Chapter 4

Human Genetics and the Constitution

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HOW CONSTITUTIONAL ISSUES MAY ARISE

The previous chapter described rapid progress in biological science, and some of the uses to which the new knowledge maybe put. Understanding of the nature of living organisms, and especially of human bodies and brains and behavior, directly affects how we act toward each other and toward the physical environment. Thus the new biology may have not only physical, economic, and social effects but also political and legal implications. From these political and legal implications, constitutional issues may arise as governments:

- attempt to regulate new decisions that people must make, or new choices that people can enjoy;
- collect biological and genetic information about people;
- try to use biological knowledge or technologies to modify the behavior of individuals or groups;
- act to remove or control risks that are newly disclosed by biological knowledge; or
- respond to community demands to declare some kinds of scientific knowledge undesirable, for reasons of safety, ethics, or other values.

These propositions assume that governments are acting responsibly, legitimately, in the interests of the general welfare, and in accord with the wishes of a majority of the population. The constitutional issues are likely to arise not because governments assume new authoritarian powers as predicated in novels such as 1984 or films such as *Clockwork Orange*, but because biology-based technical capabilities make the exercise of traditional powers of government more effective; or because they give individuals more power over their lives, and in so doing bring them into conflict with each other or with values held by the community at large.

When people are able to choose non-traditional means of using their environment, of reproducing themselves and designing their families, of maintaining the life or easing the death of helpless family members, it is inevitable that questions will be raised about whether or not the State has a legitimate interest in these decisions and is obligated to act to assure the general welfare or to enforce the society's ethical values.

Governments may assume an obligation to collect biological or genetic data about people in order to protect public health, to provide compensatory benefits or protections, to assess the effectiveness of government programs or services, or for other legitimate purposes. Governments may step in to mediate the use of biological data by third parties, such as employers or insurers. Governments may attempt to use biology-based techniques to modify individual or group behavior in the interest of the individual-as in efforts to prevent drug use, smoking, alcoholism, or other high risk behaviors, or in the interest of the community—for example, drug or hormone therapy to control violent aggressive behavior.[2] As we become potentially more effective in detecting exposure to infectious diseases, vulnerability to environmental or occupational diseases, or special susceptibilities to other widespread hazards, in the absence of a technical "fix" the demands to use strong social

[1]Much of the material in this chapter, not otherwise cited, draws on a report, "Constitutional Implications of the 'New Biology'," prepared for OTA by Dr. Sheila Jasanoff of Cornell University's Program on Science, Technology, and Society, April 1987.

[2]See U.S. Congress, Office of Technology Assessment, *Criminal* Justice, *New Technology, and the Constitution*, OTA-CIT-366 (Washington, DC: U.S. Government Printing Office, March 1988), for a discussion of the potential use of such therapies in the criminal justice corrections system,

controls to reduce such risks will increase. Research itself is sometimes seen as imposing societally unacceptable risks, especially when it involves modifying natural life forms or life processes.

The collection or use of biological information about people *is* particularly fraught with potential constitutional issues because of the likelihood that it will infringe on individual autonomy or privacy, or will violate current standards of due process and equal protection of the laws.[3] But issues of constitutional magnitude may also arise in connection with governmental efforts to control risks presented by industrial, agricultural, or environmental applications of the new biology. There maybe conflicts over the separation of powers, especially between the courts and the legislature. Attempts to regulate potentially hazardous research or the dissemination of knowledge may raise fundamental First Amendment concerns.

This chapter discusses some of the direct applications of the "New Biology" that are likely to raise constitutional problems. These are, first, some applications of genetic engineering to people: diagnosis of hereditary diseases, including prenatal diagnosis, human gene therapy, and genetic screening in the workplace. Other implications of genetic engineering for people are discussed in later chapters on medicine and public health. Secondly, some broad questions involving current or proposed limitations on bioengineering research or technological applications are discussed.

[3]Private actions, such as those of corporations, will ordinarily be insulated from direct constitutional challenge.

GENETIC ENGINEERING AND PEOPLE: DIAGNOSIS AND THERAPY

Gene Therapy

Human gene therapy refers to the deliberate change of genetic material within a human patient, with the intent of correcting a specific genetic defect.' There are two possible kinds of human gene therapy, somatic cell therapy and germ cell therapy.

Somatic cell therapy will not cause inherited or inheritable changes. It might be, for example, a means of replacing the defective gene in the bone marrow cells of a child affected by genetic immune deficiency. (These bone marrow cells produce blood cells.) If successful, this would "cure" the child, but would have no effect on his or her own future offspring; genetic immune deficiency could still be handed down. In contrast, germ cell therapy would not help already mature people, but would involve inheritable alterations, that is, characteristics that could be handed on to the patient's future offspring.

Germ cell therapy, involving inheritable alterations, is unlikely to be undertaken in humans in the near future because it is technically too difficult and too risky. The success rate in animals has been low, and the danger of damage to other genes is high. Most medical investigators probably consider the risk of this technique in humans too great for the foreseeable future.[5] Moreover, some genetic scientists argue that germ cell therapy may not prove superior to existing technologies.

Somatic cell therapy may become possible in the near future. In June 1988, scientists announced that they had succeeded in correcting, in animals, a serious genetic defect in liver cells, and described this as "an important first step toward a form of human gene therapy. "[6]

'For further detail and elaboration see U.S. Congress, Office of Technology Assessment, *Human Gene Therapy—A Background Paper*, *OTA-BP-BA-32* (Washington, DC: U.S. Government Printing Office, December 1984), from which this section is in part abstracted.

[5]According to Dr. Bernard Davis, Professor Emeritus of Bacterial Physiology, Harvard University.

[6]According to Harold M. Schmeck, "Gene Technique Used To Correct Liver Defect, " *New York Times*, June 16, 1988. The research was to be described in the June *Proceedings of the National Academy of Sciences*.

In mid-July 1988, the NIH Biosafety Committee was scheduled to begin review of a proposed experiment (within NIH) to attempt gene transplants in patients enrolled in an experimental cancer treatment program.[7]

Gene therapy (on either somatic or germ cells) can take several forms. A new gene may be inserted into a cell; a gene already in a cell may be altered; a defective gene may be removed from a cell by surgery. Gene modification or gene surgery can now be performed in some viruses, yeasts, and bacteria but not in humans or in other animals. Gene insertion is now possible, although not yet considered ready to be put into practice in treating people.

New material that is inserted would code for (i.e., direct the production of) necessary proteins, or would regulate production of particular proteins either to suppressor enhance their production. There are many possible ways of inserting DNA or genes into cells:

- physically injecting the material into individual cells,
- treating DNA chemically in such a way that cells are induced to take it up,
- fusing the cells to membranes that contain the DNA, or
- designing viruses that will carry the desired DNA material and "infect" targeted cells with it.

At present, all of these methods are in early stages of development.

With germ cell therapy, gene insertion would be performed on the cells of an embryo within a few hours of fertilization. Therefore all cells of the embryo would be affected as they develop and differentiate into a fetus. It is theoretically also possible to insert new genes into sperm or ova, or into the cells that produce them. With good techniques for in vitro fertilization, successful gene therapy on ova and sperm has come to seem more feasible. But with sperm there is still the difficulty that while only one sperm fertilizes an egg and thus transmits its characteristics, huge numbers of sperm are used in the attempt at fertilization, even with artificial insemination or in vitro fertilization. Gene therapy involving cells that produce ova and sperm would require invasive techniques and presumably therapy on many cells. Only one, or very few, ova would have to be modified.

