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Genetic Technology: Law and Policy for the Brave New World

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GENETIC TECHNOLOGY: LAW AND POLICY FOR THE BRAVE NEW WORLD

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During the past several years, developments in the biomedical sciences relating to genetics have given rise to dramatic possibilities for human intervention in the basic genetic processes.[1] Such intervention may be directed towards the reduction or elimination of disease of genetic origin.[2] It may be directed towards the gratification of parental desires for children with predetermined biological characteristics. It may also be directed towards the modification of the natural processes of evolution—a modification of the basic characteristics of living creatures, including man. The intervention may be through negative means such as abortion to eliminate fetuses with undesirable characteristics or measures to discourage marriages or child-bearing where defective children may result,[3] or it may be through positive means such as therapy or the encouragement of marriages and child-bearing likely to produce desired results. There has been a comprehension on the part of the biomedical community that these developments will have a profound impact on society, and the biological community has undertaken to engage representatives of other disciplines—

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1. In order to enhance comprehensibility of this paper to its primary audience, no effort has been made to describe the fundamental principles of genetics or the scientific state of the relevant biomedical knowledge and techniques. The author has attempted to describe the relevant scientific and technological matters simply, and free of scientific jargon, based on his own exposure to these matters in the course of various interdisciplinary projects. Indeed, the author readily concedes that he is in no way expert in these matters; at the same time, he is convinced that lawyers and others interested in the policy implications are fully capable of pursuing these questions on the basis of articulated conclusions without any need for a comprehensive understanding of the underlying data. For a simple discussion of many of the basic scientific principles see REPORT OF THE SCIENCE POLICY RESEARCH DIVISION, CONGRESSIONAL RESEARCH SERVICE TO THE SUBCOMM. ON SCIENCE, RESEARCH, AND DEVELOPMENT OF THE HOUSE COMM. ON SCIENCE AND ASTRONAUTICS, 92D CONG., 2D SESS., GENETIC ENGINEERING, EVOLUTION OF A TECHNOLOGICAL ISSUE, (Comm. Print 1972) [hereinafter cited as REPORT OF THE SCIENCE POLICY RESEARCH DIVISION]; Vukowich, *The Dawning of the Brave New World—Legal, Ethical, and Social Issues of Eugenics,* 1971 U. ILL. L.F. 189 [hereinafter cited as Vukowich].

2. For estimates of the substantial costs to society of genetic disease see REPORT OF THE SCIENCE POLICY RESEARCH DIVISION, *supra* note 1.

3. For a discussion of negative eugenics programs see Vukowich, *supra* note 1, at 214-31.

philosophers, theologians, lawyers, ethicists, sociologists, etc.—in speculations and discourse as to the social consequences of the use of the new genetic knowledge. To this end, a major interdisciplinary conference was held on this subject in October, 1971. The keynote address was delivered by Dr. Tracy Sonneborn, an Indiana University geneticist. In this address, Dr. Sonneborn identified three major categories of present and potential use of genetic knowledge.[4] The following discussion is based on the three categories discussed by Dr. Sonneborn.

First, it is now technologically feasible to identify individuals who are carriers of certain abnormal genes and chromosomes and therefore, as parents, risk producing children with genetic disease.[5] In addition, it is now feasible, through a procedure known as amniocentesis,[6] to make a positive identification of the actual presence of certain genetic conditions in the fetus. These capabilities, which are expected to broaden to include more such conditions and diseases, greatly expand the options available to potential parents. An individual's knowledge that he in fact carries abnormal genes or chromosomes can assist him in making sound decisions as to marriage and procreation. Knowledge that a fetus will be born with a serious genetic disease provides the parents with the option of avoiding great misery and expense by electing to terminate the pregnancy by abortion. Indeed, this latter capability can be used on an even broader basis to terminate pregnancies where it is determined that the fetus will be born with characteristics which are less than optimum from the standpoint of the parents' desires. For example, it is presently possible reliably to determine the sex of the fetus through amniocentesis, thereby enabling the parents, theoretically at least, to elect abortion to prevent the birth of a child of the "wrong" sex so that they can try again for the "right" sex.[7]

Although these techniques may be completely justifiable when used to expand the options of individuals within the context of the physician-patient relationship, more difficult questions are presented by use of

4. Sonneborn, *Ethical Issues Arising From the Possible Uses of Genetic Knowledge*, in ETHICAL ISSUES IN HUMAN GENETICS 1 (B. Hilton, D. Callahan, M. Harris, P. Condliffe, & B. Berkley eds. 1973) [hereinafter cited as ETHICAL ISSUES].

5. This can be accomplished simply with a blood test.

6. A long needle is inserted into the abdomen of a pregnant woman in order to withdraw a small quantity of amniotic fluid. Analysis of this fluid enables confirmation or negation of the presence of a large number of genetic disorders in the fetus with a very high degree of reliability. Experience to date suggests that amniocentesis involves only minimal risk to either woman or fetus.

7. In December, 1972, the author presented a paper at the annual meeting of the American Association for the Advancement of Science in which he stated that it was now technically feasible for parents to choose the sex of a child. This was given wide press coverage. The author thereafter received several letters from eager women in Canada and the United States requesting information as to where they might go to obtain information as to choosing the sex of their next child.

these techniques on a mass basis. Numerous programs have been developed to bring the benefits of this new genetic knowledge to the public at large through "genetic screening" to identify carriers of genetic conditions in order to assist them in making use of the available options. A number of states have, in fact, enacted legislation providing, and in some cases requiring, genetic screening for sickle cell anemia.[8] The necessity for and desirability of such statutory screening programs, and the constitutionality of mandatory genetic screening statutes, are subject to question. Beyond these questions, however, there are fundamental issues as to how the information derived from genetic screening will be used. Although it can be argued that a useful purpose is intrinsically served by providing individuals with greater knowledge of their genetic characteristics, this is by no means clear. Such knowledge, especially when it is not actively solicited in the physician-patient relationship, can have a profound, perhaps traumatic, effect on the individual. If, moreover, the information is communicated to third parties, this can be injurious to the individual. Concern has been expressed that information developed in screening for sickle cell anemia will be communicated to third parties or to data banks with the result that the individual may be stigmatized or that he may be denied insurance or employment on the basis of the information.[9]

Particularly difficult questions are raised by the possibility that genetic dossiers may be used by government for public health purposes. Existing statutes prohibiting consanguineous marriages or the marriage of persons with various diseases or biological deficiencies may be broadened to ban or regulate the marriage of persons with genetic characteristics indicating a probability that any children born will be defective. The interest of the state in preventing the birth of genetically defective children, and in protecting future generations, may lead to laws mandating abortion to prevent the birth of such children. Aside from such negative eugenics laws, it is not difficult to visualize use of genetic dossiers by the state in positive eugenics programs to improve the quality of the population. Development of reliable data establishing a link between genetic characteristics and aberrant or antisocial behavior could provide government with new methods of minimizing crime and for identifying potential criminals for purposes of special treatment.[10]

The second potential use of the new genetic knowledge relates to *in*

8. For a discussion of these statutes see Powledge, *The New Ghetto Hustle*, 1 SAT. REV. OF THE SCIENCES, Feb., 1973, at 38 [hereinafter cited as Powledge].

