivador, "Experimentation sur l'Homme en Psychiatrie et en Psychologie Médical", 8th C.I.O.M.S. Round Table Conference, op.cit., p.219

41/ Document E/CN.4/1173, Annex, p.16.

42/ Louis Lasagna, "Special Subjects in Human Experimentation", Daedalus, op.cit., pp. 456-457.

220. Considerable complications arise when those involved in human experimentation are prisoners or detainees. In some countries, including the United States, there has been widespread use of prisoner-volunteers for human experimentation. Professor Lasagna, while admitting the possibility of using prisoners for human experimentation, considers indisputable the following points:

> "... No experiment [should be allowed] that is brutal, inhuman, or badly designed or executed.
>
> ... Relevant issues should be decided by a review committee - qualified scientists who are not implicated in the research, and possibly laymen, including prison officials."43/

In other countries, including the Federal Republic of Germany, experimentation on prisoners is prohibited. Thus, Execution of Penalties Act of 1969 of the Federal Republic provides as follows: "It shall be unlawful to perform medical experiments on prisoners, even with their consent".44/ At the CIBA Foundation Symposium on medical care of prisoners and detainees, a paper by Professor Marc Klein was presented which included the following:

> "Can a prisoner make free decisions? ... I can ... enumerate here the motives that can incite a prisoner to volunteer to take part in proposed experiments: remission of penalty for good conduct, getting away from hard work, receiving better food or a privileged position in comparison with other prisoners. Perhaps some prisoners are idealists who believe in dedicating themselves to the benefit of humanity or who want to pay for their 'faults.' In our opinion, the prisoner is never free to decide, nor is he completely informed and consenting, particularly when facing a doctor proposing to experiment on him."45/

221. Specking about experimenting on dying patients, Dr. Blumgart said:

> "The propriety of pharmacological and other studies in dying patients has been defended, particularly if patients are unconscious or dying after renal failure or cerebrovascular accident. But it is difficult to discern any difference in the obligation of the physician to the patient under such circumstances. If, however, the patient experiences no pain or discomfort, observations of scientific value, such as the chemical analyses of blood, are permissible."46/

43/ Ibid., p. 454.

44/ Federal Republic of Germany, Execution of Penalties Act, Publ. No. 144/1969, para. 67.

45/ Mark Klein, "Problems from biological experimentation in prisons", CIBA Foundation Symposium 16 (new series), Medical Care of Prisoners and Detainees, Amsterdam, 1973, p. 67.

46/ Herrman L. Blumgart, op.cit., p. 269.

Emphasizing the need for protection in case of dying patients, Professor Lasagna pointed out:

> "Unquestionably, there have been instances in the past where dying patients have been subjects without being aware of it, the justification being that 'they were dying anyway'. It is not possible to defend such an attitude, legally or ethically, and I shall not attempt to do so. But the problems here are not unique to the dying patient, and the technique of obtaining consent should, in general not differ essentially in terminal and non-terminal patients."47/

222. A study group at the consultation on experiments with man mentioned in paragraph 209 above suggested that the following guideline should be included in the Helsinki Declaration:

> "Consent of the patient and/or the volunteer is normally an essential prerequisite and should not be obtained by duress. As a rule informed consent can only be obtained from mentally competent persons. An essential condition for valid consent is the full disclosure of the general nature and the risk of the experiment. Before giving consent the patient or the volunteer has the right to consult his family and his own physicians. Special care must be taken in the case of minors, mentally handicapped and old people, who are unable to give fully informed consent and in the case of persons who might be considered to be under any type of duress. Free, valid or informed consent does not reduce the investigator's responsibility."48/

6. Views of Governments

223. The Government of Argentina considers that the subjects of experimental procedures "must be informed in advance of all the risks to which they are directly and indirectly exposed in undergoing the experiment, as also of its purpose, scope and results" and that "any experiment undertaken on human beings should be preceded by a very careful study of its technical aspects and ethical implications which should be carried out by a team other than that which is to make the experiment".49/

224. The Government of Austria expresses the following view:

> "The problem whether and to what an extent experiments may be performed on the individual for the purposes of scientific research and the testing of new medicaments and techniques is particularly hard to solve. It is common knowledge that such experiments are indispensable for the production of new remedies while it is contrary to the essence of human rights to treat the individual as an object. The underlying principle should be that experiments performed on the individual can be deemed admissible only to the absolutely necessary extent and with the consent given by the person concerned after a previous and full warning of

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47/ Louis Lasagna, op.cit., p. 525.

48/ World Council of Churches, Experiments With Man, op.cit., p. 25.

49/ Information forwarded by the Government of Argentina on 30 May 1974.

the foreseeable consequences. Furthermore it must be stipulated that with such experiments all conceivable precautions must be taken to avoid harm to be caused to the test person.

...

It is noted that pursuant to article 67 of the Austrian Act concerning the Execution of Sentences performance of medical experiments on prisoners is inadmissible even if a prisoner consents thereto.50/

225. The Government of Hungary reports that in Hungary a new procedure may be applied if it does not retard or nullify the result to be expected from the method of treatment which has already been tested in medical practice. The agreement of the patient or, in certain cases, of the legal representative or relative is required for the application of a new procedure.51/

226. The Government of Japan stressed that the Declaration of Helsinki of 1964 must be fully respected in performing experiments and adds:

"It goes without saying that the consent of the recipient based on his free and spontaneous will is the minimum requirement in performing experiments whether or not the experiments are performed for a medical purpose."52/

227. The Government of Norway cites excerpts from Professor Erik Enger's book Kontrollerte Kliniske forsøk ("Controlled Clinical Experiments"):

"It often happens that the principle of controlled experiment cannot be put into practice in accordance with the requirements of full information and voluntary consent.

...

In this respect the [Helsinki] Declaration is out of step with norms which apply in those parts of the world where the principle of controlled experiment is an accepted form of research. ... Full information and voluntary consent are ideal requirements which ought to be satisfied if this proves possible in practice.

...[I]t must be proper, in certain situations, not to give fuller information. But then it is important to clarify the borderline between use and abuse. To assist in this, the author would suggest three points: Point 1. If the intention is to use individuals in a controlled clinical experiment without absolutely adhering to the principle of full information and voluntary consent, there must be an acceptable ratio between the experiment's possible benefits and its risks. Point 2. The experiment

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50/ Information forwarded by the Government of Austria on 11 November 1974.

51/ Information forwarded by the Government of the Hungarian People's Republic on 19 August 1975.

52/ Information forwarded by the Government of Japan on 22 March 1974.

must not in any reasonably predictable manner threaten the individual's life or health. Point 3. Operative encroachements on the individual's physical and mental integrity must be on as small a scale as possible.

The experienced clinical researcher should be able to use these points for reaching a compromise between consideration for the individual's integrity and the need for medical progress by means of controlled experimental procedures."53/

228. The Government of Romania expresses the view that nobody has the right to experiment without the free consent of the human subject obtained after full explanation of possible consequences of the experiment, which should be authorized by competent medical authorities and performed in special centres.54/

229. The Government of Singapore forwarded the Code of practice on medical research and experimentation involving human beings of 28 May 1973, which includes the following rules:

"(1) [Human experimentation procedure] will require the application to, and the approval of the Medical Research Council, Singapore, before it can be undertaken.

In its consideration of the application the Research Council will balance the innovative method of treatment and the chance of advancing knowledge and the possible benefit to the patient.

(2) The free and informed consent of the patient must be obtained. This consent can be withdrawn at any time. ...

(3) Proper preparations should be made to protect the experimental subject against possibility of injury, disability or death."55/

230. The Government of Sri Lanka states that in this country "professional ethics protect the individual against unjustified experiments in particular".56/

231. The Government of the Ukrainian Soviet Socialist Republic states that the laws of the Republic do not provide for experiments on human beings.57/

232. The Government of the USSR states:

"USSR law does not allow experiments on human beings.

Clinical trials of new medicaments are conducted after the medicaments have been carefully tested on animals to establish their safety and specific effects; they are used in accordance with strict instructions for diseases where they have been shown by experiments to have a beneficial effect."58/

53/ Information forwarded by the Government of Norway on 15 April 1974.

54/ Information forwarded by the Government of the Socialist Republic of Romania on 29 April 1974.

55/ Information forwarded by the Government of Singapore on 13 March 1974.

56/ Information forwarded by the Government of Sri Lanka on 5 March 1974.

57/ Information forwarded by the Government of the Ukrainian Soviet Socialist Republic on 23 October 1974.