The practical advantage of somatic cell therapy as opposed to germ cell therapy is that it could be performed on individuals at any stage of development rather than on an early stage embryo. If necessary, repeated attempts could be made. The reliability of a gene transfer procedure would not have to be as high. But somatic cell therapy might not be applicable to disorders that affect multiple tissues or organs, since the cells of each tissue or organ would have to be altered. It would not be applicable to cells that do not divide, such as brain cells. Finally, it would not prevent the inheritance of the same defects by children of the successfully treated patient.

The first attempt to use gene therapy in humans occurred in 1970 and 1973 in the unsuccessful experiments of an American researcher, Dr. Stanfield Rogers, and a German colleague. But because these trials predated the establishment of institutional review boards, they did not provoke much ethical debate.[8] Recombinant DNA techniques were first used for prenatal detection of disease only in 1982.[9] Yet two years earlier, UCLA scientist Dr. Martin Cline used recombinant DNA techniques in treating human subjects.[10] Cline's patients were two patients with thalassemia (inherited anemia) in Italy and Israel.

Dr. Cline had not gotten approval from appropriate review committees in either the United States or abroad. There was wide agree-

[7]The gene to be translated is a marker gene, that would enable scientists to track the migration of special white blood cells introduced into the patient's body to attack tumor cells. Margaret Chase, "Human Gene Transplants Closer to Reality as Researchers Pursue Bid for for Experiment," *Wall Street Journal*, July 13, 1988.

[8]OTA, op. cit., footnote 4, pp. 44-45.

[9]The first success was prenatal detection of sickle cell disease: see J.C. Chang and Y. W. Kan, "A Sensitive New Prenatal Test for Sickle-Cell Anemia," *New England Journal of Medicine*, vol. *307, 1982*, pp. 30ff.

[10]Judy Arech et al., *Law, Science and Medicine* (Mineola, NY: Foundation Press, 1984), pp. 168-169.

ment in the scientific community that the experiments were both premature and unethical.[11] The National Institutes of Health terminated two grants to Cline, who resigned his division chairmanship. The episode raised substantial questions about the enforceability of existing guidelines governing research with human subjects. According to a 1984 OTA study, the Cline experiments "may have catalyzed formation of a consensus that the time was not ripe" for germ line therapy .12 The question whether such treatments should ever be attempted, and, if so, under what conditions, awaits resolution through further public debate.

There are professional, ethical, and religious objections to human gene therapy, which may or may not involve constitutional questions. The usual way that such debates are conducted is in political, ethical, and legal terms, formulated as proposed or alternative public policies. However, either side may and often does, as an ultimate resort, assert a constitutional right or a constitutional prohibition on behalf of its position. Increasingly, the Supreme Court has put reproductive choices under the umbrella of "privacy, that is, within the sphere of personal autonomy in which government should not intrude without a compelling public interest. A brief look at the various positions taken in this and related controversies may therefore point to potential or emerging constitutional issues.

In 1980, the U.S. Catholic Conference, the Synagogue Council of America, and the National Council of Churches jointly sent to the President of the United States a letter expressing concern that "prowess might surpass prudence" in the application of genetic engineering to human subjects. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral& search issued a report, *Splicing Life*, in November 1982. '3 In June of 1983 a resolution signed by 56 religious leaders and 8 scientists and ethicists was sent to Congress.[14] It urged that "efforts to engineer specific genetic traits into the germ line of the human species should not be attempted. "

Other objections to or concerns about human genetic engineering may apply to either somatic cell or germ cell therapy:[15]

- Scientific evidence that the treatments will work to the patients' benefit is not yet adequate.
- Precautions against deliberate misapplication may be inadequate.
- Gene therapy may be no more effective, economical, safe, or acceptable than alternative treatments.
- The patients or their surrogate decisionmakers may not be adequately informed about the risks and benefits of the therapy.
- The effects may not be reversible or treatable.

Objections to human gene therapy have focused particularly on germ cell therapy because it affects future generations. By definition, future generations cannot give consent to the procedure, and there is a risk of propagating unpredictable and possibly undesirable effects. These objections can be made to many other procedures, of course, that affect the likelihood of future descendants and possibly their characteristics (e.g., medical support for diabetics that now allows them to bear children). More generally, some people point to the possibility of changing the genetic characteristics of human populations or of diminishing the genetic diversity among human populations. These possibilities too are not specific to or limited to genetic engineering as compared to other human activities, both individual and collective, that may affect offspring, including

[11] At the time the experiments were performed, Cline's protocol was pending approval before the-UCLA review committee. Cline had prior approval from a review committee in Israel, but for a protocol that was somewhat different from the one he actually used.

[12] OTA, op. cit., footnote 4, p. 46.

[13] President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Splicing Life, No.* 83-600500 (Washington, DC: U.S. Government Printing Office, November 1982).

[14] Congressional Record, June 10, 1983, S8202-8205; the resolution was introduced by Senator Mark Hatfield.

[15] This list, like much of the other material presented in this chapter, was developed for and presented in *Human Gene Therapy–a Background Paper,* already referenced, footnote 4. The objections have in some cases been paraphrased or restated here.

many medical treatments. They are perhaps raised more urgently because genetic engineering represents a systematic, purposeful, and unprecedented intervention of a kind that has not been possible before.

Some public apprehension about germ line therapy centers on the speculation that such interventions will gradually erode concepts of humanity and personhood, that specialized people might be "designed" for certain purposes (such as excelling at athletics, or soldiering), or that some faculties or traits such as intelligence or longevity could be enhanced selectively, creating superior classes of people. Some also fear that an all-powerful state may use gene therapy to modify human behavior or engineer new breeds of humans, possibly through cross-species transfer of genes.[16]

Constitutional principles are most directly challenged by three general questions that increasingly are raised with regard to potential scientific and medical interventions. The first is the question of whether there is a "right to do experiments" or a "right to use scientific knowledge" embedded in the First Amendment; this question is discussed in some detail below.

The second is whether there is a "right to treatment, " where such treatment is life-saving and technically available but is economically or otherwise a scarce resource. The existence of such a right is often advanced by ethicists or public interest advocates, but it has not been recognized legally or constitutionally.[17] It is discussed further in chapter 6 on medical interventions, particularly with regard to treatments that are either very high cost, which limits access to them, or which are scarce because only a few institutions or individuals are equipped to perform them.

The third question is whether there is an implicit constitutional right to refuse treatment, for oneself and for dependents unable to speak for themselves. This question is also discussed in chapter 6 on medical interventions, in relation to refusal of life support systems for those who can not survive without them. It arises also in discussion of criminal justice, when treatment becomes (now or potentially) an alternative to or complement to punishment for violent and aggressive behavior.[18] No definitive answer can be given to the question; but the answer appears to be that there is evolving and still highly qualified recognition of an explicit right to refuse treatment, within the sphere of personal privacy. Nevertheless, the State also has an enforceable interest in the decision under some conditions.

Mandated treatment of specific genetic disorders as a precondition to receiving a marriage license has been suggested.[19] This would be by today's standards a highly controversial policy, raising serious questions of due process and equal protection. But in this area, values and standards have changed over time. Just as compulsory vaccination has been consistently upheld by the Supreme Court as a legitimate State policy designed to prevent the spread of communicable diseases,[20] it could be argued that mandatory gene therapy would similarly prevent the vertical transmission of disease from one generation to the next. Further legal precedents might be found in several cases in which courts ordered cesarean sections over the objections of the patient to protect the life of the fetus, as discussed in chapter 6. These observations lead directly to consideration of eugenic policies in earlier periods of American constitutional history.

[16] See, for example, Ted Howard and Jeremy Rifkin, *Who Should Play God? (New* York, NY: Dell, 1977).