9. *See* Lubs, *Privacy and Genetic Information*, in ETHICAL ISSUES, *supra* note 4, at 267.

10. *See* notes 40 & 41 infra & text accompanying.

vitro fertilization. It is now possible to extract human eggs from a woman and to fertilize them *in vitro*.[11] It is believed that scientists may attempt in the near future[12] to implant such a fertilized egg in the uterus of the woman from whom the eggs were obtained in the expectation that she would then proceed to bear and give birth to a child in a normal manner.[13] This technique, if perfected, is obviously beneficial, since it provides a means whereby a woman who is otherwise incapable of having her eggs fertilized in the normal manner could have children. On the other hand, before the technique can be regarded as perfected, there will have to be human experimentation, and in the process of experimentation, there will be a first child born as a result of *in vitro* fertilization and then a few others will follow. What will be their fate in society as the first "test tube babies," objects certainly of great scientific, if not public, curiosity? And what is the morality, indeed the legality, of performance of this experiment, even with informed consent of the mother, when there exists at least the possibility that the experiment will produce a defective, deformed, or monstrous child? What are the interests of such a potential child in the performance *vel non* of the experiment which will bring him into this world?[14]

The concept of *in vitro* fertilization involves a number of interesting alternative scenarios. It will open the door to surrogate motherhood—to wombs for rent. One can visualize the possibility that a woman may undertake, for a fee, to have the fertilized egg of another woman implanted in her womb in order that the donor of the egg may have her—and her husband's—biological child without the burden of child-bearing. In the eyes of the law, whose child will it be: the child of the donor of the egg or the child of the surrogate who bears and delivers the child? And would contracts for surrogate motherhood be legally enforcible? In another scenario, the egg might be fertilized, with or without the knowedge and

11. Experiments have already been conducted in which eggs have been removed from women, fertilized *in vitro* in a laboratory and grown in a laboratory culture to the blastocyst stage, *i.e.*, the stage reached in humans seven to eight days after fertilization at which the early embryo normally implants itself in the uterine lining. Kass, *Babies by Means of In Vitro Fertilization: Unethical Experiments on the Unborn?*, 285 N.E.J. MED. 1174 (1971) [hereinafter cited as Kass].

12. REPORT OF THE SCIENCE POLICY DIVISION, *supra* note 1, at 18; Kass, *supra* note 11.

13. This technique has been widely used in animal husbandry and has been tested in laboratory animals to the point that the blastocyst of a mouse has been implanted in the uterus of the mouse with full development and successful reproduction. REPORT OF THE SCIENCE POLICY RESEARCH DIVISION, *supra* note 1, at 19.

14. For a discussion of the ethical and policy issues see Kass, *supra* note 11; Ramsey, *Shall We "Reproduce"? The Medical Ethics of In Vitro Fertilization*, 220 J.A.M.A. 1346 (1972); Ramsey, *Shall We "Reproduce"? Rejoinders and Future Forecast*, 220 J.A.M.A. 1480 (1972).

consent of the donor, for implantation in a woman who is a stranger to the entire transaction. Or scientific researchers may use the fertilized egg for experimentation to observe the processes of embryonic maturation or to see how long it can be made to develop *in vitro*. At the end of the road, perhaps, scientists may be able to maintain a fetus *in vitro* to the point of "birth."

Closely related to *in vitro* fertilization is the possibility of cloning.[15] In cloning, the nucleus of the egg would be removed and replaced by a nucleus obtained from a body cell of a particular individual. Theoretically at least, this would result in the development of an individual who is biologically identical to the individual who donated the nucleus, thus creating the possibility of producing multiple biological carbon copies of any given individual. For example, it might be possible through cloning to produce ten, a hundred, or any number of biological carbon copies of a Willie Mays, an Edward Teller, or a Moshe Dayan.

The third category of use of genetic knowledge relates to more direct genetic surgery or other forms of genetic therapy. Such techniques may be practiced to remedy disease or to eliminate defects which may result in diseased offspring.[16] They may also be practiced for reasons of positive eugenics, to improve the quality of children of specific parents, or to improve generally the quality of future generations by further deliberate intervention in the processes of evolution.

Use of all of these technologies will have an obvious impact on various traditional substantive areas of the law. For example, there will be questions as to the legal duties and privileges arising in the doctor-patient relationship; there will be questions as to privacy; some applications of *in vitro* fertilization or cloning would raise substantial legal issues as to parentage and relationships between individuals; and involvement of government in the use of genetic knowledge and technologies would raise constitutional questions. Problems such as these, with which the law will eventually have to reckon are so unique that it would be idle speculation to attempt to predict how the law will respond to these new stimuli. The purpose of this paper, therefore, is not to explore the manner in which substantive law will be affected by the new genetic technology, but rather to discuss the processes through which laws may evolve to govern its use.

A basic distinction must be drawn between two major categories of use of genetic technology. The first category involves decisions which are made by individuals on a voluntary basis. An individual has, or seeks, knowledge as to what can be accomplished through use of genetic knowl-

15. REPORT OF THE SCIENCE POLICY RESEARCH DIVISION, *supra* note 1, at 21-22.
16. *Id.* at 26-28.

edge and technology, and voluntarily, in conjunction with his physician or other practitioner of genetic technology, submits to some form of treatment. The second category involves the possibility that government will decide to use the new genetic knowledge for purposes of the public health or welfare. Such possibility might involve requirements or inducements for genetic screening or treatment or the enactment of laws which in one way or another may restrict the freedom of persons with specified genetic conditions.