58/ Information forwarded by the Government of the USSR on 25 July 1974.

233. The Government of the United Kingdom pointed out that 59/

> "Before medicines can be sold or supplied for the purpose of a clinical trial in the United Kingdom it is necessary to have obtained, or to have been exempted from the need to obtain, a clinical trial certificate. The issue of such a certificate does not, however, absolve the clinician from consulting an ethical committee, or the ethical committee from considering the precise protocol and nature of the trial."

The Government further said that the Medical Research Council draws a distinction between procedures contributing to the benefit of the individual and procedures not of direct benefit to him. As far as the latter category is concerned "the individual has rights which must not be infringed and ... he must be a volunteer in the sense that he must consent freely, with a proper understanding of the nature and consequences and what is proposed."

The Government cites the report of the Royal College of Physicians of London of 1967 which stressed that:

> "hospital authorities have a responsibility to ensure that facilities exist by which clinical investigations undertaken in their hospitals are subject to appropriate scrutiny; to this end they should ensure that a group of doctors, including some with experience of clinical investigation is set up and that projects are subject to the approval of this group."

It also summarizes recommendations made by the Royal College of Physicians in a report of 1973 regarding the composition of ethical committees to which all proposed clinical research investigations should be referred for approval. The report emphasized the need for a full explanation to the individual of any procedure not intended to benefit him and that he should be completely free to decline to participate or to withdraw at any stage. In the report attention is drawn to the fact that a drug has been granted a Clinical Trial Certificate or a Product Licence by the Licensing Authority on the recommendation of the Committee on Safety of Medicines in no way absolves an ethical committee from investigating the ethical aspects of that trial.

59/ Information forwarded by the Government of the United Kingdom on 8 August 1974.

II. THE MORAL AND LEGAL POSITION OF THE PHYSICIAN WHO IS INVOLVED IN EXPERIMENTAL PROCEDURES

1. Statement of problems involved

234. The physician who is involved in experimental procedures has to cope with a dilemma that is posed by the sometimes conflicting demands of experimentation and therapy. "Ethical biomedical research", write B. Barber and his colleagues, "requires the successful balancing of two important values. As physician the researcher holds the value of humane therapeutic treatment. As scientist, he holds the value of scientific success through priority of discovery. Very often, these two values can both be achieved fully, or in some ethically satisfactory balance, in a given piece of research using human subjects. ... Sometimes, however, emphasis on one value may make the achievement of the other difficult. For example, too great a concern for patients in general, or for some particular patients, may prevent a researcher from carrying out a piece of work that might lead to an important discovery. On the contrary, as some researchers themselves have alleged, an ambitious researcher may press too hard with his 'new' ideas and his quest for scientific recognition to the detriment of his human subjects". 1/

235. Renée C. Fox and Judith P. Swazey point out that under optimal conditions the clinical investigator's dual responsibilities are complementary, but conditions are not always optimal. In many situations experimental and therapeutic considerations pull in opposite directions and the researcher is faced by serious practical questions: At what point should the researcher make the move from animal to human experimentation? What kind of survival rates justify the continued use of a procedure? At what point does one feel justified in using a new treatment in more ordinary medical circumstances, where the patient is not in the terminal phases of his illness? The heavy emotional strain that uncertainty and the experiment-therapy dilemma place on the research physician is intensified by the unusually close relationship that develops between physician and patient in experimental medicine. 2/

236. In relation to experiments on volunteers the question inevitably arises: "Is it ever, under any circumstances, fair to ask some people to undergo unnecessary hazards to insure the later well-being of many other people they will never get to know?" 3/

2. Moral position of the physician involved in experimental procedures

237. One of the first questions the investigator must face is the scientific validity of the experimental procedure. Professor David D. Rutstein emphasized:

> "It may be accepted as a maxim that a poorly or improperly designed study involving human subjects - one that could not possibly yield scientific facts (that is, reproducible observations) relevant to the question under study - is by definition unethical. Moreover, when a study is in itself scientifically invalid, all other ethical considerations become irrelevant. There is no point in obtaining "informed consent" to perform a useless study. A worthless study

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1/ B. Barber, J.J. Lally, J.L. Makarushka, D. Sullivan, op.cit., pp.59-60.

2/ Cf. Harvard University, Programme on Technology and Society, 1964-1972, A Final Review, Cambridge, Massachusetts, 1972, pp.43-44.

3/ Albert Rosenfeld, The Second Genesis: the Coming Control of Life, New York, 1969, p.89.

cannot possibly benefit anyone, least of all the experimental subject himself. Any risk to the patient, however small, cannot be justified. In essence, the scientific validity of a study on human beings is in itself an ethical principle." 4/

238. Scientific validity of the experimental procedure does not liberate the researcher from other ethical norms. Professor Ole Jacob Broch pointed out that an experimenting physician must "follow his own conscience and his professional ethics, whose claims are much stricter than those of the law." He continues:

"It is a dangerous view that the result justifies the experiment. An experiment is ethical or unethical according to the manner in which the task is initially formulated. It does not become more ethical because it yields valuable results, even if mankind is to derive great benefit from it. Some research workers rationalize such considerations concerning the usefulness of their work and regard themselves as benefactors of mankind. Professor Beecher of Harvard University asks who has given the research worker a divine right to pick his martyrs." 5/

239. Albert Rosenfeld has written:

"All too often, it seems likely that extraordinary life-preserving measures - experimental surgery, for instance - are undertaken more to advance knowledge in the ultimate hope of saving future patients than with any realistic hope of saving the patient of the moment. But 'a doctor must recognize', says Dr. Ayd, 'that he does not have the right to urge a dangerous remedy or a new procedure without just cause. However desirous he may be of learning, or making progress, or of doing something for the common good the practitioner must not yield to the temptation to "sell" his proposal in order to acquire the necessary authorization. All men have inalienable rights which transcend any considerations of science or of the good of others.' 6/

...

"On the other hand, Dr. Reed - as cautious as anyone - wondered whether a decision on the side of over-caution did not carry an equal burden of ethical responsibility. 'Suppose the right combination of circumstances comes to pass' he said ' with recipient and donor both answering the most rigid criteria, and both of them on hand at the right moment, in an institution which has a team of experienced open-heart surgeons as well as a competent backup team equipped with the latest and best immunological knowhow. This combination would occur only rarely, but when it does, and this is the patient's only chance, must we not ask ourselves: Do we have a moral right not to try a transplant?' 7/

...

4/ Davin D. Rutstein, op.cit., p.524.

5/ Ole Jacob Broch, Det kunstige menneske, Medisinsk forskning og etikk, Oslo, 1969, pp.61, 75.

6/ Rosenfeld, op.cit., p.81.

7/ Ibid., p.82.

"Some people talk and act as if they believed medical progress was possible without human experimentation. But how? Nothing could be more obvious than the fact that, if you can't use a new therapy on people, then people can never use the therapy. And there is no such thing as a riskless human experiment. No matter how painstaking the lab work, the experimenter can never be absolutely sure, when he gives a man a pill never before swallowed by any human being, that the subject will not drop dead on the spot. In general, the public is aware that risks must precede the benefits." 8/

240. The most important ethical norms by which the experimenting physician should be guided are set forth in professional codes of ethics, in particular in the Nuremberg Code and the Declaration of Helsinki. The first and foremost of them is the duty of the investigator to receive the informed consent of the subject. "It is a personal duty and responsibility which may not be delegated to another with impunity", stresses the Nuremberg Code. 9/ "Consent should, as a rule, be obtained in writing", states the Declaration of Helsinki, "However the responsibility for clinical research always remains with the research worker; it never falls on the subject even after consent is obtained." 10/

241. Speaking at the IVth Besançon colloquium on human rights in France, F. Cabanne and A. Marin emphasized that

" ... the free and informed consent of the patient in no way diminshes medical responsibility. Such consent by no means authorizes the investigator to undertake any kind of experimentation. The patient accepts the margin of risk. The physician alone is responsible for exposing this subject to a tolerable margin of risk." 11/

242. Doctors should carefully weigh risks run by patients during experimental procedures in the light of foreseeable benefits to them. In the Nuremberg Code it is laid down that an experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury. No experiment should be conducted where there is a priori reason to believe that death or disabling injury will occur; the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment; proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.

243. In the Declaration of Helsinki it is stressed that clinical research cannot legitimately be carried out unless the importance of the objectives is in proportion to the inherent risk of the subject; every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject; special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

8/ Ibid., p. 88.