"Note, however, that Congress chose to make kidney dialysis available to all for whom it is medically necessary; to many people this indicated implicit recognition of at least an ethical right to treatment.

[18] See the earlier report in OTA's Constitutional *Bicentennial* series, *Criminal Justice, New Technologies, and the Constitution*, op. cit., footnote 2.

[19] Daniel J. Kevles, *In the Name of Eugenics* (Berkeley, CA: University of California Press, 1985).

[20] *Jacobson* v. Massachusetts, 197 U.S. 11 (1905). This is discussed in detail in ch. 5.

Genetic Control: The New Biology and the Old Eugenics

After the writings of Francis Galton in 1865[21] beliefs concerning the "superiority" of some racial types and the "unfitness' of other racial and ethnic groups tragically flourished in both Europe and the United States. These beliefs provided the justification for a variety of State-sponsored eugenic policies[22] whose aim was to discourage the multiplication of allegedly unfit individuals. The mass tragedies of genocide in Europe and legal and social discrimination and persecution in the United States are far beyond the scope of this report. To look at only a few of the much narrower eugenic policies or programs that were adopted in the United States is sufficient to provide a framework for asking whether the new biology could lead in its turntoa"new eugenics, raising serious constitutional issues.

Eugenics doctrines in so far as they labeled entire races and national or ethnic populations as "inferior' or 'unfit implicitly contributed to Federal and State laws and policies that preserved racial segregation and restricted immigration in the late 19th and 20th centuries.[23] They were also directed at preventing reproduction by certain types of individuals, especially "mental defective," and this objective also led to State laws and constitutional challenges.

Two themes were especially prominent in the thinking of the pre-World War II eugenicists. First, they claimed scientific support for their policies of selective propagation, relying in large part on quantitative studies of the "transmission of traits" through successive generations. Second, eugenic policies during the period of their greatest success were motivated to a significant extent by considerations of economic efficiency. "Hereditary" criminality, pauperism and mental defectiveness, it was alleged, were imposing heavy burdens on the taxpayer. In describing the case of the notorious Jukes family of "social misfits, " the American Eugenics Society noted that it would have cost the State $150 to sterilize the original couple and $25,000 to segregate one member for life; by comparison, the total cost to society imposed by the descendants of the couple was estimated as over $2 million.[24]

Arguments such as these fueled eugenically inspired legislative and judicial decisions in a number of areas. Many of these laws have remained in force and are generally, although not universally, accepted as sound legally and ethically. For example, by 1914, some 30 States had marriage laws that either restricted marriages among the mentally unfit and venereally diseased or else declared such unions voidable.[25] But starting in 1907, a number of States enacted laws granting authority to the State to sterilize certain classes of people: habitual criminals, idiots, or the insane. A challenge to the Virginia sterilization statute was carried to the U.S. Supreme Court in 1927 as Buck v. Bell.[26] This case will be discussed at greater length in later chapters. Here it is sufficient to note that, swayed by the scientific and public welfare arguments advanced on behalf

[21] Sir Francis Galton, 1822-1911, a cousin of Charles Darwin, was a pioneer in the study of trait inheritance in humans. He did the first systematic studies of twins, and is regarded as the father of scientific eugenics. Among his books are *Human Genius, 1862,* and *Natural Inheritance, 1889.*

[22] A word *that* means "pertaining to the production of good offspring. Eugenic policies are intended to discourage the multiplication of allegedly "unfit" or inferior individuals, to encourage the reproduction of healthy or fit or superior individuals, or to encourage high reproduction in some racial or ethnic groups and discourage or forbid the reproduction of others. They generally have ideological or political purposes but are almost always defended or justified on some scientific grounds, however selective or distorted the presentation of the associated data and/or theory may be.

[23] The strength of eugenics doctrines was reflected in immigration laws beginning with the Exclusion Act of 1882, which restricted Chinese immigration, and continuing in laws of 1891, 1903, and 1907, which excluded those with certain diseases, criminal records, and radical political beliefs. Economic motives were also important, i.e., the opposition of organized labor. The driving forces in the laws of 1921 and 1924, excluding orientals and setting quotas by country of origin, were "frankly racial"; the quota system was re-enacted by the McCarran Walter Act of 1952 and only gradually voided after 1965. See Rowland Berthoff, "United States: The People—Population Origins, " in the *Encyclopedia Americana,* International Edition, 1986, vol. 27, pp. 529-31,

[24] Daniel J. Kevles, *In the Name of Eugenics* (Berkeley, CA: University of California Press, 1985), p. 93.

[25] 1 bid., p. 99.

[26] *274* U.S. *200* (1927).

of the State, the Court upheld a sterilization order against a 17-year-old retarded woman, with Justice Oliver Wendell Holmes commenting, "Three generations of imbeciles are enough."

The history of sterilization laws since Buck v. Bell has been mixed. In 1942 the U.S. Supreme Court invalidated a State sterilization statute on Equal Protection grounds.[27] However, in 1976 the Supreme Court of North Carolina declared a roughly similar statute constitutional in view of the procedural protections afforded to the petitioner. The court noted that the people of North Carolina "have a right to prevent the procreation of children who will become a burden on the State. "[28] In the 1970s, with much attention focused on the potential problems of overpopulation and depletion of resources, there were some other indications of a revival of earlier eugenic themes. One well-known geneticist[29] wrote:

> Thus, in an overpopulated world it can no longer be affirmed that the right of the man and woman to reproduce as they see fit is inviolate. . . . The right that must become paramount is not the right to procreate but rather the right of every child to be born with a sound physical and mental constitution, based on a sound genotype.

Recent emphasis on the constitutional right of individuals to make decisions about reproduction without governmental regulation have framed the issue differently; they have focused on the right of individuals not to bear children rather than the right to bear children, and thus have tended to throw into shadow the older issue of whether government can act to discourage or prevent childbearing. Genetic screening and counseling are seen as mechanisms for enhancing the reproductive options available to "at risk" couples, particularly in the aftermath of the liberalization of abortion in Roe v. *Wade.*

The mere fact that such choices are currently left to the discretion of individual couples and their physicians does not entirely rule out the possibility of future State intervention, or at least of renewed proposals for State intervention. The discovery of genetic bases for a wide variety of illnesses and disorders, both physical and mental, promises to put the study of heredity on a more secure scientific footing than was available to the earlier generation of eugenicists. The theme of social costs of genetic disorders and mental retardation is implicitly woven into estimates of the frequency of genetic illnesses.

In a much more general sense, research findings about genetic and biochemical factors in mental performance, ability, aptitudes, or health often appear to arouse concerns about "equality," "equity," and "equal opportunity." Research on improved methods of measuring such mental attributes also arouse such concerns, and "intelligence testing" has somehow come to be taken as a code word for antidemocratic beliefs. In some cases, this is merely an exercise in anti-intellectualism, but in other cases it reflects a well-grounded concern that scientific information about inherent differences among people may easily be distorted into justification of policies that establish or preserve different standards of rights and liberties, and different classes of citizenship.