The Private, Voluntary Use of Genetic Technology

Heretofore, the concern of the law with biomedical science and technology has been focused primarily on the one-to-one relationship between physician and patient and on the rights and obligations flowing from this relationship. There has been very little effort at affirmative government regulation of medical practice. This undoubtedly reflects the fact that medicine is a self-regulating profession in which abuse is minimized through the application of ethical principles and standards of peer review. Accordingly, virtually all of the law relating to the physician-patient relationship is to be found in common law precedents. It is to be expected, therefore, that the legal system will initially take cognizance of the new genetic technology as the courts are called upon to decide cases brought by patients who allege that they were in some way wronged by what the genetics practitioner did or did not do. As such cases are decided, a body of law directly pertinent to genetic technology will come into existence.

Accordingly, subject to legal principles which will evolve in time through case-by-case decisions, physicians will use genetic knowledge as they see fit, hopefully with informed consent of their patients, in the light of their profession's ethical standards. In this connection, it should be noted that use of genetic knowledge will represent a substantial expansion of the traditional role of the physician. Traditionally, the physician's function has been to treat and cure his patient's disease. Increasingly in recent years, there has been a recognition that the physician's function is also to try to prevent his patient from developing disease. To a large extent, however, the physician's use of genetic technology is not directed towards the treatment or prevention of disease in his patient, but rather to the treatment or prevention of disease in the patient's future offspring. If such future offspring is a fetus, it can be argued that the fetus is also the physician's patient, but there is a logical difficulty with this position where the treatment or prevention of the disease involves killing the fetus by abortion. More obviously, the physician can hardly be regarded as treating or preventing disease when he employs procedures intended to enable parents to produce a child of a chosen sex or with other desired biological char-

acteristics. A major component of the use of genetic knowledge is, therefore, provision of a service which will make the patient happier or enhance his sense of well-being. This extension of the physician's role is not a unique phenomenon. Performance of "abortions on demand" or cosmetic surgery, for example, may also be beyond the scope of the treatment or prevention of disease. It remains to be seen whether the medical profession will adopt any limitations on the purposes for which genetic technology will be used.

It is, of course, possible that society may react to the use of genetic technology through enactment of regulatory laws. This is not likely to result, however, unless the medical profession itself fails to curtail practices which society regards as abusive. On the other hand, even absent abuse, one can visualize the possibility that the broad social consequences of individual decisions, in the aggregate, may warrant regulatory action. For example, the use of genetic techniques giving parents the option to choose the sex of their children could result in a serious imbalance of the ratio of males to females in our society, with obvious social consequences. Government may well have a legitimate interest in taking regulatory action to prevent or correct this imbalance. And, although the recent Supreme Court decisions on abortion suggest that the fetus is an expendable non-person,[17] there may be sufficient interest in preventing injury to a fetus to warrant regulation of practices which may result in the birth of a defective child. Similarly, if *in vitro* fertilization produces "wombs for rent" or surrogate child-bearers, there would be an obvious need for regulation. In short, genetic intervention in individual cases would appear to involve, to a greater extent than in the case of other medical procedures, important societal interests. It is worth noting, if this societal interest is sufficient to sustain regulation of actions flowing from decisions made in the physician-patient relationship, that this would extend the long arm of governmental authority into a new area of personal decisionmaking where the need for intense privacy has heretofore been recognized.

In general, therefore, genetic intervention undertaken in the context of the usual doctor-patient relationship will not result in any unique legal questions. It would appear that the self-governing mechanisms of the medical community can deal effectively with the new kinds of questions that are presented. The courts will, of course, pass upon alleged wrongs resulting from the physician's treatment of his patients, and the possibility exists that affirmative regulation may be necessary if abuses or social problems appear.

On the other hand, the problem of genetic screening by private agen-

17. Doe v. Bolton, 93 S. Ct. 739 (1973); Roe v. Wade, 93 S. Ct. 705 (1973).

cies on a voluntary, consensual basis warrants special attention. Although screening programs may be under the supervision of a physician, they do not necessarily or usually involve the normal one-to-one relationship between physician and patient. Indeed, the person screened may never encounter a physician in the entire process of screening. The major purpose of genetic screening is, of course, to develop information as to whether a person who is screened is at risk of producing a child with genetic disease. Three basic types of questions have been raised as to the legal relationships between a screenee and the screening agency. First, what information must the screening agency give to a candidate for screening in order to meet the requirement for informed consent if, indeed, informed consent is legally necessary? For example, must the subject be informed of the risk of infection incident to the taking of blood? Must he be informed, before screening, of the consequences if there is a positive finding? Must he be informed that disclosure to him of a positive finding could have a substantial effect on the subsequent course of his life? Second, does the screening agency have a duty to inform the screenee as to the results of the screening? Must he be informed of negative findings? Will the screening agency be liable if it negligently fails to inform the screenee of a positive finding? May the screening agency deliberately withhold disclosure of positive findings because, for example, it believes disclosure might be psychologically devastating to the subject? Third, what duty does the screening agency have to maintain the confidentiality of the results of screening in individual cases? If the results of screening are positive, may the screening agency pass on the information to relatives of the subject who may be similarly affected? May it disclose the results to insurance companies, employers, or government agencies? It is difficult to provide reliable answers to any of these questions on the basis of presently existing precedents, since all of the precedents arise in the context of the traditional one-to-one physician-patient relationship which does not exist in genetic screening programs. What can be said is that in the cases involving the physician-patient relationship, there seems to be no suggestion that specific informed consent is required in connection with relatively routine diagnostic proceedings;[18] no clear requirement for informing the patient as to the diagonostic results, except perhaps in connection with a proposed

18. No decisions have been found imposing a requirement for informed consent in connection with relatively simple diagnostic procedures such as blood tests. Such requirement has been found primarily with respect to experimental procedures, therapeutic procedures involving significant risk and in cases in which alternative courses of treatment were available. *E.g.*, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972). Nevertheless, since the need for informed consent is likely to be measured after the fact in the light of the consequences giving rise to litigation, the prudent physician will make an effort to disclose significant risk to the patient and obtain his explicit consent.

course of treatment;[19] and no absolute requirement for confidentiality of the results of the diagnosis.[20] It seems doubtful that more stringent requirements would be found in areas not involving the special doctor-patient relationship.