9/ Law Reports of Trials of War Criminals, op.cit., Vol.VII, pp. 49-50.

10/ Text furnished by the World Medical Association on 14 March 1974.

11/ F. Cabanne and A. Marin, "Les Droits de l'Homme Malade devant les Nouveaux Programmes Therapeutiques", IVe Colloque de Besançon "Les Droits de l'Homme en France", 17-19 Janvier, 1974, Université de Besançon, p.15.

244. Professor B.N. Halpern of the College of France, Paris, said at the conference on biomedical science and the dilemma of human experimentation that in the case of the therapeutic trials "the doctor alone with his patient, himself takes the decisions that pledge his conscience. No strict legislation can be applied to therapeutic trials; the only valid rule is that the risk to be ran should be proportionate to the gravity of the illness". 12/

245. Professor Herrman L. Blumgart pointed out in respect of therapeutic experimental procedures that:

> "the physician must recognize the individual's right to participate in decisions affecting his physical welfare. A few patients resent any explanation of the nature of their illness. And, at times, information must be withheld from the patient in his own interest and transmitted instead to some responsible member of the family. Most patients, however, are comforted when the nature of their illness and its expected course are explained in kindly and considerate terms. No condition is so complex that it cannot be explained in simple, intelligible language. To clothe the illness in unintelligible terminology only increases the patient's anxiety." 13/

246. At the United Nations Seminar on Human Rights and Scientific and Technological Developments, held in Vienna in 1972, certain safeguards were advocated in respect of clinical testing of drugs in therapeutic procedures, including the prohibition of the possibility of waiver by the subject of liability for negligence on the part of those carrying out the experiment. 14/

247. In non-therapeutic experiments doctors bear a special responsibility. In the Declaration of Helsinki it is pointed out that, in purely scientific clinical research without therapeutic value to the persons subjected to it, it is the duty of the doctor to remain the protector of the life and health of that person, particular attention being paid to receiving informed consent; the investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator; the investigator or the investigating team should discontinue the research if in his or their judgement, it may, if continued, be harmful to the individual.

248. Drs. A. de Coninck, P. Dorr and J.R. Fagnart summarize the duties of doctors in non-therapeutic experimental procedures in the following way:

> " ... The responsible physician has the following obligations:
>
> (1) He must limit this type of experimentation to areas in which it is impossible to obtain valid results by another method, such as experimentation on animals.

12/ C.I.O.M.S. Round Tables, 1. Biomedical science, etc., op.cit., p. 28.

13/ Herrman L. Blumgart, op.cit., p. 255.

14/ United Nations Seminar on Human Rights and Scientific and Technological Developments, held in Vienna, Austria, 19 June - 1 July 1972, document ST/TAO/HR.45, para. 80.

(2) He must remain the protector of the life and health of the subject of the experiment and must refrain from or discontinue the experiment if he anticipates any danger to the subject.

The physician is not released from this responsibility by the consent of the subject.

(3) He must allow the subject freedom of choice. For this purpose:

(a) the subject must have been informed, in a detailed manner and in the presence of a witness, of the purposes and methods of the research and of any risks it might entail to his health;

(b) his freedom of choice must not be diminished by his physical, mental or legal condition or by any degree of dependence vis-à-vis the investigator;

(c) the consent must be expressed in writing;

(d) the subject must at any time be free to discontinue the experiment." 15/

3. Legal position of the physician involved in experimental procedures

249. Because of the prevailing availability of new medical procedures and medicaments, a physician may increasingly find himself in danger of legal action. This also presents a human rights problem. Dr. Henry K. Beecher, Dorr Professor of Research in Anaesthesia at Harvard University, had written the following:

"The [basic legal] doctrine is, 'the physician experiments at his peril' ... In this harsh stand the law is unrealistic, for as every able physician knows, the adequate practice of medicine involves continual experimentation. No two patients respond precisely alike to any therapeutic procedure. There is no 'standard' patient. Even in ordinary practice the able doctor experiments until his treatment is successful, or the patient goes elsewhere, or he dies." 16/

One source of the legal risks involved in experimental procedures is the uncertainty in some countries of the law governing organ transplants. 17/

250. After referring to cessation of cerebral function as the medical criterion of death, 18/ Mr. Albert Rosenfeld has written:

15/ Drs. A. de Coninck, P. Dorr and J.R. Fagnart, Etude sur le problème de la recherch expérimentale sur l'homme et son application aux greffes d'organes. Bruxelles, 1971, Imprimérie médical et scientifique (S.A.), p.12.

16/ H.K. Beecher, "Human Studies: Protection of the Investigator and the Subject is Necessary", Science, Vol. 164, 13 June 1969, pp. 1256-1258.

17/ See Law and Ethics of Transplantation. A CIBA Foundation Blueprint, London, 1968.

18/ See E/CN.4/1172/Add.1, paras. 220 et seq.

"When a patient is still breathing and his heart is still beating, many doctors would still feel rather uneasy about signing a death certificate, no matter how inactive the brain .... 'This is a very intriguing problem,' said a prominent American surgeon, ... 'It must be approached very carefully to avoid the day when someone says, "You let my father die just to give his kidney to another person".' In such a case doctors would indeed leave themselves open to suit or prosecution. As a matter of fact, even the full consent and approval of the next of kin is no insurance against this." 19/

251. It has been pointed out that the law has not as yet set out in full the permissible limits for experimentation with human beings. Professor Ole Jacob Broch has written:

"The question of legal liability in the case of clinical experiments is not at all clear. Such cases have very rarely been put to the test. It will be very difficult to lay down specific rules of law as to what is and what is not permissible. As far as I know, this has not yet been done in any country. Each case must be judged on its merits. The court will obviously attach great importance to the ethical rules which the various medical associations have drawn up as guidelines. To judge by the cases which have come before the courts, the patient will certainly be expected to have given his consent with a full knowledge of the facts whenever an experiment is made which involves a demonstrable risk or considerable inconvenience.

"It may be assumed that the courts will regard it as their main task to protect the patient's reasonable interests and will give that consideration priority over the claims of research." 20/

David W. Meyers characterizes the state of law in respect of experimentation with human beings as "unsettled and unsatisfactory". 21/

252. It has been stressed that there is almost no statutory law in the field. 22/ Some legislative acts mentioned in paragraphs 210-213 above refer to ethical requirements in human experimentation in general form, but contain no provisions as far as the legal liability of doctors is concerned.

253. The Drug Amendment Act of the United States and later regulations in this field are cited by some authors as examples of legislative acts establishing responsibilities of the experimenting doctor. 23/ This Act requires physicians to obtain advance, informed consent of all those to whom the experimental drugs are prescribed, but permits the physicians to decide within their own discretion whether and when it is "not feasible or, in their professional judgement, contrary to the best interests of such human beings" to inform them that their use of the drugs is experimental and to seek their prior, voluntary consent.

19/ Rosenfeld, op.cit., p.62.

20/ Ole Jacob Broch, op.cit., p.75.

21/ David W. Meyers, op.cit., p.73.

22/ David W. Meyers, op.cit., p.74.

23/ Louis L. Jaffe, "Law as a System of Control", Daedalus, op.cit., pp.413-414. William J. Curran, op.cit., pp.561-570, David W. Meyers, op.cit., pp.74-76; Irving Ladimer, "Clinical testing of drugs: a partnership for research", 8th CIOMS Round Table Conference, op.cit., pp.199-200; Herbert L. Ley, Jr., M.D., "Federal Law and Patient Consent", Annals of the New York Academy of Sciences, Vol.169, Art.2, New Dimensions in Legal and Ethical Concepts for Human Research, New York, 1970, pp.523-532.

254. Regulations promulgated in this field by the Food and Drug Administration in 1966, as later amended, require that the consent of the individual be obtained in all cases where the investigational drugs are administered "primarily for the accumulation of scientific knowledge". In those therapeutic instances, where the investigational drugs are being used for the treatment of the particular patient, the regulations still require that consent be obtained in "all but exceptional cases". For purposes of imposing the consent requirement, the regulations define "exceptional cases" as being those in which

> "... it is not feasible to obtain the patient's consent or the consent of his representative, or in which as a matter of professional judgement exercised in the best interests of a particular patient under the investigator's care, it would be contrary to that patient's welfare to obtain his consent."