Prenatal Diagnosis

Prenatal diagnosis of genetic or hereditary diseases is already a major application of molecular genetics. For prenatal diagnosis, fetal cells are used that are cultured from the amniotic fluid, or from a biopsy of the placenta even earlier in pregnancy. Such diagnosis is particularly often used with an older mother because of the increased probability that her fetus will have an extra chromosome 21, which causes Down's syndrome. A procedure called chorionic villius sampling is used in fetal assessment to detect chromosomal disorders such as Down's syndrome as early as 9 weeks into pregnancy. The risks in such procedures

[27] *Skinner v. Oklahoma, 316* U.S. *535 (1942).*

[28] In re Moore, *289* N.C. *95 (1976).*

[29] Bentley Glass, former president of the American Institute of Biological Science, as quoted by Frederick Ausubel, Jon Beckwith, and Kaaren Janssen, "Stimulus/Response: The Politics of Genetic Engineering," *Psychology Today,* June 1975, p. 34. The authors of the *Psychology Today* article were themselves then biological scientists on the faculty of Harvard University.

to a child subsequently born alive are believed to be small, but are not well known.[30]

When both parents carry a particular single-gene recessive defect, one-fourth of the embryos, on average, will have two copies of that defective gene and hence will manifest the disease if they live long enough. More than 2,000 such single-gene diseases are now known, and as many as 2 percent of newborns have a genetic disease.[31] Some genetic diseases do not manifest themselves until after child-bearing age. Although most hereditary diseases are rare, some are not. The sickle cell gene is carried by about 10 percent of American Blacks and the cystic fibrosis gene by about 5 percent of Caucasians.

Several hundred of these diseases can now be diagnosed prenatally, some by tests for the gene product and others by examination of the DNA. It is likely that eventually scientists will be able to diagnose prenatally most single-gene diseases. This knowledge inevitably raises the question of terminating such pregnancies, forcing people to make decisions wherein the past there was no early warning and thus no occasion for choice.

Some hereditary diseases can be avoided by sex selection. Because the sex of a fetus can be determined from the amniotic fluid early in pregnancy it is technically possible to "select" the sex of a desired child by aborting when the fetus is of the other sex; this has led some to fear that the natural balance between males and females could be upset where there are strong cultural preferences for one sex. But sex selection sometimes has a medical rather than a cultural objective, since some hereditary diseases are gender-linked. For example, the common form of hemophilia is manifested overwhelmingly in males, compared to females.

New techniques are likely to provide other means of sex selection. Japanese scientists recently disclosed a high rate of success in sex selection through a technique of sperm separation by centrifuge, which depends on differences in the DNA content of sperm bearing an X chromosome, which produce females, and those bearing a Y chromosome, which result in males.[32]

Attempts to delegalize abortion through constitutional amendment, or by persuading the Supreme Court to reconsider its position that abortion falls within the protected zone of private decisionmaking, will run counter to the societal effects of increasing capability in prenatal diagnosis of hereditary disease. The desire to exercise a choice is the primary motivation for using the technique; and while use of the technique could in theory be prohibited, it has always proved difficult to enforce prohibition of the generation of knowledge that is strongly desired and readily produced.

Genetic Screening in the Workplace

Genetic screening may potentially be used to detect specific hereditable diseases, or a genetic susceptibility to certain diseases that are not directly inherited, or special vulnerabilities to environmental risks.

Scientists are now identifying genes that have no obvious direct effects on health, yet are statistically associated with future health outcomes or with life expectancy. In some cases these may turn out to be "markers" or "indicators' only vocationally associated with other genes that produce disease, with no disease-causing characteristics themselves.

Other traits may be governed by genes that are not always expressed. For example, a specific gene appears to indicate a propensity for Alzheimer's disease, rather than a direct inheritance of it; not all those with the gene show the disease. A genetic defect governing lipid

[30] Jain Chalmers, director of Britain's perinatal epidemiological unit at Radcliffe Infirmary, Great Britain, and Thomas C. Chalmers, M. D., Boston Veterans Administration Medical Center, in a letter to the editor of The *New York Times* published Oct. 8, 1987.

[31] V.A. McKusic, *Mendelian Inheritance in Man*, 6th ed. (Baltimore, MD: The Johns Hopkins University Press, 1983).

[32] The doctors reporting the technique say that in their clinics the technique is used only to produce females for couples with a family history indicating the likelihood of a sex-linked hereditary disease. The method is now being tried in several U.S. clinics, according to newspaper accounts. See Walter Sullivan, "New Way Devised To Pick Child's Sex, *New York Times*, Sept. *23, 1987, Sec.* A.

metabolism seems to predispose the bearer to early coronary thrombosis. Understanding of the complex immune system may in the future reveal much about resistance to various infectious diseases, or susceptibility to degenerative diseases ranging from ulcerative colitis to diabetes, which are now recognized as having an auto-immune component.[33] Molecular biology may play a large role in advancing the understanding of infectious agents, as it did in identifying and characterizing the lethal human immunodeficiency virus that causes AIDS.

Tests are being developed for genetic patterns that expose one to special risk from an environmental factor, or higher-than-usual sensitivity to toxic factors in the environment.[34] For example, some people have a variant form of a single gene that results in a deficiency in an enzyme called glucose-6-phosphate dehydrogenase (G-6-PD). Should these people chance to take drugs for malaria, or eat fava beans, the lack of the G-6-PD enzyme may cause the destruction of their red blood cells, resulting in an acute anemia. Some scientists expect that they may also suffer this response if they are exposed to chemicals that are similar to the antimalarial drugs. They could meet this exposure in the workplace; EPA lists more than 55,000 different chemicals used in production in this country. Genetic screening or testing could, in theory, warn such people and their employers that they would be at special risk in certain work assignments or workplaces.

It is these emerging capabilities that raise the controversial possibility of employers screening employees or job applicants for genetic traits. They might do so either to reduce occupational illness (and liability) by avoiding the use of workers with high susceptibility to toxins or other environmental hazards in the workplace, or to reduce the cost of employee health benefits by reducing the incidence of genetic illnesses. It should be emphasized here that predisposition is a statistical statement and is not a prediction that any one individual will develop a disease.

The possibility of screening for environmental susceptibilities at present is very limited, since so far there have been identified only a few known genetic defects in the ability to detoxify certain chemicals. Only 2 to 6 of these have high enough effects to serve as reliable guides; all are rare.[35] However, more may be identified in the future. When and if such screening becomes more reliable, it could find widespread use in at least some industries where mutagens or other toxic substances in the workplace remain a problem.

Screening for general disease potential as opposed to specific genetic illness may also remain of limited use for some time. Even when some genes are statistically correlated with increased susceptibility to certain diseases, small differences in susceptibility or resistance to environmental factors within the normal range are not likely to be useful in terms of screening for employment or insurance purposes.

Genetic testing in the workplace, for special susceptibility to environmental or occupational hazards, is still in its infancy; it has been often discussed but is apparently little used at present.[36]

The difficulty is that what may be seen as a benefit and protection for a worker may also be seen by some workers as unfairly depriving them of livelihood or job opportunities, or as usurping their individual prerogative to make decisions about what risks they will assume. This point would become even more po-

[33] That is, abnormal production of antibodies, or the Production of cells that attack a normal tissue as though it were a foreign material.

[34] US Congress, Office of Technology Assessment, *The Role of Genetic Testing in the Prevention of Occupational Disease, OTA-BA-194* (Washington, DC: U.S. Government Printing Office, April 1983).

[35] Edith F. Canter, "Employment Discrimination Implications of Genetic Screening in the Workplace Under Title VIII and the Rehabilitation Act," *Amen"can Journal of Law and Me& cine,* vol. 10, 1983, p. 5, *speaks* of at least five valid genetic screening procedures. Dr. Bernard Davis, professor emeritus of microbial genetics at Harvard University, vouches for only two.

[36] A 1982 survey by OTA found that although only 6 out of 366 companies were then using such techniques, another 55 stated that they might do so within the next 5 years (OTA, op. cit., footnote 34, p. 5.) Little is known about whether the incidence of genetic screening has increased in the last 5 years.

litically and ethically sensitive if the genetic pattern in question is peculiarly associated with an ethnic, racial, or gender group already subject to social and occupational discrimination.