Genetic screening does, however, involve some additional considerations. Informing a person that he is the carrier of genetic disease, and that this situation cannot be corrected, may have a traumatic effect on him and could alter the course of his future life. This traumatic effect can be exacerbated if the information is disclosed to his family, his potential spouse, employers, or insurance companies.[21] It would seem desirable that disclosure of the information to the individual who has been screened be coupled with adequate professional counseling services. This raises the question whether some form of government regulation may be necessary to ensure that genetic screening is conducted by responsible agencies, with adequate professional staff, and with safeguards to minimize the possibility of adverse consequences. At the very least, it would be desirable to require that all genetic screening programs include a carefully thought out statement, to be given to all potential screenees, articulating the policies of the screening agency with respect to these matters. Such a statement would in itself serve to define the legal rights and duties of the parties and

19. Most decisions imposing liability on a physician for withholding information arise in situations in which the patient required the information in order to give his informed consent to a proposed therapy. Even in such cases, the physician is privileged to withhold information if he believes disclosure would be harmful to the patient. Lester v. Aetna Casualty & Surety Co., 240 F.2d 676 (5th Cir. 1957); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960); Hunt v. Bradshaw, 242 N.C. 517, 88 S.E.2d 762 (1955). On the other hand, it would appear, despite the lack of authority, that a physician would be found negligent if he failed to disclose a treatable condition to his patient where the patient sustained injury as a consequence of lack of treatment or delayed treatment. This question seems, in any event, to be largely hypothetical in relation to genetic screening programs since their very purpose is to inform the persons screened of genetic abnormalities.

20. The legal duty of a physician to maintain information concerning his patient in confidence is subject to a number of exceptions. He may disclose information to governmental bodies as validly required by law. Davis v. Rodman, 147 Ark. 385, 227 S.W. 612 (1921); Skillings v. Allen, 143 Minn. 323, 173 N.W. 663 (1919). Disclosure to the patient's spouse is generally permissible. Pennison v. Provident Life & Accident Ins. Co., 154 So. 2d 617 (La. App. 1963); Curry v. Corn, 52 Misc. 2d 1035, 277 N.Y.S.2d 470 (Sup. Ct. 1966). In Simonsen v. Swenson, 104 Neb. 224, 177 N.W. 831 (1920), it was held that a physician was not liable for informing a hotel in which his patient was staying that the patient had a contagious disease. In Berry v. Moench, 8 Utah 2d 191, 331 P.2d 814 (1958), it was stated that a psychiatrist was privileged to disclose to a prospective bride that his patient, the prospective groom, had a pyschiatric disorder. Disclosures to other parties have likewise been upheld. Hague v. Williams, 37 N.J. 328, 181 A.2d 345 (1962) (disclosure to a life insurance company); Clark v. Geraci, 29 Misc. 2d 791, 208 N.Y.S.2d 564 (Supp. Ct. 1960) (disclosure to an employer).

21. *See* M. Frankel, *Genetic Technology: Promises and Problems,* THE GEO. WASH. U. PROGRAM OF POLICY STUDIES IN SCIENCE & TECHNOLOGY, MONOGRAPH NO. 15, at 68-73 (1973).

would avoid the vagaries of resolution under the present highly uncertain common law principles.

Use of Genetic Technology by Government

It is, of course, a legitimate function of government to promote and protect the public health.[22] To this end, government provides medical facilities and personnel for the prevention and treatment of disease and adopts various measures intended to prevent the spread of contagious and infectious diseases. It is clearly within the power of government to identify persons with communicable diseases[23] and to adopt measures to prevent their communication.[24] In these respects, the rights of individuals must yield to the more substantial rights of society as a whole.[25] Thus, for example, it has been recognized that the government may require all persons to be vaccinated for small pox even though some persons may be injured by the vaccination.[26] It is clear, moreover, that such powers of government are not limited to those exercised for the protection of the existing population. There is ample precedent for the proposition that the public health powers of government may be exercised in order to protect future generations from the spread of disease through genetic processes.[27]

A number of states have already taken cognizance of the new capabilities of genetic science in enacting statutes providing or requiring genetic screening with respect to sickle cell anemia. Sickle cell anemia is a blood disorder which exists predominately in blacks. It is an autosomal recessive condition, which means that it can be transmitted genetically only if both parents are carriers of the sickle cell gene. In such cases, there is one chance in four that any child of that couple will be born with the disease. A child born with sickle cell anemia will almost always experience excruciatingly painful "sickle cell crises" caused by blockages of the capillaries. There is no known cure for the disease, and most affected persons die by the age of forty. Individuals who are carriers of the sickle cell gene are described as having "sickle cell trait" and are under no substantial disability except that symptoms of the disease may be experienced under certain circumstances, *e.g.*, at high altitudes.

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22. Holden v. Hardy, 169 U.S. 366, 395 (1898). As stated in Roe v. Wade, 93 S. Ct. 705 (1973), "a state may properly assert important interests in safeguarding health." *Id.* at 727.

23. Rock v. Carney, 216 Mich. 280, 185 N.W. 798 (1921).

24. *See generally* 39 Am. Jur. 2d *Health* § 29 (1968).

25. Jacobson v. Massachusetts, 197 U.S. 11 (1905).

26. *Id.*

27. Buck v. Bell, 274 U.S. 200 (1927). The public health power of the states has been described in the broadest possible terms as permitting enactment of "health laws of every description" so long as it does not infringe constitutionally granted rights. Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

Some of the states which have enacted legislation concerning sickle cell anemia *require* screening of all persons for the trait and for the disease. Screening is variously required under these statutes at birth, upon entry into school, or as a prerequisite for a marriage license.[28]

The wisdom of and necessity for mandatory screening for sickle cell anemia are open to serious question. Identification of sickle cell anemia at any early age may enable ameliorative management of the diseased individual, but no cure is available. Identification of the carriers of the sickle cell gene at birth or upon entry into school would not appear to have any useful purpose, since the information is really relevant only with respect to decisions as to marriage and procreation. On the other hand, for a child to be labeled as a sickle cell carrier could have an emotionally traumatic effect on him and an adverse effect on his employability and insurability.