"Not feasible" is defined as those situations in which the investigator is not capable of obtaining consent because of his inability to communicate with the patient or his representative, as, for example, when the patient is in a coma and his representative cannot be reached and it is imperative that the drug be administered without delay.

255. Commenting on these regulations, Professor Louis L. Jaffe maintains:

> "... detailed legal prescription of the physician's or experimenter's conduct is ill-advised. To be sure, there are no prescribed penalties - except the displeasure of the FDA - against the physician or experimenter who does not follow this procedure. Nevertheless, it is unwise to establish by law a situation in which the responsible actor is either hindered in the application of his expertise or is required to forswear himself. As a matter of fact, the 'displeasure of the FDA' can be severe: the 'disbarment' of the investigation, forbidding the experimenter to receive investigational drugs. If a false statement is made as to consent in reporting to the sponsor of the investigation, this can be ground for such action even if unintentional ... and a federal felony if intentional." 24/

256. It is pointed out that cases decided by courts are of limited value in helping to shed light on the legal status of experimentation as such and the legal status of the physician involved in experimental procedures. Irving J. Ladimer has made the following comments:

> "'Reported cases have not yet considered modern controlled medical research as such, and have not yet established limits within which human research may be pursued. Cases which have involved conduct labelled "experimentation" have been decided basically on issues of disclosures or consent, negligence, lack of qualification, improper activity (quack procedures, medicines or devices) or unlicensed practice of medicine usually arising in cases of departure from accepted diagnosis, therapy or other practice. These fact situations, sometimes erroneously called experimentation, have tended to confuse or have failed to recognize the distinction between research and practice.'" 25/

24/ Louis L. Jaffe, op.cit., pp.413-414.

25/ See, Journal of Public Law, Vol. 467, N 3 (1954), p.570.

David W. Meyers has written:

> "... as yet no case has come before the courts, been tried and decided, on the basis that here was a truly experimental situation, carried out with all proper care, and only after obtaining the subject's full and knowing consent for the primary purpose of determining the desirability of the new drug or form of treatment, and only secondarily involving considerations of curing the particular patient, assuming that he was not a fully healthy volunteer.
>
> In other words, research indicates that no physician has ever defended a lawsuit, be it for civil damages or criminal sanctions, on the basis that the method of treatment involved was experimental in nature, but was carried out with the patient's consent and with all due care, and therefore no liability of either nature could ensue." 26/

257. One of the most recent American cases involving, though indirectly, the question of medical experimentation with human beings was Hyman v. Jewish Chronic Disease Hospital. In July 1963 three physicians injected live cancer cells into twenty-two patients of the Hospital in an experiment to test their immunity and reactions. The patients were not told that the injections contained cancer cells and were led to believe the injections were a part of their normal therapy. The physicians claimed their action was justified, there being no increased medical risk to the patients of contracting cancer from the injections. This was disputed. Sanctions imposed on two of the three doctors found guilty of fraudulent and deceitful conduct under New York Education Law S 6514 (2), providing for revocation, suspension or annulment of licences, were upheld under judicial review. In the opinion of the Appellate Division of the Supreme Court of the State of New York, it was stated that the Hospital's "future policy will be in accordance with petitioner's contention that experiments such as the one here involved should be done only with the patient's written consent after the patient has been properly informed." 27/

258. Another case touching an experimentation in the context of using a new treatment is the British case Hunter v. Hanley (1955). The plaintiff alleged negligence on the part of the defendant physician who had deviated from standard practice. The suit was unsuccessful, it being held that the mere fact that defendant had deviated from standard practice did not, of itself, constitute proof of negligence. In the opinion of Lord President Clyde it was pointed out:

> "in regard to allegations of deviation from ordinary professional practice ... such a deviation is not necessarily evidence of negligence. Indeed it would be disastrous if this were so, for all inducements to progress in medical science would then be destroyed. Even a substantial deviation from normal practice may be warranted by the particular circumstances. To establish liability by a doctor where deviation from normal practice is alleged, three facts require to be established. First of all it must be proved that there is a usual and normal practice; secondly it must be proved that the defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no man of ordinary skill would have taken if he had been acting with ordinary care.

26/ David W. Meyers, op.cit., pp.73-74.

27/ Jay Katz, Experimentation with Human Beings, (Russell Sage Foundation, New York, 1972), p.43.

There is clearly a heavy onus on the pursuer to establish these three facts, and without all three his case will fail. If this is the test, then it matters nothing how far or how little he deviates from the ordinary practice. For the extent of the deviation is not the test. The deviation must be of a kind which satisfies the third of the requirements just stated." [Emphasis added] 28/

259. Professor Paul A. Freund characterizes the legal requisites in the United States for liability-free experimentation with human subjects in the following way:

"The legal requisites for legitimate, liability-free experimentation can be described in threefold form: the exercise of due care in administering the procedures; soundness of the experimental design, in that it must not be incapable on its face of producing significant results and its known hazards must not be disproportionate to the ends sought; and informed, voluntary consent, unless the subject's participation is enlisted for his direct benefit and explanation would be detrimental to his well-being, in which case it will be prudent to secure the informed consent of a member of the family." 29/

260. Summarizing existing law dealing with experimentation with human subjects, David W. Meyers writes:

"It is somewhat strange that, while so many private codes to govern medical experimentation have been promulgated in recent years and opinions delivered by various practitioners, churchmen and laymen, few of these pronouncements have found their way into recognized legal expressions of the courts and legislatures.

...

"The medical practitioners in this area, as in others we have discussed which involve surgical intervention of a controversial nature, must work in the shadow of the criminal law and its unclearly defined assault and negligent homicide jurisdictions. Clearly, the law would appear to accept the recognized amount of therapeutically-aimed 'experimentation' that goes on in so many physician-patient relationships.

"It is probably also true that the law will accept consent as a justification for minor injuries and temporary impairments of health suffered in order to test sound scientific hypotheses in the interests of medical science and the advance of knowledge. As the current law stands, the boundaries of this legal acceptance are ill-defined. That they must necessarily be loosely defined is one thing; that they must remain ill- or un-defined is quite another. It is, however, undoubtedly true that reckless experimentation not aimed at the acquisition of scientific knowledge will not be tolerated by the law, nor probably will non-therapeutic experimentation which entails the likelihood of serious harm to the health or bodily integrity of the subject, unless compelling public interest were involved, as in the training of astronauts. Still, however, these are largely only predicitions, not statements of existing law dealing with experimentation. 30/

28/ See David W. Meyers, op.cit., p.85.

29/ Paul A. Freund, "Legal Frameworks for Human Experimentation", Daedalus, op.cit., p.321.

30/ David W. Meyers, op.cit., pp.92-93.

4. Views of Governments

261. The Government of Argentina, expressing its view in respect of moral and legal position of the experimenting physician, stresses the need for the licensing of any drug and any application of a new procedure to be preceded by carefully controlled and correctly performed experiments with comparable "study" and "control" groups and goes on:

> "any experiment on a human being should be preceded by a careful study of its technical aspects and ethical implications which should be carried out by a team other than that which will make the experiment. Legislation on the subject should be based on these two principles and, in accordance with them, the health authorities at all levels should appoint technical and ethical committees to establish the standards to which all records of attested studies should conform. The committees would also be responsible for supervising the experiments carried out under their control and would decide whether those carrying out the experiment had gone beyond the ethical limits laid down, in which case, depending on the gravity of the circumstances, they would be called upon to appear before the ordinary criminal courts." 31/

262. The Government of Austria points out:

> "There is a variety of problems relating to details such as selection of test persons; judgment on whether such experiments are absolutely necessary; control of such judgment and implementation of the experiment; consequences of an unfavourable outcome of the experiment to the person performing it, to the relatives of the test person and to the latter if, for instance, he suffers incurable harm. These all are questions which can hardly be answered in general due to the differences of the circumstances in which such experiments are performed, There is therefore some doubt whether rules for this sphere can be established at all. This can perhaps be done for specific groups of problems such as that of control while it will hardly be feasible to regulate all respective problems. The decisive factor will therefore be the moral and ethical attitude of those intending to make such experiments." 32/

263. The Government of Japan stresses that the Declaration of Helsinki must be fully respected in performing experiments. 33/

264. The Government of Norway cites a passage from Professor Erik's book Kontrollerte Kliniske forsøk ("Controlled Clinical Experiments") in which, inter alia, it is pointed out:

> "When an assessment of treatment is so devised that we are provided with reliable, comprehensive information in the shortest possible time, this must be done in conformity with the best traditions of medical practice. It may

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31/ Information forwarded by the Government of Argentina on 30 May 1974,

32/ Information forwarded by the Government of Austria on 21 November 1974.