The employer has a legal responsibility to protect workers from known occupational hazards.[37] This would not, at present, require the employer to use genetic screening even if highly reliable tests for a particular susceptibility were available; but if the employer chose to use such tests and then assigned susceptible workers to a high-risk environment, the employer would probably be found negligent. Unless the worker had been informed of the risk and refused re-assignment, he or she would probably be covered by workers' compensation laws, and the employer could face punitive damages. These are statutory protections, rather than constitutional principles, which would not apply against private sector employers.

Commonly used genetic screening tests include those for detecting glucose-6-phosphate dehydrogenase (G-6-PD) deficiency and sickle cell trait. Experts differ as to their reliability. In 1985 the U.S. Air Force Academy decided not to admit any candidates who exhibited the sickle cell trait,[38] because this condition could cause an oxygen deficiency in the blood at high altitudes, which in turn could cause fainting while piloting a plane. The sickle cell trait affects Blacks, and is found in about 10 percent of Black Americans. The Academy eventually abandoned their policy under the threat of lawsuits based on the charge that the policy discriminated against Blacks. The scientific validity of the Academy's presumptions was challenged, but both the objections to and the withdrawal of the decision were based on legal and political considerations rather than on the question of scientific validation of the presumption about occupational risk based on genetic information.

Although that case involved a Federal employer, genetic testing would be for the most part an instrument used by private companies. Accordingly, legal objections to such policies could be made, if at all, only under the two major anti-discriminatory statutes directed against private employers, the Civil Rights Act of 1964 and the Rehabilitation Act of 1973, rather than directly under the Constitution. Such civil rights legislation may indicate congressional interpretation of the intent and goal of basic constitutional principles, and the aim of extending to the private sector the restraints which the Constitution itself imposes on government.

Title VII of the Civil Rights Act prohibits overt discrimination based on racial, ethnic, and gender categories except where the employer can show that disparate treatment is correlated with a "bona fide occupational qualification. " Some genetic traits associated with hypersusceptibility to disease (at a high enough prevalence to be of interest to employers) may be associated with particular ethnic or racial groups, but most are not, so that overt discrimination against such classes would be difficult to demonstrate.[39] The Rehabilitation Act applies only to employers receiving Federal assistance, but it protects all "qualified handicapped individuals, " which could be argued to apply to workers excluded from jobs as a result of genetic screening. The Act defines a "handicapped individual" as any person who "has a physical or mental impairment which substantially limits one or more of such person's major life activities"; to bring genetic traits within the definition of impairment would require a broader reading, since such traits are harmful only after exposure to hazardous workplace conditions.

The recent Supreme Court decision in School *Board of Nassau County v. Arline*[40] illustrates such an expansive reading. The case involved a claim for job reinstatement by a school teacher suffering from tuberculosis. The

[37] For more detailed analysis of the legal and ethical points involved, see ibid., pp. 111-151.
[38] Kevles, op. cit., footnote 19, p. 278.

[39] Canter, op. cit., footnote 35, pp. 328-336; OTA, op. cit., footnote 34, pp. 123-126.
[40] *School Board of Nassau County v. Arline*, 55 U. S.L.W. 4245 (Mar. 3, 1987).

decision confirmed that a contagious disease could be regarded as a handicap within the meaning of the statute and that a handicap may include not merely an actual impairment, but also a social perception of the impairment that substantially limits a person's major life activities. The decision seemed to indicate that a potentially strict standard for evaluation would be placed on job exclusions based on genetic traits, and suggested that courts will look very carefully at job restrictions imposed solely because of a risk of future disability.

The protections afforded by the Rehabilitation Act and Title VII are suggestive but not conclusive as far as concerns raised by large-scale genetic testing in the workplace. Neither of these Acts appears to apply directly to the case at hand. The Courts might apply different standards to government as an employer. Congress might apply different standards to equal employment opportunities for genetically limited or susceptible private sector employees, if it has to deal with the issue directly. At best, in providing for legal challenges to employment discrimination, both Acts make it possible for courts to scrutinize the genetic screening methods and rationale. They may thus provide some protection against the use of frivolous or invalidated scientific techniques to promote undesirable social ends.[41] In summary, neither Congress or the Court has as yet made definitive statements about the constitutional status of genetic testing; but they will almost surely be challenged to do so at some future time.

[41] See, for example, Thomas Murray, "The Perils of Prediction," *Genetic Engineering News*, January 1985, pp. 6-7.

BIOLOGICAL RESEARCH: SHOULD THERE BE "FORBIDDEN KNOWLEDGE"?

The Right To Do Research

The new biology has provoked demands that some areas of research be made "off limits," or at a minimum, heavily regulated. One source of these demands is the perception that certain aspects of bioengineering pose grave risks to human safety or to the natural environment. Another source is the perception that in altering inheritable human characteristics, and in certain other potential activities such as interspecies gene transfer, we are violating natural or divine laws or fundamental ethical principles. Neither of these concerns is necessarily unique to biological science and technology, however.

Advanced technology provides great benefits, but often also carries risks to people and to their environment. Some people, at times, see technology as out of control, and society as failing to act to prevent possibly disastrous side effects. As modern science pushes ever closer to questions about the origin of the universe, the nature of life, and the determinants of human behavior, some people are concerned that scientific theories may threaten to erode cherished values and undermine traditional institutions.

These perceptions lead some people, including some scientists, to argue that those areas of research should not be pursued further. A few kinds of knowledge, they say, should be forbidden. Or people may see the methods necessary to gain scientific knowledge as ethically unacceptable. Other people, equally thoughtful and concerned, argue that all knowledge is valuable, and that scientific freedom is constitutionally protected. Both in this century and in the 19th century, research has been conducted—especially experiments on human subjects without their informed consent—that would now be considered unethical and would not be undertaken or allowed by most American research institutions.

Examples of such controversies occurred in the 1950s about atomic energy, in 1974 around recombinant DNA research; and in the mid-1980s around the experimental release of engineered organisms into the environment. A sim-

ilar controversy surrounds fetal research. There are demands that some or all experimentation on animals be forbidden. These are only a few of many recent examples of disputes over the existence of a right to choose freely among topics for research, to choose methods of carrying out research, or to communicate the results.[42]

This section is not concerned with either pub lic policy issues or ethical issues, per se, but only with the question of whether there is a constitutional challenge inherent in such issues. Specifically, this section of the chapter is concerned with the question of whether there is a constitutional guarantee of "the right to conduct research, " and if so, the scope and limits of that right.

The Atomic Energy Act of 1946 placed vast areas of research off limits to non-governmental researchers and required licensing and regulation of research using radioactive materials. The great mathematicion, John von Neumann, told the Congress:

> It is for the first time that science has produced results which require an immediate intervention of the government. . . . A vast area of research impinges on . . . the vital zone of society and clearly requires rapid and general regulation.

As discussed in an earlier OTA report, Sci*ence, Technology, and the First Amendment* (January 1988), when the dictates of national security appear to conflict with individual rights of free speech and free press guaranteed under the First Amendment, the Supreme Court has consistently said that there must be a "balancing of interests. " First Amendment rights, although strongly protected, are not absolute. The constitutionality of the restraints on research that are included in the Atomic Energy Act has been generally assumed and has not been challenged before the Court. Scientific institutions, and the public in general, appear to have shared the judgment of Congress that the awesome power of nuclear technology and the risks that it entails justify overriding any constitutional protection enjoyed by scientific research.