There are some who question the constitutionality of the mandatory sickle cell screening statutes.[29] It is argued, deductively, that mandatory screening violates the right to privacy, particularly with respect to decisions as to marriage and procreation, established in *Griswold v. Connecticut*,[30] *Eisenstadt v. Baird*,[31] and the abortion decisions.[32] It is difficult to see, however, how mandatory sickle cell screening is more objectionable from the standpoint of privacy than pre-marital screening for venereal disease and prohibitions against marriage of close relatives and persons with venereal or other diseases. It is argued also that mandatory genetic screening for sickle cell anemia is unconstitutional because it serves no useful purpose.[33] This argument is based on the distinction between contagious and infectious diseases which may spread rapidly and affect entire populations, and genetic disease which, although communicable vertically, affects fewer people, and spreads much more slowly. It is based also on the proposition that for some detectable genetic diseases, such as sickle cell anemia, unlike other diseases within the scope of the public health power, no cure is available. It seems clear, however, that screening for sickle cell anemia is constitutionally defensible against these arguments. As pointed out above,[34] the welfare of future generations is a legitimate concern of the government.[35] Moreover, the absence of a cure is not decisive.

28. For a discussion of these statutes see Powledge, *supra* note 8, at 38.

29. Such questions have, for example, been raised and intensively discussed at meetings of the Genetic Task Force of the Institute of Society, Ethics and the Life Sciences.

30. 381 U.S. 479 (1965).

31. 405 U.S. 438 (1972).

32. Doe v. Bolton, 93 S. Ct. 739 (1973); Roe v. Wade, 93 S. Ct. 705 (1973).

33. Such questions have, for example, been raised and intensively discussed at meetings of the Genetics Task Force of the Institute of Society, Ethics and the Life Sciences.

34. *See* Jacobson v. Massachusetts, 197 U.S. 11 (1905).

35. *See, e.g.*, Perez v. Lippold, 32 Cal. 2d 711, 198 P.2d 17 (1948); State v. Troutman, 50 Ida. 673, 299 P. 668 (1931); Beans v. Denny, 141 Ia. 52, 117 N.W.

Government may have a legitimate interest in such screening if for no other purpose than to reduce the number of children born with genetic disease who might burden the public health resources of government.[36]

There are, however, two bases on which the mandatory sickle cell screening statutes may in fact be vulnerable to constitutional attack. First, as noted, it is difficult to identify any legitimate governmental interest in the screening of infants and children. Second, to the extent that these screening programs are directed only towards the black population, either by statutory language or by implementation of the statutes, it can be argued with force that they violate the equal protection clause of the fourteenth amendment. It is clear that a discriminatory burden imposed upon a particular racial group is inherently suspect under the fourteenth amendment, but may be justified in terms of a compelling governmental interest.[37] It is not clear, however, that absent invidious discrimination, and with a reasonable basis, government may not constitutionally single out a particular racial group for special benefits. Nor is it clear to what extent mandatory sickle cell screening is a benefit or a burden.

The problem of sickle cell screening is illustrative of a broader problem related to the fact that some genetic diseases are present predominately in specific ethnic groups. For example, Tay-Sachs distase is found almost exclusively in Jews of Eastern European origin, and Cooley's anemia is found primarily in people of Mediterranean origin. If government is to screen for carriers of these diseases, it is obviously uneconomical to screen everyone. The new genetic capabilities, therefore, are suggestive of the possibility that racial and ethnic backgrounds may be constitutionally relevant and appropriate for purposes of classification for genetic screening.

The mandatory screening for genetic conditions is, however, only a starting point. The ability to readily identify carriers of genetic disease

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1091 (1908); Shackleford v. Hamilton, 93 Ky. 80, 19 S.W. 5 (1892); Ryder v. Ryder, 66 Vt. 158, 28 A. 1029 (1894); Grover v. Zook, 44 Wash. 351, 87 P. 638 (1906); Peterson v. Widule, 157 Wis. 641, 147 N.W. 966 (1914).

36. *Cf.* State v. Acker, 26 Utah 2d 104, 485 P.2d 1038 (1971) (upholding a law requiring motorcyclists to wear crash helmets); *accord,* Love v. Bell, 171 Colo. 27, 465 P.2d 118 (1970); Commonwealth v. Coffman, 453 S.W.2d 759 (Ky. 1970); State v. Edwards, 287 Minn. 83, 177 N.W.2d 40 (1970); People v. Newhouse, 55 Misc. 2d 1064, 287 N.Y.S.2d 713 (Ithaca City Ct. 1968); State v. Anderson, 3 N.C. App. 124, 164 S.E.2d 48 (1968); State v. Craig, 19 Ohio App. 29, 249 N.E.2d 75 (1969); State v. Lombardi, 104 R.I. 28, 241 A.2d 625 (1968); State v. Laitinen, 77 Wash. 2d 130, 459 P.2d 789 (1969). The fluoridation cases are also relevant. The courts have generally upheld fluoridation measures, a form of compulsory medication, on the basis of general benefit to the community. Chapman v. Shreveport, 225 La. 859, 74 So. 2d 142 (1954); Readey v. St. Louis County Water Co., 352 S.W.2d 622 (Mo. 1966); Kraus v. Cleveland, 163 Ohio St. 559, 127 N.E.2d 609 (1955); Dowell v. Tulsa, 273 P.2d 859 (Okla. 1954).

37. Loving v. Virginia, 388 U.S. 1 (1967).

may well be only a first step in public health measures to limit the spread of such disease. The specific purpose of the mandatory sickle cell screening statutes is not clearly articulated. They are, presumably, based on the premise that individuals who know they are carriers of the disease will at least tend to take appropriate action to avoid giving birth to diseased children, thereby tending to reduce the incidence of the disease in the population. It is possible, however, that society will find the preventability of such diseases to be so alluring that it will take further positive steps to ensure that diseased children are not brought into the world. It is not difficult to visualize the enactment of laws which will prohibit marriage of couples who are definitely at risk of having children with specified genetic defects.[38] Nor is it difficult to visualize the enactment of laws requiring amniocentesis to determine whether a fetus in fact will be born with genetic disease. It would be a logical extension, although one involving obvious constitutional problems, to require abortion in the case of certain such diseases which cannot be treated effectively and where the birth of the child might impose substantial burdens of care on society.[39]

There is also another troubling possibility with respect to government's use of genetic screening or information gained through screening. There presently is some evidence linking the XYY chromosomal abnormality[40] with some forms of aberrant behavior.[41] If this link should be firmly established, or if other genetic conditions are clearly linked to antisocial behavior, use of the information could be a highly useful tool in dealing with the problem of crime. Restrictions could be placed on the marriage of persons at risk of producing an XYY child; or, if the XYY condition is diagnosed in a fetus, abortion might be made mandatory. Alternatively, XYY boys might be subjected to special education designed to minimize antisocial conduct, or they might be subject to special surveillance, or to suspicion when police authorities are attempting to solve a crime.