33/ Information forwarded by the Government of Japan on 22 March 1974.

be justly maintained that it is ethically correct to act in such a way as to make it possible to come to reliable conclusions on the value of particular method of treatment, rather than to make use of this method in the belief that it might be helpful."

...

"There is reason to hope that the Norwegian Medical Association will give a more differentiated expression of its attitude to the Helsinki Declaration, and that the ethical norms may be brought into line with clinical research as it has been carried on for many years in our own and other countries." 34/

265. The Government of the Republic of Viet-Nam expresses the view that:

" ... any physician who undertakes experimental treatment bears full moral responsibility therefor. As regards legal liability, several factors are involved:

- the patient's consent, whether informed or otherwise;
- the physician's evaluation of the risks;
- the results of experiments previously conducted on animals ..." 35/

266. The Government of Romania believes that doctors performing experiments without due authorization should be judged by the Doctors' College from the point of view of medical ethics and that cases of serious infringement of the rights of the subjects should be referred to courts. 36/

267. The Government of the United Kingdom states:

"This is a matter on which the United Kingdom Government has a limited interest, matters of medical ethics generally being for the profession itself.

...

"Clinical research investigations not of direct benefit to the patient present special problems in relation to children and mentally handicapped persons; an investigation on a child or adult incapable of a proper understanding of the nature and consequence of the procedure and of giving a true consent would in United Kingdom law constitute an assault." 37/

34/ Information forwarded by the Government of Norway on 15 April 1974.

35/ Information forwarded by the Government of the Republic of Viet-Nam on 27 March 1974.

36/ Information forwarded by the Government of Romania on 29 April 1974.

37/ Information forwarded by the Government of the United Kingdom on 8 August 1974.

III. THE PROTECTION OF THE PUBLIC AGAINST HARM FROM CHEMICALS INTRODUCED INTO FOOD PRODUCTION, PROCESSING, PACKAGING AND STORAGE

1. Uses of food additives

268. Although man has been using food additives in one form or another throughout recorded history, it is only in recent decades that concern has arisen as to the propriety of such action. The chemicals that are introduced into food during its production, processing, packaging and storage comes under the broad category of food additives, which the Joint FAO/WHO Expert Committee on Food Additives has defined as:

> "... non-nutritive substances added intentionally to food, generally in small quantities, to improve its appearance, flavor, texture or storage properties." 1/

269. The functions of additives may be classified into five broad categories: flavourings, colours, preservatives, texture agents and a miscellaneous group. 2/

(a) Flavourings

270. Although flavouring agents were at first natural aromatic oils, by 1900 almost all flavourings in use were synthetic except for vanilla, lemon, orange, peppermint and wintergreen 3/. Indeed, flavourings constitute the largest class of food additives, numbering approximately 1,400 4/. Not only are flavourings currently being used extensively but it is predicted that their use will increase. A great deal of work and research has been and is being done on additives generally called "flavour enhancers" 5/. These additives intensify or modify the flavour of foods. They include monosodium glutamate, which has been in use for many years, and more recently, maltol, used in foods high in carbonhydrates 6/.

(b) Colours

271. It has been pointed out that "canned and pulped fruits and vegetables [may lose] some of their original colour during the processing necessary for their preservation." 7/ Colours may be added to restore those lost. Colour additives not only make food more appetizing in appearance but also enhance the appreciation of flavour: 8/

1/ General Principles Governing the Use of Food Additives, Report of the Joint FAO/WHO Expert Committee on Food Additives, First Session Rome, Italy, 3-10 December 1956, FAO Nutrition Meetings Report Series, 1957, No. 15, WHO Technical Report Series 129, p.4.

2/ G.O. Kermode, "Food Additives", Scientific American, March 1972, Vol. 226, No. 3, p.16.

3/ Ibid.

4/ Ibid.

5/ Ibid.

6/ Ibid.

7/ General Principles Governing the Use of Food Additives, op.cit., pp.7-8.

8/ Op.cit., G.O. Kermode, p.16.

"Many people have become accustomed to the standardized colour of a food product and would not accept the product if the colour were substantially changed, even though nothing else had been done to the food. One need think only of blue or red butter to recognize the importance of accepted colour." 9/

Colourings, many of them synthetic dyestuffs, must not only correctly colour the food, but also remain stable throughout the food processing and storage where needed; they must thus be able to withstand high pressures and temperatures. 10/

(c) Preservatives

272. It has been estimated that about 20 per cent of the world's food supply is lost through food spoilage 11/. Additives have been developed and are extensively used for the specific purpose of preventing such spoilage. It has been observed that: "These food additives include a great number of agents which retard the onset of deterioration. Among these are the antioxidants, various types of antimicrobial agents, inert gases, curing agents for meats, and many spices." 12/ As the producers of food become further removed, both in time and distance, from the ultimate consumer, food preservation gains greater importance.

273. The type of additive used depends on a number of factors, including the kind of food, the method of manufacture, the way in which the food is packaged or stored and the nature of the microorganisms that cause spoilage 13/. Thus to preserve baked goods, which spoil rapidly, such additives as sodium diacetate, acetic acid, lactic acid, monocalcium phosphate, sodium propionate and calcium propionate are employed, while

"Sorbic acid and its salts have many uses, such as preventing mold in cheese, syrup and confections containing fruit or sugar. Benzoic acid and sodium benzoate serve as preservatives in margarine, fruit-juice concentrates, juices and pickled vegetables. Sulfur dioxide is widely used to inhibit mold and discoloration in wine, fruit pulps, fruit-juice concentrates, fruit drinks requiring dilution and dried fruits and vegetables." 14/

Since food spoilage may be caused by the action of microorganisms, antibiotics are also used as preservative additives:

"Antibiotics commonly have a more transitory effect than the traditional preservatives and are more selective. These advantages are significant when antibiotics are directed against known food pathogens and when their action is required only during the manufacturing stage." 15/

9/ Ibid.

10/ Ibid.

11/ Ibid., p.18.

12/ General Principles Governing the Use of Food Additives, op.cit., p.7.

13/ G.O. Kermode, op.cit., p.18.

14/ Ibid.

15/ Ibid.

274. Food preservative additives are not only used to prevent food spoilage but also to maintain the quality of the food. Thus, there are additives that prevent discolouration of food 16/. In addition there are those called antioxidants 17/ that prevent rancidity in the fatty components of foods such as vegetable oils, cereals, nuts and precooked meats and fish. Some of the most effective types of antioxidants, such as vitamins C and E have the additional advantage of nutritive value 18/. It has been said that:

> "It is desirable in all circumstances to maintain the nutritional quality of foods, but this is of special importance in countries in which the supply of essential nutrients in the usual diet is marginal or deficient. Any losses may then become serious and it is particularly necessary to avoid losses of the less stable vitamins. A typical example of the use of an additive in checking such losses is the addition of an antioxidant to edible fats which contain substantial amounts of beta-carotene or vitamin A, destruction of which may be accelerated by the onset of rancidity during storage. In certain circumstances the nutritional value of a food may incidentally be enhanced by the use of additives. Thus, ascorbic acid, when employed as an antioxidant will increase the antiscorbutic value of foods, such as fruit products, to which it is added, while the colouring of margarine with beta-carotene will enhance its vitamin A activity." 19/

(d) Texture agents

275. These agents, which include emulsifiers, stabilizers and thickening agents, constitute, in terms of quantity consumed, the largest class of additives 20/. These additives are

> "... used to improve the texture of bakery products, to impart smoothness to ice cream, and to give uniform consistency to processed fats such as shortening and margarine. In many cases the product would not be widely acceptable unless such agents are used in manufacture." 21/

Through the use of these additives many of the new convenience foods have become practical 22/.

16/ Ibid., p.19.

17/ Ibid.

18/ Ibid.

19/ General Principles Governing the Use of Food Additives, op.cit., pp.6-7.

20/ G.O. Kermode, op.cit., p.19.

21/ General Principles Governing the Use of Food Additives, op.cit., p.8.

22/ G.O. Kermode, op.cit., p.19.