In July 1974, leading American scientists called for a temporary worldwide moratorium on research on recombinant DNA, because of the uncertain risks involved in the possibility of escape from the laboratory. Scientists throughout the world voluntarily observed the artificial moratorium. At an international conference at Asilomar, California, in February 1975, a consensus was reached among scientists that certain types of research should be prohibited because of potential hazards, and other types of research should be subjected to stringent, safety precautions. The National Institutes of Health (the principle source of funding for recombinant DNA research) later promulgated guidelines that incorporated the Asilomar agreement, which would be binding on research institutions accepting Federal funding. These do not forbid any research or research techniques, but they had almost that effect at an early stage of the research since most of the laboratories depended on governmental funding.

Again in this decade research on reproductive techniques and on bioengineering have impinged on sensitive areas and aroused the cry of "forbidden knowledge. " It can be confidently expected that new discoveries, because of the secrets they promise to reveal, and emerging technologies, because of the risks they appear to entail, will in the future also bring about such debates.

The claim of constitutional protection for research rests on the thesis that the First Amendment guarantee of freedom of speech necessarily also protects some kinds of action. To exercise one's right to speak, one must also be free to think, formulate concepts and hypotheses, perform calculations, and if one is dealing with scientific ideas, to plan and carry

[42] A generation earlier, atomic energy research was protested on ethical grounds, and it was later prohibited for non-governmental scientists, although in the interest of national security. Still earlier, research on birth control was protested. Many people have grave ethical or religious objections to research on biological and chemical weapons, or on any weapons. Some people object only to some potential applications of basic research, others argue that no effective separation can be kept between basic knowledge and undesirable applications.

out experiments.[43] In this respect, the reasoning that research is protected is analogous to the rationale for the protection given to the press in newsgathering. It says that the right to gather information (from willing sources) is necessary and integral to the right to publish or disseminate information. Since the press does not however have any greater right to gather information than have any other persons, presumably by the same analogy, scientists have no right to conduct activities that can be forbidden to non-scientists.

The Court has in some situations distinguished between "pure speech, " and action (which might include research), and has said that restrictions on the latter are more easily justified. The Court will still take into account whether the action, or activity, is essential to generating and communicating information.[44] The physical activity of research is however probably more likely to involve State interests that justify regulation, such as public health and safety, than is pure scientific communication and publication.

Some constitutional scholars make the claim that science has a specially protected status under the Constitution, and in particular under the First Amendment.[45] The prohibition on governmental establishment of religion, according to this argument, was motivated in part by the strong intent to prevent religion from interfering with science; the Framers of the Constitution were steeped in the Enlightenment accounts of religious opposition to Galileo and to Newton.

There have been few judicial decisions that have directly addressed the implications of the First Amendment for the constitutional status of science. A 1961 Supreme Court case, invalidating a state prohibition on the teaching of evolution, relied on the First Amendment prohibition against establishment of religion rather than directly on the protection of science. In subsequent cases in 1975, 1982, and 1987, also dealing with the teaching of evolution and "creation science, lower courts have followed this lead. They struck down state statutes that fostered "an excessive entanglement with religion, but did not explicitly base their decisions on constitutional protection of science.

The Supreme Court has ruled that the First Amendment "protects works, which taken as a whole, have serious literary, artistic, political, or scientific value" even when, by some community values, those works might be considered obscene. An Indiana obscenity law when applied to research materials at the Kinsey Sex Institute at the University of Indiana was invalidated[46] because "the state has unconstitutionally intruded itself into . . . protected activity . . . the right of scholars to do research and advance the state of man's knowledge. " Most obscenity cases, however, have been concerned with literary rather than scientific works.

In several cases academic social scientists have claimed the privilege of withholding their sources of information from juries or courts, to protect future research opportunities. The varying outcomes of these cases suggest, but do not definitely establish, a First Amendment right to do research.[47] In one such case, a Federal court said,

> Society has a profound interest in the research of its scholars, work which has the unique potential to facilitate change through knowledge.[48]

None of these decisions appear to establish definitively that there is a First Amendment right to conduct research, or that there is a constitutional prohibition on government restriction or regulation of it. The prevailing conclusion is that scientific activity has general

[43]For a detailed exegesis of this argument, see John A. Robertson, "The Scientist's Right To Research: A Constitutional Analysis, " *Southern California Law Review, vol. 51,* No. 6, September 1978.

[44]Ibid., citing *Saxbe v. Washington Post Co.*, 417 *U.S. at* 958.

[45]Steven Goldberg, "The Constitutional Status of American Science, " *University of Illinois Law Forum,* vol. 1979, No.1, 1979, pp. 1-6ff.

[46]*Henley v. Wise*, 303 F. Supp.62 (N. D.Ind. 1969).

[47]Robertson, op. cit.. footnote 43, pp. 1240-42.

[48]*Richards of Rock ford, Inc. v. Pacific Gas & Electric Co.,* vol. 71 F.R. D. 388 (N. D. Cal. 1976), at 390.

First Amendment protection, but may be limited or regulated where there is a clear State interest that outweighs individual rights.

A separate argument is that the right to conduct research is protected under the Fourteenth Amendment provision that says that no State shall

> . . . deprive any person of life, liberty, or property, without due process of law.

In the early 1920s, the Supreme Court said that this clause

> . . . denotes not merely freedom from bodily restraint but also the right . . . to contract, to engage in any of the common occupations of life, to acquire useful knowledge . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.[49]

But the Court has been reluctant to extend this argument to activities other than intimate personal and family decisionmaking, and has never applied it to experimentation.

The Special Case of Bioengineering Field Releases

Just over 10 years after recombinant DNA research began on a major scale, it reached a stage at which field research beyond the laboratory was desirable and practical. This required the deliberate introduction of engineered organisms into the open environment. The first major experiment of this kind involved bacteria that displace other microorganisms which promote frost damage by nucleating ice on the leaves of crop plants. Candidates for further tests are engineered bacteria that act as pesticides, fix nitrogen in plants, emulsify spilled oil or oil residues, destroy toxic wastes, concentrate valuable minerals from dilute sources, and recently, organisms designed to fight Dutch Elm disease, when injected into trees infected with the fungus that causes the disease. Even at this early stage, there are a long list of potentially beneficial engineered organisms being developed for testing.

The White House Office of Science and Technology Policy issued, in June 1986, a "Coordinated Framework for the Regulation of Biotechnology, " specifying the agencies responsible for approving commercial technology products and regulating field tests and planned releases of engineered organisms into the open environment.[50]

Controversy over their controlled release beyond the laboratory raised public policy issues involving acceptable levels of risk and regulatory responsibility." Some scientists, especially ecologists, believe that there are significant risks of ecological disasters on a local and regional basis that argue for a very strict monitoring and regulating of such experiments for a long time to come. Some scientists and public interest advocates have strenuously objected to any release of engineered organisms.[52] The Foundation on Economic Trends, an interest group led by Jeremy Rifkin, has several times challenged in court both plans for field experiments and the White House Coordinated Framework for their regulation.[53]

The court cases have focused on public policy issues of levels of risk, and not on constitutional issues, except in so far as a public interest group was found to lack constitutional

[49] *Meyer v. Nebraska,* 262 U.S. 390 (1923).

[50] These include th, Food and Drug Administration, various components of the Department of Agriculture, and the Environmental Protection Agency. 51 Fed.Reg. 23339.

[51] U.S. Congress, Office of Technology Assessment, *New ~evelopments in Biotechnology-Field-Testing Engineered Organisms: Genetic and Ecological Issues, OTA-BA-350* (Washington DC: U.S. Government Printing Office, May 1988).