Beyond these considerations lurks the possibility that government may seek to use genetic technology for purposes of positive eugenics, *i.e.*, to upgrade the quality of the population. One can visualize, for example,

38. *See* Farrow & Juberg, *Genetics and Laws Prohibiting Marriage in the United States,* 209 J.A.M.A. 534 (1969).

39. *See* Note, *Eugenic Sterilization—A Scientific Analysis,* 46 DENVER L.J. 631 (1969).

40. In a normal human being, there are two sex chromosomes. The sex chromosomes are known as "X" and "Y." The normal female has two "X" chromosomes (XX), and the normal male has an "X" chromosome and a "Y" chromosome (XY). In some cases, a male has an extra "Y" chromosome, and this is known as the "XYY chromosome abnormality."

41. For a summary of present evidence with respect to this question see Hook, *Behavioral Implications of the Human XYY Genotype,* 179 SCI. 139 (1973).

that government at some future date might have an interest, for reasons of national defense, national prestige, or public health, in using genetic techniques to make people larger, smaller, healthier, brighter, calmer, etc.

Some suggest that such possibilities need not be of special concern since, it is argued, government has long had it within its power to practice positive eugenics on the basis of pre-existing knowledge by laws seeking to maximize "good" marriages and minimizing "bad" marriages.[42] Recent history teaches us, however, that government has a greater propensity to deal with social problems through a technological "fix" than through a wholly social "fix." For example, the availability of water fluoridation technology has induced government to deal with the public health problem of dental decay in children, although it has long had the capability to deal, perhaps more effectively, with this problem through measures restricting the manufacture and sale of candy and chewing gum. Automotive air pollution is dealt with through incorporation of new gadgetry, rather than through restrictions on automobile use. There is, therefore, a real possibility that government will avail itself of the new genetic technology for the betterment of society. This possibility is enhanced because of the reality of international diversity. While American society may find the notion of positive eugenics thoroughly repugnant, it is by no means clear that other societies, those of China or the Soviet Union for example, will refrain from such practices. If another nation should embark upon a successful program for upgrading its people so as to produce super-intellects, super-soldiers, or even super-athletes, would it be possible for the United States to stand idly by, watching, but not seeking to emulate these accomplishments?

Decisionmaking Processes

Given the magnitude of the possible societal impact of the potential use of genetic knowledge, it is certain that our society will be compelled to make public policy decisions in this area, or at least to make decisions as to whether or not such decisions should be made. Generally speaking, there are four kinds of decisions which will be made with respect to use of the technology.

At the most elementary level, decisions will be made by individuals. Physicians will decide that something can be done in a particular case or situation, and persons who want to have the service performed will decide to have it done.

At the second level, the physician's decision to proceed or not to proceed, and the manner in which he does proceed, may be subject to deci-

42. *See, e.g.*, J. Maddox, The Doomsday Syndrome 9 (1972).

sions made by the medical community relating to the standards prescribed for the practice of medicine. These standards may be found in the ethical codes of the medical associations, in the general consensus of the profession as to what is proper and improper, and in the standards and peer review procedures of hospitals. Although such standards are not law, and are not legally enforceable, departure from the standards may result in professional sanctions and are relevant in determining a physician's liability in the event a patient should bring suit. General standards of this kind may also emerge from public or quasi-public bodies such as the National Institutes of Health, the National Institute of Medicine, or the National Academy of Sciences. Such pronouncements, although again not legally enforceable, have great moral force. These private policy-making bodies act as a buffer between the medical profession and the law. They deal effectively with many issues which otherwise would become the subject of resolution or regulation through formal legal processes. The buffer is, however, not completely effective, since cases arising out of the physician-patient relationship in fact frequently reach the courts.

At a third level, it is to be expected that legal standards relating to the use of genetic knowledge will initially emerge in the courts as patients who feel aggrieved, rightly or wrongly, about the consequences of the use or nonuse of genetic technology in their cases seek legal remedy. The first such cases will be decided by reference to precedents involving other medical procedures. Eventually, however, a body of judge-made law specifically applicable to genetic technology will evolve. What this body of law will be cannot be predicted; nor can it be predicted whether or not it will be deemed adequate for the protection of the various individual and societal interests that are involved. The process of judicial law-making is slow and uncertain. Law is made by the courts only in retrospect, with respect to factual situations which arose months or years earlier. The process of deciding today's cases by analogy to or distinction from the precedents of the past frequently results in a period of trial and error before sound law is made.

The fourth level of policy-making is that of legislation, the process of conscious, deliberate articulation of standards which are intended for prospective application. Generally speaking, legislatures are slow to enact regulatory laws. Legislatures are busy and overworked. They have difficulty enough in dealing effectively with pressing immediate problems and are reluctant to deal with problems which appear to be only hypothetical and speculative. There is, moreover, sound justification for legislative restraint, since premature regulation of technology may stifle progress and cast the development of the technology in a mold which, in retrospect, may be less than optimum. For these reasons, it is usually the case that

regulatory laws are not enacted until the need is clearly demonstrated by events; indeed, all too frequently regulation is not provided until long after a crying need for it clearly exists. It simply cannot be expected, therefore, that a legislature would in 1973 seriously consider legislation relating to potential sexual imbalances in the population, the potential problem of "wombs for hire" in *in vitro* fertilization or the potential problems incident to cloning.

If, therefore, the law follows its usual pattern of response to technology, it is likely that it will not begin to deal seriously with the problem of controlling a particular use of genetic knowledge until after that use has become a flourishing reality. At that stage, however, the problem of enacting needed regulatory laws is complicated by the fact that important vested interests in the use of the technology will have come into being. An eager public will be clamoring for the immediate, personal benefits to them with scant regard for the larger social issues which may be involved.