(e) Miscellaneous additives

276. There are a host of other additives whose specific functions vary, but the basic purpose of which is either to make food more attractive to the consumer or more economical to manufacture. Thus there are acids, alkalis, buffers and neutralizing agents which affect the degree of acidity in such foods as baked goods, soft drinks, chocolate and processed cheese 23/. Humectants maintain a certain level of moisture and anticaking agents keep salt and powders free flowing 24/. Glazing agents are used to make food surfaces shiny 25/; while firming additives prevent flaccidity in fruits and vegetables and are also used in the manufacture of cheeses 26/. Release agents help separate foods from surfaces they touch during manufacture and transport 27/. There are foaming agents and foaming inhibiters; the former are used in such items as whipped cream, while the latter, for example, impede the foaming action of pineapple juice, allowing the speedier filling of cans during packaging 28/. It has been written that:

> "The desire that certain foods should be without colour, and the preference for a certain consistency in a food or beverage for a clear beverage, or for other special properties in ... foods, has led to the use of other additives such as bleaching agents, thickeners and clarifiers." 29/

277. Even if the only function of food additives were effectively to increase the supply of food, this would be of great importance, particularly in view of world population growth. Thus:

> "... if food production is to increase enough to keep pace with population growth and the effort to improve nutrition generally in undernourished areas, chemicals that are not normally part of food will inevitably play an increasingly important role." 30/

278. The additives considered above are intentionally added to food to produce certain desired results. There are, however, also techniques and operations which add, during the course of food production, substances which cannot later be eliminated. Typical examples are processing aids such as solvents and filter aids, and additives in animal feeds. 31/

23/ Ibid.

24/ Ibid.

25/ Ibid.

26/ Ibid.

27/ Ibid.

28/ Ibid., p.21.

29/ General Principles Governing the Use of Food Additives, op.cit., p.8.

30/ G.O. Kermode, op.cit., p.15.

31/ Hans P. Mollenhauer, "Legal and Ethical Implications of the Use of Food Additives", C.I.O.M.S. Round Table Conference on Human Rights, 14, 15, 16 November 1973, p.3.

2. Threats to human rights posed by the use of food additives

279. As is pointed out by the National Research Council of the National Academy of Sciences of the United States of America:

> "A continuing problem facing industry and the public is that of establishing that a particular use of a chemical in food production, processing, packaging, or storage will not be harmful to the consumer. It is generally recognized that absolute assurance that a usage will not prove harmful in any degree is unattainable. Therefore, effort is directed toward assuring that the hazard associated with a use is very small in relation to the health, agricultural, and economic benefits to be derived." 32/

280. This passage serves to indicate that the introduction of chemicals into the above-mentioned processes is in a sense experimental in relation to the general public. In addition, the report states that "some studies with volunteers ... for the purpose of assessing toxicity" of the chemicals in question have been made; and in this connexion problems of experimentation are again met. Foremost among the possible dangers of food additives is the health hazard of certain of them:

> "There is a growing concern for the potential effects on health of the increasing number of food preservatives, colours, artificial sweeteners, anti-biotics, hormones, pesticide residues, radioactive substances, etc., which may induce harmful changes in food. As was recently mentioned, 'in the last decade the use of food additives (and even more of pesticides) has grown on an almost geometric scale.'" 33/

281. The use of additives has become so extensive that it has been estimated that in the United States, in 1967, 3.5 kilograms per head per annum of food additives were consumed and that there is an expected increase of about 70 per cent by 1980 34/.

282. Artificial growth stimulants used on livestock and crops may have harmful consequences for human beings who eat such food if these chemicals manifest stability after intake. The hormone-like diethylstilbestrol, which is used to fatten livestock before slaughter, has been found to leave residues in the prepared meat, and when pregnant women ingest a quantity of this drug, there is the hazard that their offspring may develop a rare type of cancer 35/. The addition of hormones to animal feeds has, in fact, been prohibited in a number of

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32/ Some Considerations in the Use of Human Subjects in Safety Evaluation of Pesticides and Food Chemicals, A Report of the Ad Hoc Sub-Committee on Use of Human Subjects in Safety Evaluation of the Food Protection Committee, Food and Nutrition Board, National Academy of Sciences, Publication 1270, Washington, DC, 1965, p.3.

33/ J. de Moerloose, "A Survey of International and National Codes and Legislation in Selected Areas", C.I.O.M.S. Round Table Conference on Human Rights, 14, 15, 16 November 1973, p.43.

34/ Hans P. Mollenhauer, op.cit., p.2.

35/ "F.D.A. Warns on Hormone in Pregnancy", New York Times, 10 November 1971.

countries. The employment of strong antibiotics in animal feeds to protect the animal from various diseases has also come under considerable criticism. The danger lies in the development of resistant bacteria after extended application of these antibiotics. As stated by the United States Commissioner of Food and Drugs, Charles C. Edwards, "in most cases this resistance is transferable and presents a potential health hazard to humans" 36/ in that it establishes a bacterial population not amenable to normal therapeutics.

283. Additives intentionally added to food present similar dangers. Cyclamates, which are artificial sweeteners, had been used extensively in the United States until 1969, when it was found that under certain conditions, large doses could cause cancer of the bladder in rats 37/, alter the effectiveness of anti-coagulants in humans, disrupt the reproductive system, and affect the absorption of certain drugs 38/. "As a result saccharin is now being critically reviewed in the United States and in other countries." 39/ Another additive, sodium nitrite, which is used to fix the red colour in frankfurters, sausages and hams has also been discovered to constitute a cancer producing agent 40/. Sulphur dioxide, which is widely used to inhibit mould and discoloration in wine, fruit pulps and drinks, and dried fruits and vegetables, may destroy vitamin B_1. 41/ Monosodium glutamate (MSG), an additive widely used in certain foods, has given rise, in some persons, to Kwok's disease, which results in tension of the neck and face muscles, headache, nausea and giddiness 42/.

284. It has been mentioned that antibiotics are sometimes added to foods to prevent spoilage. However, this may result in two major problems: that "changing the normal spoilage pattern of certain foods may result in unfamiliar forms of spoilage that consumers cannot recognize" 43/ and that the liberal use of these additives might produce resistant strains of pathogens that could affect humans 44/.

285. Apart from the toxic qualities of certain additives, there "... is the possibility of using additives for fraudulently passing off inferior products under misleading names, covering up the use of faulty raw materials, or wanting factory hygiene." 45/ Thus with the use of colourings, preservatives, seasonings and tenderizers it is possible to disguise inferior food or incipient putrefaction: 46/

36/ Speech at annual meeting of Animal Health Institute in Boca Raton, Florida, April 1970, reported in Chemical and Engineering News (Washington, D.C.), 4 May 1970, p.13.

37/ G.O. Kermode, op.cit., p.21.

38/ James Turner, The Chemical Feast, (New York, Grossman, 1970) pp.14-16, 18.

39/ G.O. Kermode, op.cit., p.21

40/ Ibid.

41/ Ibid., p.18.

42/ Ibid., p.18.

43/ Ibid., p.21.

44/ Ibid.

45/ Hans P. Mollenhauer, op.cit., p.5.

46/ E/CN.4/1084, para.36; see also General Principles Governing the Use of Food Additives, op.cit., p.9.

"There is a greater risk of deception in the use of food additives with foods sold in the raw state than with processed foods ... distributors may be tempted to use additives to give inferior products the appearance of more expensive varieties. Moreover, the consumer does not usually expect that raw foods will contain intentional additives." 47/

3. Existing and proposed safeguards

286. Basic to these problems are the techniques for testing, for the presence of the additive and its toxicity or, more properly, the testing of the possible health hazard. "Toxicity is the ability of a material to cause harm, whereas the health hazard is the probability that it will do so." 48/

287. Until relatively recently, the means for testing foods were limited to general appearance, taste and smell. It was not until the middle of the 19th Century that testing of food was begun to be put on a sound scientific basis 49/. The following description has been given of one procedure currently followed:

"Since humans cannot be used for testing by exposing them to unknown chemicals for a substantial period of time, tests are made on rats and other animals such as mice and dogs. Test animals are fed quantities of the additive that far exceed the amount likely to be found in food. Tests are made both for short periods and over the animal's lifetime and are often continued into succeeding generations. Any change in growth, body function, tissue and reproduction is reported, as is the incidence of tumours.

"The largest dose that appears to produce no effects in animals is taken, and a safety factor reducing that dose by about 100 is applied in most countries in order to arrive at an acceptable dose for humans. The 'acceptable daily intake' thus calculated is the daily intake that for an entire lifetime appears to be without appreciable risk on the basis of all known facts at the time. It is expressed in terms of milligrams of the additive per kilogram of body weight. One must then calculate how much of the additive a person might be expected to ingest in a day from all dietary sources and compare this figure with the acceptable daily intake in order to decide whether the applications of the additive should be permitted and whether the specific tolerances or maximum limits required for it by good manufacturing practices in individual foods are safe to the health of the consumer." 50/

288. One basic problem is that the results on test animals may not be valid for humans:

47/ General Principles Governing the Use of Food Additives, op.cit., p.9.