[52] An OTA background paper, *Public Perceptions of Biotechnology* (OTA-BP-BA-45, May 1987) based on a national public opinion survey by Louis Harris & Associates, indicated that 52 percent of Americans believe that genetically engineered products are at least somewhat likely to present a serious danger to people or the environment, but 66 percent think that overall, genetic engineering will make life better, and a majority will accept relatively high levels of risks to gain the potential benefits. Also 55 percent would approve the environmental release of an organisms that would significantly increase farm production, even if there was a small (one in a thousand) risk of losing a local species of plants or fish. But only 1 in 5 of those surveyed reported that they had heard about potential dangers of genetic engineering and only 12 percent could describe a potential risk or problem.

[53] William G. Schiffbaner, "Regulating Genetically Engineered Microbial Products Under TSCA, *Environmental Law Reporter, News* and Analysis, vol. 15 (1985), pp. 10279-10288.

standing to sue. [54] However, they reflected a tension between Federal authority based on the Commerce Clause and State police power.[55]

Opponents of field experimentation have two major concerns: whether genetic transfers between species are inherently hazardous because they may inadvertently create new or more virulent pathogens, and whether the widespread introduction of modified or novel organisms could cause major ecological disruptions. A National Academy of Sciences Committee on the Introduction of Genetically Engineered Organisms into the Environment concluded that there is no evidence of unique hazards in the transfer of genes between unrelated organisms, and the risks associated with the introduction of such life forms are much the same as those associated with any introduction of unmodified organisms into a new environment.[56]

The report, read carefully, was stronger than these conservative conclusions suggest. A number of facts should be kept in mind. Modified organisms, whether genetically engineered or changed by traditional breeding practices, are generally not as fit for survival in the wild as natural progenitors and tend to be at a competitive disadvantage for survival and propagation. Pathogenicity usually depends on a large number of traits existing together, and the possibility of a narrow genetic change inadvertently converting a nonpathogen to a pathogen is remote. An engineered organism will most likely have been modified in only one regard and will behave otherwise like the parent strain; other associated and unintentional changes are likely to be detrimental to the organism. The transfer of genetic material to new species rarely leads to its persistence in a population unless strong selection criteria are applied.

Some ecologists urge that the risks may indeed be most likely when a modified organism is returned to its own natural environment, rather than anew one, because it is more likely to persist and because food chains or predator-prey relationships may be subtly disturbed by the modification.[57]

These factors indicate that risk of significantly detrimental impacts from a planned release of bioengineered life forms is small, but cannot be entirely dismissed. At a minimum, there are the same risks of environmental disruption that are attendant on any introduction of a new species or a modified species; these risks depend on the nature of the organism and the nature of the environment, and not on the way in which the organism was changed.

This is both a technical issue and a public policy issue, and like many public policy issues, it can also be articulated as a constitutional issue. In this case, those who protested the research on the grounds that it was inherently hazardous were not raising a constitutional issue; soon afterward, however, another scientist was forced to stop testing the use of engineered organisms because he had not gotten governmental approval. In that case, the underlying constitutional issue of a "right to do research" could be raised.

Federal preemption in environmental regulation is well established, although Federal statutes reflect some continued deference to the traditional police power of the States. There are numerous statutory provisions that allow State governments to assume enforcement obligations under Federal regulatory schemes and in many cases to set standards stricter than those adopted by Federal agencies. Some statutes explicitly provide that Federal law does not preempt State common law provisions relating to compensation and liability.[58]

[54] In December 1986, the Federal Court for the District of Columbia dismissed two suits filed by Rifkin. For an account, see Mark Crawford, "Court Rejects Rifkin in Biotech Cases," *Science*, vol. 235 (1987), p. 159.

[55] See, for example, William G. Schiffbaner, op. cit., footnote 53, pp. 10279-10288.

[56] The Committee's report is entitled *Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key Issues* (Washington, DC: National Academy Press, 1987).

[57] Based on extended discussions in sessions on Release of Engineered Organisms at the annual meeting of the American Association for the Advancement of Science, Boston, MA, Feb. 13, 1988.

[58] Occupational Safety and Health Act, Sec. 4(b)(4).

The issue of "deliberate field release" has somewhat overshadowed the 1970s issue of the risk of accidental release, but this may not last. In September 1987, virologist at the National Institutes of Health (NIH) began to introduce the genetic code of the AIDS virus into mouse embryos, in order to develop an animal model of the latency phase of the disease in humans. They then became the target of a lawsuit by the Foundation on Economic Trends, the public interest group that had led the fight against field releases. In this case, no intentional release by NIH is contemplated; but the public interest group says that the mice used in the experiment might escape, and by breeding with wild mice, create an animal reservoir for the disease. The lawsuit asks that NIH be stopped from funding or performing "hazardous research" and that guidelines for DNA research projects be reviewed.

The "deliberate release" issue can be constrained to an argument about the adequacy of risk assessment and the adequacy of government regulation of experiments. The issue of laboratory research is somewhat different in that opponents ask that research be prohibited because an intolerable risk is alleged to be inherent in the research and unavoidable.[59] It should be noted that recombinant DNA experiments are no longer limited to a few highly monitored scientific laboratories but are going on in hundreds of commercial, governmental, and academic laboratories, and even in some high school biology courses.

The public interest lawsuits succeeded in delaying by 4 years a University of California field test of a genetically altered bacterium capable of increasing the frost resistance of fruit and vegetable crops.[60] The fact that resistance by a small but dedicated group stalled a scientific activity deemed harmless by several State and Federal agencies, as well as many scientists, led some citizens to want to reduce the role of "lay" courts in such "scientific" controversies.

Some people have in the past strongly advocated the notion of a specialized Science Court to evaluate technical arguments. This proposal, however, has apparently dropped out of active discussion in recent years.[61] In the carefully designed system of checks and balances created by the Constitution, groups that raise substantial objections to Federal policies related to science and technology are, like other interest groups, entitled to a hearing when those objections are based on reasonable concerns, interests, and values.

The Use of Human Tissue or Cells

Human tissue and cells can be used for a variety of diagnostic, therapeutic, research, and commercial purposes.[62] There are three major sources of human tissues and cells: patients, volunteer research subjects, and cadavers and aborted fetuses (including those from both natural and induced abortions). The question of ownership of human tissues and cells became important in 1980 because the Supreme Court ruled that new life forms could be patented, and this appeared to mean that biological products containing or consisting of altered human cells and genes would be patentable. Soon thereafter Congress amended the patent statute to encourage patenting and licensing of inventions resulting from government-sponsored research.[63]

Physicians outside of the United States have just begun to experiment with brain grafts of human fetal tissue to treat victims of Parkin-

[59] William Booth, "Of Mice, Oncogenes, and Rifkin," *Science*, vol. 239, pp. 341-344, Jan. 22, 1988. Also, Amy McDonald, "AIDS Work With Mice Stirs Debate," *The* Scientist, vol. 2, No. 1, Jan. 11, 1988. p.1.

[60] *Foundation on Economic* Trends v. *Heckler, 756* F.2nd 142 (D.C, Cir. 1985).

[61] For discussion of the pros and cons of the Science Court, see for example Arthur Kanrowitz, "The Science Court Experiment: Criticisms and Responses," *Bulletin of the Atomic Scientists*, April 1977, pp. 44-53.

[62] U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology-Ownership of Human Tissues and Cells, OTA-BA-337* (Washington, DC: U.S. Government Printing Office, March 1987), pp. 7-19.