The basic problem is, of course, that the development and use of genetic technology will, as in the case of other technologies, be incremental. Genetic knowledge is derived from diverse sources such as cancer research, botanical applications, and animal husbandry, all of which are beneficial. The techniques, when successfully used in animal experimentation, may become ripe for human application. When a human patient appears who can benefit from the procedure, an experiment may be attempted. If the experiment fails, it may be attempted in second or third patients, perhaps with some improvement in technique based on knowledge derived from the initial failures. If it produces the desired result, use of the technique will be extended to other patients. The successful use having been established, there is a precedent for the use of broader or new techniques. At every stage, the potential or demonstrated benefits are obvious and immediate with respect to the patients. Potential adverse consequences, particularly to society as a whole, tend to be relatively remote and speculative. Why, therefore, it is said, should we deprive people of these immediate and obvious benefits because of a generalized concern about adverse consequences? It is time enough to worry about the adverse consequences when we know with certainty that they exist. Even if adverse consequences become demonstrable, the case for regulation is not clear. Then the exercise becomes one of balancing the benefits against the adverse consequences. The fact of the matter is that it is very difficult to turn off a technology, however adverse its consequences may be, after its use has become established. Usually, the most that can be done is to regulate its use as to attempt to minimize the adverse consequences while avoiding any loss of its benefits.

It is unlikely, therefore, that society will prevent the emergence of

any of the applications of the new genetic knowledge. The best that can be hoped for is that as they emerge they will be wisely used. If this assessment is correct, we are on the way to the "brave new world," and it is useful to consider what that world will be. It will be a world in which there would be far less disease and far fewer defective human beings, and, consequently, far less of the human suffering and misery which is incident to the existence of diseased or defective individuals. The use of genetic technology for negative eugenic purposes will also reduce the prevalence of other undesirable biological characteristics. Individuals will have knowledge of their genetic characteristics, and will be able to choose mates with desired genetic characteristics. Parents will have options to choose the sex and other biological characteristics of their children. In many cases parents will eschew the sexual component of reproduction in favor of being "bred" so as to produce optimum children. Great men and women will permit themselves to be perpetuated, in multiple copies, by offering the nucleii of their body cells for use in cloning. Children will be born without the traditional biological relationship to mother and father, and those who are the product of cloning will have a complex and uncertain biological and legal relationship with their parents, their biologically identical "sponsor," and their biologically identical fellow-clones who have different parents. Scientists will perform laboratory experiments on surplus fetuses or fetuses generated for the purpose of the experimentation, and babies will be born in the laboratory without benefit of a mother. Scientists will endeavor to "upgrade" and "improve" the biological nature of man. This effort may result in the creation of a new species of man, *i.e.*, superman. Conversely, scientists will create new species of subhuman animals by "mating" man with baboons, dolphins, or dogs. If such creatures come into existence, will they have a role or function in "society?" Will we regard them more as man than as baboon, dolphin, or dog? Government will be able, even if not necessarily tempted, to use genetic technology for its own, hopefully beneficient, purposes.

Is such a world good or bad, desirable or undesirable? Do we move towards this world with hope or with fear? These questions cannot be answered except in terms of one's own system of values. On the other hand, this brave new world which can be foreseen is so different from the world we know, so much an intervention in the forces of nature, that movement in that direction should be the result of conscious decision by society itself and not the result of aggregative individual decisions made in terms of individual wishes without regard for the ultimate social consequences. There no doubt are many in our society who will view the brave new world with utter distaste or even horror. If their view should prevail,

what could be done to halt the seemingly inexorable march towards this new world?

Our American society places a high premium on individual freedom to think, to do research, and to create. The acquisition of increasing knowledge is regarded as beneficial per se. We have never attempted to restrict the directions in which scientific research may proceed or the quantum of effort which is directed towards any particular scientific goal.[43] The absolute freedom to do research means that increasing scientific knowledge will inevitably be translated into technological capability. Our basic premise has been that science itself should be free and unregulated, and that regulation, if needed, should be imposed only on the technological applications of scientific knowledge. But, as discussed above, there are immense practical and political problems involved in dealing effectively with new technologies which are introduced incrementally as a result of small, individual decisions where benefits are always immediate and obvious and where adverse consequences are remote and speculative. If, then, it is true that what man can do he will do, that scientific advance leads inevitably to technological application, it would appear that the process can be interrupted only if restrictions are imposed on the research itself. Such restrictions are, however, intolerable in our present society and, of course, would present serious constitutional problems.

The problem is greatly complicated by the role of government as the principal sponsor of scientific research and development. Before World War II, there was only nominal financial support for scientific research from government sources. Scientists were impelled to do research in those areas into which they were led by their own curiosity supported by whatever funds they could find. Since World War II, however, the federal government has made a massive commitment to the financial support of scientific research and development. Billions of dollars have been expended on scientific education, with a consequent enormous increase in the number of scientific workers in the population, and on the funding of specific research projects. As a result, most basic scientific research is done today with federal funding, and scientific resources are drawn into

43. It should be noted, however, that the availability of funds for the support of scientific research and development may have a powerful influence on the scientific goals which are pursued by individual investigators. Thus, for example, if the federal government makes substantial funds available for research and development of therapies for genetic disease and does not support research and development on techniques for preventing such disease, there will be a strong tendency for diversion of scientific effort towards the former and away from the latter. Indeed, the scientific community has become so accustomed to reliance on public funding that it has been suggested that a decision to abandon support of a particular line of research and development constitutes a "suppression" of that technology. *See* Dyson, *Death of a Project*, 149 SCI. 141 (1965).

those areas of research in which federal funding is available. This massive federal support has some important implications. The time scale for the sequence of events from initiation of basic research to introduction of resulting technology has been dramatically compressed, causing a tremendous acceleration in the rate of scientific and technological advance. In addition, the role of government as sponsor of scientific research and development has an inevitable tendency to lead to government's promoting the use of the resulting technology. In the very nature of the political and bureaucratic processes, it is obvious that government officials will be reluctant to be cast in the position of having spent millions of dollars on research which serves no useful purpose. Thus, where the National Institutes of Health provide substantial funding for a particular area of research relating to "health," there are powerful pressures to see that the results are in fact used for "health." Similar interests and pressures exist with respect to the congressional sponsors of such research funding. When a resulting technology is ripe for application, the governmental sponsors adopt a classic form of advocacy: (1) use of the technology involves obvious and substantial benefits to the public health; (2) although there may be adverse consequences, we do not know this with certainty except in the light of experience with its use; (3) if experience demonstrates that there are adverse consequences, we may be able to eliminate or ameliorate the adverse effects through some other technological "fix;" (4) if the adverse consequences remain, we can enact regulatory laws which will enable us to benefit from the technology while appropriately minimizing the adverse effects; and (5) if all else fails, we can, of course, stop the use of the technology. It would appear to be axiomatic, therefore, that government sponsorship of a technology increases the inevitability that it will, in fact, be used, since the government's vested interest causes it to act more as promoter than regulator.