48/ Toxic Hazards of Pesticides to Man, WHO Technical Report Series No. 114, October 1956, p.5.

49/ G.O. Kermode, op.cit., p.15.

50/ Ibid., p.21.

"The extrapolation of toxicologic information from experimental animals to man leaves unanswered certain questions relating to toxicity and hazard. Ultimately the answers must be found empirically in human experience, by epidemiologic studies, or by controlled study in man. There are clear-cut areas of toxicology for which animal study can give little or no information concerning man. They include systemic sensitization and allergic reactions, minor nervous system disturbances, and some subjective reactions. In other areas, animal study can indicate what events might occur in man but does not permit sure prediction that they will occur. Such matters as dose-response relationships, mode of action, metabolism, excretion and storage, and clinical response to exposures are examples."51/

289. Even the problem of determining the actual amount of a possible toxic substance that is present in food is difficult. Short of testing complete lots, sampling procedures are used. It has been found that variations of over 20 per cent have been determined by different teams testing the same sample. 52/

It has been said that:

"It is probably true to say that there will always be an area of doubt concerning the possible effects of ingesting small amounts of additives over the course of a lifetime. One cannot be fully sure of the safety of an additive until it has been consumed by people of all ages in specified amounts over a long period of time and has been shown conclusively, by careful toxicological examination, to have no harmful effects." 53/

Consequently:

"Toxicologists are rarely prepared to declare any chemical completely safe, and rightly so. There are various uncertainties in toxicological methods, such as the use of test animals; the experiment is normally directed towards known harmful effects, such as carcinogenity, so that any unknown effects can not be entirely excluded." 54/

290. A distinction may be made between nutritional or disease preventing elements added to foods, such as iodine or antimalarial drugged salt, and other such elements. However, even with respect to the presumably beneficial elements the argument is made that, on grounds not only of health but also of the right of the consumer to choose food free from medications, the addition of such substances is an abridgement of his rights. 55/

51/ Some Considerations in the Use of Human Subjects in Safety Evaluation of Pesticides and Food Chemicals, op.cit., p.18.

52/ Ibid., para. 2.5.

53/ G.O. Kermode, op.cit., p.21.

54/ Hans P. Mollenhauer, op.cit., p.6.

55/ Ibid., p.6.

291. One approach to a solution of the health hazards of food additives would be for science to develop alternative safe procedures. To a limited extent this is being attempted 56/. It is widely believed that it is the:

> "... governments' responsibility to protect the human rights of the consumer of foods by legal measures, setting, for instance, maximum limits for the presence of chemicals and 'residues', prohibiting the use of certain chemicals, requesting label declarations, where necessary, in conjunction with providing information and education on the nutritional, practical and economical value of foods.
>
> "Besides health protection, including precautionary measures, there is a need for protection against fraudulent and misleading malpractices." 57/

292. In the latter part of the 19th Century, both as a response to the problems raised by additives and with the development of scientific testing procedures, pure-food laws were enacted in many countries, to control and regulate the use of such additives 58/. It has been pointed out that:

> "One of the major problems in connexion with food additives is the satisfactory control of their use. In many countries, special agencies or departments are responsible for such control and in some, supporting scientific facilities are available. ... It is the common practice in many countries nowadays to work on the basis of 'permitted lists', that is to say, for each main category of food additives a list of permitted substances is prepared. It is also a growing practice to relate the inclusion of a substance in a permitted list to some specified use or uses and, in certain cases, to specify a particular tolerance level or levels." 59/

293. The approach varies from country to country; for instance with reference to flavour additives:

> "Some publish lists of permitted and prohibited flavours; some have a short list of prohibited flavours, many of which are natural, and others allow flavourings (both natural and synthetic) that are found only in the aromatic oils of edible plants." 60/

56/ G.O. Kermode, op.cit., p.18; see also CTN, October 1969 Bulletin No. 53, p.16. Document E/CN.4/1084, para.32, Bryan Silcock, "British Scientists Invent Super Pest-Killer", The Sunday Times, 12 January, 1975, p.1.

57/ Hans P. Mollenhauer, op.cit., p.8.

58/ G.O. Kermode, op.cit., p.15.

59/ Evaluation of the Toxicity of a Number of Antimicrobials and Antioxidants, Sixth Report of the Joint FAO/WHO Expert Committee on Food Additives, FAO Nutritional Meetings, Report Series No. 31, 1962, pp.4-6, WHO Technical Report Series No. 228, 1962, pp.4-6.

60/ G.O. Kermode, op.cit., p.16.

Similarly colour additive regulation varies among countries:

> "Many countries have fairly short lists of permitted food colours. The regulations specify purity and identity for the permitted colours and also restrict the number of foods to which colour can be added. Since most of the lists are based on the toxicological evaluation of the dyes, one might expect a reasonable degree of uniformity among the lists. It is not so, however, and therefore one of the most troublesome problems facing a food manufacturer who wants to export his products is the need to vary the colour according to the different regulations of the importing countries." 61/

294. It has been noted that there may be a health hazard connected with feeding livestock certain hormones. 62/ Accordingly, in various countries, regulations have been made with regard to this particular kind of additive. The following countries prohibit the use of hormones in animal feeds: Belgium, Bulgaria, China, Czechoslovakia, Denmark, Dominica, Germany (Federal Republic), Hungary, Israel, Italy, Luxembourg, Madagascar, Morocco, the Netherlands, Poland, Rumania, Spain, Sweden, Switzerland, Turkey, Vietnam.63/ Other countries, such as Finland 64/, Portugal 65/ and the USA 66/, specifically allow the use of these substances in animal feedstuffs, whereas a third group of countries, which includes among others Cyprus 67/, Greece 68/, Iceland 69/, Norway 70/ and the United Kingdom 71/, do not specifically prohibit such additives. However, most of the countries cited allow the inclusion of vitamins and antibiotics to animal feeds, subject to various regulations concerning type and amount. 72/ Indeed, in 1962, a special committee in the United Kingdom investigated the efficacy of such antibiotic additives and found not only that they did not harm humans but also that their use should be recommended. 73/

61/ Ibid., pp.16-17.

62/ New York Times, 10 November 1971.

63/ Dehove, R.A., 1974: La réglementation des produits alimentaires et non alimentaires Répression des fraudes et contrôle de la qualité, 8th ed., Paris, Commerce Editions publishers.

64/ Animal Feedstuffs; Regulations Governing their Manufacture and Sale in European Countries. FAO Legislative Series No. 4, Rome 1963, p.55.

65/ Ibid., p.155.

66/ Document E/CN.4/1084 para. 33; see also New York Times, op.cit.

67/ Ibid., p.33.

68/ Ibid., p.85.

69/ Ibid., p.90.

70/ Ibid., p.139.

71/ Ibid., p.206.

72/ FAO Legislative Series No. 4, Rome, 1963, op.cit.

73/ Ibid., p.206.

295. An example of investigation and regulation on a broad front to guard against the problems posed by the extensive use of food additives is provided by the USSR:

"The protection of foodstuffs against pollution by harmful substances is a country-wide undertaking conducted under the authority of branches of the Ministries of Health of the USSR and of the Union Republics. New chemical substances can be used in the production and processing of foodstuffs only with the permission of the Ministry of Health of the USSR.

"The quality of foodstuffs and their raw materials and of packaging, the conditions and duration of storage, and the permissible chemical additives level are laid down in State standards and technical specifications, which are required by law to be approved by the health authorities. The use of chemical substances, for example food additives, is governed by health regulations and instructions approved by the Ministry of Health of the USSR.

"It is also worth mentioning that an extensive programme is being carried out to improve food quality control and inspection methods.