[63] Public Law 96-517. Human cell lines have been patented and commercialized since that time. See OTA, op. cit., footnote 62, ch. 2.

son's disease.[64] Fetal tissue is far less likely to be rejected than adult tissue grafts, and more likely to regenerate itself and grow with the host body. Many experts expect that it will become possible to use fetal tissue grafts in repair of other central nervous system disorders, or to treat radiation injuries. Other possibilities are the use of fetal grafts of pancreatic islet cells to correct juvenile diabetes, and fetal heart muscle grafts for repairing or even gradually replacing damaged hearts. These procedures have not yet been developed. Any therapeutic use of fetal tissue in the United States is highly controversial; in the spring of 1988 a moratorium was placed on any federally funded research that uses fetal tissue for transplant purposes, and NIH researchers were instructed by the Assistant Secretary for Health not to treat patients with fetal tissue implants until legal and ethical issues have been further studied. In July 1988, the Administration announced that it would reconstitute a bioethics board that was first created in 1974 and dissolved in 1981.[65]

Fetal tissue comes from fetuses that have undergone spontaneous or induced abortion. The use of such tissue is objected to by some people on the grounds that:

- it might be used to encourage, justify, or lend moral support to the use of abortion as a birth control technique;
- it might create a commercial market for fetal tissue; or
- some women might become pregnant in order to produce fetal tissue that is needed by someone they love, or even to produce it for sale.

Other people object to the use of fetal tissue as inherently morally reprehensible.

In short, any medical, commercial, or research use of fetal tissue in the future will almost certainly encounter strong ethical and political objections. It is possible that, in the future, scientists may find a way of growing embryonic cells in culture; this may or may not be less disturbing to those who object to the use of fetal tissue.[66] In any case, pressure to allow the use of fetal tissue will almost certainly grow if it is successfully used in other countries to treat life-threatening disorders. Some of this conflict could take the form of debates over First Amendment rights. In such cases, the assertion that there should be a zone of 'forbidden knowledge' that is either excessively hazardous or ethically abhorrent could be countered by an assertion of a right to do research under the umbrella of the right to free speech. This argument would most likely be used in the early, experimental stages of such new medical procedures, since government has a well-established right to regulate the later practice of medicine.

Federal Guidelines on Funding of Research

The early NIH Guidelines on recombinant DNA research, unlike the atomic energy legislation, did not restrict the right of researchers to carry out experiments. They concerned only the government refusal to fund research in certain areas. The guidelines have since been revised so that they do not seriously restrict the areas of research, but still impose certain safety requirements on how the research is conducted. The penalty for violation is still only loss of Federal funding.

It is doubtful that a constitutional challenge could be made to these guidelines. There are few constitutional constraints on the power of the government to spend, but there are even fewer limits on its power not to spend. A government decision not to fund a specific research project would clearly be unconstitutional if the decision were found to be based on racial discrimination, and there are legal requirements

[64]The first operations, transplanting tissue frOm a spontaneously aborted fetus to the brains of two Parkinson's disease patients (with the consent of both parents of the fetus) was performed in Mexico City in late 1987. Larry Rohter, *'Implanted Fetal Tissue Aids Parkinson Patients," *The New York Times,* Jan. 7, 1988.

[65]Gina Kolata, "Ethics and Fetal Research: Government Begins to Move," *New York Times,* July 31, 1988, p. E7.

[66]William Regelson, M. D., Professor of Medicine, Medical College of Virginia Hospitals, in a letter to the editor of *The New York Times,* Oct. 8, 1987.

for competition and fairness; but beyond such incidental constraints, selectivity is proper and necessary.

Not every experiment that scientists wish to conduct can be funded, and the government obviously must select those that have the most merit. The judgment as to how beneficial the resulting knowledge might be is surely an appropriate criterion for selection. The judgment that the resulting knowledge would not be beneficial or would not justify its expense is also appropriate.

At this point, however, a possible question arises. Some demands that research be restricted, or discouraged by cutting off government funding, are based on the assertion that the objective of the research is morally and ethically repugnant or unacceptable. For example, there have been such objections to weapons research, or to certain kinds of weapons research such as biological warfare. There have also been such objections to the concept of human cloning, or to interspecies genetic exchanges in higher animals. If funding decisions were shown to be based on "religious doctrines" they could be challenged under the First Amendment's Establishment Clause. However, religious doctrines would have to be clearly distinguishable from general moral abhorrence, which the Supreme Court has allowed as a basis for exercise of State police power.[67]

Both those who argue that some research should be forbidden and those who advocate full freedom of research fail at times to distinguish clearly between the objectives of stopping research, or stopping the government from funding research, or reducing particular perceived risks. Both sometimes fail to distinguish between public policy issues and constitutional issues. Strictly speaking, the question of a constitutional right to do such research could be raised only when individuals or institutions were prohibited from engaging in such research on their own, independent of government funding. Federal guidelines and regulations about how research is done are less likely to be challenged. It has become generally accepted that the Federal Government may regulate the way in which research is conducted by recipients of Federal funds (although in such cases the Courts would undoubtedly still give strong consideration to any asserted countervailing State interest, such as safety).

Nevertheless, restrictions either on an area for research, or the content of research that may be done with Federal funding, are likely to evoke more controversy in the future, because government is likely to be the only source of adequate funding for areas in which industry has no interest.

[67] For example, in the recent case dealing with enforcement of laws against sodomy (the case involved an act committed with another adult male in the bedroom of the respondent's home) the Supreme Court said that "there is no fundamental right to engage in homosexual sodomy, " and defended the State's right to outlaw it in part because "Proscriptions against that conduct have ancient roots. " It specifically denied assertions that the belief that sodomy is immoral and unacceptable is "an inadequate rationale to support the law, " saying that "the law. ., is constantly based on notions of morality. " *Bowers v. Hardwick*, 106 S. Ct. 2841,92 L. Ed.2nd 140,54 U S.L.W. 4919.

INTERSECTIONS BETWEEN BIOLOGY AND THE CONSTITUTION: OVERVIEW

The map of possible intersections between biology and the Constitution suggests that certain key concepts of constitutional law may need to be reexamined in the light of new scientific knowledge. Among these are the concepts of "privacy" and "equality."

In *Griswold v. Connecticut*,[68] in 1965, the Court explicitly articulated the doctrine that the penumbra created by several fundamental constitutional rights defines a "zone of

[68] 381 U.S. 479.

privacy. ” Decades earlier, Justice Brandeis argued for “a right to be let alone, ” basing this right on the Fourth and Fifth Amendments. The right of privacy, as discussed in chapter 2, contains both the concept of autonomy and the concept of confidentiality of personal information. Modern challenges to the Fourth Amendment prohibition on “unreasonable searches and seizures” have largely focused on search from a distance—i.e., wire tapping and later remote sensing—but new challenges are arising from government acquisition of information from body tissues and emanations (breath, blood, semen), including genetic information. Other challenges are arising from the collection and aggregation, in computerized data banks, of personal information, which may include genetic information. Both kinds of intrusion on privacy are discussed in some detail in chapter 5, which deals with medical record keeping.

The advance of science is almost certain to provide new and sophisticated techniques for distinguishing among individuals in terms of biological characteristics or capabilities. Science may eventually provide an objective basis for some classifications that law has preferred to treat as arbitrary. It will be a significant challenge for the legal system to ensure that such knowledge does not erode the precious but fragile fabric of social equality that is one of the major constitutional achievements of this century.

Privacy as a constitutional norm may also be reassessed. Privacy has been recognized as central to notions of liberty and individual autonomy as a sphere preserved from arbitrary government action. Rapidly advancing techniques for reducing the individual to a collection of biological facts and measurements are likely to increase the need for explicitly defining the scope and nature of this guarantee.

Nevertheless, it is well to remember that not every social dislocation that might be produced by the new biology must, or should, be a matter of constitutional concern. Many issues will be resolved by Congress, the public, professional groups and interest groups without being raised to the level of constitutional challenge. Debate on such issues has already been joined, and its robust character is grounds for optimism that the political process shaped by the Constitution will continue to work well in the coming century.