The enormous advances in genetic science and technology in the United States have occurred in large part because of government financial support. Although both the government sponsors and the scientists whose work has been sponsored are fully aware of the important ethical and policy issues that exist with respect to future use of the knowledge derived from the sponsored activities, these issues have not surfaced in the decision-making processes relating to government support of the research. The general tendency has been to confine discussion of these problems within small groups of elite experts in the relevant scientific disciplines and, occasionally, to seek to involve broader elite groups, including experts from other disciplines, in these speculations. No effort has been made to engage the public generally in consideration of the ultimate potential implications of the use of knowledge which will be derived from the research the public

is presently being asked to fund. To do so might, of course, confuse and alarm the public unnecessarily, because we don't know yet what is or is not possible, and the potential implications are entirely speculative. Thus to involve the scientifically uneducated public in a debate about the possible brave new world of the future could result in a foolish negative reaction leading to public policy decisions to curtail or terminate these highly beneficial research programs.

The present system, therefore, involves the accelerated inevitability that the new genetic technologies will become ripe for use and that they will in fact be used, at least for a time. The decisions to proceed on this course are made by small elite groups and are submitted to Congress, for ratification in the appropriations process, without exposition of the basic long-term policy issues. This system reflects a fundamental deficiency in the democratic process. The decisions made today on support of genetics research will shape tomorrow's world, and the public is entitled to participate fully in consideration of today's public policy decisions which may represent a virtually binding commitment as to what the future conditions of society will be. This is not to say that the brave new world will emerge only as a consequence of federal funding. No doubt it will come, although at a considerably later date, even if there is no government support at all. In either event, whether the technology comes into being as a result of small, incremental, individual decisions, or more rapidly through government sponsorship, it is undeniably true that in a democratic society the public, acting through responsive legislatures, should have the maximum opportunity to shape the society in which it, and future generations, will live.

A major difficulty standing in the path of effective public participation is the problem of the "two cultures."[44] Scientists are dedicated to the relentless pursuit of truth. They are intolerant of the political processes in which ignorance, emotion, and bias so often shape public policy decisions that are not consistent with truth. They fear the possibility, if scientific matters are opened to public debate, that "wrong" decisions will be made: that beneficial projects will be terminated, that public funds will be expended on less than optimum programs, and, to some extent, that their own sources of government funding will be curtailed, thereby depriving them of the opportunity to perform their good works. Scientists tend to think, accordingly, that the solutions to these problems lie in better scientific education of the public, in electing more scientists to legislative

44. The notion of "two cultures" originated in C.P. SNOW, THE TWO CULTURES AND THE SCIENTIFIC REVOLUTION (1959). The two cultures discussed by Snow are characterized by him as the "literary intellectuals" and the "scientists," and he discussed the difficulties in communication between these two groups.

bodies, or in entrusting decisions on scientific questions to scientific bodies.

But science is not a special, sacrosanct category in our society. It is no more esoteric or worthy of protection than economics, sociology, agriculture, or law. We are accustomed in our society to making public policy decisions in these areas on the basis of bruising political debate involving frequent error and falsehood, and to the inevitability that "right" decisions are commonly not made. If our society wanted to ensure that "right" decisions are always made, it would not be dedicated to the democratic process. There is, therefore, no reason why we should proceed on the assumption that our decisionmaking mechanisms for questions of science policy must be constructed to produce "right" decisions. Science, after all, speaks with a strong and prestigious voice and has ready access to the press and other forms of political communication. It has the ability to defend truth vigorously and to seek to correct "wrong" decisions if they are made.

It is to be hoped, therefore, that those who are presently serving as the midwives for the emergence of the new genetic technology will recognize a public responsibility to tell the public fully, candidly, and in language the public can understand, where the new knowledge in genetics may take us as this knowledge is expanded and used. The benefits should be fully articulated because they are important; and the potential adverse consequences of use, whether or not it is believed there will be use, should be discussed with equal force. Only then will the democratic process be able to produce decisions which reflect the values of our society. It is more important that decisions be made in this manner than that "right" decisions be made. It is possible, of course, that the forces already in motion cannot be checked, but it is possible that they can be retarded, and this may be advantageous in giving society more time to reflect upon, and adjust to, what may be the inevitability of the brave new world.

It is not, of course, suggested that public policy decisions with respect to genetic technology be made without the inputs of the scientific community. As Sir Harold Himsworth has noted, scientifically based matters of political importance are never concerned with established knowledge, but only with fields where possibilities and opportunities have been opened but not yet established.[45] It is important that the questions thus raised be assessed by expert bodies not afflicted with excessive, often self-serving, enthusiasms. The conclusions reached by such expert bodies are of the utmost importance in the process of public policy decisionmaking. Of greater importance, however, is that their conclusions not be accepted *ex cathedra* as binding on the policy-makers. Their conclusions in them-

45. Himsworth, *The Human Right to Life: Its Nature and Origin*, in ETHICAL ISSUES, *supra* note 4, at 169.

selves, and the processes through which these conclusions are reached, involve substantial value judgments. The intermediate value judgments, as well as the ultimate conclusions, should be subject to broad public scrutiny and debate.

Finally, it is important to note the significance of genetic technology at the international level. As Dr. Robert L. Sinsheimer has observed: "One of the greatest threats to the rational development of genetic modification will appear if it should become captive to irrational, nationalist purposes."[46] A "genetics race" could have even more dangerous consequences than an "arms race." It is imperative that steps be taken to establish some form of international controls in this area.

46. Sinsheimer, *Prospects for Future Scientific Developments: Ambush or Opportunity,* in ETHICAL ISSUES, *supra* note 4, at 349.