"Protection of foodstuffs from pollution by harmful chemicals is therefore being tackled on a broad scientific and country-wide basis. The violation of health regulations and standards incurs disciplinary or administrative action, or criminal proceedings under USSR law." 74/

296. The Government of Hungary has written:

"The increasing use of chemicals in agriculture and the food industry represents an ever-increasing task for health officials. Continuous research and assessment, a steady development and progress of health rules and effective controls guarantee the timely solution of the problems appearing in increasing numbers in this field." 75/

297. The Government of Yugoslavia reports:

"There exist in Yugoslavia elaborated rules and regulations concerning the protection of the public against harm from chemicals introduced into food production, processing, packaging and storage and they are being constantly amended to comply with new achievements and discoveries in the field of science." 76/

298. Norway maintains control as follows:

"..[R]eference is made to the Act of 19 May 1933, No.3 relating to the Supervision of Food Products. In order to enforce this statute, a separate Directorate has been established with relatively wide powers. Efforts are also being made at present to arrange for all food products to be provided with a detailed trade description." 77/

74/ Information furnished by the Government of USSR on 25 July 1974.

75/ Information furnished by the Government of Hungary on 19 August 1975.

76/ Information furnished by the Government of Yugoslavia on 7 May 1975.

77/ Information furnished by the Government of Norway on 15 April 1974.

299. Because of the growing concern posed by the problem of food additives and in view of the difficulty and great expense in testing a new additive - the cost can be as much as 100,000 United States dollars 78/ - many have felt that the solutions of these problems could best be found on an international level. It has been recalled that:

> "An important step to improve the situation has been the creation of a Joint FAO/WHO Food Standards Programme which was launched in 1962. The executive body of the programme is the Codex Alimentarius Commission which in November 1970 had 99 members. [In 1975, 144 members.] Among its subsidiary bodies there is one on additives and another one on pesticide residues. The final aim of the Commission's activities is to recommend standards for acceptance by governments and their publication in the Codex Alimentarius. Once accepted, the government needs, of course, to embody the standards in the national legislation. The Codex Alimentarius Commission has, of course, to rely on the above-described Joint FAO/WHO Expert Committees on Food Additives and Pesticide Residues. For the food contaminants, an example of the activities has been the 1972 Sixteenth Joint FAO/WHO Expert Committee on Food Additives which discussed the evaluation of the contaminants mercury, lead and cadmium and established provisional weekly intakes." 79/

300. By 1972 the Codex Alimentarius Commission were preparing standards for approximately 200 different foodstuffs. 80/

301. The Joint FAO/WHO Expert Committee on Food Additives has issued 19 reports since its creation in 1956. 81/ These have been dealt with the general principles governing the use of food additives, with the evaluation of their toxicity, and with the specifications of their identity and purity. The reports and their associated monographs have covered virtually the complete spectrum of food additive classes (antibiotics, anticaking agents, antioxidants, antimicrobials, bleaching agents, colours, emulsifiers, enzymes, flavours, maturing agents, miscellaneous, preservatives, processing aids, sweetners, texture agents, thickeners).

302. It is expected that the publications arising from the work of this Joint FAO/WHO Expert Committee would:

> "... assist those concerned with food additive problems in taking decisions on the use of food additives, in making appropriate laws or regulation to control such use, in establishing appropriate tolerance levels, or in planning any further investigations that may seem desirable in relation to individual national needs and within the framework of national legislation." 82/

78/ G.O. Kermode, op.cit., p.21.

79/ J.de..Moerloose, op.cit., pp.44-45.

80/ Features, WHO Summary of Activities in 1971, January 1972, No.1, p.4.

81/ FAO Nutrition Meetings Report Series Nos. 15, 17, 29, 31, 35, 38, 40, 43, 44, 45, 46, 48, 50, 51, 53, 54. The third and fourth reports on specifications for identity and purity of food additives were published as separate volumes. WHO Technical Report Series Nos. 129, 144, 220, 228, 264, 281, 309, 339, 373. The third and fourth reports were published as separate volumes, 383, 430, 445, 462, 488, 505, 539, 557.

82/ Evaluation of the Toxicity of a Number of Antimicrobials and Antioxidants, op.cit., p.6.

303. Some governments favour an international approach. Thus the position of Ghana on this question is that:

"... the work of the FAO/WHO Codex Alimentarius Commission should be further strengthened, developed and expanded.

"All Governments should be urged to give maximum support to the work of the Commission and adopt measures for the enforcement of standards that are established by the Commission.

"An international code of ethics and practice for the production, processing storage, packaging and the transportation of food and food products should be formulated.

"In the interest of public health, the International Organization, Governments and Food Industries should be urged to promote and encourage research on the short-term and long-term effects of chemicals introduced into food production, processing, packaging and storage.

"Finally, every possible assistance should be given to the developing countries for the establishment and development of realistic and meaningful food quality control programmes." 83/

304. Similarly, the United Kingdom considers "... that it would be useful to consult the FAO/WHO Food Standards Programme about the work done through the Codex Alimentarius Commission in disseminating information on additives and contaminents and drawing up world-wide (and regional) compositional and hygienic standards for food and for pesticide residues." 84/

305. It has been maintained, however, that:

"...the needs for food additives and their possible uses and applications vary so widely from country to country that a single pattern of legislation is not feasible on a world-wide basis. It is, of course, clear that groups of countries may agree on joint permitted lists. Such developments are welcome and may represent a valuable contribution to the promotion of international trade." 85/

It has also been noted that:

"Special care should be exercised in the use of additives in foods that may form a major part of the diet of some section of a community, or that will be consumed in specially large quantities at certain seasons.

83/ Information furnished by the Government of Ghana on 21 March 1974.

84/ Information furnished by the Government of the United Kingdom on 8 August 1974.

85/ WHO Technical Report Series No.228, 1962, op.cit., p.6.

"The choice of food additives should be related to the prevailing dietary patterns within a community. The availability of essential nutrients and their distribution in the foods consumed should be taken into account before the true significance of making a further addition of a particular nutrient (e.g., calcium or phosphorus) or of using an additive that may change the pattern of nutrients in a food (e.g. an oxidizing agent) can be assessed." 86/

306. It is therefore urged that:

"Any 'calculated risk' involved in the occurrence of chemicals in foods should be subject to an overall health policy decision reducing the health risk, if any, below a negligible level by applying safety factors and extending precautionary measures well into the glacis of health protection. Because of the diversity of the problem, health policy decisions must be based on broad scientific studies, including inter alia:

- investigation of the necessity to use chemicals in connexion with food, or their unavoidable presence
- toxicological evaluation, and
- studies of food intake, containing such chemicals." 87/

307. The Codex Alimentarius Commission has set forth six general principles on the use of food additives, which have been summarized as follows: 88/

(1) "... the use of an additive is justified only when it has the purpose of maintaining a food's nutritional quality, enhancing its keeping quality or stability, making the food attractive, providing aid in processing, packing, transporting or storing food or providing essential components for foods for special diets, and ... an additive is not justified if the the proposed level of use constitutes a hazard to the consumer's health, if the additive causes a substantial reduction in the nutritive value of a food, if it disguises faulty quality or the use of processing the handling techniques that are not allowed, if it deceives the customer or if the desired effect can be obtained by other manufacturing processes that are economically and technologically satisfactory."

(2) The amount of the additive should not exceed the amount necessary to achieve the desired result.

(3) Additives should conform with an approved standard of identity and purity.

86/ Specifications for the Identity and Purity of Food Additives and their Toxicoligical Evaluation: Emulsifiers, Stabilizers, Bleaching and Maturing Agents, Seventh Report of the Joint FAO/WHO Expert Committee on Food Additives, WHO Technical Report Series No.281, 1964, p.4.

87/ Hans P. Mollenhauer, op.cit., p.11.

88/ G.O., Kermode, op.cit., p.21.

(4) The additive should be adequately tested before use.

(5) The additive should be approved for use with specific foods, for specific purposes and under specific conditions.

(6) Special account should be taken of additives consumed by special groups in a community.

308. However, one writer expressed the problem of the creation of a uniform code as follows:

> "... to harmonize such laws on an international scale, when historical and cultural backgrounds are so very different and interests can be totally divergent within the food industry, among health officials and even among consumers, is a labour of herculian proportions." 89/

Another writer summarized the situation thus:

> "Food additives have become part of everyday life and undoubtedly will play an increasing role with advances in food technology. The prospect is not necessarily bad, because properly used additives can bring the consumer significant benefits. Moreover, provided that in each case sound justification for the additive is demonstrated, that government and manufacturers exercise the utmost care to ensure that the additive entails no appreciable risks to health and that clear labelling informs the consumer of the nature and composition of the product he is buying, consumers should be reasonably assured as to the safety of officially authorized food additives." 90/

89/ J.de. Moerloose, op.cit., pp.44-45.

90/ G.O. Kermode, op.cit., p.21.